Decision of the Competition and Markets Authority

Competition Act 1998

Prochlorperazine
Case 50511-2

03 February 2022

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1. Introduction and Executive Summary

Addressees of this Decision

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

1.1.1 Alliance Pharmaceuticals Limited (company number 03250064) and Alliance Pharma plc (company number 04241478);

1.1.2 Focus Pharmaceuticals Limited (company number 04522142) and Focus Pharma Holdings Limited (company number 06317129) (together the '**Focus Entities**'), Mercury Pharma Group Limited (company number 02330913), Concordia Investment Holdings (UK) Limited (company number 09821116),[1] Concordia Investments (Jersey) Limited and Advanz Pharma Corp. Limited[2] (the latter three together the '**Advanz Entities**') (all together, the '**Advanz Group**');

1.1.3 Cinven Capital Management (V) General Partner Limited (**'Cinven MGP'**), Cinven (Luxco 1) S.à.r.l.[3] (**'Luxco 1'**) and Cinven Partners LLP (together, the **'Cinven Entities'**);

1.1.4 Lexon (UK) Limited (company number 03076698) and Lexon UK Holdings Limited (company number 11217461); and

1.1.5 Medreich plc (company number 03122988), Medreich Ltd, Meiji Seika Pharma Co. Ltd and Meiji Holdings Co. Ltd,

(each a **'Party'** and together the **'Parties'**).

1.2 This Decision is issued to the persons listed in paragraph 1.1 above under section 31 of the Competition Act 1998 (the **'Act'**) and in accordance with rule 10(1) of the CMA Rules under the Act.[4]

1.3 By this Decision, the CMA finds that:

1.3.1 Alliance Pharmaceuticals Limited and Alliance Pharma plc formed part of an undertaking which is referred to in this Decision as **'Alliance'**;

[1] On 25 May 2021, Advanz informed the CMA that it intends to dissolve Concordia Investment Holdings (UK) Limited as part of a group restructuring.

[2] Concordia International Corporation changed its name to Advanz Pharma Corporation and is now Advanz Pharma Corp. Limited (see paragraph 3.11).

[3] Formerly Cinven (Luxco 1) S.A.

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

1.3.2 the following legal entities formed part of an undertaking which is referred to in this Decision as '**Focus**':

(a) from at least 22 June 2013 until 30 September 2014, Focus Pharmaceuticals Limited and Focus Pharma Holdings Limited;

(b) from 1 October 2014 until 20 October 2015, Focus Pharmaceuticals Limited, Focus Pharma Holdings Limited, Mercury Pharma Group Limited, Concordia International (Jersey) Limited, Cinven (Luxco 1) S.à.r.l. (formerly Cinven (Luxco 1) S.A.), Cinven Capital Management (V) General Partner Limited and Cinven Partners LLP; and

(c) from 21 October 2015 until at least 31 July 2018, Focus Pharmaceuticals Limited, Focus Pharma Holdings Limited, Mercury Pharma Group Limited, Concordia International (Jersey) Limited,[5] Concordia Investment Holdings (UK) Limited, Concordia Investments (Jersey) Limited and Advanz Pharma Corp. Limited (formerly known as Concordia International Corporation);

1.3.3 the following legal entities formed part of an undertaking which is referred to in this Decision as '**Lexon**':

(a) from at least 7 June 2013 until 28 February 2018, Lexon (UK) Limited; and

(b) from 1 March 2018 until at least 31 July 2018, Lexon (UK) Limited and Lexon UK Holdings Limited;

1.3.4 the following legal entities formed part of an undertaking which is referred to in this Decision as '**Medreich**':

(a) from at least 5 February 2014 until 11 February 2015, Medreich plc and Medreich Ltd; and

(b) from 12 February 2015 until at least 15 February 2018, Medreich plc, Medreich Ltd, Meiji Seika Pharma Co, Ltd and Meiji Holdings Co Ltd.

1.4 The CMA finds that an agreement was reached between Alliance and Lexon relating to Prochlorperazine 3mg buccal tablets sold in packs of 50 which is a prescription only medicine ('**Prochlorperazine POM**') (the '**Market Exclusion**

[5] This legal entity was dissolved on 29 June 2017.

Agreement')[6] which had as its object the restriction of competition. More specifically, Alliance and Lexon agreed that:

1.4.1 Alliance would indirectly (through Focus) transfer value to Lexon by exclusively supplying Focus with a de-branded version of Alliance's Prochlorperazine POM at a fixed selling price, and Focus sharing with Lexon the profits it earned from the sales of Alliance's Prochlorperazine POM; and

1.4.2 in return for that value transfer from Alliance (through Focus) Lexon would not enter the market with the Prochlorperazine POM that it had jointly developed with Medreich, and would supply only the single batch of Prochlorperazine POM necessary to avoid the application of the Sunset Clause[7] to Medreich's Prochlorperazine POM marketing authorisation ('**MA**').

1.5 In other words, Alliance and Lexon agreed that Lexon would not compete[8] with Alliance in the supply of Prochlorperazine POM in the UK in return for being paid in the form of an indirect transfer of value through Focus. That transfer of value ultimately totalled £7.86 million in the form of payments made by Focus to Lexon (of which £4.96 million was retained by Lexon and £2.90 million was passed from Lexon to Medreich).

1.6 The CMA finds that Focus and Medreich participated in the Market Exclusion Agreement, because:

1.6.1 there was an overall plan pursuing a common objective, which in this case was the implementation of the Market Exclusion Agreement as described above;

1.6.2 they were each aware of the conduct which was put into effect by Alliance and Lexon in pursuit of the common objective, or could reasonably have foreseen it and were prepared to take the risk; in this case, they were as a matter of fact also each aware of the conduct which was put into effect by each other in pursuit of the common objective; and

[6] This was referred to as the 'Overall Agreement' in the Statement of Objections of 23 May 2019 to differentiate it from the alleged individual infringements in relation to each of the agreements between (a) Alliance and Focus, and (b) Focus and Lexon in which Medreich subsequently participated in relation to the supply of prochlorperazine 3mg buccal tablets in the UK; the CMA closed its investigation of whether these agreements individually and in themselves broke competition law on administrative priorities grounds on 22 January 2021 (see paragraph 2.39 below).

[7] Under the regulatory regime, a marketing authorisation may become invalid after a period of three years due to the application of a so-called 'sunset clause' ('**Sunset Clause**'). Article 24 (4-6) of Directive 2001/83EC, as inserted by Article 1(23) of Directive 2004/27EC.

[8] In this decision, references to Lexon and Medreich 'not entering the market' and/or 'not competing' with Alliance or Focus mean that Lexon and Medreich would not supply more than the single batch required to avoid the application of the Sunset Clause (that is, the regulatory regime pursuant to which a marketing authorisation may become invalid after a period of three years if no sales of the product have been made) as agreed with Alliance as part of the Market Exclusion Agreement.

1.6.3 they each made an intentional contribution to the common objective.

1.7 Accordingly, by this Decision, the CMA gives notice to the persons listed at paragraph 1.1 above that it has decided that Alliance, Lexon, Focus and Medreich have infringed the prohibition imposed by section 2(1) of the Act (the **'Chapter I prohibition'**) (the '**Infringement**').

1.8 The Market Exclusion Agreement between Alliance and Lexon was most likely entered into by 7 June 2013, but in any event by 22 June 2013, and lasted until 31 July 2018 (the '**Infringement Period**').

1.9 Focus participated in the Market Exclusion Agreement from at least 22 June 2013 until 31 July 2018 (the '**Focus Infringement Period**'). Medreich participated in the Market Exclusion Agreement from at least 5 February 2014 until 15 February 2018 (the **'Medreich Infringement Period'**).

1.10 European Union ('**EU**') law no longer applies in the UK. This Decision does not therefore consider whether Article 101 of the Treaty on the Functioning of the European Union ('**TFEU**') has been infringed. However, under section 60A of the Act, unless it considers it appropriate to act otherwise in light of specified factors, in reaching its findings in this Decision the CMA is required to act with a view to securing that there is no inconsistency between the principles that it has applied, and the decision it has reached, and the principles of EU law and judgments of the EU courts on corresponding issues that were made before 31 December 2020. The CMA must also have regard to relevant decisions or statements of the European Commission made before that date and not withdrawn.

1.11 The CMA has decided to impose a financial penalty on each of the Parties under section 36 of the Act in respect of the Infringement.

Executive summary of the Infringement

Overview

1.12 Generic pharmaceuticals are key to the cost effective supply of drugs to the NHS and so to patients who rely on them.

1.13 There are typically three important phases in the life cycle of a drug. First, a stage of research and development where pharmaceutical companies invest significantly in the development and testing of new drugs. Second, once a drug is licensed, a stage where drug developers have the exclusive right to sell the drug for a period of time. Third, a stage where a medicine comes off patent and can be copied, allowing competition to enter the market often driving prices down significantly.

1.14 However, if that competitive entry is delayed or prevented, the drug (and so its suppliers) may be insulated from downward pricing pressure.

1.15 This is what the CMA has found happened from 2013 to 2018 in the UK in the supply of prescription prochlorperazine 3mg buccal tablets, a generic drug used for treating nausea and vomiting.

1.16 In 2013, Alliance, the sole supplier of the drug in the UK, faced the prospect of competitive entry by Lexon and Medreich, who together had developed their own version of the drug and were preparing for launch. Instead of engaging in the competitive process that would be expected to follow, Alliance and Lexon opted to enter into an arrangement, in which Medreich subsequently participated, that removed the risk of competition. Entry by Lexon/Medreich would be stalled in return for compensation from Alliance (who would remain the sole supplier) to Lexon/Medreich.

1.17 Rather than direct payment from Alliance to Lexon/Medreich, a distributor, Focus, was appointed to act as a conduit and ensure that the monopoly profits which had been protected would be divided between the Parties. Focus purchased the Alliance product, and shared the profits earned from selling it with Lexon (and, in turn, Medreich).

1.18 This arrangement persisted for five years and was a serious infringement of competition law. During this time, Lexon and Medreich received £7.86 million, despite not having launched their product, while costs to the NHS increased by some 700%.

1.19 As a result of these findings in this Decision, the CMA has issued fines to the Parties totalling £35 million.

Background and context to the Infringement

1.20 Prochlorperazine 3mg buccal tablets are effective in the treatment of nausea and vomiting. They are also used to treat migraines and dizziness due to ear problems and other causes.

1.21 This Decision is concerned with prochlorperazine 3mg buccal tablets sold in packs of 50, which is a prescription-only medicine ('**POM**') on which thousands of patients rely.[9] The provision of this medicine to patients is funded by the NHS, and ultimately, the taxpayer.

1.22 Until December 2013, these packs of tablets were supplied in the UK by Alliance under the brand name 'Buccastem' ('**Buccastem POM**'). As a branded drug, it was subject to the price and profit controls of the Pharmaceutical Price Regulation Scheme ('**PPRS**'). In June 2013, the drug tariff price for Buccastem POM was

[9] See Table 1: UK Prescriptions of Prochlorperazine 3mg Buccal tablets 2014-18.

£6.49. Although Buccastem POM was a branded product, it was not subject to any patent or data exclusivity.

1.23 The facts of the Infringement relate also to the generic (i.e. unbranded[10]) version of this product ('**Prochlorperazine POM**') which is bioequivalent to the branded Buccastem POM form. Apart from Alliance, there were no other licence holders of Prochlorperazine POM in the UK in 2013.

1.24 In the UK, the suppliers of unbranded generic drugs are in principle free to set their prices as they choose. This is because it is assumed that competition will bring down prices once generic competitors enter the market and compete on price. As a result, to the extent that a supplier of a branded drug 'de-brands' the drug, and supplies the generic version of the drug instead, that generic product would no longer be subject to the price and profit controls of the PPRS.

1.25 In June 2010, Medreich had applied for regulatory permission to market Prochlorperazine POM in the UK. It was doing this pursuant to a co-operation agreement it had with a UK wholesaler, Lexon, under which Medreich would act as the developer, licence holder and manufacturer of products, and Lexon would be responsible for commercialising the developed products in the UK. The necessary regulatory authorisation for Medreich to launch Prochlorperazine POM tablets in the UK was given by The Medicines and Healthcare products Regulatory Agency ('**MHRA**') on 9 January 2014 (albeit that it subsequently transpired that certain aspects of the licence required rectification).

1.26 As a result of their development activities, Lexon and Medreich, acting together, therefore became potential competitors of Alliance in the supply of Prochlorperazine POM in the UK by the time of the commencement of the Infringement in June 2013.

The Market Exclusion Agreement entered into between Alliance and Lexon in June 2013

1.27 The CMA has found that there was contact between individuals at Alliance and Lexon in the first half of 2013. Alliance became aware that Lexon was developing a competing, generic product to Alliance's Buccastem POM product. It is clear that management within Alliance were aware of this threat to Alliance's monopoly position in relation to the supply of these tablets in the UK and considered a number of options in terms of how best to react to this threat.

1.28 The CMA has found that most likely by 7 June 2013, but in any event by 22 June 2013, an anti-competitive agreement was reached between Alliance and Lexon relating to Prochlorperazine POM under which Lexon would be compensated for

[10] The CMA uses the term 'generic' in this decision to refer to an unbranded version of a drug.

staying out of the market. Specifically, the CMA has found that Alliance and Lexon agreed that:

1.28.1 Alliance would indirectly (through a third-party company, Focus) transfer value to Lexon by:

(a) Alliance exclusively supplying Focus with a de-branded version of Alliance's Buccastem POM product at a fixed selling price, and enabling Focus to implement a series of price increases; and

(b) Lexon entering into an agreement with Focus under which Lexon would (nominally) appoint Focus as the distributor of the Prochlorperazine POM product Lexon had jointly developed with Medreich, and, under that agreement, Focus sharing with Lexon the profits it earned from the sales of Alliance's Prochlorperazine POM; and

1.28.2 in return for that value transfer from Alliance, through Focus, Lexon would not enter the market with the Prochlorperazine POM that it had jointly developed with Medreich.

1.29 Alliance's supply of the de-branded product to Focus allowed Focus to raise the price of the product: the generic Prochlorperazine POM would not be subject to the price constraints of the PPRS, and Focus' market pricing would not be constrained by a competing Lexon/Medreich product; Focus could therefore increase the price of Prochlorperazine POM and a proportion of the profits made by Focus could be shared with Lexon. The implementation of this structure meant that there was no need for Alliance to make a direct payment to Lexon.

1.30 As part of the Market Exclusion Agreement, Alliance and Lexon agreed that Lexon would be permitted to supply, through Focus, a single batch of the Lexon/Medreich Prochlorperazine POM product; this was necessary to avoid the application of the so-called Sunset Clause to Medreich's Prochlorperazine POM licence – namely that if a product is not placed on the market within three years of the date of the grant of the licence, the licence will cease to be valid.

1.31 The CMA has found that the Market Exclusion Agreement, which involved Lexon staying off the market with the product that it had jointly developed with Medreich in return for compensation from Alliance (indirectly through Focus), had the object of restricting competition in the UK.

Focus's participation in the Market Exclusion Agreement

1.32 As described above, Alliance and Lexon foresaw a key role for a third-party pharmaceutical distributor, Focus, as part of the mechanism by which value would be transferred from Alliance to Lexon.

1.33 Alliance and Focus already had an existing contractual relationship relating to another product: in 2011, they had concluded an agreement whereby Alliance agreed to supply Aspirin 300mg E/C tablets to the only other UK supplier, Focus, at a fixed price, and Focus committed to supply Alliance's product and accepted a restriction on its ability to supply its own product.

1.34 It is clear from the contemporaneous documentary evidence that by at least 22 June 2013 Focus was aware of the Market Exclusion Agreement reached between Alliance and Lexon (or could reasonably have foreseen it and was prepared to take the risk), and can be said to have participated in the Market Exclusion Agreement from that point on. The CMA concludes: that there was an overall plan pursuing a common objective (which in this case was the implementation of the Market Exclusion Agreement); that Focus was aware of the conduct engaged in by Alliance and Lexon in pursuit of the common objective (or could reasonably have foreseen it and was prepared to take the risk); that in this case, Focus was as a matter of fact also aware of the conduct which was put into effect by Medreich in pursuit of the common objective; and that Focus made an intentional contribution to that common objective.

1.35 Specifically, as envisaged by Alliance and Lexon at the time they reached the Market Exclusion Agreement in June 2013, both Alliance and Lexon entered into supply agreements with Focus. Focus agreed with Alliance that it would exclusively supply the Alliance Prochlorperazine POM product, such that it would therefore be contractually prohibited from supplying the Lexon product but it also entered into the Focus-Lexon Heads of Terms under which it was appointed to supply the Lexon product.

1.36 Once Alliance had de-branded its Buccastem POM product in December 2013, Focus then supplied the de-branded Alliance Prochlorperazine POM product into the market, and in the years that followed dramatically increased the price of Prochlorperazine POM to wholesalers, from £8 per pack in December 2013 to a peak of nearly £35 per pack in June 2017 (an increase of over 300%).

1.37 As envisaged under the Market Exclusion Agreement, Focus paid Lexon a significant proportion of the profits that Focus made on its supply of the Alliance product from the time it started selling the de-branded Alliance product in December 2013 through to the point at which its contract with Lexon, under which Lexon should have been supplying Focus with product, terminated on 31 July 2018. Despite Focus's payment to Lexon of £7.86 million in profits under that agreement, Focus received only a single batch of Lexon/Medreich product in March 2018, for which it paid Lexon just £49,522.25, and which represented in volume less than 1% of Focus' total supply of the Alliance product to that point.[11]

[11] Focus had supplied over one million packs of the Alliance product to the end of February 2018 (see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150).

That single batch of Lexon/Medreich product as supplied to Focus accounted for a tiny percentage of market demand over the lifetime of the Infringement, and it was produced by Medreich for the purpose of avoiding the application of the Sunset Clause to Medreich's licence.

Medreich's participation in the Market Exclusion Agreement

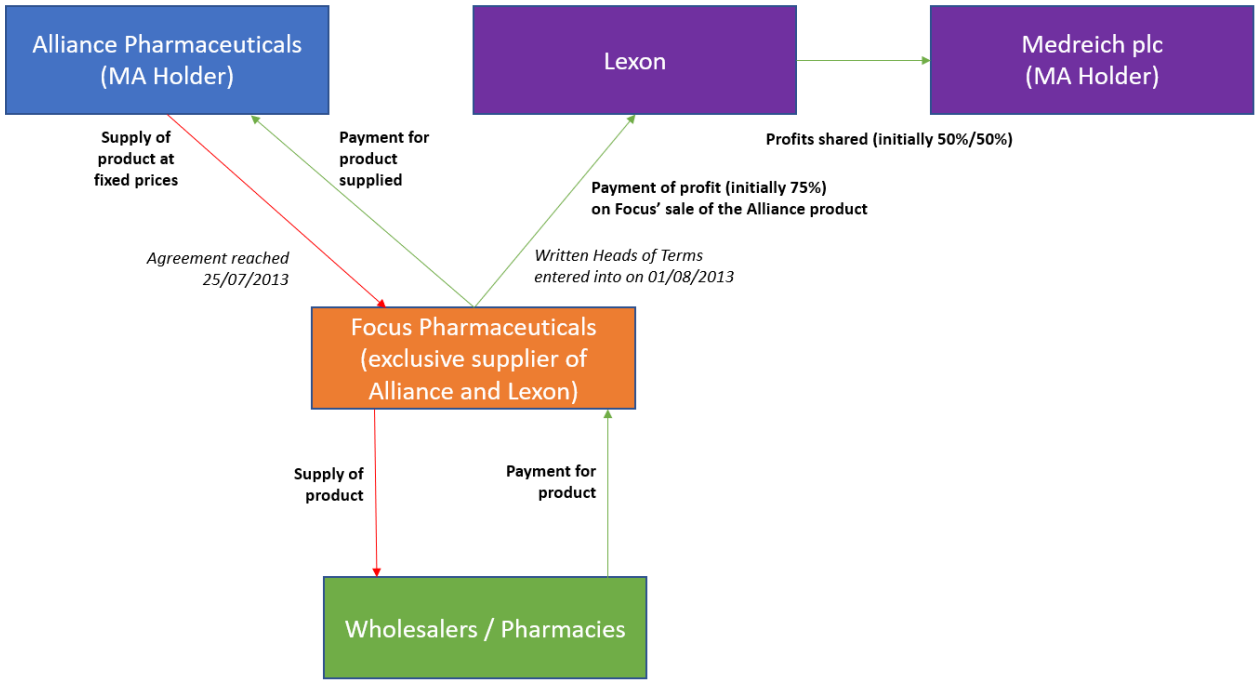
1.38 The CMA has not found that Lexon's manufacturing partner, Medreich, was aware of the Market Exclusion Agreement at the start of the Infringement in 2013. Rather, the CMA has found that by 5 February 2014 Medreich was aware of the Market Exclusion Agreement reached between Alliance and Lexon (or could reasonably have foreseen it and was prepared to take the risk), and can be said to have participated in the Market Exclusion Agreement from that point on. The CMA concludes: that there was an overall plan pursuing a common objective (which in this case was the implementation of the Market Exclusion Agreement; that Medreich was aware of the conduct engaged in by Alliance and Lexon in pursuit of the common objective (or could reasonably have foreseen it and was prepared to take the risk); that in this case, Medreich was as a matter of fact also aware of the conduct which was put into effect by Focus in pursuit of the common objective; and that Medreich made an intentional contribution to that common objective.

1.39 Specifically, Medreich accepted its share of the profit share payments Lexon received from Focus on the understanding that these were being made in return for Lexon/Medreich not competing with their own product.

Diagrammatic summary of the relationship between the Parties

1.40 The relationships between each of the undertakings involved is set out in Figure 1 below:

Figure 1: Relationship between the undertakings



The termination of the Infringement

1.41 Following the launch of the CMA's investigation in October 2017, Medreich gave Lexon formal notice on 15 February 2018 of Medreich's decision to remove prochlorperazine from the scope of their existing joint venture arrangements, and Medreich declined to receive any profit share from Lexon relating to Prochlorperazine POM sold after 31 December 2017, albeit that Medreich subsequently agreed to sell Prochlorperazine POM tablets to Lexon without any profit share component.

1.42 Medreich then applied to the CMA for leniency on 24 April 2018 and was granted a provisional Type B leniency marker under the CMA's leniency policy. Medreich provided further documents and information to the CMA under its leniency procedures, and the CMA entered into a leniency agreement with Medreich in relation to its involvement in the Infringement on 21 May 2019.

1.43 Consequently, the CMA has found that Medreich's involvement in the Infringement ended on 15 February 2018.

1.44 For the other undertakings involved, Alliance, Lexon and Focus, the CMA has found that their involvement in the Market Exclusion Agreement ended on 31 July 2018. This is the date on which the contract between Focus and Lexon terminated,

and from this date Focus no longer paid profit share to Lexon on its sales of the Alliance product.

The Parties' representations on the case

1.45 With the exception of the leniency applicant, Medreich, the Parties to the case have contested the CMA's finding that there was a Market Exclusion Agreement or, in the case of Focus, if there were such an agreement, that Focus participated in it.

1.46 The Parties' representations on the CMA's provisional findings in this case are addressed in the relevant sections of this Decision, including in the relevant annexes. The following paragraphs summarise the most important of the Parties' representations.

The Parties submit the CMA is misreading the contemporaneous evidence

1.47 The Parties have submitted that the CMA's reading of various pieces of contemporaneous, documentary evidence dating from between June 2013 and July 2017 on which the CMA relies to establish the existence of the Market Exclusion Agreement is flawed. The Parties offer alternative readings of these documents that, they say, undermine the CMA's finding of the Market Exclusion Agreement, with Focus participating in it. The CMA rejects these arguments. It finds that the plain meaning of the documents is supportive of its finding of the Market Exclusion Agreement and it rejects the Parties' alternative interpretations of these documents.

The Parties submit that Alliance was at all times unaware of Focus's agreement with Lexon, and acted unilaterally to meet the competitive threat from Lexon

1.48 The Parties, and in particular Alliance, have submitted that de-branding Buccastem POM, and entering into its fixed price supply agreement with Focus, was Alliance's unilateral response to enable it to compete most effectively with the competitive threat it expected, and continued to expect, from Lexon. The CMA rejects these arguments. It finds that Alliance's decision to de-brand, and to enter into a fixed price agreement with Focus that meant that Focus (rather than Alliance) could increase prices and earn inflated margins, is explained by its agreement to compensate Lexon (indirectly through Focus) for its agreement not to enter the market.

The Parties submit that Focus was unaware of any agreement between Alliance and Lexon and that its entry into two exclusive supply agreements, and its profit share payments to Lexon, are explained by Focus' own commercial strategy

1.49 Advanz and Cinven have submitted that Focus' decision to enter into exclusive supply agreements with each of Alliance and Lexon, including a provision whereby Focus would be obligated to pay the majority of its profits on sale of the Alliance

product to Lexon, is explained by Focus' own commercial motivations. The CMA rejects this argument. It finds that Focus' actions in entering into the two agreements, and its willingness to agree the profit share clause in the agreement with Lexon, are credibly explained only by the Market Exclusion Agreement. The explanations that Advanz and Cinven provide as to why Focus, including under AMCo's[12] ownership from 1 October 2014, would continue to pay significant profit share payments to Lexon, despite the lack of product received from Lexon/Medreich until the single batch received in March 2018, are not credible.

The Parties submit that Lexon sought to obtain product from Medreich, but Medreich could not produce it

1.50 The Parties, and in particular Lexon, have submitted that Lexon sought to obtain Prochlorperazine POM product from its manufacturing partner, Medreich, and that the reason that Medreich did not supply product until November 2017 (nearly four years after the original licence grant in January 2014) was because of difficulties Medreich experienced with the Medicines and Healthcare products Regulatory Agency regarding the validity of its licence and challenges Medreich experienced in actually manufacturing the product. The Parties submit that these difficulties also meant that Lexon and Medreich (working together) were not a potential competitor to Alliance. The CMA acknowledges that Medreich did experience both regulatory and manufacturing difficulties in relation to Prochlorperazine POM; however, the CMA finds that Lexon had nevertheless agreed not to supply commercial quantities of the product, and that Lexon and Medreich (working together) retained the potential (absent the Market Exclusion Agreement) to enter the market notwithstanding these temporary and surmountable issues.

The Parties submit that contemporaneous evidence from 2014 shows that Lexon expected to supply and Focus expected to purchase commercial volumes of Lexon/Medreich product

1.51 The Parties, in particular Advanz and Cinven, point to three email exchanges between Focus and Lexon in 2014 that refer to the supply of product, but that do not specify whether any such supply would be limited to the single batch of product needed to avoid the application of the Sunset Clause or to a plan to supply commercial volumes of the product. They submit that these show that either there was no Market Exclusion Agreement, or, if there was an agreement between Alliance and Lexon, Focus was not participating in it. The CMA rejects these claims. Although it does not rely on these documents to establish the existence of the Market Exclusion Agreement and Focus' participation in it, it finds that, when considered in the round and in the context of the surrounding documentary evidence and the Parties' conduct: (i) the documents are not explained by an

[12] Amdipharm Mercury Limited indirectly acquired Focus Pharmaceuticals Limited on 1 October 2014 (see paragraphs 3.7 and 3.10 below) with the result that the CMA refers to the management of the companies owning the Focus Entities after 1 October 2014 as '**AMCo**'.

expectation on the part of Lexon and/or Focus of the supply by Lexon to Focus of commercial volumes of Prochlorperazine POM – including a scenario in which Focus expected to order commercial volumes of Prochlorperazine POM but was being misled by Lexon as to its progress and order status; and (ii) they can each plausibly be explained by one or more interpretations that do not involve an expectation on the part of Lexon or Focus of the supply by Lexon to Focus of commercial volumes of Prochlorperazine POM product, and which are therefore not inconsistent with the existence of the Market Exclusion Agreement.

The CMA's assessment of the credibility of the Parties' submissions taken collectively and in the round

1.52 In addition to considering the Parties' submissions on specific points, the CMA has also considered the overall credibility of the Parties' submissions when assessed collectively and cumulatively. The CMA finds that the Parties' submissions would together require a series of highly improbable coincidences in their conduct.

1.53 The implication of the Parties' submissions is that Alliance's and Lexon's respective decisions to appoint Focus as distributor, and to do so at around the same time, was purely coincidental and the outcome of their own unilateral motivations: Lexon in seeking to appoint a distributor to launch its product in the market and Alliance in seeking to appoint a distributor to help it best respond to the competitive threat of the Lexon entry:

1.53.1 Focus and Lexon say that they had been in some form of discussions around Focus distributing the Lexon product for some time by summer 2013;

1.53.2 despite not having referred to Focus as a potential distributor of its product in the prior months, and despite Alliance having never previously used Focus to supply a product in the face of generic competition, Alliance says it unilaterally determined in summer 2013 that Focus was the best placed distributor to supply Alliance's de-branded Prochlorperazine POM product so as to enable Alliance to compete against the competitive threat from the forthcoming Lexon product; and

1.53.3 despite the relevance of its negotiations with one supplier to the other, the Parties submit that Focus did not inform either supplier that it was negotiating with its rival at the same time.

1.54 The implication of the Parties' submissions is also that it was an unintended coincidence that the pair of contracts put into place at approximately the same time in summer 2013 between Alliance and Focus and Focus and Lexon resulted in

Lexon/Medreich receiving over £7.86 million from the profits earned on the supply of the Alliance product. The pair of contracts involved:

1.54.1 Alliance agreeing to exceptional supply terms that resulted in Focus earning significant profits on the sale of Alliance's Prochlorperazine POM (some £14.4 million to the end of July 2018), which Alliance has stated was the consequence of its willingness to allow Focus to increase the price of its de-branded product, together with Alliance's own reluctance to benefit itself from any such price increases;

1.54.2 Focus agreeing to pass the majority of those profits on to Lexon (some £7.86 million to the end of July 2018), and to persist in making such payments in the absence of supply from Lexon in return, which Focus has stated was motivated by a range of different factors, including its desire to obtain and supply the Lexon product when it became available, but which ultimately tangibly and directly yielded for Focus only a single batch of Lexon/Medreich Prochlorperazine POM product in March 2018; and

1.54.3 Lexon receiving payments totalling some £7.86 million (to the end of July 2018) as a result of the inclusion in the contract of a clause that Lexon has stated was designed to discourage Focus from sourcing product from other suppliers, but where those payments were actually a direct result of Focus selling the product of Lexon's competitor, Alliance; Lexon then paid a proportion of that revenue (some £2.90 million) to its manufacturing partner, Medreich, which Lexon has said had failed to manufacture and supply any product until November 2017.

1.55 When considered together, the Parties' submissions also imply that a series of documents that, on their plain reading, document the existence of the Market Exclusion Agreement, are, in fact, the outcome of a variety of errors, omissions and misunderstandings that, by coincidence, provide consistent evidence of the existence of the Market Exclusion Agreement.

1.56 The CMA has explained in the relevant parts of the Decision why it considers that the Parties' various explanations for these documents should be rejected. The CMA finds that this assessment is further supported by the highly improbable coincidences that the Parties' submissions rest upon, including that: (i) both suppliers reached the view, independently, that Focus should be appointed as their distributor; (ii) that, by coincidence, they separately negotiated supply terms, that were themselves of an exceptional nature and that enabled Lexon/Medreich to receive over £7.86 million of the profits earned from the supply of the Alliance product; and (iii) a series of documents were produced that, in error, recorded consistently the terms of the Market Exclusion Agreement.

The penalties the CMA is imposing

1.57 The CMA has found that each of the Parties infringed the Chapter I prohibition intentionally, or at the very least negligently, and has decided to impose the following penalties amounting in total to £35,279,554 on the undertakings subject to this Decision:

1.57.1 Alliance is fined £7,900,000.

1.57.2 Lexon is fined £7,300,000.

1.57.3 Focus:

(a) The Advanz Group is collectively fined £10,602,934.[13]

(b) The Cinven Entities are fined £6,700,000.[14]

1.57.4 Medreich would have been fined £7,700,000, but is fined £4,620,000 after application of its 40% discount for leniency.

1.58 The legal entities liable for these fines and the amounts they must pay are set out in Chapters 7 and 8.

1.59 In setting these fines, the CMA has taken into account that the Infringement was a serious infringement of competition law.

[13] The Cinven Entities are jointly and severally liable for £1,843,380 of this amount.

[14] Certain subsidiaries within the Advanz Group are jointly and severally liable for £1,843,380 of this amount.

2. The Investigation

2.1 In this Chapter, the CMA sets out a summary of the main steps and key events in its investigation of the matters that are the subject of this Decision.

Commencement and scope of the investigation

2.2 On 13 January 2017, the CMA received an anonymous submission which alleged that a number of pharmaceutical products, including prochlorperazine, had been the subject of *'a off the record [sic] understanding to divide the market amongst themselves, stay off the market in return for a set payment'*.[15]

2.3 On 10 October 2017, the CMA opened a formal investigation under the Act, having determined that it had reasonable grounds for suspecting that the Parties (other than Cinven) and [✂] had infringed the Chapter I prohibition and Article 101 TFEU.

2.4 On 9 July 2018, the CMA decided on grounds of administrative priorities no longer to investigate whether [✂] had entered into one or more suspected anti-competitive agreements and/or concerted practices in relation to the supply of prochlorperazine 3mg buccal tablets in the UK.[16] The CMA decided to continue the investigation in respect of the other Parties (other than Cinven which was not a party to the investigation at that time).

2.5 On 23 January 2019, the CMA informed Cinven that the CMA had decided to expand the scope of the investigation under section 25 of the Act to include the Cinven Entities as party to a suspected infringement on the basis that they exercised decisive influence over the AMCo Group[17] and thus the AMCo Group's wholly owned subsidiary Focus Pharmaceuticals Limited from 1 October 2014 to 20 October 2015.[18]

Evidence gathering and engagement

2.6 In this section, the CMA provides details of key procedural steps taken in relation to evidence gathering and engagement with the Parties and third parties.

Alliance

2.7 On 10 October 2017, the CMA conducted an unannounced inspection at the premises of Alliance under section 28 of the Act.

[15] Anonymous submission to CMA 13 January 2017 (URN: PRO-E004591).

[16] Such a decision does not amount to a statement as to whether [✂] has been or is infringing competition law, nor should any inference be made to that effect.

[17] See paragraph 3.10 for an explanation and definition of AMCo Group.

[18] Letter CMA to Cinven 23 January 2019 (URN: PRO-C3395 and PRO-C3396).

2.8 On 8 November 2017 and 17 January 2020, the CMA served notices under section 27 of the Act for the production of further documents.

2.9 Information and/or documents were requested from Alliance under section 26 of the Act on 16 October 2017, 11 October 2018, 26 November 2019, 12 November 2020 and 7 May 2021.

2.10 The CMA conducted compulsory interviews with current Alliance employees under section 26A of the Act:

2.10.1 [Alliance Director 1], [✂], on 3 November 2017 and 8 October 2018;[19]

2.10.2 [Alliance Employee 2], [✂], on 3 October 2018;

2.10.3 [Alliance Employee 1], [✂], on 4 and 9 October 2018;[20] and

2.10.4 [Alliance Director 2], [✂], on 5 October 2018.

2.11 The CMA held state of play meetings with Alliance on 17 July 2018, 5 February 2019 and 31 January 2020. Alliance provided voluntary submissions to the CMA on 9 May 2018 and 25 February 2019.[21]

Focus/AMCo/Concordia

2.12 On 10 October 2017, the CMA conducted an unannounced inspection at the UK premises of Concordia International Rx (UK) Limited ('**Concordia Rx**')[22] under section 28 of the Act. In addition, the CMA conducted unannounced inspections at the domestic premises of [AMCo Director 1], [✂] of Concordia Rx and, at the time, [✂] of Mercury Pharma Group Limited,[23] under section 28A of the Act.

2.13 On 19 July 2018, the CMA served a notice for the production of further documents under section 27 of the Act. Additional information and/or documents were requested from the Concordia Rx group under section 26 of the Act on 11 December 2018, 6 February 2019, 26 November 2019, 25 November 2020, 4 March 2021 and 7 May 2021.

2.14 The CMA conducted compulsory interviews with current Concordia Rx group employees under section 26A of the Act:

[19] [Alliance Director 1] resigned as a Director of Alliance on [✂] (URN: PAD017).

[20] The CMA was informed by Alliance that it was not possible for [Alliance Employee 1] to review the transcript of his interview with the CMA or provide a statement of truth.

[21] Voluntary submission of Alliance dated 9 May 2018 (URN: PRO-C1834) and voluntary submission of Alliance dated 25 February 2019 (URN: PRO-C3822).

[22] Concordia Rx has since been renamed Advanz Pharma Services (UK) Limited ('Advanz Pharma Services'). References to Concordia Rx therefore include references to Advanz Pharma Services, according to context (URN: PAD007).

[23] [AMCo Director 1] resigned as a Director of Mercury Pharma Group Limited on [✂]. (URN: PAD066).

2.14.1 [AMCo Director 1], [✂] of Mercury Pharma Group Limited (at the time of the interview) and [✂] of Concordia Rx, on 19 October 2017;

2.14.2 [AMCo Director 2], [✂] of Concordia Rx's international business segment (at the time of the interview)[24] and [✂], on 1 November 2017 and on 7 January 2020 as [✂] of Advanz Pharma Services; and

2.14.3 [AMCo Employee 3], [✂], on 12 and 13 June 2018.

2.15 The CMA conducted compulsory interviews with former Concordia Rx group employees under section 26A of the Act:

2.15.1 [AMCo Employee], [✂] of Amdipharm Mercury Limited, on 23 October 2017;

2.15.2 [AMCo Employee 1], [✂] of Amdipharm Mercury Limited, on 23 October 2017;

2.15.3 [AMCo Employee 2], [✂] of Amdipharm Mercury Limited, on 30 October 2017;

2.15.4 [Focus Director 1], [✂] of Focus Pharmaceuticals, on 2 October 2018; and

2.15.5 [Focus Employee 1], [✂] of Focus Pharmaceuticals, on 7 February 2019; and

2.15.6 [Focus Director 2], [✂] of Focus Pharmaceuticals, on 8 January 2020.

2.16 The CMA held state of play meetings with Concordia Rx/Advanz Pharma Services on 18 July 2018, 19 February 2019 and 31 January 2020. Advanz Pharma Services provided a voluntary submission to the CMA on 1 March 2019.[25]

Cinven

2.17 As explained in paragraph 2.5 above, on 23 January 2019 the CMA expanded the scope of the investigation under section 25 of the Act to include Cinven as a party to case 50511-2.

2.18 The CMA held state of play meetings with Cinven on 29 January 2019, 18 February 2019 and 7 February 2020. The CMA transferred evidence onto its case file which it had gathered from Cinven under section 26 of the Act in cases 50395 and 50277-2.

[24] Since November 2018, [AMCo Director 2] has been the [✂] of Concordia Rx/Advanz Pharma Services (URN: PAD012).

[25] Voluntary submission of Advanz dated 1 March 2019 (URN: PRO-C3832).

2.19 Information and/or documents were requested from Cinven under section 26 of the Act on 26 November 2019 and 7 May 2021.

Lexon

2.20 On 10 October 2017, the CMA gave notice that it intended to enter the premises of Lexon to conduct an inspection under section 27 of the Act. The CMA subsequently reviewed documents provided by Lexon pursuant to that notice at the CMA offices in February 2018.

2.21 Information and/or documents were requested from Lexon under section 26 of the Act on 10 October 2017, 7 November 2018, 26 November 2019, 4 September 2020 and 7 May 2021.

2.22 The CMA conducted a compulsory interview under section 26A of the Act with [Lexon Director 1], then [✂] of Lexon, on 10 and 19 September 2018.

2.23 The CMA held state of play meetings with Lexon on 18 July 2018, 5 February 2019 and 31 January 2020.

Medreich

2.24 On 10 October 2017, the CMA gave notice that it intended to enter the premises of Medreich to conduct an inspection under section 27 of the Act. The CMA subsequently carried out an inspection pursuant to that notice at the premises of the legal advisers of Medreich in December 2017.

2.25 Information and/or documents were requested from Medreich under section 26 of the Act on 10 October 2017.

2.26 Medreich applied to the CMA for leniency on 24 April 2018 and was granted a provisional Type B leniency marker under the CMA's leniency policy. Medreich provided further documents and information to the CMA under its leniency procedures.

2.27 The CMA conducted voluntary witness interviews with former employees of Medreich:

2.27.1 [Medreich Director 2], [✂], on 2 July 2018;

2.27.2 [Medreich Employee 1], [✂], on 12 July 2018; and

2.27.3 [Medreich Director 1], [✂], on 22 November 2018.

2.28 The CMA held state of play meetings with Medreich on 18 July 2018, 5 February 2019 and 28 January 2020.

2.29 On 21 May 2019 Medreich entered into a leniency agreement with the CMA in relation to its involvement in the Infringement.[26]

[✂]

2.30 On 10 October 2017, the CMA conducted an unannounced inspection at the premises of [✂] under section 28 of the Act.

2.31 Information and/or documents were requested under section 26 of the Act from [✂] on 10 October 2017 and [✂] on 16 October 2017.

2.32 As explained in paragraph 2.4 above, on 9 July 2018 the CMA decided on the grounds of administrative priorities no longer to investigate the conduct of [✂] or [✂] in the context of case 50511-2.

Other sources of information

2.33 In the course of its investigation (including during the period in which case 50511-2 formed part of a wider investigation case 50511 into alleged anti-competitive practices agreements and/or concerted practices in relation to generic pharmaceutical products),[27] the CMA requested information and/or documents under sections 26, 27 and/or 28 of the Act from a number of entities and individuals, as follows:

Category	Entity
Suppliers or Wholesalers	[✂]
Specialists	Medicines and Healthcare products Regulatory Agency ('**MHRA**'), Department of Health and Social Care ('**DHSC**'), NHS Business Services Authority ('**NHS BSA**')
Individuals	[Medreich Director 2] (formerly of Medreich), [✂], [✂],[28] [✂]

Statement of Objections

2.34 On 23 May 2019, the CMA issued a Statement of Objections ('**SO**') to the Parties.

2.35 Following the issue of the Statement of Objections, a Case Decision Group was appointed within the CMA to act as the decision-maker[29] on:

2.35.1 whether or not the legal test for establishing an infringement had been met; and

[26] Leniency agreement between the CMA and Medreich as signed 21 May 2019, paragraph 3 (URN: PRO-C6682).

[27] See in this respect https://assets.publishing.service.gov.uk/media/5bec469740f0b667ce6707b5/case_closure_statement.pdf.

[28] [✂].

[29] Taking account of the facts and evidence before it and the Parties' representations.

2.35.2 the appropriate amount of any penalties.

2.36 The Parties submitted written representations on the Statement of Objections ('**RSO**') between 26 July 2019 and 15 August 2019.[30]

2.37 Between 25 September 2019 and 9 October 2019, the CMA held oral hearings with the Parties on the matters set out within their written representations.[31]

The end of the Brexit 'Transition Period'

2.38 On 14 January 2021, the CMA wrote to the Parties to confirm that, following the end of the Brexit 'Transition Period'[32] on 31 December 2020, EU law would no longer be applied in the UK and the CMA's investigation in Case 50511-2 Prochlorperazine would continue on the basis of the Chapter I prohibition in the Competition Act 1998 only.

Deprioritisation of part of the investigation

2.39 On 22 January 2021, the CMA closed on administrative priorities grounds its investigation of whether each of the agreements between (a) Alliance and Focus, and (b) Focus and Lexon, in which Medreich subsequently participated, in relation to the supply of prochlorperazine 3mg buccal tablets in the UK individually and in themselves broke competition law.

Draft Penalty Statement

2.40 On 14 June 2021, the CMA issued a Draft Penalty Statement ('**DPS**') to each of the Parties. The Parties submitted written representations on the Draft Penalty Statement between 2 July 2021 and 7 July 2021.[33]

2.41 Between 20 July 2021 and 26 July 2021, the CMA held oral hearings with the Parties on the matters set out within their written representations on the Draft Penalty Statement ('**RDPS**').[34]

[30] Medreich RSO, 26 July 2019 (URN: PRO-C6253); Lexon RSO, 31 July 2019 (URN: PRO-C5091); Alliance RSO, 1 August 2019 (URN: PRO-C5096); Advanz RSO, 1 August 2019 (URN: PRO-C5111); Cinven RSO, 15 August 2019 (URN: PRO-C5132). Medreich's written representations were limited to material factual inaccuracies as envisaged by Applications for Leniency and No-action in Cartel Cases (OFT1495, July 2013), paragraph 5.11.

[31] With the exception of Medreich on account of its written representations being limited to material factual inaccuracies as a leniency applicant.

[32] As provided for by the UK/EU Withdrawal Agreement.

[33] Lexon RDPS, 2 July 2021 (URN: PRO-C7416); Advanz RDPS, 7 July 2021 (URN: PRO-7472 to PRO-C7481); Alliance RDPS, 7 July 2021 (URN: PRO-C7461 to PRO-C7469); Cinven RDPS, 7 July 2021 (URN: PRO-C7439 to PRO-C7441); Medreich RDPS, 7 July 2021 (URN: PRO-C7444).

[34] With the exception of Lexon that confirmed that it did not wish to make oral representations on the matters referred to in its response.

Letter of Facts February 2021

2.42 The CMA conducted further evidence gathering following the issue of the Statement of Objections and the receipt of written and oral representations from the Parties. Further to that exercise, the CMA identified additional evidence that supported the objections set out in the Statement of Objections relating to the Market Exclusion Agreement. The additional evidence did not materially change the nature of the suspected Market Exclusion Agreement infringement described in the SO.

2.43 Accordingly, on 16 February 2021 the CMA issued a Letter of Facts[35] to the Parties providing them with the opportunity to review and respond to that new evidence. The Parties submitted written representations on the Letter of Facts between 14 April 2021 and 29 April 2021 ('**RLF**').[36]

Letter of Facts November 2021

2.44 The CMA conducted further evidence gathering following the issue of the Statement of Objections, the receipt of written and oral representations from the Parties and the issue of the February 2021 Letter of Facts. Further to that exercise, the CMA identified additional evidence that supported the objections set out in the Statement of Objections relating to the Market Exclusion Agreement. The additional evidence did not materially change the nature of the suspected Market Exclusion Agreement infringement described in the SO.

2.45 Accordingly, on 12 November 2021 the CMA issued a second Letter of Facts to the Parties providing them with the opportunity to review and respond to that new evidence. The Parties submitted written representations on the second Letter of Facts between 26 November 2021 and 30 November 2021.

Covid-19

2.46 Between 7 April 2020 and 20 July 2020, the investigation was paused in order for the CMA to reallocate resources to ensure that it was able to focus on urgent work during the Covid-19 pandemic.

[35] See *Guidance on the CMA's investigation procedures in Competition Act 1998 cases* (CMA8) 4 November 2020, paragraph 12.27.

[36] Medreich RLF, 14 April 2021 (URN: PRO-C7094), Lexon RLF, 21 April 2021 (URN: PRO-C7104), Advanz RLF, 22 April 2021 (URN: PRO-C7112); Cinven RLF, 22 April 2021 (URN: PRO-C7107); Alliance RLF, 29 April 2021 (URN: PRO-C7118).

3. Facts

3.1 This Chapter sets out the Parties and the key individuals within the Parties; it provides an overview of the relevant product, the pricing and regulatory context, and the key facts and chronological background to the conduct.

Key companies and individuals

3.2 The CMA sets out below a description of the key companies and individuals associated with the Parties in the UK with respect to this Decision.

Alliance

3.3 Alliance Pharmaceuticals Limited is a private limited company which had a turnover of £109.1 million in the financial year ending 31 December 2020.[37] Alliance describes itself as being active in the acquisition, marketing and management of healthcare products.[38] Alliance outsources capital investment activities, such as manufacturing, storage and logistics.[39]

3.4 Alliance Pharmaceuticals Limited is wholly owned by Alliance Pharma plc, a company whose shares are listed on AIM, part of the London Stock Exchange. This has been the case throughout the Infringement Period.[40]

Companies associated with Focus/AMCo/Concordia

Focus

3.5 Focus Pharmaceuticals Limited is a private limited company which had a turnover of £5.5 million in the financial year ending 31 December 2020.[41] Focus describes itself as being active in the marketing and distribution of pharmaceutical products.[42]

3.6 Focus Pharmaceuticals Limited is wholly owned by Focus Pharma Holdings Limited and this has been the case throughout the Focus Infringement Period.[43]

3.7 On 1 October 2014, Amdipharm Mercury Limited indirectly acquired Focus Pharmaceuticals Limited through its wholly owned subsidiary Mercury Pharma

[37] Annual report and financial statements of Alliance Pharmaceuticals Limited for the year ended 31 December 2020: https://find-and-update.company-information.service.gov.uk/company/03250064/filing-history, accessed on 11 October 2021.

[38] See www.alliancepharmaceuticals.com/about-us/our-business-model, accessed on 11 October 2021.

[39] See www.alliancepharmaceuticals.com/about-us/our-business-model, accessed on 11 October 2021.

[40] See paragraph 7.71.

[41] Annual report and financial statements of Focus Pharmaceuticals Limited for the year ended 31 December 2020, available at: https://find-and-update.company-information.service.gov.uk/company/04522142/filing-history, accessed on 11 October 2021.

[42] Annual report and financial statements of Focus Pharmaceuticals Limited for the year ended 31 December 2020, available at: https://find-and-update.company-information.service.gov.uk/company/04522142/filing-history, accessed on 11 October 2021, page 3.

[43] See paragraph 7.75.

Group Limited, by acquiring 100% of the shares of Focus Pharma Holdings Limited.[44]

AMCo Group

3.8 The ownership of the AMCo Group during the Focus Infringement Period can be divided into two periods:

3.8.1 from 1 October 2014 until 20 October 2015, when it was owned by private equity firm Cinven (see paragraphs 3.9 to 3.11); and

3.8.2 from 21 October 2015 until the end of the Focus Infringement Period when it was owned by the Canadian pharmaceutical group Concordia (now known as Advanz Pharma) (see paragraphs 3.12 to 3.13).

Cinven

3.9 Cinven is an international private equity firm which has €13.4 billion of assets under management. Healthcare is one of six sectors on which Cinven focuses its investment activity.[45]

3.10 The Fifth Cinven Fund ultimately acquired both the Mercury Pharma group on 31 August 2012 and the Amdipharm group on 31 October 2012, through Jersey holding company CCM Pharma Limited.[46] In 2013, Cinven integrated the Amdipharm and Mercury Pharma groups to form the '**AMCo Group**', and the top holding company, CCM Pharma Limited, was subsequently renamed Amdipharm Mercury Limited (later Concordia International (Jersey) Limited, and since dissolved).[47] The Fifth Cinven Fund held a majority stake in Amdipharm Mercury Limited, the 100% owner of the AMCo Group (including Mercury Pharma Group Limited and its subsidiary Focus Pharmaceuticals Limited) until 20 October 2015.[48]

3.11 On 21 October 2015, Cinven sold its stake in the AMCo Group to Concordia International Corporation.

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[44] See paragraph 7.75.

[45] Cinven Annual Review 2017, pages 3 and 8 (URN: PAD006).

[46] See document entitled Cinven: 'Our Investments', https://www.cinven.com/ourinvestments/default.aspx?investmentid=131, accessed on 9 November 2017 (URN: PAD065). See also document entitled 'Amdipharm Mercury Annual Review 2012', page 14 (URN: PAD086).

[47] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, questions 1 and 3 (URN: PRO-E004435).

[48] See document Cinven's 'Annex 5 _ Structure chart of the Amdipharm group following the A_1110205_0' (URN: PRO-E004441), [✂] (URN: PRO-E004120); and document 'AMCo: 'Annual Review 2014'', page 24 (URN: PAD064).

Advanz Pharma Corp. (Concordia International Corporation)

3.12 The AMCo Group is currently indirectly wholly-owned by Advanz Pharma Corp. Limited, which was previously known until 2018 as Concordia International Corporation.[49]

3.13 Advanz Pharma Corp. is an international pharmaceutical company engaged in the supply of more than 200 patented and off-patent products in over 90 countries.[50] In its last financial year, Advanz Pharma Corp. reported worldwide turnover of $525.59 million (£409.42 million).[51]

3.14 On 1 June 2021, Advanz was acquired by the private equity firm Nordic Capital.[52]

Lexon

3.15 Lexon (UK) Limited is a private limited company which had a turnover of £208.1 million in the financial year ending 30 April 2021.[53] Lexon (UK) Limited describes itself as being a wholesaler that supplies independent pharmacies in the UK.[54] In its capacity as a wholesaler, it has purchased product from Alliance as a supplier. The company also produces its own labelled products to sell on to other pharmaceutical wholesalers and chemists.[55]

3.16 On 1 March 2018 all the shares in Lexon (UK) Limited were acquired by Lexon UK Holdings Limited from a number of individual shareholders.[56]

3.17 Lexon has had a longstanding contractual relationship with Medreich in the form of a Product Development and Profit Sharing Agreement entered into in 2008.[57]

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[49] www.prnewswire.com/news-releases/concordia-international-corp-announces-name-change-to-advanz-pharma-corp-300757781.html, accessed on 4 March 2019 (URN: PAD007). Advanz Pharma Corp. was renamed Advanz Pharma Corp. Limited on 1 January 2020, when it changed its domicile to Jersey (https://www.advanzpharma.com/media/uploads/Advanz-Pharma-Corp.-Limited-Management-Discussion-and-Analysis-17-March-2021.pdf).

[50] www.prnewswire.com/news-releases/concordia-international-corp-announces-name-change-to-advanz-pharma-corp-300757781.html, accessed on 4 March 2019 (URN: PAD007).

[51] Advanz Pharma Corp.'s consolidated annual financial statements for the financial year ending 31 December 2020 (https://www.advanzpharma.com/media/uploads/ADVZ-Financials-Annual-with-Audit-opinion-2020-FINAL-17032021.pdf). Turnover is converted from US $ to £ at a Bank of England 12 month average spot rate of 1.284:1 for the year ending 31 December 2020.

[52] https://www.advanzpharma.com/news/2021/nordic-capital-acquires-specialty-pharmaceutical-company-advanz-pharma-in-deal-worth-846-million, accessed on 21 July 2021.

[53] Directors' report and financial statements of Lexon (UK) Limited for the year ended 30 April 2021, available at: https://find-and-update.company-information.service.gov.uk/company/03076698/filing-history, accessed on 27 January 2022.

[54] http://www.lexonuk.com/, accessed on 14 March 2019 (URN: PAD018).

[55] Directors' report and financial statements of Lexon (UK) Limited for the year ended 30 April 2020, page 4, available at: https://find-and-update.company-information.service.gov.uk/company/03076698/filing-history, accessed on 11 October 2021.

[56] Directors' report and financial statements of Lexon (UK) Limited for the year ended 30 April 2018, page 1 (URN: PAD019).

[57] Document entitled *'Product Development and Profit Sharing Agreement Between Medreich PLC and Lexon (UK) Limited'*, 25 February 2008 (URN: PRO-E002374).

Medreich

3.18 Medreich plc is a public limited company which had a turnover of $41.6 million (approximately £30.5 million[58]) in the financial year ending 31 March 2021.[59] The principal activity of the company is that of trading in pharmaceutical and chemical constituents and the provision of consultancy services.[60] The company also facilitates the sales and marketing of the overall group's manufacturing units around the world.[61]

3.19 Medreich plc is wholly owned by Medreich Ltd, a company incorporated in India, and this has been the case throughout the Medreich Infringement Period.[62] Since 12 February 2015, Medreich Ltd has been wholly owned by Meiji Seika Pharma Co, Ltd, which is wholly owned by Meiji Holdings Co. Ltd, a company incorporated in Japan whose shares are traded on the Tokyo Stock Exchange.[63]

Key individuals

3.20 The key individuals referred to in this Decision are set out below:

Individual and undertaking	Role
Alliance	
[Alliance Employee 1]	[✂][64]
[Alliance Director 1]	[✂][65]
[Alliance Director 2]	[✂][66]
Focus/AMCo/Concordia/Advanz	
[AMCo Director 2][67]	[✂][68]

[58] Exchange rate 0.73415 as at 11 October 2021.

[59] Annual report and financial statements of Medreich plc for the year ended 31 March 2021, available at: https://find-and-update.company-information.service.gov.uk/company/03122988/filing-history, accessed on 11 October 2021.

[60] Annual report and financial statements of Medreich plc for the year ended 31 March 2021, available at: https://find-and-update.company-information.service.gov.uk/company/03122988/filing-history, accessed on 11 October 2021, page 3.

[61] Annual report and financial statements of Medreich plc for the year ended 31 March 2021, available at: https://find-and-update.company-information.service.gov.uk/company/03122988/filing-history, accessed on 11 October 2021, page 3.

[62] See paragraph 7.61.

[63] See paragraph 7.64.

[64] Interview [Alliance Employee 1], 4 October 2018, part 1, page 8 (URN: PRO-C2909).

[65] [✂], accessed on 14 March 2019 (URN: PAD067).

[66] Interview [Alliance Director 2], 5 October 2018, page 10 (URN: PRO-C2941) and [✂], accessed on 19 March 2019 (URN: PAD067).

[67] Since [✂], [AMCo Director 2] has been the [✂] of Concordia Rx/Advanz Pharma Services: [✂], accessed on 19 March 2019 (URN: PAD012).

[68] Interview [AMCo Director 2], 1 November 2017, page 8 (URN: PRO-C1223).

Individual and undertaking	Role
[Focus Director 1]	[✂][69]
[Focus Director 2]	[✂][70]
Lexon	
[Lexon Director 1]	[✂].
Medreich	
[Medreich Director 2]	[✂][71]
[Medreich Employee 1]	[✂][72]

Prochlorperazine 3mg buccal tablets

3.21 Prochlorperazine belongs to a large group of medicines called phenothiazines and works by blocking the effects of a chemical on the brain.[73]

3.22 Prochlorperazine is available in the form of 3mg buccal tablets (which dissolve in the mouth[74]), 5mg tablets (which are swallowed), 5mg/5ml oral solution (syrup) and 12.5 mg/ml solution for injection.[75] Prochlorperazine 3mg buccal tablets are effective in the treatment of nausea and vomiting. They are also used to treat migraines and dizziness due to ear problems and other causes.[76] Prochlorperazine 5mg tablets, oral solution and solution for injection can be used to treat balance problems or dizziness (vertigo); prevent nausea or vomiting; treat schizophrenia; treat over-active behaviour or thoughts (mania); or treat anxiety in the short-term.[77]

3.23 This Decision is concerned with prochlorperazine 3mg buccal tablets sold in packs of 50 which is a prescription-only medicine ('**POM**') (known by the brand name 'Buccastem' and available as a generic version) ('**Prochlorperazine POM**'). Table 1 shows the total number of packs dispensed to patients in the UK and the total cost to NHS UK between 2014 and 2018. In 2014 the NHS spent £2.7 million in primary care on Prochlorperazine POM, whilst in 2018 the cost was £7.5 million. Total costs rose between 2014 and 2018 despite a fall in the number of packs

[69] [✂], accessed on 14 March 2019 (URN: PAD020).

[70] [✂], accessed on 26 April 2019 (URN: PAD068).

[71] Interview [Medreich Director 2], 2 July 2018, pages 13, 14, and 16 (URN: PRO-C3684).

[72] Interview [Medreich Employee 1], 12 July 2018, pages 20, 29, 34 (URN: PRO-C3666).

[73] Prochlorperazine 3mg buccal tablets patient information leaflet (URN: PAD023) and Prochlorperazine 5mg tablets patient information leaflet (URN: PAD024).

[74] Buccal medication dissolves rapidly and is absorbed through the mucous membranes of the mouth, where it enters into the bloodstream.

[75] https://bnf.nice.org.uk/medicinal-forms/prochlorperazine.html, accessed on 26 April 2019 (URN: PAD069).

[76] Prochlorperazine 3mg buccal tablets patient information leaflet (URN: PAD023).

[77] Prochlorperazine 5mg tablets patient information leaflet (URN: PAD024), Prochlorperazine mesilate 5mg syrup summary of product characteristics (URN: PAD022) and https://www.medicines.org.uk/emc/files/pil.6623.pdf (URN: PAD029).

dispensed due to rises in the Drug Tariff (see paragraphs 3.45 to 3.52 on the Drug Tariff).

Table 1: UK Prescriptions of Prochlorperazine 3mg Buccal tablets 2014-18[78]

Year	Total Tablets Dispensed	Number of Packs of 50 Tablets Dispensed	Cost to NHS in the UK (£)
2014	11,082,263	221,645	£2,654,882
2015	11,280,844	225,617	£5,172,621
2016	10,778,208	215,564	£7,963,330
2017	9,251,708	185,034	£8,173,442
2018	8,225,509	164,510	£7,547,705

Source: CMA Analysis

3.24 Prochlorperazine POM should be distinguished from 3mg buccal tablets sold in packs of 8 available 'over-the-counter' from pharmacies without a prescription from a GP ('**OTC**' or '**P'**) (known by the brand name 'Buccastem M') ('**Prochlorperazine OTC**').

3.25 In respect of POM medicines, the purchaser of medicines is essentially the NHS, and the medicine that will be dispensed is selected by a GP. The patient neither selects the medicine nor pays for it.[79] In respect of OTC medicines, consumers select their medicines and pay the price of the chosen product.

Framework of supply

Holders of Marketing Authorisations

3.26 Pharmaceutical manufacturers and distributors operating in the UK are subject to a system of licensing and inspection. Unless exempt, a medicinal product must be

[78] Excludes Prochlorperazine prescribed under the brand name Buccastem/M. Estimates for the number of packs of 50 tablets dispensed assumes that all generic prochlorperazine prescribed in the UK is dispensed in 50 packs. Pack size is not shown in the data.

England data source: https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data (URN: PAD070).

Wales data source: http://www.primarycareservices.wales.nhs.uk/prescription-cost-analysis.

Northern Ireland data source: http://www.hscbusiness.hscni.net/services/1806.htm.

Scotland data source: http://www.isdscotland.org/Health-Topics/Prescribing-and-medicines/Community-Dispensing/Prescription-Cost-Analysis/.

Scotland data only available until 2016. 2017 and 2018 have been estimated using the average yearly change in the quantity of tablets prescribed across England, NI and Wales. Scotland ingredient cost differs from the rest of the UK, and is the Gross Ingredient Cost rather than Net Ingredient Cost. This is the only cost variable that was available for Scotland.

[79] Certain patients will pay a prescription charge. However, that charge does not correspond to the price or value of the medicine being purchased.

covered by an MA before being placed on the market in the UK.[80] The competent authority in the UK is the Medicines and Healthcare Products Regulatory Agency ('**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. Where an application for an MA relates to a generic product, the manufacturer must demonstrate by means of a bioequivalence study that the generic product is therapeutically equivalent to the reference product and that standards of efficacy and safety are the same.[81]

3.27 A company holding an MA may manufacture the pharmaceutical product itself or contract with a third-party to manufacture the pharmaceutical product on its behalf. The company holding the MA is primarily responsible for ensuring the product complies with its licence and other applicable legislation, rather than the third-party manufacturer.[82]

3.28 Under the regulatory regime, an MA may become invalid after a period of three years due to the application of a so-called 'sunset clause' ('**Sunset Clause**').[83] If a product is not placed on the market within three years of the date of the grant of the MA, the MA will cease to be valid. In respect of generic medicinal products, the three year period starts on the date of the grant of the authorisation, or at the end of the period of market exclusivity or patent protection of the reference product, whichever is the later date.[84] If a product is placed on the market after authorisation, but subsequently ceases to be placed on the market in the UK for a period of three consecutive years, the marketing authorisation will also cease to be valid.[85]

Wholesalers

3.29 Wholesalers source prochlorperazine from suppliers (MA holders and/or distributors of pharmaceutical products) and sell on to pharmacies. In the UK, most pharmaceutical products are distributed through wholesalers to pharmacies.[86]

Pharmacies

3.30 Pharmacies either source prochlorperazine directly from a supplier or via a wholesaler. An explanation of how pharmacies dispense POM and are reimbursed

[80] The Human Medicines Regulations 2012, Part 4. A company may also obtain a parallel import licence, 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.

[81] See the Human Medicines Regulations 2012, and in particular Part 5.

[82] However, a third-party manufacturer may, for example, have contractual liabilities to the MA holder.

[83] Article 24 (4-6) of Directive 2001/83EC, as inserted by Article 1(23) of Directive 2004/27EC.

[84] Interpretation of Article 23a and Article 24 (4-6) of Directive 2001/83EC – the so-called "Sunset Clause" published on the gov.uk website (URN: PAD032).

[85] Interpretation of Article 23a and Article 24 (4-6) of Directive 2001/83EC – the so-called "Sunset Clause" published on the gov.uk website (URN: PAD032).

[86] CMA '*A report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business*' 29 July 2016, paragraph 13 (URN: PAD001).

by the NHS for the prescriptions they fulfil is set out in paragraphs 3.35 to 3.40 below.

The process and benefits of generic competition

3.31 This case involves the supply of unbranded, generic drugs. This section explains the difference between branded and unbranded, generic drugs and the benefits of generic competition.

Branded drugs

3.32 The main source of innovative branded medicines is from so-called 'originator' companies. Originator companies typically patent any molecule that shows promise early in the development process to protect their investment in that process. Patenting a molecule prevents other companies from copying it for a period of 20 years. The patent holder has an exclusive right to sell any derivative products for the duration of the patent.

3.33 Price focused competition between suppliers of branded drugs is limited by the fact that clinicians' awareness of prices is regarded as relatively limited, and their prescribing decision will not typically be focused on price.[87]

Generic drugs

3.34 At the expiry of the patent, generic versions of the drug can be manufactured and marketed by third parties. Once generic versions of a drug have been made available that drug is considered to have been 'genericised'.

3.35 Where a therapeutically equivalent generic product is available, pharmacies can dispense either a generic or a branded product against 'open' prescriptions that refer to the product's generic name (rather than to the brand name).

3.36 Pharmacies receive payment for the prescriptions they fulfil from the NHS patients' Clinical Commissioning Groups ('**CCGs**').[88] The price used to reimburse pharmacies dispensing drugs depends on whether the prescribed product is a branded or generic medicine. If a medicine is prescribed by brand name, the reimbursement is based on the manufacturer's list price for the prescribed product.

3.37 Where drugs are prescribed generically, that is based on a generic name, such as 'prochlorperazine buccal tablets', the drugs fall under Part VIIIA of the Drug Tariff

[87] A Department of Health study published in 2002 found that 'Most prescribers did not assimilate information on drug costs and price changes and were often unaware of prices or price changes'. Indeed, in relation to selective serotonin re-uptake inhibitors the study found that 'the percentage of correct rankings [of prices] is only marginally above 50%, which is what would be expected if GPs had no knowledge of price and simply guessed'. See Department of Health & Association of the British Pharmaceutical Industry (2002) PPRS. The study into the extent of competition in the supply of branded drugs to the NHS, pages 16 and 162 (URN: PAD031).

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

(see paragraphs 3.46 to 3.50 below). The amount pharmacies receive is set by the price of the product listed in the Drug Tariff (less any discount). Subject to any clinical guidance, pharmacies therefore have an incentive to dispense the cheapest medicine available. Generic suppliers will typically therefore compete on price to incentivise pharmacies to dispense their product and win market share from the competing branded and generic suppliers.

3.38 Many pharmacies are willing to pay more to dispense a branded product to fulfil a generic prescription to satisfy some patients' preferences for branded products.[89]

3.39 Generic drugs have become a significant feature of the UK pharmaceutical sector. NHS statistics show that by October 2018 the proportion of products dispensed by pharmacy contractors that were generic had reached more than 75%.[90]

3.40 Research suggests that competition from generic drugs typically results in significant price falls:

3.40.1 The European Commission's Pharmaceutical Sector Inquiry found that, in the EU, the price at which generic companies entered the market was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity.[91]

3.40.2 Generic entry can also have the effect of decreasing the price of the originator product. In markets where generic entry occurred, average prices dropped by almost 20% one year after the loss of exclusivity and about 25% after two years.[92] In some cases the decrease was as much as 80-90%.[93]

3.40.3 According to one UK trade association, generic drugs cost between 20% and 90% less than the original price of their brand-name equivalents.[94]

[89] OFT PPRS Market Study (2007), paragraphs 2.39 and 5.37 (URN: PAD087).

[90] Pharmaceutical Services Negotiating Committee, NHS Statistics – Dispensing statistics graphs, available at http://psnc.org.uk/funding-and-statistics/nhs-statistics/, accessed on 4 March 2019 (URN: PAD026).

[91] Sector Inquiry Final Report, Executive Summary section 2.1.2 (URN: PAD009).

[92] Sector Inquiry Final Report, paragraph 212 (URN: PAD010).

[93] Sector Inquiry Final Report, paragraph 212 (URN: PAD010).

[94] British Generics Manufacturers Association About generics, accessed on 4 March 2019 (URN: PAD005).

Price regulation of drugs in the UK

Branded drugs: the Pharmaceutical Price Regulation Scheme

3.41 From August 2009[95] until December 2013, prochlorperazine was sold in the UK by Alliance under the brand name 'Buccastem' and fell under the Pharmaceutical Price Regulation Scheme ('**PPRS**').

3.42 The PPRS is a voluntary agreement between the Department of Health and Social Care ('**DHSC**') and the Association of the British Pharmaceutical Industry which applies to manufacturers and suppliers of branded medicines to the NHS.[96] The PPRS aims to ensure that, *'safe and effective medicines are available on reasonable terms to the National Health Service'* and *'a strong, efficient and profitable pharmaceutical industry'*.[97] The PPRS does this by regulating the profits that companies can earn on sales of branded products to the NHS, rather than regulating prices directly.[98] It is not, however, intended to guarantee profits up to that level.

3.43 Under the PPRS, a scheme member has freedom to set the price of a new drug.[99] Once the price is set, the PPRS prevents the scheme member from increasing the price except in limited circumstances.[100]

3.44 A company may choose not to become a member of the PPRS or may be excluded by the Secretary of State.[101] In such circumstances, a statutory pricing scheme would apply to the company's branded products (but not to its generic drugs) (the '**Statutory Scheme**').[102] Alliance was a member of the PPRS.

Generic drugs: the Drug Tariff

3.45 For generic drugs, the policy of the DHSC is to rely primarily on competition to control prices.[103] Suppliers of generic drugs are not therefore subject to the price and profit controls of the PPRS or the Statutory Scheme.

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[95] Alliance acquired the worldwide rights to the branded product, Buccastem, from Reckitt & Colman Products Limited in August 2009, see paragraph 4.11.

[96] Section 261(7) of the NHS Act 2006; see also the 2014 PPRS, paragraph 3.14 (URN: PAD031).

[97] See the 2014 PPRS, page 9, paragraph 1.2 (URN: PAD031).

[98] ABPI's Understanding the 2014 Pharmaceutical Price Regulation Scheme, page 1 (URN: PAD033).

[99] 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 National Institute for Health and Care Excellence ('**NICE**'). NICE assesses the clinical and cost effectiveness of most new medicines launched in the UK market, see the 2014 PPRS, paragraph 7.14 (URN: PAD031).

[100] 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.

[101] Although there is provision for voluntary scheme members to be ejected from a scheme under section 261(4) of the NHS Act, in order to remove a manufacturer or supplier from the PPRS, it would be necessary for the Secretary of State to show that the PPRS was ineffective as regards that scheme member, and give the company concerned the opportunity to make representations (Section 261(4) and (5) NHS Act 2006).

[102] Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008.

[103] Health Service Medical Supplies (Costs) Bill: Committee Stage Report, 2 December 2016, page 3 (URN: PAD015).

3.46 From December 2013, Prochlorperazine POM fell under Part VIIIA of the Drug Tariff.[104]

3.47 The Drug Tariff governs the reimbursement price that pharmacies can claim from the NHS when fulfilling prescriptions (subject to any price concessions agreed between the DHSC and the Pharmaceutical Services Negotiating Committee). It is produced on a monthly basis by NHS Prescription Services.[105]

3.48 The Drug Tariff provides that a dispenser is reimbursed for medicines dispensed at a 'basic price'. The basic price of products covered by the Drug Tariff is listed under Part VIIIA of the Drug Tariff ('**Drug Tariff price**').

3.49 The fixed reimbursement price incentivises dispensers to purchase at a discount to the Drug Tariff price to make a profit margin on dispensing.

3.50 Medicines listed in Part VIIIA of the Drug Tariff fall under one of three categories which determine how the Drug Tariff price is calculated.[106] Two of those categories are relevant to Prochlorperazine POM:

3.50.1 Category A – Category A prices are based on the list price (that is, the supplier's price before customer-specific discounts) of commonly used generics that are typically readily available from several sources. The price of a drug within Category A is set using a weighted average of prices from a basket of two wholesalers and up to two generic manufacturers. There is a minimum requirement that products in Category A are listed either: (i) by two wholesalers; or (ii) by one wholesaler and by two manufacturers;

3.50.2 Category C – typically applies when a product is only available as a branded product or as a generic product from one or two sources. The price of a drug within Category C is based on a list price for a particular proprietary product, manufacturer or supplier.

3.51 Prochlorperazine POM 3mg buccal tablets were in Category C of the Drug Tariff from December 2013 (when they were de-branded) until August 2015. They moved to Category A from September 2015.[107]

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[104] In December 2013, Alliance introduced a generic version of Prochlorperazine and discontinued the Buccastem brand. Section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 30 (URN: PRO-C0367).

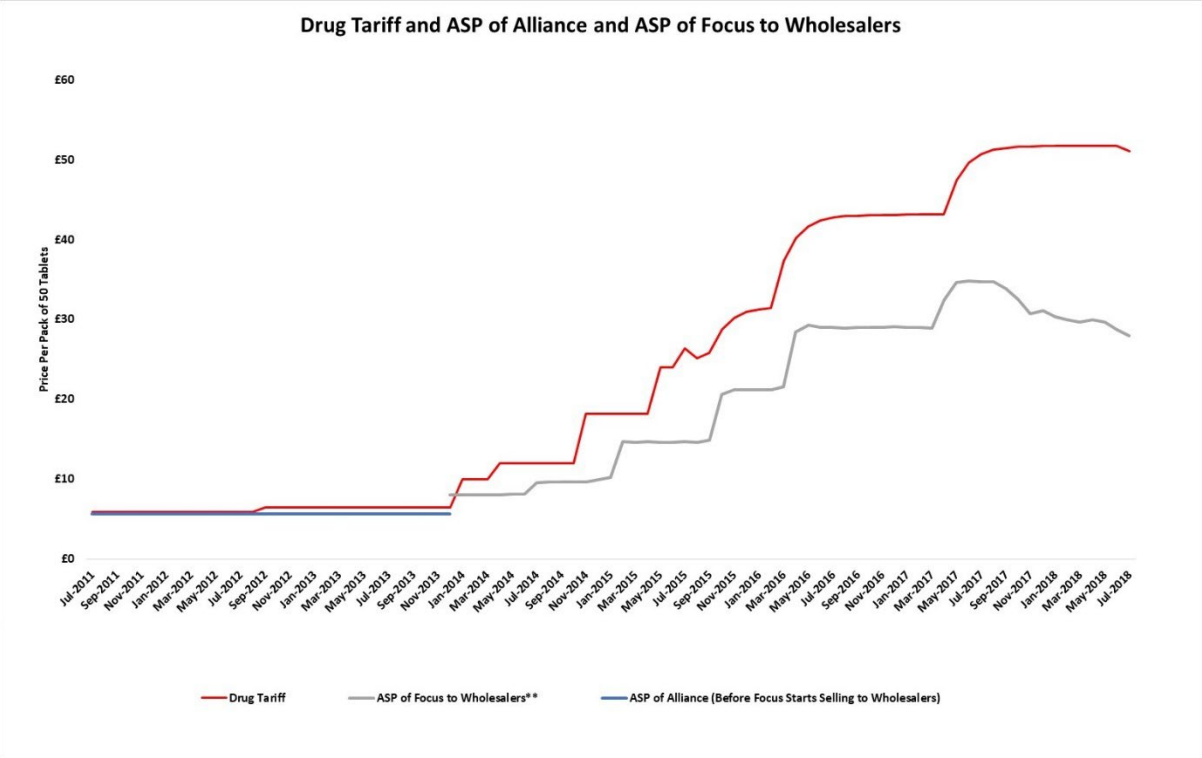
[105] See www.nhsbsa.nhs.uk/prescriptionservices.aspx. Health services are a devolved matter (Schedule 5 to the Scotland Act 1998, Schedules 2 and 3 to the Northern Ireland Act 1998 and Schedule 7 to the Government of Wales Act 2006). However, the National Assembly for Wales operates a common policy with the DHSC and therefore the Drug Tariff currently covers both England and Wales. Scotland and Northern Ireland maintain and publish separate Drug Tariffs.

[106] See DHSC, guidance notes in Part VIIIA of the Drug Tariff.

[107] Section 26 response of NHSBSA dated 1 March 2018, to the CMA Notice of 2 February 2018, Annex 9 (URN: PRO-C1501).

3.52 The chart below outlines the changes to the price of Prochlorperazine POM over time, as shown by the Drug Tariff and Focus' average selling price:[108]

Figure 2: England Drug Tariff of Packs of 50 Prochlorperazine 3mg Buccal Tablets (July 2011-July 2018) and Focus Average Selling Price[109]



[108] NHS Business Services Authority Tariff Data, https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff/drug-tariff-part-viii.

[109] Source for the drug tariff is the NHS Business Services Authority Data. The illustrative selling price of the branded Buccastem from Alliance to wholesalers, before Focus enters, is set at £5.65, based on the evidence of [Alliance Employee 1]: see Interview [Alliance Employee 1], 4 October 2018, part 1, page 140, line 16 to page 143, line 20 (URN: PRO-C2909).The average selling price of Focus is total revenue to all customers divided by total sales to all customers. The calculation therefore includes a small proportion of total volumes to customers who were not wholesalers. Less than 9% of sales by volume in any given month were to non-wholesaler customers, and there were no sales to non-wholesalers after May 2015. Source for Focus data is the section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150).

The Infringement

3.53 The key events, in chronological order, in respect of the relevant conduct are as follows:

Date	Event	Brief Description
25 February 2008	Lexon-Medreich Agreement entered into	Medreich and Lexon enter into the Product Development and Profit Sharing Agreement (the '**Lexon-Medreich Agreement**'), pursuant to which: (i) Medreich is responsible for developing marketing authorisations and manufacturing a range of products (including prochlorperazine 3mg buccal tablets and prochlorperazine 5mg tablets); and (ii) Lexon is responsible for marketing those products in the UK (including negotiating terms and prices). Lexon and Medreich agree to share all profits earned from the sales of products developed under the agreement [✂].[110]
August 2009	Alliance acquires the worldwide rights to the Buccastem brand	Alliance acquires the worldwide rights to the Buccastem brand from Reckitt Benckiser. This includes Buccastem 3mg tablets in both 50 pack POM and 8 pack OTC formulations.[111]
6 November 2009	Alliance applies for MA for Buccastem	Alliance applies for an MA to market Buccastem in the UK.
16 February 2010	Alliance is granted an MA for Buccastem	Alliance is granted an MA for Buccastem.
June 2010	Medreich applies for Prochlorperazine POM and OTC MAs	Medreich applies for MAs to market prochlorperazine POM and prochlorperazine OTC.
18 February 2011	Alliance varies its MA to include Prochlorperazine POM and OTC	Alliance applies to the MHRA to vary its MA for Buccastem to include the generic formulation, prochlorperazine. The variation is granted on 22 March 2011.
By 7 June 2013	The Market Exclusion Agreement	The CMA concludes that the Market Exclusion Agreement was most likely entered into between Alliance and Lexon by 7 June 2013, and, at the latest, by 22 June 2013.
22 June 2013	Focus participates in the Market Exclusion Agreement	The CMA concludes that Focus participates in the Market Exclusion Agreement between Alliance and Lexon from this date.
9 July 2013	Medreich's OTC MA granted	Medreich's MA for prochlorperazine OTC (PL 21880/0126) is granted.
25 July 2013	Alliance-Focus Agreement negotiated re: prochlorperazine POM	Correspondence between Alliance and Focus setting out the terms on which Focus will supply Alliance's prochlorperazine POM product.

[110] Document entitled *'Product Development and Profit Sharing Agreement Between Medreich PLC and Lexon (UK) Limited'*, 25 February 2008 (URN: PRO-E002374).

[111] Email [Alliance employee] to various recipients entitled *'Buccastem and Timodine'* dated 20 August 2009 (URN: PRO-E000801).

Date	Event	Brief Description
By 1 August 2013	Focus-Lexon Heads of Terms agreed (the '**Focus-Lexon Heads of Terms**')	The Focus-Lexon Heads of Terms (see paragraph 3.106 below) were agreed by 1 August 2013.
22 August 2013	Alliance-Focus Agreement signed (the '**Alliance-Focus Agreement**')	Alliance and Focus exchange a signed agreement relating to the supply of Prochlorperazine POM (see paragraph 3.104 below).
12 September 2013	Focus-Lexon Heads of Terms exchanged	Focus provides Lexon with a written heads of terms which provides that (i) Focus will be the exclusive distributor of Lexon's Prochlorperazine POM; and (ii) Focus will pay Lexon 75% of the profits it makes on sales of Prochlorperazine POM from any source. That document is later dated by Focus and Lexon as having been agreed on 1 August 2013.
9 January 2014	Medreich's POM MA granted	Medreich's MA for prochlorperazine POM (PL 21880/0122) is granted.
5 February 2014	Medreich participates in the Market Exclusion Agreement	The CMA concludes that Medreich participates in the Market Exclusion Agreement between Alliance and Lexon from this date.
1 October 2014	AMCo acquires Focus	AMCo acquires Focus Pharmaceuticals through a share purchase agreement. The Alliance-Focus Agreement and the Focus-Lexon Heads of Terms continue in force post-acquisition.
7 November 2014	Terms of the Focus-Lexon Heads of Terms agreed to be amended	Focus and Lexon agree to vary the Focus-Lexon Heads of Terms. The profit split of 25% to Focus and 75% to Lexon remains in place up to an average selling price of £10.50. However, where the average selling price exceeds £10.50, profits are shared 50/50. The revised terms apply from February 2015.
17 December 2014	MHRA contacts Medreich raising regulatory concerns re the Prochlorperazine POM licence	The MHRA contacts Medreich to inform it that the legal basis of its licence grant for Prochlorperazine POM is incorrect and that action is required to remedy this.
February 2015	Meiji acquires Medreich	The Medreich group (including Medreich Plc) is acquired by the Meiji group.
2 June 2015	AMCo acquires Primegen Limited ('**Primegen**')	AMCo acquires Primegen. Primegen's application for an MA for Prochlorperazine POM is pending at this point.
15 September 2015	MHRA contacts Medreich to inform Medreich of resolution of regulatory issue	MHRA contacts Medreich to confirm that both the Prochlorperazine POM and Prochlorperazine OTC licences can be considered as approved.
2 February 2016	Primegen's POM MA granted	Primegen's MA for Prochlorperazine POM is granted (PL 43659/0024).
3 February 2016	Terms of the Focus-Lexon Heads of Terms agreed to be further amended	The profit share between Lexon and Focus is renegotiated so that *all* profits are shared 50/50 between Lexon and Focus. The revised terms apply from April

Date	Event	Brief Description
		2016. At the same time, the profit share between Medreich and Lexon is amended so that, of Lexon's 50% share of the overall profits shared with Focus, Medreich is paid1/3rd (i.e. 1/6th of the overall profits) and Lexon retains the remaining 2/3rds.
December 2016	Medreich applies to extend the Sunset Clause	Medreich applies to delay the application of the Sunset Clause to its Prochlorperazine POM and OTC MAs.
April 2017	Medreich makes a further application to delay the application of the Sunset Clause	Medreich makes a further application to delay once again the application of the Sunset Clause to its Prochlorperazine OTC MA.
10 October 2017	Launch of CMA investigation	The CMA opened an investigation into the supply of, *inter alia*, Prochlorperazine POM tablets and carried out unannounced inspections at certain premises and issued notices of its intention to enter the premises of certain undertakings to conduct inspections
30 November 2017	Medreich supplies one batch of Prochlorperazine POM to Lexon	Medreich supplies one batch ([✂] packs) of Prochlorperazine POM to Lexon.
15 February 2018	Termination of the Lexon-Medreich Agreement in relation to prochlorperazine	Medreich writes to Lexon to terminate the Lexon-Medreich Agreement insofar as it relates to Prochlorperazine POM and OTC.
March 2018	Lexon supplies one batch of Prochlorperazine POM to Focus	Lexon supplies one batch ([✂] packs) of Prochlorperazine POM to Focus.
31 July 2018	Termination of Focus-Lexon Heads of Terms	AMCo treats the Focus-Lexon Heads of Terms as expiring as it was five years after the date on the Agreement (1 August 2013). From 1 August 2018, Lexon receives no further profits from Focus on the sale of Alliance Prochlorperazine POM.

3.54 The CMA sets out in detail the facts relevant to the Infringement below. The facts are presented by reference to contemporaneous correspondence in chronological order within broad subject areas, comprising:

3.54.1 Medreich's product development agreement with Lexon and the development of prochlorperazine (paragraphs 3.55 to 3.62);

3.54.2 the generic threat to Alliance's Buccastem product (paragraphs 3.63 to 3.71);

3.54.3 Lexon's contact with Alliance in relation to Lexon/Medreich's potential entry (paragraphs 3.72 to 3.87);

3.54.4 the conclusion of the relevant agreements involving Alliance, Focus and Lexon (June 2013 to September 2013) (paragraphs 3.88 to 3.106);

3.54.5 initial implementation of the relevant agreements involving Alliance, Focus and Lexon (September 2013 – September 2014) (paragraphs 3.107 to 3.129);

3.54.6 AMCo's acquisition of Focus and Primegen and AMCo's internal consideration of whether to launch a Prochlorperazine POM (paragraphs 3.130 to 3.166);

3.54.7 evolution of the agreements involving Alliance, Focus and Lexon, including AMCo's leveraging of its Primegen Prochlorperazine POM MA (September 2014 – October 2017) (paragraphs 3.167 to 3.200);

3.54.8 Medreich's participation in the relevant agreements and its regulatory and manufacturing position (August 2013 – November 2017) (paragraphs 3.201 to 3.269); and

3.54.9 termination and expiry of the various agreements (October 2017 – June 2018) (paragraphs 3.270 to 3.275).

Medreich's product development agreement with Lexon and the development of prochlorperazine

3.55 In June 2010, pursuant to the Lexon-Medreich Agreement,[112] Medreich applied for an MA to market Prochlorperazine POM and Prochlorperazine OTC in the UK.[113] In September 2011, [Medreich Employee 1] informed [Lexon Director 1] that Medreich expected those licences to *'be granted towards the end of 2012'*.[114]

3.56 During 2012, Medreich asked Lexon about Lexon's commercial expectations for Prochlorperazine POM and OTC. For example, on 20 January 2012, [Medreich Director 2] asked [Lexon Director 1] about the expected quantity of sales of prochlorperazine that should be assumed in the Medreich budget.[115] [Lexon Director 1] advised that in respect of Prochlorperazine POM he anticipated

[112] Document entitled *'Product Development and Profit Sharing Agreement Between Medreich PLC and Lexon (UK) Limited'*, 25 February 2008 (URN: PRO-E002374).

[113] Section 26 response of Medreich dated 7 November 2017, to the CMA Notice of 10 October 2017, question 5(b) (URN: PRO-C0250). See also email from [Medreich Employee 1] to [Lexon Director 1] cc [Medreich employee] entitled '*RE: Para/codeine 500/15 mg*' 6 June 2010 (URN: PRO-E002454): *'[Lexon Director 1] You will receive a mail this week confirming that both Prochlorperazine have been filed'*. See also email from [Medreich Employee 1] to [Lexon Director 1] entitled '*RE*' 18 June 2010 (URN: PRO-E002457): *'Prochlorperazine 3 mg is being uploaded now to MHRA and will complete on Monday'*.

[114] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*RE: Lexon Project Status Aug-2011*' 9 September 2011 (URN: PRO-E002504).

[115] Email [Medreich Director 2] to [Lexon Director 1] cc [Medreich Employee 1] entitled '*Prochlorperazine Maleate*' 20 January 2012 (URN: PRO-E002507).

achieving a market share of around 40% because, '*if we went for more price erosion would make it less profitable.'*[116]

3.57 In May and early June 2012, [Medreich Director 2] and [Lexon Director 1] exchanged a series of emails about the cost at which Prochlorperazine POM and OTC would be supplied by Medreich to Lexon.[117] On 31 May 2012, [Lexon Director 1] provided Medreich with a forecast for Prochlorperazine POM and OTC which assumed: (i) a 35% market share for both formulations; (ii) two MA holders; and (iii) a value per pack based on, *'current market value less reduction due to new MA holders'*. The forecast provided an estimated profit per month of £[✂] for the 50 pack and £45,167.50 for the 8 pack.[118]

3.58 [Lexon Director 1] and [Medreich Director 2] also discussed the possibility of launching the POM product in packs of 28 tablets rather than of 50. In the course of that correspondence, [Lexon Director 1] informed [Medreich Director 2] that for prochlorperazine, *'1st batch should be ready as close to licence landing in medreich [sic] livery.'*[119]

3.59 On 7 July 2012, [Medreich Employee 1] emailed [Lexon Director 1] to inform him that, in terms of the prochlorperazine licensing process, Medreich had provided a response to the latest request for information from the MHRA and that there were no outstanding requests for information.[120]

3.60 On 30 January 2013, [Medreich Director 2] emailed colleagues at Medreich asking about validation batch sizes for Prochlorperazine POM and OTC (and other drugs) and noting that the validation batches would need to be raised, *'on India for April – June Quarter…'*.[121]

3.61 [Lexon Director 1] was provided with a number of updates about the application process for prochlorperazine in the first half of 2013. For example, on 5 March 2013, [Lexon Director 1] was informed that artworks had been prepared for the

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[116] Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine Maleate*' 20 January 2012 (URN: PRO-E002509). In response, [Medreich Director 2] then queried the strategy: *'Also was wondering the strategy w.r.t 3mg especially … Would you be considering someone like [✂] or shall we go alone on this one .. as then we can start working on artworks …'* Email [Medreich Director 2] to [Lexon Director 1] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine Maleate*' 23 January 2012 (URN: PRO-E002510).

[117] Email [Medreich Director 2] to [Lexon Director 1] cc [Medreich Employee 1] entitled '*Prochlorperazine and Bisoprolol*' 28 May 2012 (URN: PRO-E002535). See also Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine and Bisoprolol*' 28 May 2012 (URN: PRO-E002536).

[118] Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine and Bisoprolol*' 31 May 2012 (URN: PRO-E002538) and Excel chart entitled '*Lexon Medreich generics new line forcasts.xlsx*' by [Lexon Director 1] dated 31 May 2012 (URN: PRO-E002539).

[119] Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*Prochlorperazine and Bisoprolol*' 1 June 2012 (URN: PRO-E002543); see also Email [Medreich Director 2] to [Lexon Director 1] cc [Medreich Employee 1] entitled '*Prochlorperazine and Bisoprolol*' 28 May 2012 (URN: PRO-E002544).

[120] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine*' 7 July 2012 (URN: PRO-E002552).

[121] Email [Medreich Director 2] to [Medreich employee] cc [Medreich employee] entitled '*Validation Batch Sizes*' 30 January 2013 (URN: PRO-E002570).

various prochlorperazine products[122] and on 16 April 2013, [Medreich Director 2] informed [Lexon Director 1] that the grant of the MAs for Prochlorperazine POM and OTC is *'imminent'*.[123]

3.62 Medreich's OTC MA was granted on 9 July 2013. Its POM MA was granted on 9 January 2014.[124]

The generic threat to Alliance's Buccastem product

3.63 Alliance acquired the worldwide rights to the branded prochlorperazine product, Buccastem, from Reckitt & Colman Products Limited in August 2009.[125] This included the rights to Buccastem 3mg tablets in both 50 pack POM and 8 pack OTC formulations.[126] At that point, there were no generic products competing with the branded Buccastem product.

3.64 Alliance first considered the potential threat from a third party launching a generic version of Buccastem in 2010. On 30 March 2010, [Alliance employee] informed her colleagues that, *'I have learned today (from a 100% source) that a competitor is planning to launch a generic Buccastem 3mg 50's as a POM also a generic OTC pack in a year …'*. By way of commercial response to that threat, [Alliance employee] suggested that Alliance could, *'[f]ile for the generic form Buccastem 50's'*.[127]

3.65 [Alliance employee] commented shortly after this, and raised various questions on the, '*Buccastem – Uk [sic] generic opportunity*' including:

> *'…2. Definition of this opportunity e.g [sic] increase profit stream from x to y as a result of genericising the 50's pack, enabling a price increase strategy to be deployed. How much money can we make and how quickly?'*[128]

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[122] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*Fwd: Prochlorperazine 3mg and 5mg*' 05 March 2013 (URN: PRO-E002578).

[123] Email [Medreich Director 2] to [Lexon Director 1] entitled '*FW: Prochlorperazine*' 16 April 2013 (URN: PRO-E002587).

[124] Section 26 response of Medreich dated 7 November 2017, to the CMA Notice of 10 October 2017, question 5(e) (URN: PRO-C0250).

[125] Email [Alliance employee] to 'Alliancepharma' cc various recipients entitled '*Internal Announcement. Allaince acquires two more barnds*" [sic] dated 18 August 2009 (URN: PRO-E000799).

[126] Email [Alliance employee] to various recipients entitled '*Buccastem and Timodine*' dated 20 August 2009 (URN: PRO-E000801). Following this acquisition, Alliance varied the relevant MAs to have them changed to Alliance's name, section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 4 (URN: PRO-C0367).

[127] Email [Alliance employee] to [Alliance employee] cc [Alliance employee] and [Alliance employee] entitled '*Buccastem attack*' 30 March 2010, page 2 (URN: PRO-E000804).

[128] Email [Alliance employee] to [Alliance employee] cc [Alliance employee] entitled '*Buccastem: Uk generic opportunity*' [sic] 8 April 2010 (URN: PRO-E000806). An Alliance Established Products report from April 2010 also noted that *'Alliance was '…investigating the potential launch of a Buccastem generic. Simultaneously evaluating the value add opportunity if we launch a generic ourselves'.* Alliance document entitled *'Established Product Business Unit (EPBU) Business Performance Report April 2010',* page 2 (URN: PRO-E000813). The equivalent document from the following month described that: *'Buccastem generic Regulatory (JS) has commenced application for Generic Prochlorperazine 3mg tabs (Buccal). Project Cobra is now progressing further and will follow after full appraisal'* Alliance document entitled *'Established Product Business Unit (EPBU) Business Performance Report May 2010'*, page 2 (URN: PRO-E000825).

3.66 During 2010, [Alliance employee] communicated with [Lexon Director 1] in relation to the launch of a generic prochlorperazine 3mg product. On 16 April 2010, [Alliance employee] emailed to ask [Lexon Director 1], *'I know you cant [sic] tell me who is going to launch a generic Prochlorperazine 3mg but do you know if its [sic] an oral dose or Buccal version ?[sic]'* to which [Lexon Director 1] replied on the same day, *'I think its [sic] oral dose.'* On 2 July 2010, [Alliance employee] then sent a reply to ask [Lexon Director 1], *'Do you have any update on the prochlorperazine – eg launch date/oral/buccal version?'* to which [Lexon Director 1] replied on the same day, *'Sorry I don't but I think it is still over a year away'*.[129] While [Lexon Director 1] did not specify who the potential entrant was in this email, it is notable that, in accordance with the Lexon-Medreich Agreement, Medreich applied for an MA to market Prochlorperazine POM and Prochlorperazine OTC in the UK in June 2010 (see paragraph 3.55 above).

3.67 During 2010 and 2011, Alliance continued to plan how it might respond to the launch of a generic form of Buccastem.[130] These plans culminated in Alliance making the decision to vary its existing MAs for Buccastem to also allow it to sell the generic form, prochlorperazine.[131]

3.68 During 2011, [Alliance employee] also met and corresponded with [Focus Director 2] as regards the distribution of various Alliance products, including Aspirin 300mg E/C and Buccastem. Specifically, [Focus Director 2] emailed [Alliance employee] to say:

> *'In follow-up to our meeting on possible supply of Aspirin E/C. Please find attached a simple draft supply agreement we have used before. The key terms are we are happy to purchase exclusively from Alliance, but we would want exclusivity on distribution… As we discussed on Friday we are happy to look at Distributing [sic] either… or Buccastem for you if required, we would be pleased to look at a proposal.'*[132]

3.69 [Alliance employee] forwarded [Focus Director 2]'s email and provided comments to [Alliance employee] on the rationale for entering into an agreement with Focus. Her email shows that Alliance was, or at least should have been, aware that

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[129] See email [Lexon Director 1] to [Alliance employee] entitled '*Re: Prochlor*' 2 July 2010 (URN: PRO-E000823).

[130] See email [Alliance employee] to [Alliance employee] and others in Alliance, entitled '*Cobra Project Plan*' 29 September 2010 (URN: PRO-E000834). See also Alliance Operational Business Plan 2011, Established Products, presentation, slide 9 (URN: PRO-E000835): *'If the generic threat moves PCT's to write nationally as generic then we need to be in a position to defend our market'*. See also Email [Alliance employee] to [Alliance employee] cc [Alliance employee] and [Alliance Employee 3] entitled '*Data to support Cobra generic launch*' 7 February 2011 (URN: PRO-E000868).

[131] See section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 4 (URN: PRO-C0367). See also email [Alliance employee] to Established Products BTU (Alliance) entitled '*Prochlorperazine submission – Project Cobra*' 17 February 2011 (URN: PRO-E000876). The variation was finalised on 22 March 2011 – see section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 4 (URN: PRO-C0367). After varying its MA, Alliance continued to consider its options if a generic did enter the market. See in particular Alliance presentation entitled '*Strategy Meeting EPBU [Alliance employee]*', dated 29 and 20 June 2011, slide 48 (URN: PRO-E000932).

[132] Email [Focus Director 2] to [Alliance employee] entitled '*Meeting Follow-up*' 20 June 2011 (URN: PRO-E001466).

entering into the agreement with Focus and supplying Focus with unbranded product would allow Focus to increase the price of the product. Specifically, [Alliance employee] commented on the potential for Alliance to supply Focus with unbranded, rather than branded, product, and for Focus to effect an increase in the price for the unbranded product over the course of the agreement:

> *'… ideally generic pack so they can get the tariff increase … its [sic] our NHS price holding the Cat A generic down. … they would sort the tariff out and gain from it – they would like a 2 year deal with us and then after 2 years we could trigger NuSeals 300mg back in again ? [sic] generic [sic] would be a lot higher – in the region of £8 per pk.'*[133]

3.70 The commercial rationale behind Alliance's agreement with Focus for Aspirin 300mg E/C (Nuseals) was considered in an Alliance strategy meeting presentation authored by [Alliance employee] on 29/30 June 2011:[134]

3.71 Alliance entered into an agreement with Focus in relation to the distribution of Aspirin 300mg E/C Tablets on 4 July 2011 ('the **Aspirin Agreement**'). That agreement provided that Focus would be the exclusive distributor in the UK of the Alliance unbranded product and would only supply Aspirin 300mg E/C Tablets that Focus source from Alliance.[135] The backdrop to this agreement is relevant in this

[133] Email [Alliance employee] to [Alliance employee] entitled '*Re: Meeting Follow-up*' 21 June 2011 (URN: PRO-E000926).

[134] Alliance presentation entitled '*Strategy Meeting EPBU [Alliance employee]*', dated 29 and 20 June 2011, slide 49 (URN: PRO-E000932).

[135] Section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 18 (URN: PRO-C0367).

context given that Prochlorperazine POM would subsequently be added to the scope of this agreement between Alliance and Focus (see paragraph 3.102 below).

Lexon's contact with Alliance in relation to Lexon/Medreich's potential entry

3.72 As previously noted, in 2010 [Lexon Director 1] had informed [Alliance employee] that he was aware of a potential generic entrant for prochlorperazine (see paragraphs 3.66ff above); however, at that time, the evidence obtained by the CMA shows that he did not provide Alliance with any details as to the identity of the potential entrant.[136]

3.73 On 27 February 2013, [Alliance Employee 2] emailed her colleague [Alliance employee] asking her to, *'do a quick check on Rama [a licensing subscription service] for Buccastem/Prochlorperazine. [Alliance Employee 1] has mentioned a competitor is due to bring out another line in a few weeks'*.[137] The minutes of an Alliance '*UK Review & Planning Meeting*' held on 14 March 2013 recorded that [Alliance Employee 1] had held discussions with Lexon, and set out various options to respond to the threat of potential entry:

> *'[Alliance Employee 1] has had discussions with contacts at Lexon on threat of generic prochlorperazine, look at Cobra again. Do nothings [sic], deal on branded or launch generic. 8-12 weeks for that. Not approved yet, they have said coming out in 6 weeks. All Lexon licenses are PLP [parallel import]I, this might be PI [parallel import], less of a threat. There are other products in the world. Keep dialogue open. Keep very close eye on.'*[138]

3.74 At this point in time, Lexon had been provided with updates from Medreich about the steps being taken by Medreich in the lead up to approval of the MAs for prochlorperazine (see paragraph 3.61 above).

3.75 On 18 March 2013, an internal Alliance email made further observations concerning the possible launch of a product by Lexon. It reported that [Alliance Employee 1] would stay in touch with Lexon to try to gain further information in order for Alliance to be able to determine what course of action Alliance would take

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[136] See email [Lexon Director 1] to [Alliance employee] entitled '*Re: Prochlor*' 2 July 2010 (URN: PRO-E000823).

[137] Email [Alliance Employee 2] to [Alliance employee] entitled '*rama*' 27 February 2013 (URN: PRO-E000969). 'Rama' is a subscription service managed by the MHRA providing licensing information about products authorised in the UK. A hard copy notebook obtained by the CMA during its inspection at Alliance (CXH007) contained an entry written by [Alliance employee] on page 1 dated 1 March 2013 recording *'Buccastem – Potential generic threat -> switch to generic packaging. – Lexon?'* (URN: PRO-E003981).

[138] Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' meeting dated 14 March 2013 09:00 – 12:00, page 8 (URN: PRO-E000971). The reference to 'Cobra' in that document is a reference Alliance's early plan to de-brand Buccastem see paragraph 4.15 above. The reference to PLPI is a reference to a parallel import product licence. A different document also entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' recording the minutes of the meeting held on 14 March 2013 (URN: PRO-E000979) records the minutes differently on page 5, noting that: *'[Alliance Employee 1] contact at Lexon has confirmed they have a product coming out in 6 weeks, not on Rama yet. All of Lexon's licenses are PLPI; this would be less of a threat. Options would be to do nothing, do a deal on Buccastem or launch Alliance generic (project Cobra); this would take 8-12 weeks. [Alliance Employee 2] and [Alliance Employee 1 will monitor closely and keep dialogue with Lexon open.'*

to respond to the introduction of a generic product by Lexon and considered the potential for some form of deal with Lexon, potentially involving adjusting the price of the branded product (a 'brand equalisation deal'):

> *'Further to the meeting earlier today…*
>
> *Lexon have communicated their intention to launch a generic version of Buccastem.*
>
> *Having reviewed all the other products in the Lexon portfolio these have been mostly identified at [sic] PLPI licenses imported from across the EU. If this is what they progress for Prochlorperazine the situation is not as bad as if they are launching a straight generic as the prices are likely to still be quite high. …*
>
> *[Alliance Employee 1] will make contact with Lexon again to keep dialogue open and try to gain further information.*
>
> *We then make an assessment on the pricing required for a brand equalisation deal with either Lexon or another partner once more info is know [sic] from the points above…*
>
> *[Alliance Employee 1] please let us know if you gain any further information from [Lexon Director 1] [sic] so we can start to formalise a plan.'*[139]

3.76 On 21 March 2013, an internal Alliance email recorded that Lexon had communicated to Alliance[140] that they would be launching a generic product, and listed different strategies that could be adopted in response:

> *'Please see below for a summary of the meeting yesterday and update on the latest situation.*
>
> *Lexon have communicated they have a generic license [sic] for both the 8s and 50s buccal prochlorperazine 3mg. The product is coming from India with low CoGS. We believe it may be Bukatel…*
>
> *The options for Alliance now are as follows:*
>
> *1) De-brand Buccastem, launch generic prochlorperazine in to Category A and name price.*

[139] Email [Alliance Employee 2] to [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 18 March 2013 (URN: PRO-E000976).

[140] [Alliance Employee 1] was in contact with Lexon at this point: see paragraphs 3.73 and 3.74 above. The increased detail in Alliance's understanding of the nature of the threat posed by Lexon from the email of 18 March 2013 (URN: PRO-E000976) compared with the email of 21 March 2013 (URN: PRO-E000986) indicates that there had been some contact between Alliance and Lexon during this period.

2) *De-brand Buccastem and gain supply of generic from Lexon, launch into Category A with an increase in price due to an increase in CoGS. Sell Lexon product in Alliance livery. The problem with this option is there are 2 years' worth of Buccastem M stock already manufactured.*

3) *Alliance to supply Lexon with generic product.*

[Alliance Employee 2] and [Alliance Employee 1] will be meeting with Lexon in Gloucester on the 12th April to discuss supply further.'[141]

3.77 In response to that email, [Alliance Employee 1] indicated that his preference was for Alliance be in a position to be able to supply a generic version of Buccastem, stating that, *'I think it would be prudent to expedite a move to a generic version… to give flexibility of options. Also you may want to investigate timelines for printing componentry and potential repacking costs to generic to alleviate the brand stock issue…'*.[142]

3.78 On the same day, [Alliance Director 2] (who was copied into the email chain above) emailed [Alliance Director 1] and [Alliance Director 3] to inform them that, *'…unfortunately the Buccastem threat would appear to be real, and not a PI threat. We are working on our defence strategy accordingly and I'll keep you informed as this is pulled together. I am not yet convinced that our own generic is the right way to go, but need to see the facts first.'*[143]

3.79 On 25 March 2013, [Alliance Director 1] emailed [Alliance Employee 2] assessing the threat of a generic version of Buccastem, stating *'Given the uniqueness of the product and the complex generic prescription, such products often have a good survival of branded'*.[144]

3.80 On 9 April 2013, [Alliance Employee 1] contacted [Creo Pharma employee] to discuss prochlorperazine.[145] [Alliance Employee 1] wrote, *'I would also like to pick your brains regarding options for prochlorperazine now that Lexon are coming with a generic for both the 50 pack and 8 pack in the 3mg. Is there a good time to*

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[141] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986). Relatedly, in August 2013 Alliance considered, in response to a threat that Auden McKenzie might start supply a generic version of Alliance's branded product Symmetrel 100mg, de-branding Symmetrel 100 mg and supplying Auden McKenzie with its newly de-branded generic product.

[142] Email [Alliance Employee 1] to [Alliance employee] and [Alliance Employee 2] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000987).

[143] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*FW: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000988).

[144] Email [Alliance Director 1] to [Alliance Employee 2] entitled *'Buccastem/Prochlorperazine generic threat'* 25 March 2013 (URN: PRO-E000990). Relatedly, in an April 2013 UK Operational Report it was noted that another Alliance branded medicine, Xenazine, had retained 70% market share despite two generic entrants, and contemplated retention of the Xenazine brand in the face of a third generic entrant, see Alliance document *'UK Operational Report April 2013'* (URN: PRO-E004769).

[145] Creo Pharma informed the CMA that the distribution of prochlorperazine was discussed at a meeting between [Alliance Employee 1] and Creo Pharma on 28 February 2013, see section 26 response of Creo Pharma dated 17 October 2018, to the CMA Notice of 4 October 2018, question 2(a) (URN: PRO-C2624).

talk?'[146] A month later, on 8 May 2013, [Alliance Employee 1] emailed [Creo Pharma employee] stating that, *'[l]ooks like we are going to launch prochlorperazine as a generic so there is potential to add this into the mix in a few months. Mum's the word.'*[147] Creo Pharma is a company that provides generics, commercial brands and specialist supply products to the wholesale, pharmacy and hospital sectors. [148]

3.81 As anticipated in the email referred to in paragraph 3.76, on 12 April 2013, a meeting was held at a hotel in Gloucester, between [Alliance Employee 1], [Alliance Employee 2] and [Lexon Director 1].[149]

3.82 On 18 April 2013 [Alliance Director 2] emailed [Alliance Employee 1] regarding the potential debranding of Alliance's Atarax product stating, *'let's bring into the mix with our discussions with Creo on Monday before we decide'*. On 29 April 2013, [Alliance Employee 1] responded to [Alliance Director 2], *'I think it would be appropriate to proceed with generating a generic to provide us with options going forward as we could argue we are now in the 'preparing to defend' stage of the product's lifecycle'* suggesting that Alliance would contemplate supplying recently de-branded products through Creo Pharma.[150]

3.83 The minutes of the Alliance '*Community and Consumer Products Report*' held in May 2013 also show that, at that time, Alliance was considering appointing Creo Pharma to distribute Prochlorperazine POM:

> *'Progressing launch of generic Prochlorperazine to combat the anticipated launch of competitor product by Lexon. First available manufacture will be early August. Planning split batch of Buccastem and Prochlorperazine.*
>
> *Collaborating with [Alliance Employee 1] to progress this and submit to Cat A. Prochlorperazine 3mg will potentially be marketed/traded through Creo Pharma.'*[151]

3.84 On 16 May 2013, Alliance held a '*UK Review & Planning Meeting*' which was attended by [Alliance Director 1], [Alliance Director 2] and [Alliance Employee 1] among others. The notes of that meeting discuss the option of launching a generic product while retaining the Buccastem brand:

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[146] Email [Alliance Employee 1] to [Creo Pharma employee] entitled '*Meeting 22nd'* 9 April 2013 (URN: PRO-E000991).

[147] Email [Alliance Employee 1] to [Creo Pharma employee] entitled '*Indapamide*' 8 May 2013 (URN: PRO-E000995).

[148] Writing in January 2014 in respect of his 2013 performance appraisal, [Alliance Employee 1] described Creo Pharma as able to manage *'key generics'* and Prochlorperazine POM as *'one of APL's key brands'* demonstrating that Alliance regarded Creo Pharma as capable of managing product such as Prochlorperazine POM (see [Alliance Employee 1] *2013 Appraisal* 30 January 2014 (URN: PRO-E001322)).

[149] Interview [Alliance Employee 2], 3 October 2018, page 22, lines 1-20 (URN: PRO-C2945).

[150] Email [Alliance Employee 1] to [Alliance Director 2] cc [Alliance Director 1] and [Alliance Director 3], entitled *'RE: Generic Atarax'* 29 April 2013 (URN: PRO-E004766).

[151] Community and Consumer Products Report, dated 13 May 2013, page 5 (URN: PRO-E001008).

*'Progress launch of own generic prochlorperazine and put into Category A. still [sic] 40% branded prescription so could not discontinue Buccastem. No adjustments to forecasts yet, once we know we will make changes. Mid-July for stock. CCG gain to prescribe a brand, need to be ready on this if it will be used**. Need more info., [Alliance Employee 1] set up small team to look at the options to have a set plan in place**'.*[152] *[emphasis in original].*

3.85 On 21 May 2013, [Alliance Employee 2] emailed [Alliance employee] copying [Alliance Employee 1] asking her to confirm that *'40% of scripts are written branded'* noting that *'this is quite important for the planning of the introduction the generic into the market place.'*[153]

3.86 On 23 May 2013, [Alliance Employee 1] emailed colleagues at Alliance indicating that he was still considering that Creo Pharma would distribute Prochlorperazine POM: '*I am reviewing a contract regarding supply of a number of our generic portfolio to a specialist company (Creo) that operates exclusively in the generic market. The first product is … (others are expected to follow – … – prochlorperazine as and when) …*'[154]

3.87 [Alliance Employee 1] informed the CMA in interview that he and [Lexon Director 1] had another face to face meeting in May 2013 at which Prochlorperazine POM was discussed.[155]

The conclusion of the relevant agreements involving Alliance, Focus and Lexon (June 2013 to September 2013)

3.88 On 7 June 2013, [Alliance Director 2] emailed [Alliance Director 1] and [Alliance Director 3] and informed them that:

'… Buccastem Defence plan [Alliance Director 1] and [Alliance Director 3] – [Alliance Employee 1] has worked up a plan which I'm comfortable with but I'd also like him to take you through his thoughts – if he can he'll get you both together, if not, separately. Either way we need a direction by end of play next Thursday…'[156]

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[152] Meeting notes entitled 'UK Review & Planning Meeting – Alliance Pharmaceuticals' meeting, dated 16 May 2013 09:00 – 12:00, page 6 (URN: PRO-E000999).

[153] Email [Alliance Employee 2] to [Alliance employee] cc [Alliance Employee 1] entitled *'Generic Prochlorperazine'* 21 May 2013 (URN: PRO-E001002).

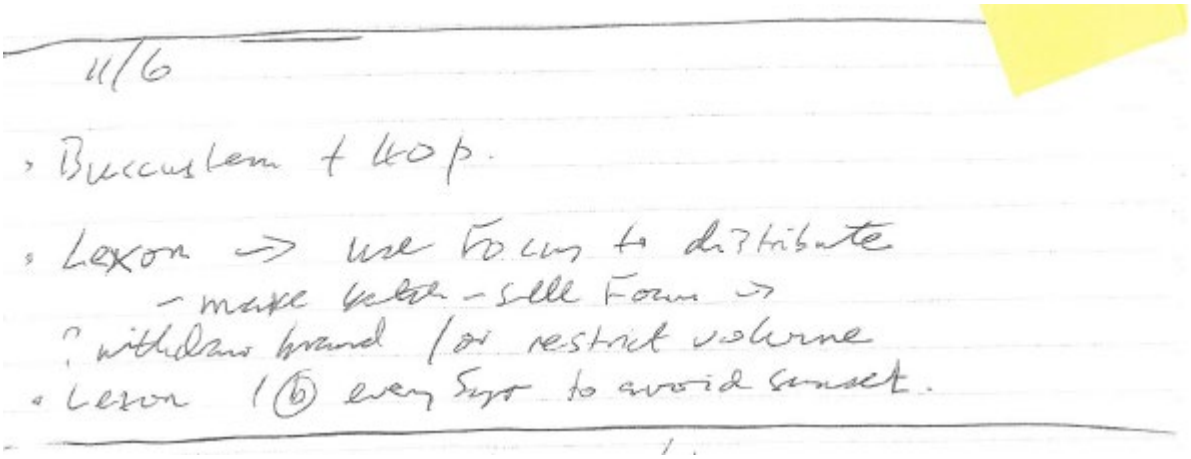
[154] Email [Alliance Employee 1] to various recipients at Alliance entitled *'Supply of stock to third party distributor'* 23 May 2013 (URN: PRO-E001005).

[155] Interview [Alliance Employee 1], Part 1, 4 October 2018, page 26, lines 20-24 and page 27, line 18 to page 28, line 4 (URN: PRO-C2909) see also section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017 (URN: PRO-C0367). The previous meeting was scheduled for 12 April 2013, as set out in the email referred to in paragraph 3.76.

[156] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*CCG switch and Buccastem defence*' 7 June 2013 (URN: PRO-E001009).

3.89 On 10 June 2013, [Alliance Employee 2] emailed colleagues at Alliance informing them that, '*We have a project ongoing to plan to react to the threat of a generic Prochlorperazine 3mg buccal entrant in the UK market. One of the options we are reviewing would be to cease manufacturing the branded 50s pack and drive all sales to a generic pack produced by Alliance but sold by another partner eg Focus…'*[157] This is the earliest written evidence from 2013 obtained by the CMA in which it was contemplated that Focus would potentially sell Alliance's Prochlorperazine POM.

3.90 During the CMA's inspection at Alliance, the CMA obtained the notebook of [✂], [Alliance Director 1], which contained the following entry dated 11 June 2013:[158]



3.91 That notebook entry states that:

11/6

- Buccastem + 40p
- Lexon → use Focus to distribute
  - make batch – sell Focus →

    ? withdraw brand / or restrict volume
- Lexon 1 [batch][159] every 5yr to avoid Sunset.

3.92 [Alliance Director 1] stated in interview that there was a *'good probability'* that the notes were of a meeting with [Alliance Employee 1].[160] [Alliance Employee 1]

[157] Email [Alliance Employee 2] to [Alliance employee] and others at Alliance entitled '*Buccastem*' 10 June 2013 (URN: PRO-E001010).

[158] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

[159] During an interview with the CMA, [Alliance Director 1] confirmed that the 'b' within a circle was his shorthand for 'batch' see interview [Alliance Director 1], 8 October 2018, page 87, lines 9-12 (URN: PRO-C2944).

[160] Interview [Alliance Director 1], 8 October 2018, page 95, lines 18-24 (URN: PRO-C2944). In his witness statement, [Alliance Director 1] stated that *'[i]t appears that the notebook entry may represent my rough notes of a briefing by [Alliance Employee 1] in relation to APL's strategy for prochlorperazine'* (Alliance RSO, Annex 1, [Alliance Director 1] witness statement, paragraph 6.3 (URN: PRO-C5097)).

confirmed in interview that he was the person most likely to have briefed [Alliance Director 1] about the 'defence plan'.[161]

3.93 The CMA has set out its interpretation of this notebook entry in detail in paragraphs 5.191 to 5.194: namely that it records a briefing provided by [Alliance Employee 1] to [Alliance Director 1] on 11 June 2013 about a commercial discussion [Alliance Employee 1] had with [Lexon Director 1].

3.94 On 11 June 2013, [Alliance Employee 1] emailed [Alliance employee] and [Alliance Employee 2] to inform them that the competitor's licence would be granted under the name *'Medreich'*.[162] As outlined in paragraphs 3.55 to 3.62, Lexon and Medreich were working together to bring Prochlorperazine POM and OTC to market in the UK.

3.95 On 22 June 2013, [Focus Director 1] emailed [Focus Director 2] to set out his understanding of Focus' position going forward in relation to the supply of Prochlorperazine POM:

> *'[Focus Director 2] In case [Alliance Employee 1] rings you , the agreement [Lexon Director 1] made was we initially buy at 25% off thier [sic] current trade price for the initial stock to allow us to open generic bins etc . When Alliance discontinue brand we purchase from them at current trade less 12.5% ie they keep the current asp and Focus sell the generic pack.*
>
> *Generic Pricing [sic] will depend on market and Focus will set !*
>
> *Deal between Focus and [Lexon Director 1]. 25/75% profit share in Lexon favour (as it is his licence)*
>
> *Volumes look higher on ethics line than I thought !*
>
> *We can have a chat on Monday . I am waiting on [Alliance Employee 1] ringing me back , but have [Lexon Director 1] chasing to see what is happening…'*[163]

The CMA sets out its interpretation of this email, together with [Focus Director 1]'s comments about it in interview to the CMA, in detail in paragraphs 5.190 to 5.272 below.

3.96 On 24 June 2013, [Lexon Director 1] and [Focus Director 1] exchanged a series of emails in which [Focus Director 1] informed [Lexon Director 1] that he had *'not*

[161] Interview [Alliance Employee 1], 9 October 2018, part 2, page 9, lines 11-18 (URN: PRO-C2910).

[162] Email [Alliance Employee 1] to [Alliance employee] and [Alliance Employee 2] entitled '*RE: RAMA*' 11 June 2013 (URN: PRO-E001014).

[163] Email [Focus Director 1] to [Focus Director 2] entitled 'Fwd: *Prochlorperazine IMS*' dated 22 June 2013 (URN: PRO-E001476).

heard back from [first name of Alliance Employee 1]', to which [Lexon Director 1] replied that he would *'chase [first name of Alliance Employee 1] in the morning'*.[164]

3.97 On 3 July 2013, Alliance informed its manufacturer of prochlorperazine that the *'decision has been made to pack the majority of Buccastem 50's in the new Generic Prochlorperazine livery from the next order…The 8's pack will remain unchanged."*[165]

3.98 On 10 July 2013, [Focus Director 1] emailed [Lexon Director 1] forwarding a copy of a RAMA subscription service report[166] and stating *'I take it the Medrich [sic] licence is yours exclusively before I send this to [Alliance Employee 1]'*.[167]

3.99 On 18 July 2013, [Focus Director 1] emailed [Focus Director 2] setting out the predicted profitability of Focus' supply of Alliance's Prochlorperazine POM based on increases to Focus' ASP and allowing for Focus to retain 25% of those profits:

> *'Just doing the preparation for meeting with [Alliance Employee 1] and this looks like a good addition to our range . Assuming the brand is discontinued and we get all the prescriptions , and Alliance agree to sell to us at their current ASP of trade less 12.5% (current trade =£6.49)*
>
> *Below is based on an initial Trade price for Focus of £10 rising to £12 and then £14 and allowing 20% for wholesale to get our ASP*

Monthly Volume	*Focus COG*	*Focus ASP*	*Focus monthly profit (25%)*
25,250	*£5.68*	*£8.00*	*£14,645*
25,250	*£5.68*	*£9.60*	*£24,745*
25,250	*£5.68*	*£11.20*	*£34,845*

> *The plan is to add this to the Aspirin supply agreement to get things moving quickly , It [sic] is likely we will get some product in Aug and the generic should be available for Oct .(poss Sept) [sic]'.*[168]

[164] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood*' dated 24 June 2013 (URN: PRO-E000325).

[165] Email [Alliance employee] to [Dechra Pharmaceuticals Manufacturing employee] cc various recipients entitled '*Buccastem/Generic Prochlorperazine Version Packing'* 3 July 2013 (URN: PRO-E001021).

[166] RAMA is a subscription service managed by the MHRA providing licensing information about products authorised in the UK.

[167] Email [Focus Director 1] to [Lexon Director 1] entitled '*Fwd: Rama as requested*' 10 July 2013 (URN: PRO-E000326).

[168] Email [Focus Director 1] to [Focus Director 2] entitled *'Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

3.100 On 25 July 2013, [Focus Director 1] emailed [Alliance Employee 1] summarising the outcome of a meeting discussing the supply of Alliance Prochlorperazine POM by Focus which had taken place between them earlier that week:

> *'Thanks for meeting me earlier this week…Please see below for a brief summary of our discussion…*
>
> ***Prochlorperazine 3mg x 50 Tabs***
>
> *We agreed an exclusive supply agreement for Prochlorperazine 3mg Tabs , [sic] and agreed this could be added as an amendment to the schedule of products in the already signed Distribution agreement for Aspirin 300mg Gastro-resistant Tabs.* ***Action [Alliance Employee 1] to draft the amendment and send to [Focus Director 1] for signing.***
>
> *Generic product will be available from October 2013 – Batch [sic] size for generic pack is 80,000 packs, however, this can be called off by Focus in quantities of 40,000 packs.* ***Action [Focus Director 1] to raise order and send through Forecast [sic] for the next 12 months***
>
> *The initial order for generic will be priced at £4.85 a pack and this will rise to £5.65 per pack from Jan 2014.*
>
> *It was also agreed that Focus could order some of the brand in September at £4.85 to allow us to open the generic bins in wholesale prior to the delivery of the true generic in Oct…'*[169] *(emphasis in original).*

3.101 The fact that [Focus Director 1] and [Alliance Employee 1] had agreed the terms on which Alliance would supply Focus with Prochlorperazine POM was reflected in the minutes from an internal *'Focus Sales Meeting'*, dated 30 July 2013, which note that, in relation to *'Prochlorperazine 3mg tabs'*, Focus, *'have a supply agreement with Alliance on this product'*.[170]

3.102 On 6 August 2013, [Alliance Employee 3] emailed [Alliance Director 3] and [Alliance employee] regarding a forecast decline of volumes of Prochlorperazine POM supplied to Focus noting:

> *'Forecast figures are based on current usage and also a moderate decline as you withdraw a brand and, as a consequence, there is confusion in the market. Also if the price increases then volumes will decline as alternatives are sought by prescribers. The forecast is 40k units for the first four months*

[169] Email [Focus Director 1] to [Alliance Employee 1] entitled *'Meeting summary'* 25 July 2013 (URN: PRO-E003735). [Alliance Employee 1] replied to [Focus Director 1]'s email of 25 July 2013 on 5 August 2013, stating that *'I am sitting down with legal to update the contract with the new product for supply with the terms previously communicated and should be able to provide you with a copy for review this week…'* Email [Alliance Employee 1] to [Focus Director 1] entitled '*Meeting summary*' 5 August 2013 (URN: PRO-E001029).

[170] Meeting notes entitled '*Focus Sales Meeting*', dated 30 July 2013 (URN: PRO-E001482).

to reflect a stock build which the vendor has agreed, this is currently being documented.'[171]

3.103 On 20 August 2013, [Focus Director 1] and [Alliance Employee 1] exchanged a series of emails about amending the existing agreement between Alliance and Focus for the supply of Aspirin 300mg E/C from Alliance to Focus to include Prochlorperazine POM (see paragraphs 3.68 to 3.71 above). [Alliance Employee 1] ultimately sent a copy of the original agreement and addendum to [Focus Director 1] on 21 August 2013.[172] The next day [Focus Director 1] posted a signed copy of the amendment to [Alliance Employee 1],[173] and Focus placed its first order for Prochlorperazine POM with Alliance.[174]

3.104 The key, relevant terms of the agreement between Alliance and Focus, and the subsequent addendum to include Prochlorperazine POM, were as follows:[175]

*'**2. Appointment***

Subject to SUPPLIER [Alliance] obtaining a Marketing Authorisation for each Product, SUPPLIER appoints FOCUS to be, and FOCUS agrees to act as, an exclusive distributor of the Products in the United Kingdom during the currency of and in accordance with the terms of this Agreement.

3. Duration

Subject to all other provisions of this Agreement, the Agreement shall remain in force in respect of each Product for a period of five years starting on the date FOCUS launches the Product in question for sale in the United Kingdom (the 'Initial Period') and then, unless terminated at the expiration of the Initial Period by either party giving to the other at least six months' prior written notice, shall continue in force until terminated by either party giving to the other like notice to take effect at any time after the Initial Period.

4. Marketing and Distribution Obligations

…

[171] Email [Alliance Employee 3] to [Alliance Director 3] and [Alliance employee] entitled *'FW: sales units forecast review – UK'* 6 August 2013 (URN: PRO-E001030).

[172] Email [Alliance Employee 1] to [Focus Director 1] entitled '*Meeting summary*' 21 August 2013 (URN: PRO-E003744).

[173] Email [Focus Director 1] to [Alliance Employee 1] entitled '*PO 9164959 to 9164961*' 22 August 2013 (URN: PRO-E001058). On 27 August 2013, [Alliance Employee 1] emailed [Focus Director 1] to confirm he had received the signed copy of the amendment, and had countersigned and posted the amendment back to Focus Email [Alliance Employee 1] to [Focus Director 1] entitled '*Contract*' 27 August 2013 (URN: PRO-E003749).

[174] Email [Focus employee] to [Alliance employee] entitled '*PO 9164959 to 9164961*' 22 August 2013 (URN: PRO-E001047).

[175] Section 26 response of Alliance, part two, dated 16 November 2017, to CMA Notice dated 2 October 2017, Appendix 2, Alliance-Focus Agreement (URN: PRO-C0369).

(3) FOCUS shall not, without the prior written consent of SUPPLIER, during the Initial Period of this Agreement sell or market in the United Kingdom any products having the same active ingredient and pharmaceutical form as any of the Products and compete with the Products…

6. Forecasting, Ordering and Supplies

(1) Subject to all other provisions of this Agreement, FOCUS shall during the Initial Period of this Agreement and, subject to SUPPLIER being willing and able to supply the same, obtain its requirements for supplies of the Products for the United Kingdom exclusively from SUPPLIER for the purpose of this Agreement, and SUPPLIER shall, subject to its not being prevented or prohibited by any circumstances beyond its reasonable control, supply the same to FOCUS…

7. Prices and Payment

...

(2) SUPPLIER may give FOCUS at least two month's written notice to increase the price for supplies of any Products. The increase may be up to the percentage increase in SUPPLIER's costs of procuring supplies for the Product in question unless otherwise agreed between the parties. SUPPLIER must at the request of FOCUS supply evidence to support the rate of increase. Unless exceptional circumstances apply (to be demonstrated by SUPPLIER to FOCUS)…

11. Early Termination

In case either party

withholds from the other for a period of one month or more from a payment due date any monies due to the other, or

commits or permits any substantial breach of any terms of the Agreement and fails to remedy that breach (if such breach is capable of being remedied) within thirty days of receiving written notice from the other party, or

has a receiver or administrator appointed in respect of any of its assets, or

enters into any arrangement or composition with its creditors, or

goes into liquidation whether voluntary or compulsory (except for the purpose of reconstruction or amalgamation), or

incurs any substantial change in the ownership of its business, or has its business taken over, nationalised or closed down in whole or in part by the executive or judicial authorities in their respective home country

then the other party shall have the option at any time by notice in writing to terminate this Agreement immediately, but such termination shall be without prejudice to the rights of either party against the other then accruing or accrued in respect of the event giving rise to such termination or otherwise under this Agreement.

Addendum

This Addendum & Amendment is made on the 22nd August 2013 to the agreement made on 4th July 2011…

***The Schedule** is amended as follows*

Product	***Product Licence Number***	***Supply Price***	***Minimum order***
Aspirin 300mg gastro-resistant tablets in packs 100's	*PL 16853/0063*	*…*	*…*
Prochlorperazine maleate 3mg buccal tablets in packs of 50's	*PL 16853/0101*	*Initial 40k packs: £4.85 Subsequent orders: £5.65*	*40k packs of 50's.*

3.105 On 12 September 2013, [Focus Director 1] emailed [Lexon Director 1] attaching a *'Heads of Agreement'* (the Focus-Lexon Heads of Terms) and stating that:

> *'As per our discussions please find attached Heads of agreement for Prochlorperazine 3mg Tabs supply. If you agree with this please print and sign two copies and return to me for signing at the office , [sic] I will then return a copy to you.'*[176]

[176] Email [Focus Director 1] to [Lexon Director 1], entitled '*Heads of agreement for Prochlorperazine 3mg Tabs*' 12 September 2013 (URN: PRO-E000329). On 8 August 2014, [Lexon Director 1] sent an email to [Focus Director 1] attaching a copy of the Focus-Lexon Heads of Terms stating, *'Have dated it the same as you'*. The copy of the Focus-Lexon Heads of Terms attached to that email had been signed by both [Focus Director 1] and [Lexon Director 1] and dated 1 August 20133759). The attached signed version of the agreement is the document entitled *'Heads of Agreement'* signed 1 August 2013 (URN: PRO-E000429).

3.106 The key, relevant terms of the Focus-Lexon Heads of Terms as implemented[177] were as follows:

> *'**Structure of Agreement***
>
> *Lexon will Supply [sic] FP [Focus Pharmaceuticals] with Prochlorperazine 3mg Tablets from its UK MA and provide all relevant documentation relating to the licence to distribute the product in the Territory.*
>
> *Territory is the United Kingdom.*
>
> *This agreement is based on FP being granted exclusive distribution rights to the product…*
>
> *FP will be supplied a UK pack from Lexon. FP will then be responsible for all sales and marketing of said pack to the wholesale /Retail and Hospital market in the agreed Territory…*
>
> *FP will be responsible for negotiation of commercial agreements between FP and its Customers in the Territory. Lexon has no commercial Liability for these agreements.*
>
> *FP will also be responsible for forecasting of sales volumes during the period of the agreement. FP will provide Lexon with a rolling 12 month forecast…*
>
> ***Terms…***
>
> *A Profit share will be in place relating to a 25% (FP) / 75% (Lexon) Profit to be the sum generated from sales less cost of purchase of the goods..*
>
> *If FP has Sales for Prochlorperazine 3mg Tabs from any other source than Lexon Licence the same profit share will be applicable.*
>
> ***Period of agreement and Termination Notice period:-***
>
> *The agreement will run for 5 years from signing of Heads of agreement.*
>
> *Termination Notice period will be 6 months for either party.*
>
> *Exclusivity only applies if the target Forecast volumes are achieved per annum by product. – To be agreed between FP and Lexon.'*[178]

[177] The copy of the Focus-Lexon Heads of Terms sent by [Lexon Director 1] to [Focus Director 1] of 8 August 2014 (see document entitled *'Heads of Agreement'* signed 1 August 2013 (URN: PRO-E000429)) was materially the same as that attached to [Lexon Director 1]'s email to [Focus Director 1] on 12 September 2013 (URN: PRO-E000330) (see note 176), save that the later copy provided for *'Profit to be the sum generated from sales less cost of purchase of the goods'* whereas the equivalent wording in the earlier copy was *'after FP distribution costs and Cost of goods have been taken*

Initial implementation of the relevant agreements involving Alliance, Focus and Lexon (September 2013 – September 2014)

3.107 On 12 September 2013, at a Lexon board meeting, [Lexon Director 1] stated that *'Prochlorperazine is due to be launched next month from which healthy returns are expected'*.[179] At this time, Medreich only had its Prochlorperazine OTC product and had not yet received its Prochlorperazine POM licence.

3.108 On 19 September 2013, Focus placed an order with Alliance for 5,000 *'Prochlorperazine Buccal tablets 3mg (50)'* at £4.85 per pack.[180] This particular order appears to have been discussed at a Focus sales meeting on 25 September 2013, where it was noted that *'Orders are in and should be available w/c 25th November but these may come forward, [Focus Director 1] will advise. We will have 5,000 packs of the brand which will be offered to Lexon by [Focus Employee 1].'*[181]

3.109 On 1 November 2013, in response to a query from a colleague at Lexon relating to sales to wholesalers of the Alliance branded product *('can we do buccastem [sic] into aah [sic] uk [sic]?'*), [Lexon Director 1] replied *'No don't push it. The brand is going to be discontinued and double in price soon'*.[182] Later that month, [Lexon Director 1] informed a colleague, in response to an enquiry about the availability of Lexon's 50 pack *'Prochlorperazine 3mg tabs'* in the UK, that *'Generic is due to us [Lexon] on Monday'*.[183]

3.110 On 5 November 2013, [Alliance Employee 1] sent [Focus Director 1] an email attaching the notice Alliance had sent out on 4 November 2013 relating to the withdrawal of the branded Buccastem 3mg tablets in 50 pack from the market.[184] This was done in anticipation of the forthcoming sales by Focus of Alliance's generic Prochlorperazine POM.

3.111 On 7 November 2013, [Focus Employee 1] emailed [Focus Director 1] setting out the trade and wholesale price for *'Prochlorperazine Buccal Tablets'*, as well as another product. She remarked specifically in relation to sales of the product to Lexon (as a wholesaler) that *'In addition to the customers listed above, Lexon will*

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into account'. The reconciliation statements evidencing the implementation of the Focus-Lexon Heads of Terms subsequently showed costs of goods being deducted to calculate the profit, but not Focus' distribution costs (see paragraph 4.63).

[178] Document entitled *'Heads of Agreement'* signed 1 August 2013 (URN: PRO-E000429).

[179] Document entitled *'Lexon (UK) Limited Board Meeting Minutes'*, dated 12 September 2013, page 2 (URN: PRO-C0054).

[180] *Focus Purchase Order*, dated 19 September 2013 (URN: PRO-E001064).

[181] Document entitled *'Focus Sales Meeting'*, dated 25 September 2013 (URN: PRO-E001492).

[182] Email [Lexon Director 1] to [Lexon employee] entitled '*RE: can we do buccastem into aah uk?*' 1 November 2013 (URN: PRO-E000334).

[183] Email [Lexon Director 1] to [Lexon employee] entitled '*RE: Lexon Product Query*' 28 November 2013 (URN: PRO-E000342).

[184] Email [Alliance Employee 1] to [Focus Director 1] entitled '*RE: Prochlorperazine*' dated 5 November 2013 (URN: PRO-E003755).

be offered the Prochlorperazine Tablets. I would suggest giving them 15% off trade …, but if you want [Lexon Director 1] to have the same pricing as mainline wholesale then just let me know.'[185]

3.112 On 14 November 2013, [Focus Director 1] emailed [Focus Director 2] about Focus' budget for 2014. In relation to Prochlorperazine POM, [Focus Director 1] wrote that *'… the current market is 25,000 per month but i [sic] have assumed some lost volume with the price increases . [sic] Again I have put us increasing Asp mid year but have also added to sales meeting agenda for discussion on timings and levels we can go to'*.[186]

3.113 On 3 December 2013, [Alissa Healthcare employee] emailed [Lexon Director 1] asking, in respect of the Focus Prochlorperazine 3mg product: *'… they've just got a PIP code … I guess if it's not your product then they will be launching soon?'*. On the same day, [Lexon Director 1] responded *'It's mine'.* [187]

3.114 Alliance discontinued Buccastem POM[188] and started to supply Prochlorperazine POM exclusively to Focus in December 2013.[189] [Focus Employee 1] communicated the fact that stock was available to [Lexon Director 1] on 5 December: *'The stock has arrived this afternoon – I'm seeing you tomorrow morning so we can sort out an order then'*.[190]

3.115 On 3 January 2014, [Focus Director 1] sent [Lexon Director 1] the first *'reconciliation'* statement for Focus' sales of Alliance's Prochlorperazine POM stating *'Please find attached the reconciliation for Dec sales of Prochlorperazine 3mg Tabs . [sic] Moving forward this will be done on a quarterly basis as per the agreement . [sic] Can you please raise an invoice on Focus for £80,631.56 and mark for the attention of [Focus employee] or myself .'*[191] The reconciliation statement set out for Prochlorperazine POM by month for the previous quarter the volume of product sold, the net turnover, the cost of goods, the profit and then the 75% share of that profit *'owed to Lexon'* by Focus. [Lexon Director 1] forwarded this email to colleagues at Lexon, stating, *'We also need to accrue half of this for*

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[185] Email [Focus Employee 1] to [Focus Director 1] entitled '*Re: Nov dealing levels*' 7 November 2013 (URN: PRO-E003758).

[186] Email [Focus Director 1] to [Focus Director 2] entitled '*FW: other OLS for budget*' 14 November 2013 (URN: PRO-E003759).

[187] Email [Lexon Director 1] to [Alissa Healthcare employee] entitled '*Re: Prochlorperazine 3mg . . . Focus*' 3 December 2013 (URN: PRO-E000343).

[188] Section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 30 (URN: PRO-C0367).

[189] Email [Alliance Employee 1] to [Alliance employee] and others entitled '*RE: Prochlorperazine 3mg Tablets*' 4 December 2013 (URN: PRO-E001092); see also section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 30 (URN: PRO-C0367).

[190] Email [Focus Employee 1] to [Lexon Director 1] entitled '*RE: Prochlorperazine Tabs*' 5 December 2013 (URN: PRO-E000344).

[191] Email [Focus Director 1] to [Lexon Director 1] cc [Focus employee] entitled '*FW: Prochlorperazine Reconciliation December 2013*' 3 January 2014 (URN: PRO-E000346) and attachment entitled '*Prochlorperazine Reconciliation December 2013*', 3 January 2014 which showed the cost of goods being deducted from a net revenue figure to generate profit, with *'75% Profit Share owed to Lexon'* (URN: PRO-E000347).

Medreich'.[192] Lexon subsequently forwarded a copy of the Prochlorperazine POM reconciliation spreadsheet to Medreich (see paragraph 3.204 below).

3.116 Medreich's MA for Prochlorperazine POM was granted on 9 January 2014.[193]

3.117 On 10 January 2014, [Focus employee] emailed two purchase orders to [Alliance employee] and [Alliance Employee 1] each for 40,000 packs of Prochlorperazine POM for delivery by 1 May 2014 and 2 June 2014 respectively.[194]

3.118 Following the commencement of Focus' sales of Alliance's Prochlorperazine POM in December 2013, and Lexon's receipt of the reconciliation statement in January, the Lexon Board Minutes from 14 January 2014 record that, *'[Lexon Director 1] discussed the status of drug development. Prochlorperazine has now been launched …."*[195]

3.119 Prochlorperazine POM was also discussed in a Focus sales meeting on 28 January 2014. The minutes record, *'… discuss profit share agreement with Lexon – [Focus Director 1] … Review pricing in March 2014 – ALL'*.[196]

3.120 Writing in February 2014 in respect of his performance appraisal for 2013, [Alliance Employee 1] described an area of his expertise as '*generic threat management – Prochlorperazine*'. He summarised that, *'The management of external companies and individuals has ensured the value will be maintained in Prochlorperazine (EP biggest product going into 2014).'* Further to this, [Alliance Employee 1] wrote *'margin generation for this product should be stable'* going into 2014.[197]

3.121 On 13 February 2014, [Alliance Employee 1] was contacted by a colleague in Alliance to inform him that two further licences had been granted in January 2014 to Medreich for prochlorperazine (the 5mg licence and the 3mg POM licence). [Alliance Employee 1] responded, *'… yes saw this and was aware. I thought it was coming in December so mid Jan not a surprise'*.[198]

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[192] Email [Lexon Director 1] to [Lexon employee] and [Lexon employee] entitled '*FW: Prochlorperazine Reconciliation December 2013*' 3 January 2014 (URN: PRO-E000348). Lexon subsequently raised an invoice for its 75% share of the profits from Focus Email [Lexon employee] to [Lexon employee], [Lexon Director 1], [Focus Director 1], cc [Focus employee], entitled '*RE: Prochlorperazine Reconciliation December 2013*' 7 January 2014 (URN: PRO-E003772).

[193] Email [Medreich employee] to [Medreich Employee 1], cc [Medreich Director 1] and [Lexon employee] entitled 'FW: *PL 21880/0122 PL 21880/0121*' 9 January 2014 (URN: PRO-E002701).

[194] Email [Focus employee] to [Alliance employee] and [Alliance Employee 1], cc [Focus employee], entitled *'New PO's 9165131 and 9165132'* (URN: PRO-E001099); *Focus Purchase Orders 10 January 2014* 10 January 2014 (URN: PRO-E001100).

[195] *Lexon Board Minutes,* dated 14 January 2014, page 3 (URN: PRO-E000374).

[196] *Focus Sales Meeting Minutes,* dated 28 January 2014, page 5 (URN: PRO-E003779).

[197] [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014, pages 17 and 18 (URN: PRO-E001103).

[198] Email [Alliance Employee 1], to [Alliance employee] entitled '*RE: Monthly list of granted marketing authorisations: Marketing authorisations granted in January 2014*' 13 February 2014 (URN: PRO-E001108).

3.122 On 4 April 2014, [Alliance Employee 1] forwarded the*, 'latest forecast from Focus'* to colleagues in Alliance.[199] The forecast is for consistent orders of 40,000 units being made throughout 2014 and into 2015.[200]

3.123 On 7 April 2014, [Focus employee] sent [Lexon employee] and [Lexon employee] a profit share reconciliation for Prochlorperazine POM for January to March 2014, showing profit from sales with 75% of this owed to Lexon for Q1 2014.[201]

3.124 The profit share reconciliation pattern – whereby Focus would email Lexon at the start of a quarter (January, April, July, October) with a reconciliation statement for the previous quarter, and Lexon would then email Medreich with an apportionment for Medreich's share – continued until December 2017.[202] Lexon continued to receive profits on Focus' sales of Alliance's Prochlorperazine POM until the expiry of the Focus-Lexon Heads of Terms on 31 July 2018.[203] A full schedule of the profit share figures, together with references to the relevant correspondence within the case file, is set out in Annex I:.

3.125 On 9 April 2014 (a Wednesday), [Focus Director 1] emailed [Focus Director 2] to inform him that he was meeting with [Lexon Director 1], *'on Monday … for a proper meeting !!!'*. The following Monday would have been Monday 14 April 2014. In [Focus Director 2]'s reply to that email, he observed that, *'in general I am happy to help him as a friend on stuff, but in business terms we are more likely to be friendly competitors long term rather than partners'*.[204]

3.126 On Monday 14 April 2014, [Lexon Director 1] emailed [Focus Director 1] at 12:49 and referred to issues with sourcing Prochlorperazine POM:

> *'My sincere apologies but [✂]*
>
> *As you know the API comes from a third party and [✂]*
>
> *I should have a further update from them in June*
>
> *Once again I do apologise for the confusion but as I am sure you can guess there is nothing short terms I can do to address the problem'.*[205]

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[199] Email [Alliance Employee 1] to [Alliance employee] entitled '*FW; Prochlorperazine Forecast – April 2014*' 4 April 2014 (URN: PRO-E001116).

[200] *Focus Prochlorperazine Forecast – 04 04 14*' 4 April 2014 (URN: PRO-E001117).

[201] Email [Focus employee] to [Lexon employee] and [Lexon employee], cc [Lexon Director 1] and [Focus Director 1] 7 April 2014, entitled '*Prochlorperazine Reconciliation Q114*' (URN: PRO-E003789) attaching document pdf entitled '*Prochlorperazine reconciliation Q114*' (URN: PRO-E003790).

[202] Section 26 response of Lexon, dated 27 November 2018, to CMA Notice of 7 November 2018, question 3(b) (URN: PRO-C2977). See also email [Medreich employee] to [Lexon Director 1] entitled '*Joint Venture and Management Responsibility*' 15 February 2018 (URN: PRO-E003647).

[203] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 3(b) (URN: PRO-C3149).

[204] Email [Focus Director 1] to [Focus Director 2] entitled '*Lexon meeting*' 9 April 2014 (URN: PRO-E003793).

[205] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794).

3.127 [Focus Director 1] responded in the evening of the same day, initially at 19:37, *'Thanks for the update [sic] I totally understand the issues involved and we can revisit in June when you have more information.'*[206] Some minutes later, at 19:49, [Focus Director 1] sent a further response to [Lexon Director 1], which read, *'With regard to our discussion regarding the agreement on profit share I agree with your comments and we shall continue with the current agreement as signed in the heads of agreement'*.[207]

3.128 The Focus Sales Meeting minutes of 29 April 2014 stated, *'Prochlorperazine 3mg tabs Profit share with Lexon will remain the same following discussions. Tariff has now moved up to Focus Trade Price of £11.98.'*[208]

3.129 On 8 August 2014, [Focus Director 1] emailed [Lexon Director 1] attaching a copy of the Focus-Lexon Heads of Terms signed as dated 1 August 2013.[209]

AMCo's acquisition of Focus and Primegen and AMCo's internal consideration of whether to launch a Prochlorperazine POM

3.130 As set out below, during 2014 and 2015 AMCo acquired both Focus and Primegen. As a result of these acquisitions, AMCo (through Focus) continued to enjoy the benefits of the supply agreement entered into between Alliance and Focus at the same time that AMCo (through Primegen) was taking steps to secure its own MA for Prochlorperazine POM.

3.131 On 29 September 2014, the shareholders of Focus and AMCo entered into a sale and purchase agreement dated 1 October 2014 whereby AMCo acquired all the shares in Focus.[210] The agreement included the payment of Deferred Consideration for various items, including the continuation of, *'Relevant Agreements'*. One such *'Relevant Agreement'* was described as, *'Lexon/Alliance Prochlorperazine'*.[211]

3.132 On 1 October 2014, [Alliance Employee 1] emailed colleagues at Alliance to inform them that AMCo had acquired Focus. [Alliance Employee 1] noted that, *'…For APL*

[206] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795).

[207] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

[208] *Focus Sales Meeting* minutes 29 April 2014, page 4 (URN: PRO-E003799).

[209] Email [Focus Director 1] to [Lexon Director 1] entitled '*FW: Emailing: 20140808172223*' 8 August 2014 (URN: PRO-E000426); *20140808172223.pdf* August 2014 (URN: PRO-E000427).

[210] Agreement for the sale and purchase of Focus Pharmaceuticals executed 29 September 2014 but dated 1 October 2014 (URN: PRO-E003826).

[211] Email [Focus employee] to [Focus Director 1], [Focus Director 2] and [Focus employee] entitled 'FEETS System' 6 February 2015 (URN: PRO-E003864) and attachment 'Focus Executive Earnout Tracking System 6 February 2015, page 1 (URN: PRO-E003865).

products distributed through Focus Pharma (Aspirin EC 300mg and Prochlorperazine 50's) I anticipate no change in operations in the near future…'[212]

3.133 On 21 October 2014, [AMCo Employee 1] emailed [Focus Director 1] and [Focus Director 2] attaching a spreadsheet setting out 'price optimisation' for Focus products. That document contemplates a percentage price increase for, *'prochlorperazine 3mg x 50'* of 80.2% (from an ASP of £9.60 to £17.30).[213]

3.134 In Spring 2015, AMCo entered into negotiations with [Primegen employee] to acquire Primegen, a pharmaceutical company with a number of generic products. On 14 May 2015, [AMCo Employee 2] emailed [AMCo Director 1], [AMCo Director 2] and others at AMCo to explain his proposal to include Prochlorperazine POM, which had previously not been included as one of the products that would be purchased by AMCo, as part of the Primegen acquisition:

> *'Based on a recent with [sic] the Focus team, they briefed us on the situation for 2 products in the Primegen portfolio which are excluded from the deal, but Focus said would be interesting. Prochlorperazine buccal tablets is [sic] due for launch in Q4-15…Focus have both products on the market…*
>
> *Prochlorperazine Buccal tablets … this product makes ~£5.5m GP for the originator (Alliance Pharma). Focus distributes the product for them and makes 15% distribution fee (about £850k GP). The Alliance product is branded,*[*214*] *so no pricing upside. However, we could take 50% of the market and make £2.5m profit instead of £850k, and upside of >£1.5m per year. The Alliance product is the only product, but give supply to Focus and retain most of the margin…*[215]

3.135 On 15 May 2015, [AMCo employee] emailed colleagues at AMCo attaching an updated model of the contemplated Primegen acquisitions. That model anticipated obtaining 40% market share for Prochlorperazine POM in FY16 increasing to 50% in FY18 and FY19.[216]

3.136 On the same day, [AMCo Employee 2] provided the following overview of Prochlorperazine POM; although [AMCo Employee 2] referred to the Primegen product as being the '*first generic version'*, in fact Alliance had already de-branded

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[212] Email [Alliance Employee 1] to [Alliance employee] entitled 'AMCo buys Focus Pharma' 1 October 2014 (URN: PRO-E001139).

[213] Email [AMCo Employee 1] to [Focus Director 1] and [Focus Director 2] cc [AMCo Director 1], AMCo entitled 'Work stream charter' 21 October 2014 (URN: PRO-E001512) and attachment (URN: PRO-E001513).

[214] Note: in fact, Alliance had already de-branded its product by this point: see paragraph 4.62.

[215] Email [AMCo Employee 2] to [AMCo Director 1] and [AMCo Director 2] (amongst others) entitled '*URGENT feedback required*' 14 May 2015 (URN: PRO-E001578).

[216] Email [AMCo employee] to [AMCo Employee 2] amongst others entitled '*RE: Prochlorperazine forecasts*' 15 May 2015 (URN: PRO-E001581) and attachment *150515 Capital model – Commercial Assumptions v6*' (URN: PRO-E001583).

its product and was supplying the generic, Prochlorperazine POM, to Focus by this point (see paragraph 3.114):

> *'…Whilst the ordinary tablets are cheap and widely available, there is a buccal tablet (which adheres to the cheek) which currently has no competition. The price of this product has been rising steadily and the Primegen product will be the first generic version. We expect to be able to achieve a 50% market share without having to compromise greatly on price'.*[217]

3.137 On 4 June 2015, [AMCo Employee 2] emailed [AMCo employee] about milestone payments owed to Primegen in which he noted that, *'we are very keen to encourage earliest possible launch of Prochlorperazine Buccal'*.[218]

3.138 On 11 June 2015, [AMCo employee] emailed [Focus Employee 1], asking for her advice in relation to whether AMCo should launch its own Prochlorperazine POM based on the Primegen MA:

> *'We need to look at this product and see if it is worth us launching this into the market. I believe you have an agreement in place with this product so what we need to work out is can we leverage us having the potential to launch this product to get you a better deal for focus [sic] or launch it ourselves and try and get a better share of the market with lower COG's [sic].'*[219]

3.139 [Focus Employee 1] forwarded that email to [Focus Director 2]. He replied to [AMCo employee]'s original query on 15 June 2015:

> *'We are currently sole supply (100% market share) of this product into the UK market through a distribution agreement, we make approximately 22% Gross margin [sic].*
>
> *The discussions we had on the product during the acquisition was to leverage the license [sic] to improve margin and secure the business long term.'*[220]

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[217] Email [AMCo Employee 2] to [AMCo employee] entitled *'RE: Product write up for the Deloitte slide – is this OK for the products?*' 15 May 2015 (URN: PRO-E001585). See also Email [AMCo Employee 2] to [Pharmacloud employee] entitled '*RE: Prochloperazine*' [sic] 19 May 2015 (URN: PRO-E001595) and Email [Pharmacloud employee] to [AMCo Employee 2] entitled '*Draft commercial DD* report' 21 May 2015 (URN: PRO-E001601) and attachment *Commercial due diligence: Primegen* Pharmacloud 18 May 2015 (URN: PRO-E001602).

[218] Email [AMCo Employee 2] to [AMCo employee] entitled '*Project Capital Milestones*' 4 June 2015 (URN: PRO-E001608).

[219] Email [AMCo employee] to [Focus Employee 1] cc [AMCo Employee 4] entitled '*Prochlorperazine Buccal 3mg*' 11 June 2015 (URN: PRO-E003874).

[220] Email [Focus Director 2] to [AMCo employee] cc [Focus Director 1], [Focus Employee 1], [AMCo Employee 2] and [AMCo Employee 4] entitled '*Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E003874)

3.140 On 15 June 2015, [AMCo Employee 2] replied to [Focus Director 2]'s email indicating that he was discussing Prochlorperazine POM with [AMCo Director 2] and [AMCo Director 1] the following day and that [AMCo Employee 4] was, *'pulling together the business case for the product'*. That business case was considering*, 'the upside which we can expect to get from an improved deal with the originator'* and *'the value of the deal on a standalone basis…'*.[221] Following this email, [Focus Director 2] emailed [AMCo Employee 4] offering to provide, *'a steer on the commercials of the 2 scenarios'*. [AMCo Employee 4] accepted this offer and asked [Focus Director 2] for his input to*, 'build the different cases'* and noting that *'if launching our product would jeopardise your project with Alliance ... that need [sic] to be taken into consideration'*.[222]

3.141 On 15 June 2015, [Focus Director 1] replied separately to [Focus Director 2]'s email referred to in paragraph 3.139 stating that:

> *'They will f this up !!! [sic] I will reiterate the market position to [AMCo Director 1] when I speak to him on weds [sic] and if you can once again take [AMCo Employee 2] through it when you speak to him . [sic] If they push alliance [sic] or lexon/medreich [sic] too much it will end up being a car crash for all'.*[223]

3.142 In response to an email from [AMCo Employee 2], also sent on 15 June 2015, asking to discuss Prochlorperazine POM, [AMCo Director 2] replied that:

> *'I am aware of some of the background to this but obviously do not want to share freely around the organisation so we need to think about the best strategy and how to communicate.'*[224]

3.143 On 24 June 2015, [AMCo employee] emailed [AMCo Employee 2] and [AMCo Director 2] regarding Prochlorperazine and asked *'What is this about again? Is*

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[221] Email [AMCo Employee 2] to [AMCo employee] and [Focus Director 2] cc [Focus Director 1] [Focus Employee 1], [AMCo Employee 4], [AMCo Director 2] and [AMCo Director 1] entitled '*Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E003874). [Focus Director 2] replied to this email letting [AMCo Employee 4] know that if she wants *'a steer on the commercials of the 2 scenarios just ask myself or [Focus Director 1]'*: Email [Focus Director 2] to [AMCo Employee 4] and [Focus Director 1] entitled '*Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E003874). [Focus Director 1] replied to [AMCo Employee 2]'s email informing that *'I have a telecom with [AMCo Director 1] and [AMCo Director 2] on weds [sic] maybe you can join that one and I can talk you through the impact of the options on the market so the right decision is made'* Email [Focus Director 1] to [AMCo Employee 2], entitled '*Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001618).

[222] Email [AMCo Employee 4] to [Focus Director 2] cc [AMCo Director 2] entitled '*RE: Prochlorperazine Buccal 3mg*' 16 June 2015 (URN: PRO-E001623). On the same day [AMCo Employee 2] emailed [AMCo Employee 4] to tell her that he had spoken to [AMCo Director 2] to *'give him a bit more background about the options for this product'* and asking [AMCo Employee 4] to *'make sure that you discuss with him to agree the final commercial plan'* Email [AMCo Employee 2] to [AMCo Employee 4] entitled '*RE: Prochlorperazine Buccal 3mg*' 16 June 2015 (URN: PRO-E001626).

[223] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616).

[224] Email [AMCo Director 2] to [AMCo Employee 2] entitled *'RE: prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001619).

there a conflict of interest with the Focus guys?' to which [AMCo Employee 2] responded, *'Will uodate* [sic] *you later'*.[225]

3.144 On 25 June 2015, [AMCo Director 2] emailed [AMCo employee] and [AMCo employee] about a *'UK Strat Plan'* PowerPoint in which, in relation to *'Upward movement on primegen [sic] products'*, he stated that *'Prochlorperazine – increase focus profit by £500k a year based on us having the MA but not necessarily launching in 2016…'*[226]

3.145 On 29 June 2015, [AMCo Employee 4] emailed a number of colleagues at AMCo[227] attaching a presentation entitled *'Project CAPITAL BD Workstream'*. Slides 15 – 17 of that presentation provided an overview of the situation in relation to *'Prochlorperazine Buccal Tabs 3mg x 50'*. On slide 15, *'[o]pportunity & risks'* were noted as:

> *'Opportunity: Launch as INN Generic*
> *Jeopardize the Focus-Alliance relationship'*

Slide 16 compared two different scenarios:

Prochlorperazine Buccal Tabs 30mg x 50 - UK

	Scenario 1 – AMCo to launch Primegen's MA	**Scenario 2** – continue the OLS supply Alliance – Focus
	AMCo Model	**FOCUS model**
# competitors	Potentially: 2 - Alliance & Lexon and other future registrations	other future registrations
Pricing (% discount)	£ 14.00 (Aprox. 42% discount vs June'15 - DT)	COG £ 5.60 + Profit Share If AVS > £ 10.50 = 50:50
Average Selling Price £	£ 14.00 - flat during 5 years	40% discount vs DT
DT Price assumption	Does not increase more than £ 23.98	To increase up to ≈ £ 36.00 and keep if flat
MS%	**MS% - POM**	**MS% - POM**
Y1	15%	100%
Y2	33%	100%
Y3	33%	100%
Y4	33%	100%
Y5	33%	100%

[225] Email [AMCo employee] to [AMCo Employee 2] and [AMCo Director 2] entitled 'Prochlorperazine' 24 June 2015 (URN: PRO-E001629).

[226] Email [AMCo Director 2] to [AMCo employee] and [AMCo employee] entitled *'RE: sorry got stuck on calls with Alliance and [AMCo employee] with you in 5 mins*' 25 June 2015 (URN: PRO-E001631).

[227] Email [AMCo Employee 4] to various colleagues at AMCo entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) and its attachment presentation entitled *'Project CAPITAL BD Workstream'*, dated 20 June 2015 (URN: PRO-E001636).

Slide 17 of the presentation indicates that the 5 year cumulative contribution generated by scenario 2 (Focus) was £6,871,000 compared to £2,782,000 for scenario 1 (Primegen).[228] The presentation therefore showed that it was a more profitable strategy for Focus (AMCo) not to commercialise its Primegen Prochlorperazine POM MA (whereby it would compete with Alliance and Lexon), but rather to continue to supply the Alliance product (under which arrangement it did not face competition from Lexon). The CMA's analysis of AMCo's consideration of the situation is discussed in further detail in paragraph 5.154.2(b)ii.

3.146 On 24 July 2015, [AMCo employee] emailed [AMCo Employee 2] and other colleagues at AMCo indicating that the launch date for '*Prochlorperazine Tablets*' (relating to the Primegen MA) was *'Sept 16'*.[229]

3.147 The AMCo PPRM Report for August 2015 stated in respect of Prochlorperazine POM:

> *'[AMCo employee] to confirm if we will launch given the situation with Focus / Medreich. In any case, the MA needs to be obtained ASAP to have leverage when negotiating terms with Lexon.'*[230]

3.148 On 3 August 2015, [AMCo Employee 4] emailed colleagues at AMCo attaching minutes of an internal meeting which recorded that *'PPRM recommended for APPROVALED [sic]'* Prochlorperazine POM and commented that *'the MA granted in Primegen's name will be transferred to Focus. It will be discussed in a separate meeting if the product will be launched.'*[231]

3.149 On 25 August 2015, [AMCo employee] emailed [AMCo employee] attaching the *'August PPRM draft presentation'*; in respect of Prochlorperazine POM, this noted that, *'**[AMCo employee]** to confirm if we will launch given the situation with Focus / Medreich'*.[232]

3.150 A handwritten note obtained from AMCo's premises during the course of the CMA's inspection makes the following observations in respect of Prochlorperazine POM, including that if AMCo were to launch its own product *'Medreich could decide to launch w/ own MA'*:[233]

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[228] Presentation entitled '*Project CAPITAL BD Workstream'* 30 June 2015, slide 15-17 (URN: PRO-E001636).

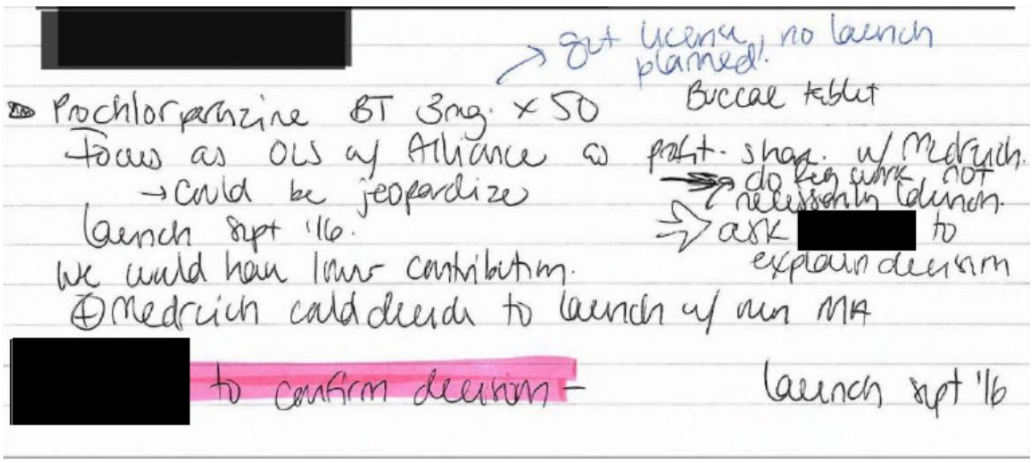
[229] Email [AMCo employee] to [AMCo Employee 2] and other colleagues at AMCo entitled '*RE: Updated Version- 7 2015 Strat Plan Projects – Final*' 24 July 2015 (URN: PRO-E001644).

[230] Report entitled '*PPRM Report AUG 2015'* August 2015, page 5 (URN: PRO-E004024).

[231] Email [AMCo Employee 4] to [AMCo employee] and [AMCo employee] entitled '*RE: Primegen Approvals*' 3 August 2015 (URN: PRO-E001649), attaching *Primegen: PPRM Meeting* 14 July 2015, page 2 (URN: PRO-E001650).

[232] Email [AMCo employee] to [AMCo employee] entitled '*August PPRM draft presentation*' 25 August 2015 (URN: PRO-E001668) attaching presentation entitled '*Pharma Pipeline Review Meeting – August 2015*' 25 August 2015, page 60 (URN: PRO-E001669).

[233] Advanz Hard Copy Document TXT021, page 1 (URN: PRO-E004055).



3.151 On 21 September 2015, [AMCo employee] emailed colleagues at AMCo attaching a document entitled *'Strategic Projects Month Report – August 2015'*. In respect of Prochlorperazine POM, that document noted that *'MA needs to be obtained ASAP to have leverage when negotiating supply terms with the current partner'*.[234]

3.152 Similarly, the AMCo PPRM Report for September 2015 noted the following in relation to the status of the launch plans for the Primegen Prochlorperazine POM:

> *'No plans to launch for now. Launch plans pending outcome of discussions with Medreich. 3 Options: 1) We manage to negotiate better margins once we have the MA (most likely) 2) We launch with Primegen livery once we have teh [sic] Primegen MA 3) We launch in 2016 with Focus livery.'*[235]

3.153 On 9 December 2015, [AMCo Employee 4] emailed colleagues, copying [AMCo Director 2], stating in respect of Prochlorperazine POM that *'AMCO is not planning to launch this product from Primegen. Just to keep a dormant MA. Thanks to this imminent MA, Focus has negotiated with Lexon and improved the profit share agreement we had with them…The pipeline tracker mentions Sept-2016 as this would have been the date the product would had [sic] been in the market.'*[236]

3.154 On 16 December 2015, [AMCo Director 2] emailed [Focus Director 2] to ask him, in relation to Prochlorperazine POM, *'[d]o you think we need to get some stocks of the primegen [sic] sku or are we full [sic] confident this will not be needed?'* [Focus Director 2] replied, *'I would always get some to have in the warehouse as an*

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[234] Email [AMCo employee] to [AMCo Director 1], [AMCo Employee 2] and [AMCo employee], all AMCo entitled '*SDG Strategic Projects Monthly Report ([✂]) – August 15*' 21 September 2015 (URN: PRO-E001680) attaching *Strategic Projects Monthly Report – August 2015* 21 September 2015, page 8 (URN: PRO-E001681). See also Email [AMCo Employee 2] to various AMCo colleagues entitled '*PPRM Outputs – 23 September 2015*' 23 September 2015 (URN: PRO-E001683) and Email [AMCo employee] to [AMCo Employee 4] cc [AMCo Director 2] entitled '*RE: Prochlorperazine business case*' 25 September 2015 (URN: PRO-E001684) which indicate AMCo would only obtain batches of Prochlorperazine POM if negotiations failed.

[235] Email [AMCo employee] to [AMCo employee] entitled '*PPRM Report for September 15 for [✂]*' 20 October 2015 (URN: PRO-E001704) attaching Excel spreadsheet entitled '*PPRM Report September 2015*' 20 October 2015 (URN: PRO-E001705).

[236] Email [AMCo Employee 4] to [AMCo employee] and [AMCo employee] cc [AMCo Director 2] entitled '*Pipeline tracker updated – Prochlorperazine buccal tablets 3mg*' 9 December 2015 (URN: PRO-E001728) attaching excel spreadsheet entitled '*V2 Dossier_Prochlorperazine buccal tablets – UK updated Dec.2015*' 9 December 2015 (URN: PRO-E001729).

insurance against anything going wrong with the existing supply chain on the understanding it may get written off.'[237]

3.155 On 22 January 2016, after being informed by [AMCo Director 2] that the MA for Prochlorperazine POM was expected to be granted within 30 days, [Focus Director 1] indicated to [AMCo Director 2] that the next step was, *'Once the licence has been granted I contact [sic] [Lexon Director 1] re new terms'*.[238]

3.156 On 2 February 2016, Primegen's MA for Prochlorperazine POM was granted.[239]

3.157 On 8 February 2016, [AMCo Director 2] and [Focus Director 1] corresponded on what volumes of Prochlorperazine POM should be manufactured. [Focus Director 1] advised:

> *'I wouldn't manufacture too much we carry 3/4 months buffer of the alliance [sic] manufactured product and have orders placed on 16 week lead times so even with the notice period if it fell down we should still have time to manufacture and not go out of stock. We sell approx 22,000 packs a month so maybe a month or two of stock of our own (This product will most likely get destroyed as is only a safety net so I guess you won't want to write off too much value)'.*[240]

3.158 The same day, [AMCo Director 2] was asked about the AMCo strategy for Prochlorperazine POM by [Focus Employee 1], *'I was under the impression that we were obtaining the licence but not proceeding with launch due to the Focus agreement on the Alliance product. Is the objective no longer to pursue an amended profit share with Lexon upon receipt of the licence?'* [AMCo Director 2] confirmed, *'… that is the exact strategy and I met with [Lexon Director 1] on Weds [sic] and agreed an instant 50;50 share. It will be effective April 1st'*. When [Focus Employee 1] explained that she had been confused by [AMCo Director 2]'s provision of volume numbers to colleagues, he responded:

> *'Don't worry about that stuff. We always need to be mindful of the other team members. The new products team spend a huge amount of time and effort getting the product to market and can sometimes be deflated when we say we have done a deal and actually do not want product. My job is to*

[237] Email [Focus Director 2] to [AMCo Director 2] entitled '*RE: Prochlorperazine tabs*' 16 December 2015 (URN: PRO-E001733).

[238] Email [Focus Director 1] to [AMCo Director 2], cc [Focus Director 2] 22 January 2016 (URN: PRO-E001746).

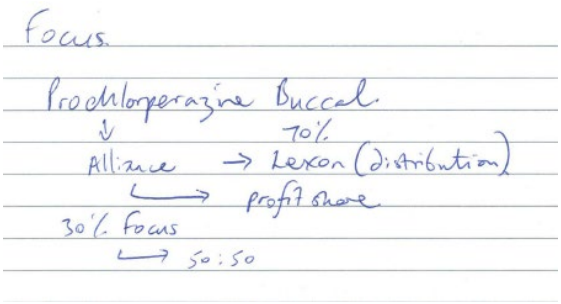
[239] Email [Kinedexe employee] to [AMCo Director 2] entitled '*FW: PL 43659/0024 - Prochlorperazine 3mg Buccal Tablets*' (URN: PRO-E001750) attaching pdf '*Grant*' (URN: PRO-E001751) and pdf *'spc-doc*' (URN: PRO-E001752).

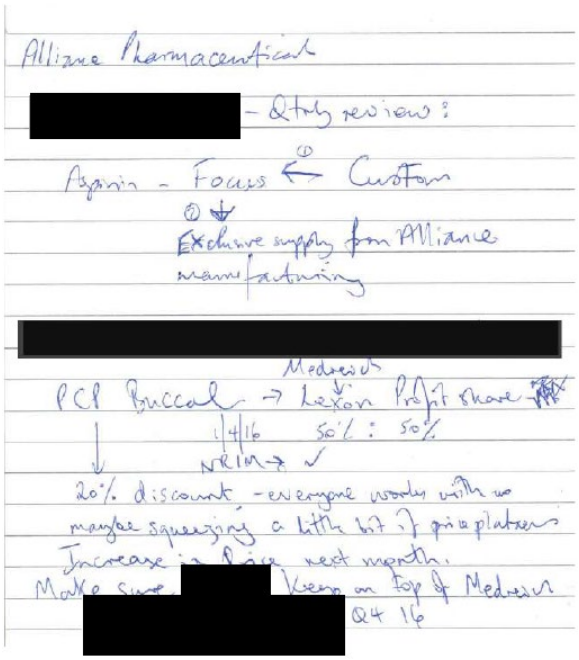
[240] Email [Focus Director 1] to [AMCo Director 2] entitled '*RE: Recipharm meeting on Thursday*' 8 February 2016 (URN: PRO-E001759). The same day, [AMCo Director 2] asked colleagues in AMCo to *'manufacture 25k of Prochlorperazine Buccal tabs please'* Email [AMCo Director 2] to [AMCo employee] and [AMCo employee] cc [Focus Employee 1] entitled '*RE: Quick questions*' 8 February 2016 (URN: PRO-E001762).

ensure what we may do commercially does not demotivate others. That said I will be providing figures so we have stock just in case.'[241]

3.159 Primegen's grant of a licence for Prochlorperazine POM was brought to the attention of [Alliance Employee 1] on 9 February 2016 by a colleague who highlighted that the new licence was listed on the RAMA database. On 11 February 2016 he asked his colleague to *'drill down on this one to gain more clarification'*.[242]

3.160 Shortly after [AMCo Employee 3] [✂], he made several entries into his notebook detailing the existing arrangements for prochlorperazine:[243]





3.161 In an internal email to colleagues discussing the calculation of the value of the Primegen Prochlorperazine POM development product, [AMCo Director 2]

[241] Email [AMCo Director 2] to [Focus Employee 1], entitled '*Re: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757).

[242] Email [Alliance Employee 1] to [Alliance employee] cc various others entitled *'RE: New licences granted 2-9th Feb*' 11 February 2016 (URN: PRO-E001241).

[243] [AMCo Employee 3] Notebook EMN010, pages 24 and 29 (URN: PRO-E004038).

summarised AMCo's position in relation to Prochlorperazine POM internally as follows:

> *'…what we are valuing is the Primegen MA for Prochlorperazine. We have utilised that MA to negotiate better profit share terms on our legacy Focus product. Thus while we do not have stock yet and we have stock issues with [✂] which means we cannot launch, the MA itself already has value and this needs to be calculated so [AMCo Employee 4] can populate her NPV…*
>
> *The old terms were a 70:30 [sic] profit share in the partners [sic] favour. If you use this as the baseline then we have the gross contribution value of the Focus product without the Primegen MA*
>
> *The new terms are a 50:50 profit share. The difference between this profit share and the old profit share is the incremental value of the Primegen MA and the figures [sic] [AMCo Employee 4] needs for her NPV.'*[244]

3.162 During April, May and June 2016, AMCo and [✂] discussed the terms on which [✂] would supply product.[245] These discussions were reflected in an internal AMCo document from 19 May 2016 entitled *'[✂] Product Portfolio Status*' which contained the following comment in relation to '*Prochlorperazine 3mg Buccal Tablets*':

> *'This is a back up source of stock. [✂]'*[246]

3.163 On 26 July 2016, AMCo confirmed to [✂] that it would order two batches of prochlorperazine (instead of five batches as had previously been discussed).[247]

3.164 Between September and December 2016, AMCo and [✂] engaged in correspondence about the manufacture of the two batches. [✂] indicated there were some difficulties in relation to sourcing active pharmaceutical ingredient

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[244] Email [AMCo Director 2], to [AMCo employee] and [AMCo Employee 4] entitled '*prochlorperazine*' 26 May 2016 (URN: PRO-E001825).

[245] See Email [AMCo employee] to [AMCo Director 2] cc [AMCo employee] (AMCo) entitled '*FW: [✂]/AMCO meeting minutes*' 25 April 2016 (URN: PRO-E001800); Email [AMCo employee] to [AMCo Director 2] cc [AMCo employee] entitled *'FW: [✂]/AMCo meeting minutes'* 25 April 2016 (URN: PRO-E001802); AMCO presentation entitled '*Pharma Pipeline Review Meeting*' 28 April 2016 (URN: PRO-E001804) which notes that *'[✂] increased hugely the supply price for Prochlorperazine so appraisal is under review by commercial'*; and Email [AMCo employee] to [AMCo Director 2] and [AMCo Employee 4] cc [AMCo employee] entitled *'RE: Amco- [✂]: Telecom – Prochlorperazine UK Launch'* 27 June 2016 (URN: PRO-E001853).

[246] Document entitled *'[✂] Product Portfolio Status'* 19 May 2016 (URN: PRO-E001820). See also Email [[✂] employee] to [AMCo employee] cc various others entitled '*AMCO Products*' 2 May 2016 (URN: PRO-E001805); Excel spreadsheet entitled '*Phama Pipeline Review Meeting Report May 2016*' 23 May 2016 (URN: PRO-E001822); and Email [AMCo employee] to [AMCo employee] cc [AMCo Employee 4], [AMCo employee] and [AMCo employee] 17 June 2016 (URN: PRO-E001841) attaching excel spreadsheet entitled '*PPRM Report June 2016*' 17 June 2016 (URN: PRO-E001842).

[247] Email [AMCo employee] to [[✂] employee] cc various others entitled '*RE: AMCo: [✂] list of actions. Meeting on 6_7_2016*' 26 July 2016 (URN: PRO-E001877). The decision to order two batches was made by [AMCo Employee 3] – see Email [AMCo Employee 3] to [AMCo employee] cc [AMCo Employee 4], [AMCo employee] and [AMCo Director 2] entitled '*Re: Amco- [✂]: Telecom – Prochlorperazine UK Launch*' 1 July 2016 (URN: PRO-E001853).

('**API**') and [✂]'s capacity to manufacture.[248] A summary of the situation appears in a December 2016 Report, *'[✂] delayed manufacturing to Q2 2017. … They have highlighted issue with import of API to India. The API supplier will have to register in India'*. In the *'PPRM Decisions & Actions'* column*, 'Prochlorperazine Buccal Tablets (Primegen) 3mg'* was described as, *'This project is a "Nice to Have". It should not be placed on priority with [✂]'*.[249]

3.165 On 10 January 2017, [AMCo employee] provided commentary on the status of the development of the Prochlorperazine POM in which he stated, *'It's an ongoing study started by Primegen and we are not going to launch the product …'*.[250]

3.166 On 7 March 2017, [AMCo employee] described the status of the Primegen Prochlorperazine MA as being that *'…The product in your list is one we already have approved but are not going to launch. It was acquired as part of the Primegen product portfolio. There are technical difficulties in the manufacturing with the current partner (again, [✂] India) and they do not want to continue the project.'*[251]

Evolution of the agreements involving Alliance, Focus and Lexon, including AMCo's leveraging of its Primegen Prochlorperazine POM MA (September 2014 – October 2017)

3.167 Between 2014 and 2016 there were a number of amendments to the terms of the various agreements, including an increase in the transfer price from Alliance to Focus and amendments to the profit share split between Focus, Lexon and Medreich. The documentary evidence detailing these amendments is set out below.

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[248] See Email [[✂] employee] to [AMCo employee] and various others, cc various others entitled '*RE: Prochlorperazine Procurement of API Under Advance | Consequences | Liability*' 3 September 2016 (URN: PRO-E001900); Email [AMCo employee] to [AMCo employee] cc [AMCo employee] entitled '*FW: Prochlorperazine PO*' 9 September 2016 (URN: PRO-E001901); Presentation entitled '*Concordia Global Operations – GNPI Monthly Review Meeting*' 8 October 2016 (URN: PRO-E001915). Presentation entitled '*Concordia Global Operations – GNPI Monthly Review Meeting*' 12 December 2016 (URN: PRO-E001954); Email [AMCo employee] to [AMCo employee] cc [AMCo employee] entitled '*RE: New product launch*' 13 December 2016 (URN: PRO-E001955).

[249] Excel spreadsheet entitled '*PPRM Report – December 2016*', sheet *'PPRM REPORT*', cells (L,15) and (M,15) (URN: PRO-E002007). Similarly, on 31 October 2016, [AMCo Employee 4] provided comments to colleagues within AMCo in relation to pipeline products. This included Prochlorperazine POM, where she stated: *'… this was considered as [sic] "launch" in 2016, what was implemented in the old pipeline tracker is the upside business after we negotiated the new profit share with Lexon (see email attached). The product that will be manufactured in [✂] is not considered as a launch.'* Email [AMCo Employee 4] to [AMCo employee] and various others, cc [AMCo employee] entitled '*RE: Pipeline Tracker – Oct – [✂] comments*' 31 October 2016 (URN: PRO-E001925). Similarly, an AMCo PPRM Report from January 2017 stated that Prochlorperazine POM was *'Not a priority project with [✂].-> on hold for now ….'* Excel spreadsheet entitled '*PPRM Report January 2017*' 20 January 2017, cell (L,14) (URN: PRO-E001979). See also *Pharma Pipeline Review Meeting – January 2017*' 17 January 2017 (URN: PRO-E001975) which notes that there were no further plans for Prochlorperazine POM *'until priority projects are closed*'.

[250] Email [AMCo employee] to [AMCo employee] cc [AMCo employee] entitled '*Re: Prochlorperazine Tablets 24M Payment milestone*' 10 January 2017 (URN: PRO-E001967).

[251] Email [AMCo employee] to [AMCo employee] and [AMCo employee] cc [AMCo employee], [AMCo employee] and [AMCo employee] entitled '*RE: Details on 2017 launches*' 7 March 2017 (URN: PRO-E002022). See also Presentation entitled '*Concordia Global Operations – GNPI Monthly Review Meeting*' 17 March 2017 (URN: PRO-E002005) and Presentation entitled '*Concordia Global Operations – GNPI Monthly Review Meeting*' 17 March 2017 (URN: PRO-E002021) which makes similar observations.

3.168 On 4 November 2014, [Focus Director 1] emailed [Lexon Director 1] to describe the outcome of a meeting they had had the previous day. In his summary of the meeting, [Focus Director 1] reported that Lexon had ordered stock of Prochlorperazine POM and that the terms of the profit share were to be amended:

> *'Following our meeting yesterday I am just confirming the agreement regarding prochlorperazine 3mg tabs . [sic]*
>
> *You have placed an order for stock and would expect the stock to arrive in early 2015 , once you have a confirmed date I can place a purchase order on you for the stock . [sic]*
>
> *We agreed an amendment to the profit share agreement in that up to an Asp [sic] of £10.50 the profit share will remain at 25%(Focus)/75% (Lexon) , over an ASP of £10.50 the profit share will become 50%(Focus)/50%(Lexon). I will amend the heads of agreement to mirror this and send on to you .'*

[Lexon Director 1] replied the same morning:

> *'…I will advise as soon as I have a firm date for availability of released product along with the exact volumes.*
>
> *Regards the change to the profit share. Yes I am happy to proceed with your proposal'.*[252]

3.169 On 5 November 2014, [Focus Employee 1] emailed [Focus Director 2] outlining a number of price increases due to take place in December 2014/January 2015. The *'New Trade Price'* for *'Prochlorperazine Buccal Tablets 3mg x 50'* was listed as £18.22 with a *'New Wholesale Price'* of £14.58.[253]

3.170 On 7 November 2014, [Focus Director 1] emailed [Lexon Director 1], copying [Focus employee], to confirm the changes to the Focus-Lexon profit share that had been discussed:

> *'Just for completion we have agreed an amendment to the attached signed Heads dated 1/8/13 regarding Prochlorperazine 3mg Tabs, in such that the profit share arrangement has been amended to the below.*

[252] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832). Later that day [Focus Director 1] emailed [Focus employee] to inform him of the amendment to the agreement see email entitled '*Prochlorperazine profit share*' 4 November 2014 (URN: PRO-E001516). See also Email [Focus Director 2] to [Focus employee] entitled '*Revised Budget*' 8 December 2014 (URN: PRO-E003844) where the budget implications of the amendments to the profit share terms are discussed.

[253] Email [Focus Employee 1] to [Focus Director 2] entitled *'FW: Price amendments*' 5 November 2014 (URN: PRO-E001517).

A profit share will be in place relating to a 25%(FP)/75%(Lexon) up to an Average [sic] selling price of £10.50, for any sales over an Average Selling Price [sic] of £10.50 the profit share will be 50%/(FP)/50%(Lexon)

All other parts of the Heads of Agreement remain unchanged.'[254]

[Lexon Director 1] replied the same day indicating '*That's fine to proceed with*'.[255]

3.171 On 24 November 2014, [Focus Director 1] emailed [Alliance Employee 1] regarding Focus' volume forecasts for 2015:

'Thanks for meeting with me today , [sic] just to confirm regarding the Prochlorperazine forecasts for 2015 the forecast remains as previously sent, if the expected competitor product gets launched in 2015 we can review the forecast at this point…'[256]

3.172 On 1 December 2014, [Alliance employee] emailed [Alliance Employee 1] regarding 2016 sales forecasts for Prochlorperazine POM stating: *'Prochlorperazine – Removed half the sales due to the generic entering the market'.*[257]

3.173 On 17 December 2014, [Alliance employee] emailed [Alliance Employee 1] asking him, amongst other things, *'prochlorperazine: why is the number of orders lower in 2016?'* [Alliance Employee 1] replied:

'I am *aware of another generic entrant probably Q3 of 2015. I am expecting therefore to supply only a % of the market going forwards into 2016. There is a risk this may effect Q4 in 2015 also. Niche generics – they burn bright for a period and then lose value…'*[258]

3.174 On 23 January 2015, [Focus employee] emailed [Focus Director 1] attaching a forecast for Prochlorperazine POM orders. That forecast shows consistent stock delivery of 40,000 units of Prochlorperazine POM tablets from Alliance in March, April, June, July, September, October and December 2015, with a further order of

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[254] Email [Focus Director 1] to [Lexon Director 1] cc [Focus employee] entitled '*Prochlorperazine 3mg Tabs Heads of Agreement*' 7 November 2014 (URN: PRO-E003833).

[255] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg Tabs Heads of Agreement*' 7 November 2014 (URN: PRO-E003835). [Focus Director 1] confirmed the amendments internally the same day: *'For your information please see belowI [sic] have agreed an increase in the profit share for Focuswith [sic] Lexon over an ASP of £10.50, We [sic] are implementing a price increase for start of next year that will take us over this number.'* Email, [Focus Director 1] to [AMCo Director 1] and [AMCo Employee 1] entitled '*FW: Prochlorperazine 3mg Tabs Heads of Agreement*' 7 November 2014 (URN: PRO-E003836).

[256] Email [Focus Director 1] to [Alliance Employee 1] entitled '*Meeting 24th Nov*' 24 November 2014 (URN: PRO-E003842). See also *Copy of Established Products – 21 10 schedules.xlsx*' dated 20 October 2014 (URN: PRO-E001148) - an Alliance budget prepared for 2015 indicates a variance of *'-25%'* for Prochlorperazine POM. The explanation provided is *'6 x 40,000 unit orders expected in 2015. Declining volume and Focus stock build in 2014'*.

[257] Email [Alliance employee] to [Alliance Employee 1] cc [Alliance employee] and [Alliance employee] entitled *'Established Products sales unit forecast – Nov 14'* 1 December 2014 (URN: PRO-E004839).

[258] Email [Alliance Employee 1] to [Alliance employee] entitled '*RE: EP Queries from [✂]*' 17 December 2014 (URN: PRO-E001152).

40,000 units in January 2016. It also forecasts average monthly sales of 25,000 units per month from March 2015 to February 2016.[259]

3.175 On 28 January 2015, [Focus Director 1] emailed [Alliance Employee 1] to discuss new transfer prices for Prochlorperazine POM agreed between Alliance and Focus:

> *'It was good to meet up with you yesterday, I have reviewed the transfer costs following our discussion regarding market prices on both Aspirin 300mg E/C Tabs and Prochlorperazine 3mg Tabs.*
>
> *As we discussed new orders are forecast for both products in June 2015 and I propose that the new prices below are effective from these purchase orders.'*

Product	*Current Transfer Price*	*New Transfer Price effective 1st June 2015*
Aspirin 300mg E/C Tabs x 100	*...*	*...*
Prochlorperazine 3mg Buccal Tabs x 50	*£5.65*	*£6.10*

> *I will be asking [Focus employee] to place the next purchase orders at the start of Feb and will ask him to apply the new prices to the orders.'*[260]

3.176 On 29 January 2015, [Alliance employee] responded to a question posed by [Alliance Director 3] on 9 January 2015[261] and stated that the reason, '*why is 2016 forecast [for prochlorperazine] much lower than 2015?'* was because *'[a] competitor is joining the market in mid-2016'*.[262] No explanation is given in the correspondence as to which competitor [Alliance employee] had in mind.

[259] Email [Focus employee] to [Focus Director 1] entitled '*Allaiance [sic] Pharma forecast and orders*' 23 January 2015 (URN: PRO-E003858) and attachment (URN: PRO-E003859).

[260] Email [Focus Director 1] to [Alliance Employee 1] entitled '*New Transfer Costs*' 28 January 2015 (URN: PRO-E003860). Following this email [Alliance Employee 1] asked whether orders Focus had already placed for Prochlorperazine POM could be *'applied at this new price'*. [Focus Director 1] accepted the application of the new price for the orders from April onwards. Email [Alliance Employee 1] to [Focus Director 1] entitled '*RE: New Transfer Costs*' 28 January 2015 (URN: PRO-E003863). See also Email [Focus Director 1] to [Focus employee] and [Focus employee] cc [Focus Director 2] entitled *'New transfer pricing Alliance Pharma*' 28 January 2015 (URN: PRO-E001537).

[261] Email [Alliance Director 3] to [Alliance employee], [Alliance employee], [Alliance employee], [Alliance employee] and [Alliance employee] entitled *'Re: Sales unit review'* 9 January 2015 (URN: PRO-E004843).

[262] Email [Alliance employee] to [Alliance Director 3] and [Alliance employee] entitled '*RE: Sales unit review*' 29 January 2015 (URN: PRO-E001157).

3.177 On 2 March 2015, Alliance stopped supply of the branded OTC 8-pack product, Buccastem M, to Lexon.[263] This was later discussed between [Alliance Employee 1] and [Alliance employee] on 18 June 2015, with [Alliance Employee 1] commenting that *'Just not sure why we stopped supplying Lexon? I need to understand and explain why we perhaps should.'*[264]

3.178 On 27 March 2015, [Alliance Employee 1] emailed [Alliance Director 2] regarding updated 2015 sales forecasts for Prochlorperazine POM stating:

> *'[Alliance Director 2] the significant increase is due to an additional forecasted order (at a higher sale price) of Prochlorperazine in Dec. There is always a risk that this falls out due to the competitor (expected Q4 now) but currently confidence is high this order will materialise.'*[265]

3.179 The minutes of a Western Europe Quarterly Performance meeting on 21 April 2015 noted *'Prochlorperazine [Alliance Employee 1] to look into maintaining the value as there is a competitor possibly coming out in October. [Alliance Employee 1] has forecast a drop next year.'*[266]

3.180 On 28 May 2015, [Alliance Employee 1] sent an email to [Alliance Director 2] in which he noted that *'[h]igh cash generative and therefore attractive generics prochlorperazine and … attract competition and value declines (major impact 2016 and 2017).'*[267]

3.181 On 26 June 2015, [Focus Director 1] emailed [Lexon Director 1] about a further amendment to the Focus-Lexon Heads of Terms:

> *'Just to confirm our conversation last week, as you know we will have our own prochlorperazine licence available later this year and therefore we agreed an increase in our profit share agreement with yourselves from Oct 15. From 1st Oct 15 the profit share will become 50/50 for both parties on all sales of the product.*
>
> *Can you please confirm this is also your understanding of our discussions and I can implement at our end. Please note the Qtr 3 reconciliation will*

[263] Email [Alliance employee] to [Lexon employee] cc [Alliance employee] entitled '*RE: order 381713*' 2 March 2015 (URN: PRO-E001165). Note that Alliance had continued to sell the branded Buccastem M product after de-branding the Prochlorperazine POM.

[264] Email [Alliance Employee 1] to [Alliance employee] entitled '*RE: Buccastem 8*' 18 June 2015 (URN: PRO-E001185). Note that there was mobile phone contact between [Alliance Employee 1] and [Lexon Director 1] in June 2015, July 2016 and September 2016, including a phone call on 20 September 2016 (see URN: PRO-E003933 to PRO-E003941).

[265] Email [Alliance Employee 1] to [Alliance employee] and [Alliance Director 2] cc [Alliance employee] entitled *'RE: Sales Unit Forecasting Update Mar 15 – Established Products'* 27 March 2015 (URN: PRO-E001169).

[266] New Alliance Western Europe Quarterly Performance Meeting (Part1) minutes, 21 April 2015 (URN: PRO-E004747).

[267] Email [Alliance Employee 1] to [Alliance Director 2] entitled '*EP Strategy Numbers*' 28 May 2015 (URN: PRO-E001180).

reflect the current agreement and the new agreement will only come into force for the Qtr 4 reconciliation.'[268]

3.182 Referencing the Primegen MA (see paragraph 3.130 to 3.166) [Lexon Director 1] replied stating that, *'Licence does not seem to be granted yet?'*[269] [Focus Director 1] replied stating that, *'[a]s discussed I will advise when granted'*.[270]

3.183 The same day, [Focus Director 1] sent an email to [Focus Director 2], updating him about the revised terms of the Focus-Lexon-Medreich Agreement, and the increase in price of product from Alliance:

> *'Cost of good s [sic] is now £6.10 from Alliance (was £5.65 but we gave them a little upside) – I may try to get this back down when i [sic] see him next but don't assume I have for your model .*
>
> *Current agreement is 25% profit share up to £10.50 ASP to Focus, and 50/50 over £10.50.*
>
> *New agreement it will be 50/50 on all sales so effectively an additional £1.10 per pack to Focus from 1st Oct 15.'*[271]

3.184 A few hours later, [Focus Director 1] provided a further update to [Focus Director 2]:

> *'[Lexon Director 1] has been back on the phone the 50/50 wont [sic] start until licence grant – Medrich wont [sic] go for 1st Oct ! and [sic] looking at [AMCO employee]'s e mail [sic] it looks like the launch date is July 16 so I presume the licence was further away than [Primegen employee] suggested . [sic] So we won't see any upside this year.'*[272]

3.185 On 12 August 2015, [Focus Employee 1] wrote to [Lexon Director 1] to inform him of a price increase in relation to *'Prochlorperazine Buccal Tablets'* which would take effect on 1 October 2015, *'From this date our price into mainline wholesale will be £21.10, so yours will change at the same time…it is moving from Cat C to Cat A in September I won't be surprised if there are further tariff rises.'*[273]

3.186 On 1 September 2015, [Focus Director 1] emailed [Alliance Employee 1], stating that his Prochlorperazine POM forecast would, *'assume no immediate competition.*

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[268] Email [Focus Director 1] to [Lexon Director 1] entitled '*prochlorperazine 3mg Tabs*' 26 June 2015 (URN: PRO-E003877).

[269] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg Tabs*' 26 June 2015 (URN: PRO-E003878).

[270] Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg Tabs*' 26 June 2015 (URN: PRO-E003879).

[271] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg*' 26 June 2015 (URN: PRO-E001633).

[272] Email [Focus Director 1] to [Focus Director 2] entitled *Prochlorperazine 3mg*' 26 June 2015 (URN: PRO-E001634).

[273] Email [Focus Employee 1] to [Lexon Director 1] cc [Lexon employee] entitled '*Prochlorperazine Buccal Tablets*' 12 August 2015 (URN: PRO-E000542).

However I am budgeting that we may get some mid way through next year to cover myself.'[274]

3.187 An internal Alliance document dated 10 September 2015 forecasts a -42% variance for *'Prochlorperazine'* in 2015/16 with the following comment made, *'Competitor entering market mid 2016, reducing sales volume by 50%'*.[275] The document does not explain which company Alliance was referring to.

3.188 An internal Alliance paper on the 2016 budget prepared for the 17 December 2015 board meeting stated:

> '*Prochlorperazine volumes are expected to drop in 2016 due to competitor entering the market (impact of -£0.7m sales and gross margin -£0.6m), with a corresponding reduction in orders from 8 (2015) to 5 (2016).*'[276]

3.189 On 3 February 2016, [Focus Director 1] emailed [AMCo Director 2] about Prochlorperazine POM, noting that *'… I spoke to [Lexon Director 1] about Prochlorperazine and assuming the licence drops in Feb/March we will be on new deal from qtr 2 (I have told him we have stock manufactured)'*. [AMCo Director 2] replied, *'Ok good stuff. I had a call from [AMCo employee] on this yesterday – do we want to manufacture stock just in case? If so how much?? I assume the deal is 99% there so we do not want too much if any?? Obviously it is already made when I see [Lexon Director 1]* 😉*'*. [Focus Director 1] replied *'Let's have a chat tomorrow when we meet Regarding stick [sic] level etc'*.[277]

3.190 On 7 July 2016, [AMCo employee] emailed Lexon the Prochlorperazine POM profit share reconciliation for Q2-2016 with a revised profit share split: 50% profit for Focus on all sales and 50% for Lexon.[278]

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[274] Email [Focus Director 1] to [Alliance Employee 1] entitled '*RE: Update forecasts and PO's*' 1 September 2015 (URN: PRO-E001196).

[275] '*Copy of 2016 Budget summary – Established Product (8+4)*' 10 September 2015 (URN: PRO-E001205). See also Email [Alliance Employee 1] to [Alliance Director 2] and [Alliance employee] cc [Alliance Director 1] and [Alliance employee] entitled '*Buccastem 8's Question*' 18 November 2015 (URN: PRO-E001223) in which [Alliance Employee 1] notes that, in relation to Prochlorperazine POM, *'Generic expected in mid 2016 '*. Similarly, *Working capital report* 26 November 2015, page 23 (URN: PRO-E001352) notes that Alliance had forecast declining sales of Prochlorperazine POM in 2016 due to competitive entry.

[276] Document *'Alliance Pharma plc Budget 2016'* minutes, dated 17 December 2015 (URN: PRO-E001230).

[277] Email [Focus Director 1] to [AMCo Director 2] entitled '*Re: Recipharm meeting on Thursday*' 3 February 2016 (URN: PRO-E001749). Later that day [AMCo Director 2] emailed colleagues at AMCo to inform the renegotiation of the profit share was complete and that AMCo would have a better share from 1 April see - Email [AMCo Director 2] to [AMCo employee], cc [AMCo employee] entitled '*RE: PL: 43659/0024 Prochlorperazine 3mg Buccal Tablets*' (URN: PRO-E001755). See also Email [Focus Director 1] to [AMCo employee], [AMCo Director 2] and [AMCo employee], cc [Focus Director 2] and [Focus employee] entitled '*Prochlorperazine Tabs reconciliation Lexon*' 8 February 2016 (URN: PRO-E001760).

[278] Email [AMCo employee] to [Lexon employee] cc [Lexon Director 1] and [Lexon employee] [AMCo Employee 3], [AMCo employee] and [AMCo employee] entitled '*FOCUS - Prochlorperazine Profit Share Reconciliation Q2 2016*' 7 July 2016 (URN: PRO-E000703) attaching excel spreadsheet '*Prochlorperazine – Q2-2016 Reconciliation – June'16*' (URN: PRO-E000704).

3.191 On 8 July 2016, [Lexon employee] sent a profit share reconciliation to Medreich.[279] [Lexon Director 1] replied to this email commenting, *'This is wrong There is a new player and we need to accommodate that as per conversation with [Medreich Director 2] and [Medreich Director 1]'*.[280] On 12 July 2016, [Lexon employee] sent a revised reconciliation figure to Medreich in which Lexon was paid 50% of Focus' profits and Lexon paid one third of its share to Medreich.[281]

3.192 On 14 July 2016, [Lexon Director 1] emailed [AMCo Director 2] a copy of the original Focus-Lexon Heads of Terms with the comment, *'Copy of original agreement enclosed – we did change it to 50% once you got your MA'*.[282]

3.193 An internal Alliance document dated 22 September 2016 noted that in relation to Prochlorperazine POM two competitor products *'are expected between Q4 2016 and Q1 2017' and that, 'Two competitors could erode Concordia's market volume by ~60% resulting in only 1 or 2 orders required in 2017…'*.[283]

3.194 An Alliance *'Commercial Update'* from January 2017 noted that, *'Generic 8's likely to be launched by Lexon in 2017'*.[284]

3.195 On 23 March 2017, in the course of correspondence about price increases for various products including Prochlorperazine POM, [Focus Employee 1] explained to her colleague [AMCo employee] that Focus supplied certain products (including Prochlorperazine POM) only to mainline wholesalers (which would not include Lexon) but added:

> *'The only reason that Lexon gets Prochlorperazine Buccal Tablets is because they helped set up the supply agreement with Alliance Pharma (who also make our Aspirin EC 300mg).'*[285]

[Focus Employee 1]'s commentary about this document in an interview with the CMA is discussed at paragraph 5.558.

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[279] Email [Lexon employee] to [Medreich Director 2] and [Medreich employee] cc [Lexon employee] and [Lexon Director 1] entitled '*Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003128) attaching excel spreadsheet entitled '*Prochlorperazine – Q2-2016 Reconciliation – June'16*' (URN: PRO-E003129).

[280] Email [Lexon employee] to [Lexon Director 1] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130).

[281] Email [Lexon employee] to [Medreich employee] and [Medreich Director 2] cc [Lexon Director 1] and [Lexon employee] entitled '*Prochlorperazine Profit Share Reconciliation Q2 2016 – correct workings*' 12 July 2016 (URN: PRO-E003135) attaching pdf document entitled '*Prochlorperazine – Q2-2016 Reconciliation – June'16 Medreich*' (URN: PRO-E003136).

[282] Email [Lexon Director 1] to [AMCo Director 2] entitled '*RE: quick reminder*' 14 July 2016 (URN: PRO-E000614) attaching pdf document entitled '*1159_001*' 14 July 2016 (URN: PRO-E000615).

[283] Document entitled *'UK & RoI Budget',* dated 22 September 2016, page 15 (URN: PRO-E001278). See also document entitled *'Strategy Overview',* dated 26 October 2016 (URN: PRO-E001285) which notes that Prochlorperazine is expected to become a commodity generic in 2017.

[284] Alliance pdf entitled '*December 2016 Commercial Report*' 19 January 2017, page 3 (URN: PRO-E001324).

[285] Email [Focus Employee 1] to [AMCo employee] entitled '*RE: Well Pharmacy price amendments – Focus lines*' 23 March 2017 (URN: PRO-E002030).

3.196 On 4 May 2017, [AMCo Employee 3] emailed [Lexon Director 1] saying *'I see [sic] Morningside MA was granted for Prochlorperazine Buccal last month'*. [Lexon Director 1] responded that *'[t]hey have [sic] supply problem'* and noting that *'sales were down last month but I assume that's die [sic] to the increase the previous month'*.[286]

3.197 The same day, [AMCo Employee 3] wrote to colleagues at AMCo informing them*, 'we now have a competitor on our biggest Gx product – Prochlorperazine 3mg Buccal sourced for Alliance… I am meeting with Alliance Pharmaceuticals next week and will review forecasting and budget implications with this in mind.'*[287]

3.198 An internal Alliance document entitled dated 2 June 2017 recorded that, for *'Prochlorperazine'*, a *'[c]ompetitor licence already launched – Morningside… likely decrease in orders going forward'*.[288]

3.199 On 2 June 2017, [Lexon Director 1] emailed [AMCo Employee 3] asking, in relation to Prochlorperazine POM, *'[s]ales are really low still. Have Morningside pinched some do you think'*.[289] [AMCo Employee 3] replied *'…I'm not aware of wholesale switches to Morningside and sales in March were significantly higher (double) than earlier in the year'*.[290] [AMCo Employee 3] replied, noting that, *'…[a]ll customers are still purchasing so it seems that Morningside haven't got'*.[291]

3.200 An internal Alliance document dated 20 July 2017 recorded, in relation to Prochlorperazine POM, *'[FYF £1.27m margin] with now 6 orders (£212k margin per order) in forecast/budget. 6th order has now moved out to Jan 17. Working with Concordia to reinstate and potentially gain order #7. Competitor(s) are coming (Currently T + 32)'* [emphasis in original].[292]

Medreich's participation in the relevant agreements and its regulatory and manufacturing position (August 2013 – November 2017)

3.201 As outlined in paragraph 3.62 above, Medreich obtained its licence for Prochlorperazine OTC (PL21880/0126) on 3 July 2013.

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[286] Email [Lexon Director 1] to [AMCo Employee 3] entitled '*FYI*' 4 May 2017 (URN: PRO-E000655).

[287] Later that afternoon, [AMCo Employee 3] informed the same colleagues that *'I understand Morningside have a supply problem currently on this line. We therefore need to maintain price and not highlight this MA.'* Email [AMCo Employee 3] to [AMCo employee] amongst others entitled '*RE: UK Newly granted MA's – April 2017*' 4 May 2017 (URN: PRO-E002048).

[288] Document entitled '*EP Strategy Plan Forecast',* dated 2 June 2017, page 3 (URN: PRO-E001362).

[289] Email [Lexon Director 1] to [AMCo Employee 3] entitled '*Fwd: Prochlorperazine Profit Share Reconciliation May 2017*'' 2 June 2017 (URN: PRO-E000659).

[290] Email [AMCo Employee 3] to [Lexon Director 1] entitled '*Re: Prochlorperazine Profit Share Reconciliation May 2017*'' 2 June 2017 (URN: PRO-E002057).

[291] Email [Lexon Director 1] to [AMCo Employee 3] entitled '*Fwd: Prochlorperazine Profit Share Reconciliation May 2017*'' 2 June 2017 (URN: PRO-E002058).

[292] Document entitled '*UK & RoI Performance review*', dated 20 July 2017, slide 11 (URN: PRO-E001266).

3.202 On 30 July 2013, [Medreich Employee 1] emailed [Lexon Director 1] copying [Medreich Director 2] in respect of the future commercial plans for the licences, noting that:

> *'We have one 3 mg license, [Medreich employee] spoke to the Assessor of the other 3 mg and 5 mg. These are now also signed off, and we should receive the approval copies in August positively.*
>
> *What is the plan now, to commercialise these; as we can start the planning for all three from now.*
>
> *I know you were negotiating something, so please can you update us perhaps some time in August.'*[293]

3.203 Following the grant of the Prochlorperazine OTC MA (PL21880/0126), Medreich engaged in correspondence with the MHRA about the status of the Prochlorperazine POM MA (PL21880/0122). At that time there were no *'outstanding clinical or quality points'*.[294] Medreich's MA for Prochlorperazine POM was ultimately granted on 9 January 2014.[295]

3.204 On 7 January 2014, [Lexon employee] forwarded to [Medreich Employee 1] and [Medreich Director 2] a copy of the Prochlorperazine POM reconciliation spreadsheet that had been sent to Lexon by Focus (see paragraph 3.115).[296] On 8 January 2014, [Medreich Director 2] forwarded that email to [Medreich Employee 1] with the comment that:

> *'I have not actioned it as I didn't understand it …*
>
> *I thought we are still waiting for the license [sic]. . [sic] Has he gone ahead and done the deal and we are getting paid without officially having the license [sic] … that's good then.*
>
> *But this 75% profit I was not able to comprehend.'*[297]

3.205 [Medreich Employee 1] emailed [Lexon Director 1] on 8 January 2014, stating that Medreich were *'expecting the license [sic] grant letters today hopefully'* and

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[293] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled '*Prochlorperazine*' 30 July 2013 (URN: PRO-E002619).

[294] Email [Medreich employee] to [Lexon Director 1] cc [Medreich Employee 1] entitled '*RE: Medreich-Lexon regulatory update*' 27 November 2013 (URN: PRO-E002672) and *Medreich Current Regulatory Status and Tentative Time-lines for Completion of Lexon Projects*, Version-11/13 27 November 2013 (URN: PRO-E002673).

[295] Email [Medreich employee] to [Medreich Employee 1], cc [Medreich Director 1] and [Lexon employee] entitled 'FW: *PL 21880/0122 PL 21880/0121*' 9 January 2014 (URN: PRO-E002701).

[296] Email [Lexon employee] to [Medreich Employee 1] and [Medreich Director 2] cc [Lexon Director 1] and [Lexon employee] entitled '*Prochlorperazine 3mg share profit* ' 7 January 2014 (URN: PRO-E002685) attaching excel spreadsheet entitled '*Copy of Prochlorperazine Reconciliation December 2013 (2)*' 7 January 2014 (URN: PRO-E002686).

[297] Email [Medreich Director 2] to [Medreich Employee 1] entitled '*FW: Prochlorperazine 3mg share profit*' 8 January 2014 (URN: PRO-E002687).

observing in respect of the reconciliation statement that Medreich had been sent by Lexon*, 'Good that you started things in December, but neither [Medreich Director 2] nor I can follow this calculation. Please can you explain it to us so that we can act on it here internally?'*[298]

3.206 On the same day, [Lexon Director 1] emailed [Medreich Employee 1] a copy of the profit share invoice raised by Lexon to Focus without any further explanation.[299] Approximately 15 minutes after receiving [Lexon Director 1]'s email, [Medreich Employee 1] forwarded the email to [Medreich employee] asking him to raise a, *'debit note on Lexon for 50% of this amount about £40k. It should refer to "Profit share on prochlorperazine licenses" [sic]'* and informing him that *'it will be a debit note quarterly for about £70k I should think'.*[300]

3.207 On 9 January 2014, Medreich received confirmation of the approval of its MAs for both Prochlorperazine POM (PL21880/0122) and Prochlorperazine 5mg tablets (PL21880/0121).[301]

3.208 On 4 February 2014, [Medreich Employee 1] emailed [Lexon Director 1], informing him that:

> *'…We need to initiate the commercialisation of prochlorperazine. In fact to maintain our licenses [sic] we have to have api site Inspection reports. [✂] So we have to give a forecast to them [✂]…*
>
> *We have 3 licenses [sic]. According to me the Focus deal is on the 3mg POM licence only? So we should start the work now to introduce the 3 mg P [OTC] and the 5 mg in Medreich livery. I think we should also get ready to do the 3 mg POM as well, even if only so that Alliance cannot try to increase the Purchase price going forward. In fact their supply price is quite higher [sic] than the CGS, albeit we are extremely happy with the deal on the table! We do however have to be able to sell batches at some stage either in our of [sic] Focus livery as OLS as you suggest…*

[298] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled '*RE: Prochlorperazine 3mg profit share*' 8 January 2014 (URN: PRO-E002689).

[299] Email [Lexon Director 1] to [Medreich Employee 1] with no subject line 8 January 2014 (URN: PRO-E002690) attaching document entitled *'Profit Share Invoice'* 31 December 2013 (URN: PRO-E002691). [Medreich Employee 1] then forwarded that email to [Medreich Director 2], see Email [Medreich Employee 1] to [Medreich Director 2] entitled *'FW:'* 8 January 2014 (URN: PRO-E002692).

[300] Email [Medreich Employee 1] to [Medreich employee], cc [Medreich Director 2] entitled '*FW:*' 8 January 2014 (URN: PRO-E002696). The email from [Medreich Employee 1] to [Medreich employee] was then forwarded on internally within Medreich by [Medreich Director 2] to [Medreich Director 1], see Email [Medreich Director 2] to [Medreich Director 1] entitled '*FW:*' 8 January 2014 (URN: PRO-E002698).

[301] Email [Medreich employee] to [Medreich Employee 1] and [Lexon Director 1] cc [Medreich Director 2] and [Medreich Director 1] entitled '*FW: PL21880/0122 PL 21880/0121*' 9 January 2014 (URN: PRO-E002700).

…we are able to sell the product successfully, clearly, and we were just wanting to understand the rationale for tending to give exclusivity to other suppliers for our joint products.'[302]

3.209 [Lexon Director 1] replied the same day:

'The 3mg POM is best left alone as we make far much [sic] more as it is. I have agree [sic] that we make a batch every 3 years and drift it into the Alliance stock (can I have the batch size so I can plan)

The 3mg P – I am hitting a brick wall and it may be worth speaking to Alliance Pharma to create a strategy going forward as the market is really small. Perhaps I can arrange a meeting with us to meet their Product manager to get her views. Can you also in the mean time provide me with a batch size, copy of artwork approved and COGs).'[303]

3.210 Regarding [Medreich Employee 1]'s more general comment about giving exclusivity to other suppliers for Medreich/Lexon joint products, [Lexon Director 1] stated:

'I do believe though in certain instances as with the prochlorperazine 3mg it makes more commercial sense to work with a partner.'[304]

3.211 [Medreich Employee 1] replied, indicating he agreed with [Lexon Director 1]'s assessment, including the statement that the Medreich/Lexon 3mg POM product should not be marketed:

'Thanks [Lexon Director 1] I agree [sic] your points…

Prochlorperazine we will introduce 5mg only for now and [✂] 3mg we leave to you for the time being.'[305]

3.212 On 5 February 2014, [Medreich Director 2] forwarded to [Medreich Employee 1] [Lexon Director 1]'s email of 4 February 2014, with his own thoughts. As regards Prochlorperazine POM, [Medreich Director 2] wrote *'(pom / p) – ok to go with his strategy, just need to make a batch as he agress [sic] also.'*[306] [Medreich Employee 1] replied, agreeing with [Medreich Director 2], *'We should do exactly as you say. But we need to compile a spreadsheet to be updated monthly of the cost price and*

[302] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled '*Products*' 4 February 2014 (URN: PRO-E002744).

[303] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*Products*' 5 February 2014 (URN: PRO-E002750).

[304] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Products*' 4 February 2014 (URN: PRO-E002745).

[305] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*Products*' 5 February 2014 (URN: PRO-E002750). In [Lexon Director 1]'s reply of 5 February 2014 he did not raise any concerns with this proposed strategy, see Email [Lexon Director 1] to [Medreich Employee 1] entitled *'Re: Products'* 5 February 2014 (URN: PRO-E002751).

[306] Email [Medreich Director 2] to [Medreich Employee 1] entitled '*FW: Products*' 5 February 2014 (URN: PRO-E002746).

the sales and the profit share amount, just like [Lexon Director 1] does. We can circulate it quarterly.'[307]

3.213 On 6 February 2014, [Medreich Director 2] contacted [Lexon Director 1] to ask whether he was still interested in doing a 28 pack for Prochlorperazine POM or OTC. [Lexon Director 1] responded the same day, *'Wont [sic] work sorry'*.[308]

3.214 The same day, [Medreich Director 2] emailed colleagues at Medreich India providing the batch size for 3mg ([✂] tablets) and 5mg ([✂] tablets) prochlorperazine and stating that, *'[w]e intend to commercialize [sic] Prochlorperazine. The batch size as per dossier is below. Are the batch sizes reproducible in plant as I can then place orders accordingly.'*[309] No orders for Prochlorperazine POM were actually received from Lexon until 23 June 2015.[310]

3.215 On 17 February 2014, Medreich submitted a variation for PL 21880/0122.[311]

3.216 An internal Medreich document from March 2014 indicated that the '*current status'* of prochlorperazine was*, '[n]eed to audit current API site [✂]'* The same document also noted that*, '[v]alidation [b]atches of 5mg to be taken in May 2014'*.[312]

3.217 On 28 March 2014, [Medreich Employee 1] forwarded to [Medreich Director 1] the profit share correspondence [Medreich Employee 1] had received on 8 January. [Medreich Employee 1] explained *'I am trying to talk to [Lexon Director 1] to get more details on this and what to budget'*.[313]

3.218 On 28 March 2014, [Lexon Director 1] sent [Medreich Employee 1] the Prochlorperazine POM reconciliation statement from December 2013.[314] Later that day, [Medreich Employee 1] emailed [Medreich Director 1] stating, *'Talked to [Lexon Director 1] As [sic] per the attached we can budget our share of the profit share per year of £300k. There is an upside for our profit of £95k, if we can get a*

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[307] Email [Medreich Employee 1] to [Medreich Director 2] entitled '*FW: Products*' 5 February 2014 (URN: PRO-E002747).

[308] Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: Prochlorperazine*' 6 February 2014 (URN: PRO-E002756).

[309] Email [Medreich Director 2] to [Medreich employee] cc various others at Medreich entitled '*FW: Prochlorperazine*' 6 February 2014 (URN: PRO-E002752).

[310] Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, question 2.1 (URN: PRO-C3856).

[311] Email [Medreich employee] to [MHRA email address] entitled '*Prochloroperazine 3mg Tablets (Pl 21880/0122) – MHRA Folder ID; 4935166888*' 3 March 2014 (URN: PRO-E002766). Medreich stated in their response of 7 November 2017 that the approval for the addition of a '50s' blister pack was obtained on 14 March 2014 in respect of PL 21880/0122, see section 26 response of Medreich dated 7 November 2017, to the CMA Notice of 10 October 2017, question 7(d) (URN: PRO-C0250).

[312] Medreich document entitled '*Current regulatory status of newly acquired Products – updated March 2014'*, page 5 (URN: PRO-E002806). See also meeting notes entitled '*Validation Batches Medreich*' dated 7 March 2014 (URN: PRO-E002770) which notes on page 3 that Medreich's API supplier [✂].

[313] Email [Medreich Employee 1] to [Medreich Director 1], cc [Medreich employee] and [Medreich Director 2] entitled '*FW:*' 28 March 2014 (URN: PRO-E002782).

[314] Email [Lexon Director 1] to [Medreich Employee 1] 28 March 2014 entitled '*Prochlorperazine Reconciliation December 2013*' (URN: PRO-E002784) attaching Excel spreadsheet entitled *'Prochlorperazine December 2013'* (URN: PRO-E002785).

trade price increase.'[315] That email attached an excel spreadsheet, commenting on the December 2013 Prochlorperazine POM profit share reconciliation. Those comments refer to the *'Allian [sic] list price £9.98'* and an upside, *'June onwards increase the Trade price by £1, share 75% of that with Lexon'*. They also included *'Focus take 25%'* and *'We split 75% of the profit with Lexon'* and *'Upside increase Trade price from july [sic] by £1.00'*.[316]

3.219 On 7 April 2014, [Lexon employee] sent [Medreich Employee 1] and [Medreich Director 2], *'workings for full profit share of Prochlorperazine 3mg'* asking them to arrange for an invoice to be raised by Medreich for 50% of the profit share.[317] [Medreich Employee 1] forwarded this email to [Medreich employee] explaining:

> *'Please could you do the Q1 debit note for 50% of the £115781, based on the attached. I notice in fact the CGS was wrong last time, it is now a little higher. However in return the profit uplift from price increases, these are not to be shared with Alliance as that price is now fixed.'*[318]

3.220 On 7 April 2014, [Medreich Director 1] emailed [Medreich Employee 1], questioning the level of the Alliance price increase in relation to the supply of Prochlorperazine POM to Focus from 4.85 (for the initial 40,000 packs) to £5.65:

> *'1. All of us know that there is no reason for cost increase. They have charged in the p&L 13% cost increase which cant [sic] be true. Focus cant [sic] accept such price increases on costs which in any case are inflated many folds.*
>
> *2. How do we certify the costs? We all know that this product cant [sic] cost more than [✂]. There should be some discussion around this…*
>
> *3. The magnitudes will multiply once we throw additional products in to similar arrangements.'*[319]

3.221 Later that day, [Medreich Employee 1] emailed [Lexon Director 1] to ask for more information concerning the basis for the Alliance price increase:

> *'I have been asked for a detailed analysis of how the COGS has increased now to £5.47 against a cost last quarter of £4.85. This is a product that*

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[315] Email [Medreich Employee 1] to [Medreich Director 1] cc [Medreich employee] and [Medreich Director 2] 28 March 2014 entitled '*RE: Prochlorperazine 3 mg x 50 Focus"* (URN: PRO-E002787).

[316] Excel spreadsheet entitled '*Prochlorperazine 2014 budget.xlsx*' 28 March 2014 (URN: PRO-E002788).

[317] Email [Lexon employee] to [Medreich Employee 1] and [Medreich Director 2] cc [Lexon Director 1] and [Lexon employee] entitled '*Prochlorperazine 3mg share profit Jan 2014 – March 2014*' (URN: PRO-E002793) attaching Excel spreadsheet entitled '*Copy of Prochlorperazine Reconciliation Q114 (3)*' (URN: PRO-E002794).

[318] Email [Medreich Employee 1] to [Medreich employee] cc [Medreich Director 1], [Medreich Director 2] and [Medreich employee] entitled '*FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' (URN: PRO-E002795).

[319] Email [Medreich Director 1] to [Medreich Employee 1] and [Medreich employee] cc [Medreich Director 2] and [Medreich employee] entitled '*RE: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002798).

should cost some [✂], so we feel that Alliance are making still the lion's share at £1m a year profit, and we are getting about £220k each. Is there anything that can be used to help me corroborate the increase in the COGS from Focus perhaps. Could we see please the supplier invoices? I do not want to be difficult as it is a clever arrangement, but I am cutting a bit of a sorry figure with the management here, as I cannot explain how suddenly the supplier is going for this 13% cost increase.

I remember you had mentioned something to me on this, but surely not to kick in in [sic] the second quarter and before any price increases? I thought the 2 were in some way linked?'[320]

3.222 On 22 April 2014, [Medreich Employee 1] emailed [Medreich employee] stating that *'[w]e have just placed orders for prochlorperazine. So we need to arrange the audit of [✂] urgently.'* Those orders related to prochlorperazine 5mg tablets.[321] At this time, no orders had been placed by Lexon for Prochlorperazine POM.

3.223 On 3 June 2014, [Medreich Employee 1] emailed [Medreich Director 1] indicating that an audit had been booked with [✂] because Medreich *'said we were placing a PO into their system now.'* [Medreich Employee 1] further explained*, 'We want to commercialise the 5 mg license [sic]. It is only about Euro 20000 of api…'.*[322] Medreich placed an order on 24 June 2014 for API with [✂] which was to be delivered on 13 August 2014.[323]

3.224 On 22 August 2014, [Lexon Director 1] emailed [Medreich Director 2] to ask *'[p]lease can you advise batch size and landed and released COGs for prochlorperazine 3mg 50s'*.[324]

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[320] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002803).

[321] Email [Medreich Employee 1] to [Medreich employee] cc [Medreich Director 2] (amongst others) entitled '*Prochlorperazine Maleate Tablets – 5mg – 2 x 14's, 6 x 14's & 5 x 10's – for approval*'' 22 April 2014 (URN: PRO-E002808).

[322] Email [Medreich Employee 1] to [Medreich Director 1] cc [Medreich Director 2] (amongst others) (Medreich) entitled '*FW: API Prochlorperazine*' 3 June 2014 (URN: PRO-E002818).

[323] Purchase order '*4540002961 – [✂]*' 19 June 2014 (URN: PRO-E002833). The audit scheduled to take place in Q1 of 2015 was rescheduled and took place on 1 December 2015 (see Email [✂ employee] to [Medreich employee] (amongst others) entitled '*AUDIT [✂]*' 15 December 2014 (URN: PRO-E003026); Email [Medreich employee] to [[✂] employee] (amongst others) entitled '*AUDIT [✂]*' 5 February 2015 (URN: PRO-E003026); Email [Medreich employee] to [✂] employee] (amongst others) entitled '*AUDIT [✂]*' 5 February 2015 (URN: PRO-E003026); Email [[✂] employee] to [Medreich employee] (amongst others) entitled '*AUDIT [✂]*' 29 July 2015 (URN: PRO-E003026); Email [Medreich employee] to [[✂] employee] (amongst others) entitled '*AUDIT [✂]*' 29 July 2015 (URN: PRO-E003026); Email [Medreich employee] to [[✂] employee] (amongst others) entitled '*AUDIT [✂]*' 21 September 2015 (URN: PRO-E003026); Email [[✂] employee] to [Medreich employee] (amongst others) entitled '*AUDIT [✂]*' 23 September 2015 (URN: PRO-E003026); and Email [[✂] employee] to [Medreich employee] (amongst others) entitled '*AUDIT [✂]*' 25 September 2015 (URN: PRO-E003026).

[324] Email [Lexon Director 1] to [Medreich Director 2] entitled '*[No subject]*' 22 August 2014 (URN: PRO-E000434). In response to this, [Medreich Director 2] forwarded on previous correspondence between him and [Lexon Director 1] providing details on cost of goods, see Email [Medreich Director 2] to [Lexon Director 1] entitled '*FW: Prochlorperazine and Bisoprolol*' 26 August 2014 (URN: PRO-E002865) attaching excel spreadsheet entitled '*lexon medreich generics new line forecasts*' (URN: PRO-E002866).

3.225 On 27 August 2014, [Medreich Director 2] emailed a colleague in Medreich discussing the potential for manufacture of a batch of Prochlorperazine POM and OTC. He stated:

> *'There maybe [sic] a possibility of doing a batch of Prochloroperazine [sic] 3mg.*
>
> *In the license [sic] [✂] tablets batch size is registered.*
>
> *From the equipment point of view are we ok as this is not a big line and we do need small batch sizes.*
>
> *So if can confirm that [✂] tablets is ok to manufacture will be great.'*[325]

3.226 Further correspondence within Medreich on this issue on 2 September 2014 indicates (wrongly) that the minimum batch size for manufacturing was [✂] tablets.[326] [Medreich Director 2] informed [Lexon Director 1] of this.[327] [Lexon Director 1] then forwarded this information on to [Focus Director 1].[328] [Focus Director 1] responded to this email, *'Thanks mate I will update you on requirements soon , [sic] What would be the lead time'*.[329] [Lexon Director 1] then replied to say, *'Initially I would say 20 weeks for the first then 12weeks [sic] thereafter'*.[330]

3.227 On 17 December 2014, Medreich received an email from the MHRA indicating that:

> *'It has come to our attention that the reference medicinal product (Buccastem) used for the initial application was itself approved as a generic. Thus the legal basis of the application (Article 10.1) was incorrect and the marketing authorisation for Prochlorperazine Maleate 3 mg Buccal tablets PL 21880/0126 should not have been approved on that basis… '.*[331]

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[325] Email [Medreich Director 2] to [Medreich employee], cc [Medreich employee] entitled '*FW: Prochloroperazine 3mg*' 27 August 2014 (URN: PRO-E002867).

[326] Email [Medreich employee] to [Medreich Director 2] cc [Medreich employee] entitled '*Re: Prochloroperazine 3mg*' 2 September 2014 (URN: PRO-E002873). The figure of [✂] tablets was actually a mistake, the correct figure was [✂] tablets. See paragraph 3.233.

[327] Email [Medreich Director 2] to [Lexon Director 1] entitled '*Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E002874).

[328] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811).

[329] Email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003812).

[330] Email [Lexon Director 1] to [Focus Director 1] entitled '*Re: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003813).

[331] Email [MHRA employee] to [Medreich employee] cc [MHRA employee] entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 17 December 2014 (URN: PRO-E002900). [Medreich Employee 1] replies arranging a conference call for 22 December see Email [Medreich Employee 1] to [MHRA employee] entitled *'Re: PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets'* 18 December 2014 (URN: PRO-E002908). [Medreich Employee 1] also raised the issue at the Medreich Executive Committee meeting see *Medreich Executive Committee Meeting Minutes'* 18 December 2014 (URN: PRO-E002907).

3.228 On 22 December 2014, [Medreich Employee 1] emailed [Medreich employee] (amongst others) with regards to the communication from the MHRA of 17 December 2014 and Medreich's next steps in this respect to address that:

> *'As you can see from the below, we got the 2 licenses [sic] for P and POM status for the prochlorperazine 3 mg buccal tablet, having only done the BE study against a generic.*
>
> *We please urgently need to provide additional data. We have to make the Application [sic] like a 10.(a) application…*
>
> *… We would need to do it for both the 3 mg licenses [sic] and we need to submit the revised Data/ Dossier Amended Sections in January 2015…*
>
> *Please attach a Priority [sic] so we can retain the licenses [sic], which are very valuable to the company…'.*[332]

3.229 Following a request to the MHRA for an extension of time to respond,[333] Medreich ultimately submitted the information update to the MHRA on 27 February 2015.[334]

3.230 On 12 March 2015, [Medreich employee] emailed [Medreich employee] stating in respect of Prochlorperazine POM that Medreich was *'already receiving profit share on this product'* and that *'Sales in UK sheet will be minimal to ensure licence is kept active.'*[335]

3.231 On 4 June 2015, Medreich delivered to Lexon the first batch of Prochlorperazine 5mg tablets.[336]

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[332] Email [Medreich Employee 1] to [Medreich employee] cc [Medreich Director 2] and [Medreich Director 1] (amongst others) entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 22 December 2014 (URN: PRO-E002908). [Medreich Employee 1] also enlisted the help of [✂] to respond to the MHRA, see Email [Medreich Employee 1] to [[✂] employee] cc various individuals entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 30 January 2015 (URN: PRO-E002917).

[333] Email [Medreich Employee 1] to [MHRA employee] entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 5 February 2015 (URN: PRO-E002923). [MHRA employee] replied to this email confirming the extension of time for filing on 11 February 2015 (URN: PRO-E002930). [Medreich Employee 1] forwarded the extensions request to colleagues at Medreich and [✂] noting that, although the MHRA had only referred to licence number 21880/0126 P, he assumed *'both 3 mg licenses are affected' See* Email [Medreich Employee 1] to [Medreich employee] and [[✂] employee] cc various individuals entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 5 February 2015 (URN: PRO-E002923).

[334] Email [[✂] employee] to [Medreich Employee 1] cc various others entitled '*Prochlorperazine – Information update submission to MHRA'* 27 February 2015 (URN: PRO-E002937). Medreich was required to submit a further variation to the application on 14 May 2015, see Email [MHRA employee] to [[✂] employee] entitled '*PL 21880/0122 & -0126*' 14 May 2015 (URN: PRO-E002969). On 28 July 2015, Medreich followed up with the MHRA as to the status of the application see Email, [[✂] employee] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled *Prochlorperazine status PL 21880/0122 & 0126*' 31 July 2018 (URN: PRO-E003007). [Medreich Employee 1] also enquired as to the status of the application on 5 August 2015, see Email [Medreich Employee 1] to [Medreich employee] entitled *'PDF ARTWORKS'* 5 August 2015 (URN: PRO-E003006).

[335] Email [Medreich employee] to [Medreich employee] entitled '*Fluoxetine Licence sale*' 12 March 2015 (URN: PRO-E002945).

[336] Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, question 1.4 (URN: PRO-C3856), Annex C1 (URN: PRO-C3866), Annex C2 (URN: PRO-C3867).

3.232 On 18 June 2015, [Medreich Director 2] wrote to [Medreich employee] informing him that he intended to place *'commercial orders'* for prochlorperazine 3mg buccal tablets and asked to be advised of the *'lowest commercial batch possible in order to place orders'*.[337]

3.233 On 19 June 2015, [Medreich Employee 1] was informed by [Medreich Director 2] that the smallest batch size for prochlorperazine 3mg buccal tablets was *'[✂] tabs'*. [Medreich Employee 1] then emailed [Lexon Director 1] asking him, *'how we should plan the split between P and POM for [✂] tablets'.* [Lexon Director 1] replied on 22 June 2015, saying, *'[p]lease do all as the POM for now thanks. I am working on something with the P pack'*.[338] Despite [Lexon Director 1] having previously informed [Focus Director 1] that the batch size was [✂] tablets (paragraph 3.226 above), the CMA has not obtained any record of [Lexon Director 1] having informed [Focus Director 1] of the correct batch size.

3.234 On 22 June 2015, [Medreich Director 2] emailed [Lexon Director 1] asking him how many batches he wanted to order and what pack size. [Lexon Director 1] confirmed he wanted only one batch in the 50's pack size.[339] [Medreich Director 2] then emailed [Medreich employee] and requested that he place an order for, *'Prochlorperazine 3mg – pack of 5x10's – 1 batch.'*[340] [Lexon Director 1] sent an order to [Medreich Director 2] on 23 June 2015.[341]

3.235 The minutes of the Medreich Exco meeting held on 24 June 2015 record that [Medreich Employee 1] stated that the *'[o]rder for Prochlorperazine has been placed on India, this is for the 1 batch required in order to keep the license [sic] active'*.[342]

3.236 On 6 July 2015, [Medreich Director 2] observed in an email that:

> *'There will be few products going forward where we shall place 1 batch order on Medreich dossiers (Prochloroperazine [sic] 3mg – we have already placed 1 batch order)… When its own dossier with exhibit batches*

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[337] Email [Medreich Director 2] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled '*FW: batch size*' 18 June 2015 (URN: PRO-E002974).

[338] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*FW: batch size*' 22 June 2015 (URN: PRO-E002975).

[339] Email [Medreich Director 2] to [Lexon Director 1] entitled '*RE: FW: batch size'* 22 June 2015 (URN: PRO-E000517).

[340] Email [Medreich Director 2] to [Medreich employee] entitled '*Prochloroperazine 3mg*' [sic] 22 June 2015 (URN: PRO-E002978).

[341] Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: FW: batch size*' 23 June 2015 (URN: PRO-E002980) and attachment entitled *'Lexon PO – 416174'* (URN: PRO-E002981).

[342] Email [Medreich employee] to various Medreich colleagues entitled '*Exco minutes*' 29 June 2015 (URN: PRO-E002984) attaching '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich PLC Offices'* 29 June 2015 (URN: PRO-E002985). The order for Prochlorperazine POM was not raised with Medreich India until 10 July 2015, see Email [Medreich Director 2] to [Medreich employee] entitled '*Re: Prochlorperazine 3mg order*' 10 July 2015 (URN: PRO-E002997) and email from [Medreich employee] to [Medreich employee] and [Medreich Director 2] cc various others entitled *RE: Prochloroperazine 3mg order*' 10 July 2015 (URN: PRO-E002998).

being made in our own site, the advantage is that there is no need for full scale validation which we normally do when it's a third party dossier.'[343]

3.237 On 13 July 2015, [Medreich Employee 1] emailed [Lexon Director 1] to inform him that for an order of Prochlorperazine OTC the, *'[b]atch size would be [✂] packs'* and that the, *'price would be [✂]'*. [Medreich Employee 1] then asked [Lexon Director 1] to, *'[p]lease confirm the plan to go ahead with this line.'*[344]

3.238 During August 2015, Medreich contacted the MHRA on a number of occasions to obtain an update about the status of Medreich's Prochlorperazine POM and OTC MAs.[345]

3.239 On 11 September 2015, [Medreich employee] emailed [Medreich Employee 1] and [Medreich Director 2] to inform them that the MHRA had advised that Medreich's application was, *'still under discussion'* but that the assessor, *[✂]*.[346] [Medreich Employee 1] forwarded this email to [Lexon Director 1] on 14 September 2015.[347]

3.240 On 15 September 2015, the MHRA emailed [Medreich employee] stating that the MHRA had agreed *'that the original application could be approved under Article 10(3)'*.[348]

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[343] Email [Medreich Director 2] to various colleagues at Medreich entitled '*Nortriptyline plan*' 6 July 2015 (URN: PRO-E002992).

[344] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*Prochlorperazine 3 mg P License*' 13 July 2015 (URN: PRO-E002999).

[345] See Email [[✂] employee] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled *Prochlorperazine status PL 21880/0122 & 0126*' 7 August 2018 (URN: PRO-E003007); and Email [[✂] employee] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled *Prochlorperazine status PL 21880/0122 & 0126*' 12 August 2018 (URN: PRO-E003007); Email [[✂] employee] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled *Prochlorperazine status PL 21880/0122 & 0126*' 24 August 2018 (URN: PRO-E003007). On the same day, [Medreich employee] then forwarded this email chain on to [Medreich Employee 1] cc [Medreich employee]; and Email [[✂] employee] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled *Prochlorperazine status PL 21880/0122 & 0126*' 12 August 2018 (URN: PRO-E003007).

[346] Email [Medreich employee] to [Medreich Employee 1] and [Medreich Director 2] cc various others at Medreich entitled ''*Prochlorperazine status PL 21880/0122 & 0126_email response from [✂]*' 11 September 2015 (URN: PRO-E003009).

[347] Email [Medreich Employee 1] to [Lexon Director 1] entitled ''*Prochlorperazine status PL 21880/0122 & 0126_email response from [✂]*' 14 September 2015 (URN: PRO-E003009).

[348] Email [MHRA employee] to [Medreich employee] entitled '*RE: PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 15 September 2015 (URN: PRO-E003010). [Medreich employee] asked for confirmation from the MHRA that the MAs for both Prochlorperazine POM and OTC were approved under Article 10(3). The MHRA confirmed this and [Medreich employee] forwarded that email to [Medreich Employee 1] and [Medreich Director 2], see Email [MHRA employee] to [Medreich employee] entitled '*RE: PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 15 September 2015 (URN: PRO-E003010). The MHRA stated to the CMA that the email from [MHRA employee] 15 September 2015 was to '*inform the company [Medreich] of the approach to be taken to resolve the issue*', albeit that in terms of public documentation on the MHRA system and website '*[d]ue to administrative delays, the issue was finally resolved on Sentinel on 5 July 2016*' Email [MHRA employee] to [CMA Official] cc various others at CMA and MHRA entitled '*Re: CMA Case no. 50511-2 - notice to MHRA with questions re specific licences and operation of sunset clause on a particular licence*' 29 March 2019 (URN: PRO-C3882). The MHRA also confirmed that, contrary to its initial view in 15 September 2015, it subsequently decided that updated marking authorisation application (MAA) forms were required from Medreich (Email [MHRA employee] to [CMA Official] cc various others at CMA and MHRA entitled '*Re: CMA Case no. 50511-2 - notice to MHRA with questions re specific licences and operation of sunset clause on a particular licence*' 12 April 2019 (URN: PRO-C3882)); the correspondence between the MHRA and Medreich to obtain updated MAA forms took place between 6 July 2016 and 5 September 2016, Email [Medreich employee] to [MHRA employee] cc [Medreich employee] entitled '*RE: PL 21880/0122 PL 21880-0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 5 September 2016 (URN: PRO-E003172).

3.241 On 8 October 2015, [Medreich Director 2] emailed colleagues within Medreich stating that for prochlorperazine 3mg and another product, *'We need to push thse [sic] 2 products, I was expecting that you will do these 2 in October so that in December we could sell. Please see if you can still do in October.'*[349]

3.242 On 24 November 2015, [Medreich Director 2] corresponded with [Medreich employee] regarding an upcoming visit to Medreich's facilities by [Lexon Director 1]. [Medreich employee] indicated that Prochlorperazine POM was planned for production in January. [Medreich Director 2] responded, *'He was expecting Prochlorperazine … (Medreich) to be done in November and if I am not mistaken this was what was communicated earlier.*
Can you please rework the plan for December atleast [sic]?'[350]

3.243 On 11 January 2016, *'workings for full profit share of Prochlorperazine 3mg'* were sent on by [Lexon employee] to Medreich.[351] [Medreich Director 2] forwarded this email internally within Medreich commenting *'[t]hey have increased the SP in the market which is reflected in our share.. [sic] it's looking good at £100k per month..[sic]'*.[352]

3.244 On 9 May 2016, [Medreich Director 2] wrote to colleagues at Medreich India asking, in relation to Prochlorperazine POM, *'whats [sic] happening to this order? If we don't launch it soon, we will lose the license. Order is pending for more than 1 year.'*[353]

3.245 On 13 May 2016, [Medreich employee] wrote to the MHRA asking for confirmation about when the Sunset Clause would apply to Prochlorperazine POM and OTC.[354] The MHRA replied on 25 May 2016 indicating that for Prochlorperazine OTC (PL 21880/0126) an exemption form would need to be submitted by 9 July 2016 and for Prochlorperazine POM (PL 21880/0122) an exemption form would need to be submitted by 9 January 2017.[355]

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[349] Email [Medreich Director 2] to [Medreich employee] cc [Medreich employee], [Medreich employee] and [Medreich employee] entitled '*RE: Please advise confirmed dates*' 8 October 2015 (URN: PRO-E003013).

[350] Email [Medreich Director 2] to [Medreich employee] (amongst others) entitled '*RE: Lexon Visit on 30th Nov*' 24 November 2015 (URN: PRO-E003030).

[351] Email [Lexon employee] to [Medreich Director 2], [Medreich Employee 1] and [Medreich employee] cc [Lexon employee] and [Lexon Director 1] 11 January 2016 (URN: PRO-E003049) attaching excel spreadsheet entitled '*Prochlorperazine – Q4-2015 Reconciliation – Dec'15*' showing the profit share due to Lexon of 75% up to £10.50 with 50% over £10.50 (URN: PRO-E003050).

[352] Email [Medreich Director 2] to [Medreich employee] entitled '*FW: Prochlorperazine Profit Share Reconciliation Q4 2015*' 11 January 2016 (URN: PRO-E003055).

[353] Email [Medreich Director 2] to various colleagues at Medreich entitled '*RE: Prochlorperazine 3mg*' 9 May 2016 (URN: PRO-E003084). See also Email [Medreich Director 2] to [Medreich employee] entitled '*Please Help*' 11 May 2016 (URN: PRO-E003085) in which [Medreich Director 2] asked [Medreich employee] for his help to have prochlorperazine 3mg tablets (amongst other products) delivered *'asap'* noting *that 'these are small products, so maybe not interesting for the factory, but its [sic] important for us'*.

[354] Email [Medreich employee] to [MHRA email address] entitled '*Prochlorperazine 3mg tablets-P & POM*'' 13 May 2016 (URN: PRO-E003086).

[355] Email MHRA to [Medreich employee] entitled '*RE: Prochlorperazine 3mg tablets-P & POM*' 25 May 2016 (URN: PRO-E003097).

3.246 Also on 13 May 2016, [Lexon Director 1] sent [Medreich Director 2] a copy of an order for [✂] Prochlorperazine POM dated 23 June 2015.[356] The same day, [Medreich Director 2] emailed [Medreich employee] noting that:

> *'We have 2 licenses [sic] of Prochlorperazine 3mg:*
>
> *(1) P license – pack size 8*
>
> *(2) POM license [sic] – pack size 14/50*
>
> *There are 2 batch orders of 50's pack (POM) [sic] in system.*
>
> *Both the above licenses [sic] are facing sunset clause which means we will lose the license [sic].*
>
> *[Medreich employee] is now on it trying to apply for extension, in the meanwhile we also understand that there is a technical problem in the formula, which again means a variation.*
>
> *As we need to save the P license, I am requesting [Medreich employee] to place 1 batch order for the P license ([✂] packs) @ [✂] per pack.*
>
> *As a result, please divert 1 batch of POM order to P order, as a result produce 1 batch of 8's pack and 1 batch of 50's pack.*
>
> *Please contact [Medreich employee] for all technical/artwork clarifications, but again this product is now a huge priority.'*[357]

3.247 Also on 13 May 2016, [Medreich Director 2] emailed [Lexon Director 1]:

> *'Another problem uncovered.*
> *Prochlorperazine 3mg (both P and POM) license is expiring under sunset clause this July 2016.*
> *I have requested [Medreich employee] marked in the email to apply for license [sic] extension.*
>
> *On the orders, we have placed an order on India for the POM (50's) – 1 batch sometime [sic] ago. On chasing up, it has been found that there is a gap between registered formula and working formula at plant level.*

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[356] Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: Prochlorperazine 3mg*' 13 May 2016 (URN: PRO-E000599) attaching pdf entitled '*Lexon PO – 416174*' 23 June 2015 (URN: PRO-E000600).

[357] Email [Medreich Director 2] to [Medreich employee] cc various others entitled '*Prochlorperazine 3mg*' 13 May 2016 (URN: PRO-E003088). The 'technical problem in the formula' referred to by [Medreich Director 2] related to a 'transcription error' in the existing unit formula for Prochlorperazine POM (see Email [Medreich employee] to [Medreich employee] cc [Medreich Director 2] (amongst others) entitled 'Qty Mismatch -Prochlorperazine 3mg Tablets-UK' 17 May 2016 (URN: PRO-E003102)). A variation to correct this was filed on 3 June 2016 and was granted on 22 June 2016, see Email [Medreich employee] to [Medreich employee] cc various others entitled *'Fwd: Qty Mismatch -Prochlorperazine 3mg Tablets-UK*' 3 June 2016 (URN: PRO-E003103) and Email [Medreich employee] to [Medreich employee] cc various others entitled *'Fwd: Qty Mismatch -Prochlorperazine 3mg Tablets-UK*' 22 June 2016 (URN: PRO-E003116).

[Medreich employee] is simultaneously working on it to file variation with MHRA.

Because of sunset clause we need to do even the P pack as it's a diff [sic] license [sic] no.
Due to pack size of 8's, this will means no of packs for 1 batch will be [✂] packs.
Are you ok for us to place order? we [sic] need to this from regulatory point of view anyways ..

Wanted to bring you upto [sic] speed on this product.'[358]

3.248 On 17 May 2016, [Medreich employee] emailed a new purchase order to [Medreich employee] for one batch of Prochlorperazine 3mg 8's Tabs ([✂] packs) indicating the supply was required in July 2016.[359]

3.249 On 19 May 2016, [Medreich employee] emailed colleagues at Medreich setting out a list of products *'for which Launches are anticipated in the next 3-6 months'*. That list of products for the UK included both Prochlorperazine POM and OTC.[360]

3.250 On 29 May 2016, Medreich applied for exemptions to the Sunset Clause for both Prochlorperazine POM and OTC.[361] The MHRA granted the exemption to the Sunset Clause for Prochlorperazine OTC (PL21880/0126).[362]

3.251 On 4 July 2016, [Medreich employee] emailed [Lexon Director 1] attaching Lexon's orderbook. The orderbook included an order for prochlorperazine 3mg tablets (50's) with the required date said to be 17 June 2016.[363]

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[358] Email [Medreich Director 2] to [Lexon Director 1] cc [Medreich employee], [Medreich employee] entitled '*Prochlorperazine 3mg*' 13 May 2016 (URN: PRO-E003089). [Lexon Director 1] replied to the above email on the same day attaching a copy of a purchase order dated 23 June 2015 for [✂] packs of Prochlorperazine POM Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: Prochlorperazine 3mg*' 13 May 2016 (URN: PRO-E000599) attaching Purchase Order *Lexon PO – 416174* dated 23 June 2015 (URN: PRO-E003090).

[359] Email [Medreich employee] to [Medreich employee] cc various others entitled *'FW: Prochlorperazine 3mg'* 17 May 2016 (URN: PRO-E003091) attaching pdf *'Purchase Order 1604167'* (URN: PRO-E003092).

[360] Email [Medreich employee] to [Medreich employee] cc various others entitled '*Medreich Plc Europe (Including UK) Launch Products (3-6 months)'* 19 May 2016 (URN: PRO-E003094).

[361] Email [Medreich employee] to MHRA entitled *RE: Prochlorperazine 3mg tablets-P & POM*' 29 May 2016 (URN: PRO-E003097). The basis for requesting an exemption for both products was twofold: that there was an *'on-going procedure affecting the marketing authorisation critical for placing the product on the market'* and that there was an *'on-going planned change in manufacturing site or process and continued authorisation is required to ensure future supply to patients'*, see document entitled *'2016 Exemption Request – PL218800126'* 29 May 2016 (URN: PRO-E003099) and document entitled *'2016 Exemption Request – PL218800122'* 29 May 2016 (URN: PRO-E003100).

[362] An exemption for PL21880/0122 could not be applied for until 3 months prior to the application of the Sunset Clause, see Email MHRA to [Medreich employee] entitled '*Prochlorperazine 3mg tablets-P & POM*' 29 June 2016 (URN: PRO-E003120).

[363] Email [Medreich employee] to [Lexon Director 1] cc various others entitled '*Lexon order Book 04/07/16*' 4 July 2016 (URN: PRO-E003125) and attachment entitled *'UNICEF Orderbook 040716'* (URN: PRO-E003126). Order books were also sent to [Lexon Director 1] on 9 August 2016, 15 August 2016, 5 January 2017, 4 April 2017, 4 May 2017, 7 June 2017, 6 July 2017, 7 August 2017 all of which indicate that the orders for Prochlorperazine POM and OTC were outstanding. See, respectively, Email [Medreich employee] to [Medreich employee] cc various others entitled '*UK Order Book 9 August* 2016' 9 August 2016 (URN: PRO-E003154) and attachment (URN: PRO-E003155); Email [Medreich

3.252 As outlined in paragraphs 3.181 to 3.184 and 3.192, the profit share split between Lexon and Focus was amended in July 2016 so that all profits would be shared 50-50 from Q2 2016 onwards. On 7 July 2016, the profit share between Lexon and Medreich was also amended so that for sales in Q2 2016 onwards, Medreich received one third of the 50% of the profits paid to Lexon, rather than the 50% of Lexon profits Medreich was previously being paid. [Lexon Director 1] explained the reason for the change was because *'…[t]here is a new player and we need to accommodate that as per conversation with [Medreich Director 2] and [Medreich Director 1]'*.[364]

3.253 On 18 October 2016, [Medreich employee] commented on Medreich's half year results; he commented on the reduction in income for Medreich following the renegotiation of the profit share after the grant of the Primegen licence to AMCo, *'there is... a reduction in income from Prochlorperazine profit share. This is due to additional player in the market. This is having an impact in H1 and will continue now an additional party has a license [sic]…'* [365]

3.254 On 18 November 2016, [Medreich employee] emailed colleagues in Medreich in relation to transfer prices of products from India. He noted that *'1. Procholperazine [sic] profit share does not relate to product supplied from India, so would not form part of the reconciliation'*.[366]

employee] to [Lexon Director 1] cc [Medreich Director 2] entitled '*Lexon OB*' 15 August 2016 (URN: PRO-E003166) and attachment (URN: PRO-E003167); Email [Medreich employee] to [Lexon Director 1] cc [Medreich Director 2] and [Medreich employee] entitled '*RE:OB*' 5 January 2017 (URN: PRO-E003229) and attachment (URN: PRO-E003230); Email [Medreich employee] to [Lexon Director 1] cc [Medreich Director 2] (amongst others) entitled '*LEXON OB 04042017.xlsx*' 4 April 2017 (URN: PRO-E003273) and attachment (URN: PRO-E003274); Email [Medreich employee] to [Lexon Director 1] cc [Medreich Director 2] and [Medreich employee] entitled '*Lexon OB update*' 4 May 2017 (URN: PRO-E003302) and attachment (URN: PRO-E003303); Email [Medreich employee] to [Lexon Director 1] cc [Medreich Director 2] and [Medreich employee] amongst others entitled '*RE: ob*' 7 June 2017 (URN: PRO-E003314) and attachment (URN: PRO-E003315); Email [Medreich employee] to [Lexon Director 1] cc [Medreich Director 2] and [Medreich employee] amongst others entitled '*RE: ob*' 6 July 2017 (URN: PRO-E003324) and attachment (URN: PRO-E003325); Email [Medreich employee] to [Medreich employee] cc [Medreich Director 2] entitled '*Lexon OB*' 7 August 2017 (URN: PRO-E003356) and attachment (URN: PRO-E003357).

[364] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130). On 7 October 2016, Medreich was provided with a revised profit share reconciliation showing Medreich as receiving one third of the 50% of overall profit owed from Focus to Lexon see Email [Lexon employee] to [Medreich employee], [Medreich Director 2] and [Medreich employee] cc [Lexon Director 1] and [Lexon employee] entitled '*Prochlorperazine Profit Share Reconciliation Q3 2016*' 7 October 2016 (URN: PRO-E003178) attaching pdf document entitled '*Prochlorperazine – Q3-2016 Reconciliation – Sept'16 Medreich* ' (URN: PRO-E003179).

[365] Email [Medreich employee] to [Meiji employee] and [Medreich Director 2] cc [Medreich employee] entitled '*RE: Medreich PLC analysis*' 18 October 2016 (URN: PRO-E003183).

[366] Email [Medreich employee] to [Medreich employee] and [Medreich employee], cc [Medreich Director 1] and [Meiji employee] entitled '*RE: New Transfer prices ex-India*' 18 November 2016 (URN: PRO-E003196).

3.255 On 28 November 2016, [Medreich employee] emailed the MHRA seeking an exemption from the Sunset Clause for Prochlorperazine POM (PL 21880/0122).[367] The MHRA accepted the exemption request on 5 January 2017.[368]

3.256 On 3 January 2017, [Medreich employee] emailed [Medreich employee] asking for an update as to when the orders of Prochlorperazine POM and OTC would be dispatched to the UK. [Medreich employee] replied stating there were *'some technical issues'* and that until they were rectified, *'all manufacturing activity of Prochlorperazine 3mg has been stopped'*.[369]

3.257 On 9 January 2017, [Medreich Director 2] forwarded on to [Lexon Director 1] as an '*FYI*' an email that he had earlier sent to colleagues in Medreich:

> *'I am writing this email as [Lexon Direcctor] is up in arms against Medreich.*
>
> *We have currently 8 molecules … for which orders are placed but we don't have clarity on availability of stock.*
>
> *Some orders are more than 6 months old, through promises have been made few times Ex India.*
>
> *1. Prochlorperazine 3mg.*
>
> *…*
>
> *In this [list of 8 products] 6 products are with Lexon and he is very upset and rightly so.*
>
> *[✂]*
>
> *Also its [sic] budget time and to be honest I don't know what nos [sic] to put against these products as [sic] don't know when we will be able to launch the same.'*[370]

3.258 The following day, on 10 January 2017, [Lexon Director 1] emailed Medreich directly stating that:

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[367] The reason given for applying for the exemption was that there was an *'on-going procedure affecting the marketing authorisation critical for placing the product on the market'* and that there was an *'on-going planned change in manufacturing site or process and continued authorisation is required to ensure future supply to patients'*, see Email [Medreich employee] to [MHRA email address] entitled *'Prochlorperazine Maleate 3mg Buccal Tablets-PL 21880/0122'* 22 December 2016 (URN: PRO-E003222) and attachment entitled *'2016 Exemption Request -PL 218800122'* (URN: PRO-E003223).

[368] Email [MHRA email address] to [Medreich employee] *entitled 'Prochlorperazine Maleate 3mg Buccal Tablets-PL 21880/0122'* 5 January 2017 (URN: PRO-E003228).

[369] Email [Medreich employee] to [Medreich employee] entitled *'RE: Prochlorperazine 8s and 50s'* 4 January 2017 (URN: PRO-E003227).

[370] Email [Medreich Director 2] to [Lexon Director 1] entitled '*FW: New Products*' 9 January 2017 (URN: PRO-E003239).

'I am sorry to have to write this mail but I felt no choice [sic] but to put my concerns in writing …

It gets worse – our partners in the UK on Prochlorperazine 3mg have muted [sic] that they will probably want to serve notice on the agreement soon and without supply we will lose in excess of £180,000 per month between our companies if we are not in a position to supply…

The above stakes are getting to [sic] high for me to continue without assurance [✂].'[371]

3.259 In response, Medreich indicated that the expected delivery date for prochlorperazine 3mg was 22 March 2017.[372]

3.260 On 28 February 2017, [Medreich Director 2] responded to an email from [Meiji employee] asking for, amongst other things, information about '*Products which has [sic] not been ordered after the approval…*', as opposed to products which were available for BD activities or products where the supply had been delayed. [Medreich Director 2] stated in respect of '*products which has [sic] not been ordered after the approval*' that:

'…On top of my head [sic], I only see Prochlorperazine 3mg as there is (was) only one other supplier. But that situation is changing as 2 more suppliers have come in… and we have placed order onto [sic] India which I believe has failed at India level. When we do profit share deals, there is no written agreement, it is gentleman [sic] word and invoices are raised based on off the record workings.'[373]

3.261 On 15 April 2017, [Medreich employee] prepared an exemption request for Prochlorperazine OTC (PL21880/0126).[374] The MHRA approved that application on 24 April 2017.[375]

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[371] Email [Lexon Director 1] to [Medreich employee], cc [Medreich employee] and [Medreich Director 2] entitled '*Supply*' 10 January 2017 (URN: PRO-E000634).

[372] Email [Medreich employee] to [Lexon Director 1] cc [Medreich employee], [Medreich Director 2] and various others (Medreich) entitled '*RE: Supply*' 16 January 2017 (URN: PRO-E000637).

[373] Email [Medreich Director 2] to [Meiji employee] and [Medreich employee], cc various others at Medreich entitled '*RE: Follow up on the meeting in January*' 28 February 2017 (URN: PRO-E003257).

[374] The reason given for the request was that *'there is an on-going procedure affecting the marketing authorisation critical for placing the product on the market… [and] there is an on-going planned change in manufacturing site or process and continued authorisation is required to ensure future supply to patients'. See* MHRA document entitled '"*sunset clause" request for public health exemption from invalidation of a marketing authorisation*' dated 15 April 2017 (URN: PRO-E003290).

[375] Letter MHRA to [Medreich employee] 24 April 2017 (URN: PRO-E003292).

3.262 During May, June and July there were various updates internally within Medreich in relation to the development and despatch of new products, including Prochlorperazine POM and OTC.[376]

3.263 On 20 July 2017, [Meiji employee] emailed [Medreich Director 2] observing that:

> *'You mentioned that no supply has been made so far (and would remain so for more months to come...) for Prochlorperazine 3mg, but profit share income from this product is exceeding YTD budget (June: 210k vs 97k and YTD 355k vs 291k). Does it mean this product is so much demanded in the market now and only 5mg has been contributing so much? Then it also means loss of supply of 3mg is directly leading to loss of good business chances for us in UK market.'*[377]

3.264 [Medreich Director 2] and [Meiji employee] exchanged further emails,[378] in which [Meiji employee] asked on 21 July 2017, *'has 3mg ever been manufactured and supplied to the UK market? If not, profit share has been brought to us from 5mg only'.*[379] [Medreich Director 2] replied the same day:

> *'3mg has never been manufactured or supplied .. Profit share comes from 3mg only.*
>
> *There is a deal in place that for Medreich Not [sic] to bring 3mg in market we get royalty … But two things are crucial now:*
>
> 1. *The company with whom Lexon has done the deal wants to see our product failing which deal is off.. [sic]*
>
> 2. *Secondly from regulatory perspective we need to produce 1 batch of 3mg to avoid sunset cluase [sic] else we shall lose the license [sic]. As per sunset clause regulation we have to produce and sell 1 batch once*

[376] On 4 May 2017, [Medreich employee] contacted colleagues in Medreich to inform them a number of new products were expected to be despatched to the UK in May, including Prochlorperazine POM and OTC, see Email [Medreich employee] to [Medreich employee], [Medreich employee] cc [Medreich Director 2], [Medreich employee] and CS-Team (Medreich) entitled '*New products due from India*' 4 May 2017 (URN: PRO-E003304). On 5 June 2017, [Medreich employee] provided an update on a number of *'Lexon products'*; in relation to Prochlorperazine POM and OTC the update was that *'R&D is working on this and finger crossed [sic] result will be good. Can update you by mid next week…'*, see Email [Medreich employee] to [Medreich employee] cc [Medreich Director 2] and [Medreich employee] entitled '*RE: Lexon Order updated*' 6 June 2017 (URN: PRO-E003313). On 11 July 2017, [Medreich employee] emailed [Medreich employee] attaching a list of open orders from Lexon and noted that *'in most of the cases you would observe that the orders in system are now almost over an year. [sic]'*, see Email [Medreich employee] to [Medreich employee] cc [Meiji employee] and [Medreich Director 2] entitled '*Lexon Open Order Book*' 11 July 2017 (URN: PRO-E003331) and attachment entitled *'Lexon Products 030717'* (URN: PRO-E003332).

[377] Email [Meiji employee] to [Medreich Director 2] entitled '*Prochlorperazine – profit sharing*' 20 July 2017 (URN: PRO-E003346).

[378] [Medreich Director 2] explained that *'[Meiji employee] profit share figures are quarterly to us maybe that is the reason for the diff .. [sic] In any case this needs to be resolved else [Lexon Director 1] will be upset'*, Email [Medreich Director 2] to [Meiji employee] entitled 'RE: *Prochlorperazine – profit sharing*' 20 July 2017 (URN: PRO-E003347).

[379] Email [Meiji employee] to [Medreich Director 2] entitled '*Prochlorperazine – profit sharing*' 21 July 2017 (URN: PRO-E003351).

every 3 years to maintain the license [sic] or else MHra [sic] will kill the license [sic].'[380]

3.265 The minutes from Medreich's 'Management Committee Meeting' on 21 July 2017 observe that *'…Prochlorperazine has to be supplied otherwise there could be legal implications.'*[381]

3.266 On 11 August 2017, [Medreich employee] emailed [Medreich employee] about a further potential issue with the manufacture of prochlorperazine 3mg buccal tablets:

> *'India wants urgent assistance in order to manufacture Prochorperazine [sic] 3mg to save our license [sic] … this product is rarely manufactured red [sic] and anyway this is a matter of only one batch so India can manufacture with using dossier frequency and meanwhile we will submit the variation before next batch.'*[382]

3.267 On 21 August 2017, [Meiji employee] emailed [Medreich employee] about prochlorperazine 3mg tablets stating that:

> *'As you have discussed with [Medreich Director 2] and me last month, we are urgently waiting for the above mentioned product [Prochlorperazine 3mg tablets]. We are still strongly expecting the products will come to us during August/September.*
>
> *Otherwise we as well as our intimate customer would be facing extreme difficulties.*
>
> *Please let us know the current status and, if any delay being anticipated, please immediately improve the situation and the supply should be secured on time.'*[383]

[Medreich employee] replied that day:

> *'As we discussed we have arranged all the required material and few materials are in testing. We will initiate this batch by next week and we will*

[380] Email [Medreich Director 2] to [Meiji employee] entitled '*Prochlorperazine – profit sharing*' 21 July 2017 (URN: PRO-E003351).

[381] Document entitled *'Medreich Minutes of 28th Management Committee Meeting'* 21 July 2017, page 6 (URN: PRO-E003366).

[382] Email [Medreich employee] to [Medreich employee] entitled *RE: Prochlorperazine Tablets 3 mg*' 11 August 2017 (URN: PRO-E003358). This issue was resolved 3 days later see Email [Medreich employee] to [Medreich employee] entitled '*RE: Prochoperazine Tablets 3 mg*' [sic] 14 August 2017 (URN: PRO-E003359).

[383] Email [Meiji employee] to [Medreich employee] cc [Medreich Director 2] and [Medreich employee] entitled '*PROCHLORPERAZINE 3MG*' 21 August 2017 (URN: PRO-E003369).

despatch this batch by Sep [sic] 2017 without fail. We are closely monitoring and please be assured.'[384]

3.268 During September 2017, [Meiji employee] sent several further emails within Medreich enquiring about the status of prochlorperazine 3mg tablets and urging that this be prioritised.[385]

3.269 On 5 October 2017, [Medreich employee] emailed [Lexon Director 1] with an updated order book. In this version of the order book, the comments made in respect of the Prochlorperazine OTC order was that, *'[t]ech issue resolved, plan for mid Sept dispatch ex-India. Batch to be split against 2 SKUs.'*[386] In relation to the order of Prochlorperazine POM (detailed in paragraph 3.256) the comment was that, *'[✂] in transit'*.

Termination and expiry of the various agreements (October 2017 – June 2018)

3.270 On 10 October 2017, the CMA opened its investigation into the supply of Prochlorperazine POM tablets.

3.271 In November 2017, Medreich supplied one batch of Prochlorperazine POM (50 tablets) to Lexon.[387] This equated, after wastage, to [✂] packs of 50 tablets.

3.272 On 15 February 2018, [Medreich employee] emailed [Lexon Director 1] as formal notice to remove the supply of *'Prochlorperazine Maleate'* from the scope of the Lexon-Medreich Agreement, *'and all related arrangements (including payment of any profit share)'*.[388] Lexon stated to the CMA that Medreich declined to receive any profit share relating to Prochlorperazine POM sold after 31 December 2017.[389]

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[384] Email [Medreich employee] to [Meiji employee] cc [Medreich Director 2] and [Medreich employee] entitled '*PROCHLORPERAZINE 3MG*' 21 August 2017 (URN: PRO-E003369).

[385] Email [Meiji employee] to [Medreich employee] and [Medreich employee] cc [Medreich Director 2] entitled '*Lexon Order update*' 5 September 2017 (URN: PRO-E003381) in which [Meiji employee] stated *'Particularly prochlorperazine 3mg is extremely urgent and critical'*. Email [Meiji employee] to [Medreich employee] cc [Medreich employee] and [Medreich employee] entitled '*RE: Prochlorperazine 3mg*' 6 September 2017 (URN: PRO-E003392) in which [Meiji employee] stated that *'further delay of this product would cause a very serious problem not only to us PLC but also or more trouble to Lexon [sic]. Please let us know the most current status and I would once again ask for your very best effort to make in time.'* Email [Meiji employee] to [Medreich employee] cc various others entitled '*RE: URGENT: Prochlorperazine 3mg*' 26 September 2017 (URN: PRO-E003401) in which [Meiji employee] noted that *'this product is becoming extremely critical'* and [Medreich employee] replied that *'Stocks approved yesterday and we are adding this to the next sea container.'*

[386] Email [Medreich employee] to [Lexon Director 1] cc [Medreich employee] '*Updated Lexon OB"* 5 October 2017 (URN: PRO-E003402) and attachment entitled *'Lexon OB 051017'* (URN: PRO-E003403).

[387] Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, question 2.2 (URN: PRO-C3856).

[388] Email [Medreich employee] to [Lexon Director 1] entitled '*Joint Venture and Management Responsibility*' 15 February 2018 (URN: PRO-E003647). Further to that notification, Medreich and Lexon subsequently agreed revised cost of goods from Lexon to Medreich of *'Prochlorperazine 3mg x 8s: GBP [✂] per pack … Prochlorperazine 3mg x50s: GBP [✂] per pack'*, Email [Medreich employee] to [Lexon Director 1] entitled '*RE: india order*' 29 March 2018 (URN: PRO-E003648) and Email [Lexon Director 1] to [Medreich employee] entitled '*RE: india order*' 29 March 2018 (URN: PRO-E003648) and attachment *'Lexon PO – 721039'* (URN: PRO-E003649).

[389]) Section 26 response of Lexon, dated 27 November 2018, to CMA Notice of 7 November 2018, question 3(b) (URN: PRO-C2977).

3.273 AMCo stated to the CMA that, *'As soon as Lexon confirmed in early 2018 that its contract manufacturer had succeeded in producing saleable product, Focus ordered that Prochlorperazine from Lexon. This order was placed on 25 March 2018.'*[390] On 29 March 2018, Lexon supplied all but one of the packs of Prochlorperazine POM it had received from Medreich to Focus (that is, [✂] packs).[391]

3.274 The Focus-Lexon Heads of Terms stated that the agreement would run for 5 years from the date of the Heads of Agreement (see paragraph 3.106). AMCo stated to the CMA that the Focus-Lexon Heads of Terms terminated on 1 August 2018 and that, *'From that date onwards Focus has not paid any profit share to Lexon in relation to Prochlorperazine sourced from Alliance.'*[392]

3.275 On 19 October 2018, [AMCo employee] emailed [Lexon employee] and [Lexon Director 1]:

> *'Further to the expiry of the agreement in early August, please find attached a file setting out the profit share that applies in relation to Prochlorperazine during Q3. This includes sales of all Prochlorperazine during July, and then sales of only Lexon-supplied Prochlorperazine from the date of expiry of the agreement onwards…'*[393]

[390] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 2(a) (URN: PRO-C3149).

[391] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 2(b) and 2(c) (URN: PRO-C3149).

[392] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 3(b) (URN: PRO-C3149).

[393] Email [AMCo employee] to [Lexon employee] cc [Lexon Director 1] and various individuals at AMCo entitled '*Prochlorperazine Profit Share Reconciliation Q3 2018'* 19 October 2018, submitted as part of the section 26 response of Advanz dated 20 February 2019, to the CMA Notice of 6 February 2019, Annex 3 (URN: PRO-C3805).

4. Market Definition

4.1 When applying the Chapter I prohibition, the CMA is not obliged to define the relevant market unless it is impossible, without such a definition, to determine whether the agreement in question has as its object or effect the appreciable prevention, restriction or distortion of competition.[394] In the present case, the CMA considers that it is not necessary to reach a definitive view on market definition in order to determine whether there is an agreement between undertakings which has as its object the appreciable prevention, restriction, or distortion of competition.[395]

4.2 Nonetheless, the CMA has formed a view of the relevant market in order to calculate each of the Parties' 'relevant turnover' in the market affected by the Infringement, as this is required for the purposes of establishing the level of the financial penalty that the CMA will impose on the Parties.[396]

4.3 For the purposes of this case, the CMA has found that the '*relevant market*' is no wider than the supply of Prochlorperazine POM in the UK. The analysis below considers a product dimension and a geographic dimension.[397]

The relevant product market

4.4 This investigation relates to the supply of Prochlorperazine POM. In the circumstances of this case, the CMA has not carried out a detailed analysis with regard to whether there is substitutability between other strengths or formulations of prochlorperazine, OTC sales of 3mg Prochlorperazine nor whether other drugs may be close substitutes for Prochlorperazine POM, as it does not consider it necessary to do so. Further investigation of these issues would be liable only to result in a wider market definition, such that a market definition that is limited to Prochlorperazine POM constitutes a conservative approach for the purposes of calculating any financial penalties.

4.5 A product market limited to Prochlorperazine POM is consistent with Focus' ability profitably to sustain a series of price increases (Figure 2) when it was a monopolist

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[394] 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.

[395] See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, in which the CAT held, at paragraph 176, that in Chapter I cases *'determination of the relevant market is neither intrinsic to, nor normally necessary for, a finding of infringement'*.

[396] For the avoidance of doubt, where the term "*relevant market*" is used in this Decision, it must be understood in this context.

[397] When defining the relevant market, the CMA applies the so-called hypothetical monopolist test. The hypothetical monopolist test is employed to establish which products are close enough substitutes to be in the relevant market. First, it establishes the closest substitutes to the product that is the focus of the investigation (the 'Focal Product', which is Prochlorperazine POM in this case.) Second, it asks whether a hypothetical monopolist of the Focal Product in the geographic area in which the product is sold (the 'Focal Area') could profitably sustain a small but significant non-transitory increase in price (a 'SNNIP') above the competitive level. If such an increase would be profitable then the test is complete and the Focal Product is the relevant market. If it would not be profitable then the test is repeated by assuming that the hypothetical monopolist controls both the Focal Product and its closest substitute. That test is repeated until it is profitable for the hypothetical monopolist to sustain a SSNIP.

supplier of Prochlorperazine POM in the UK.[398] The price levels sustained by Focus were significantly above the level that Lexon and AMCo had anticipated would prevail in the event that they launched their own products in competition with that supplied by Alliance (see paragraphs 3.57 re Lexon and paragraph 3.145 re AMCo). In addition, internal documents reviewed by the CMA do not refer to other drugs, other strengths or formulations of prochlorperazine, or indeed OTC sales of 3mg Prochlorperazine having constrained the ability of Focus to implement the price increases described above, and as such do not suggest that these alternatives acted to constrain Focus' pricing.

The relevant geographic market

4.6 Consistent with previous cases in the pharmaceutical sector,[399] the CMA has concluded that the relevant geographic market is national in scope. In previous cases, differences were noted in the regulatory schemes for authorising and reimbursing medicines across countries, marketing strategies used by pharmaceutical companies, doctors' prescribing practices and prices.

4.7 The CMA considers that it is appropriate to define the relevant geographic market in this case as UK-wide, in particular because:

4.7.1 In order for suppliers to sell Prochlorperazine POM in the UK, it is necessary to obtain a MA from the MHRA, where the MA covers the whole of the UK.

4.7.2 The pricing framework which determines how pharmacies are reimbursed for the dispensing of Prochlorperazine POM (see Chapter 3, paragraphs 3.45 to 3.52 above) is specific to the UK, and not shared by other countries.

[398] Morningside was granted an MA in 2017. See Email [Lexon Director 1] to [AMCo Employee 3] entitled '*FYI*' 4 May 2017 (URN: PRO-E000655).

[399] See, for example, Case 37507 *AstraZeneca*, Commission decision of 15 June 2005, paragraph 503 and Case CA98/02/2011 *Reckitt Benckiser*, OFT decision of 12 April 2011, paragraphs 4.170 to 4.171.

5. Legal Assessment

Overview of the contents of this legal assessment chapter

5.1 The CMA sets out in this Chapter its analysis of:

5.1.1 **the applicable burden and standard of proof** in the overall assessment of the conduct that is set out in this Chapter (paragraphs 5.2 to 5.35);

5.1.2 **the legal and economic context** within which the conduct has occurred (see paragraphs 5.36 to 5.114), namely consideration of:

(a) the nature of the goods affected;

(b) the real conditions of the functioning and structure of the market; and

(c) consideration of whether the Parties were actual or potential competitors, that is (i) whether sufficient preparatory steps have been taken / firm intention and inherent ability to enter; (ii) whether there are insurmountable barriers to entry and (iii) whether there are any additional relevant factors;

5.1.3 following a conclusion on whether Alliance and Lexon were potential competitors, **whether the conduct in question amounted to an agreement and, if so, what were its terms** (paragraphs 5.115 to 5.628), that is considering:

(a) the law on what constitutes an agreement, including the legal framework for participation in an agreement;

(b) the evidence of whether there was an agreement between Alliance and Lexon; comprising: (i) documentary evidence from 2013 that Alliance would pay Lexon to stay out of the market; (ii) the entry into contractual agreements between Alliance and Focus and between Focus and Lexon; (iii) the subsequent conduct of each of Alliance, Lexon, Focus and Medreich; (iv) correspondence between Focus and Lexon in 2014 that refers to the supply of product; (v) the CMA's assessment of the credibility of the Parties' submissions taken collectively and in the round; and (vi) a conclusion on whether the conduct in question amounted to an agreement between Alliance and Lexon;

5.1.4 **whether each of Focus and Medreich participated** in an agreement between Alliance and Lexon (paragraphs 5.629 to 5.688);

5.1.5 whether an agreement reached between Alliance and Lexon amounted to an **infringement as a restriction of competition by object** (paragraphs 5.689 to 5.727); and

5.1.6 what was the **duration of the agreement** for each of Alliance, Lexon, Focus and Medreich (paragraphs 5.728 to 5.731).

The burden and standard of proof

5.2 The CMA sets out in this section its analysis of the applicable burden and standard of proof in the overall assessment of the conduct that is set out in this Chapter (paragraphs 5.3 to 5.35), namely that (a) the burden of proof sits with the CMA and (b) the standard of proof is the balance of probabilities. It sets out:

5.2.1 the legal framework for the burden of proof;

5.2.2 its application in this case; and

5.2.3 the Parties' representations on the burden and standard of proof.

Legal framework

5.3 The burden of proving an infringement of the Chapter I prohibition falls on the CMA. The standard of proof is the balance of probabilities.[400]

5.4 What evidence is likely to be sufficient to prove the infringement will depend on the circumstances and the facts.[401] In *JJB Sports*, for example, the CAT held that '*even a single item of evidence, or wholly circumstantial evidence, depending on the particular context and the particular circumstances, may be sufficient to meet the required standard*'.[402] However, in other contexts this may not suffice. In *North Midland Construction v OFT*, for instance, the CAT found that the OFT had not established an infringement on the balance of probabilities on the basis of a single item of contemporaneous evidence, capable of multiple interpretations, and subject to an unequivocal denial by the party which the OFT did not challenge in court. It held that '*[t]he combination of that unchallenged evidence… and our unresolved concerns… leave us in a position where we are not satisfied on the balance of probabilities*'.[403]

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[400] *Napp Pharmaceutical Holdings v DGFT* [2002] CAT 1, paragraph 109; *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraphs 197-204; *North Midland Construction v OFT* [2011] CAT 14, paragraphs 15-16 and 5 *AH Willis and Sons Limited v OFT* [2011] CAT 13, paragraphs 45-47, both citing *Re H (Minors)* [1996] AC 563, paragraph 586; see also *Re D (Northern Ireland)* [2008] 1 WLR 1499, paragraph 28; and *Re B* [2009] 1 AC 11, paragraph 13.

[401] *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraph 205.

[402] *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraph 206.

[403] *North Midland Construction v OFT* [2011] CAT 14, paragraphs 28 to 33.

5.5 The nature of the infringement may affect the quality of the evidence. The CAT emphasised in *Claymore Dairies* that: '*Chapter I cases will often concern cartels that are in some way hidden or secret; there may be little or no documentary evidence; what evidence there may be may be quite fragmentary; the evidence may be wholly circumstantial or it may depend entirely on an informant*'. As such, the CAT explained, '*indirect evidence and circumstantial evidence generally, may have a powerful role to play in the factual matrix of a case*'.[404]

5.6 The EU Court of Justice has held that, as a matter of EU law, the European Commission must prove infringements *'by adducing … precise and coherent evidence demonstrating convincingly the existence of the facts constituting those infringements … That evidence may consist of direct evidence, taking the form, for example, of a written document … or, failing that, indirect evidence, for example in the form of conduct'*.[405]

5.7 However, they have clarified that, *'it is not necessary for every item of evidence … to satisfy those criteria [ie precision and coherence] in relation to every aspect of the infringement. It is sufficient if the set of indicia relied on … viewed as a whole, meets that requirement'*.[406] The EU General Court has also confirmed that *'the evidence must be assessed not in isolation, but as a whole'*[407] and that *'the evidence must be assessed in its entirety, taking into account all relevant circumstances of fact'*.[408]

5.8 This is consistent with the position under English law (which applies to this matter).[409]

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[404] *Claymore Dairies Ltd v OFT* [2003] CAT 18, paragraphs 3 and 9. See also *Durkan Holdings Limited and Others v Office of Fair Trading* [2011] CAT 6, paragraph 96. Compare C-634/13 P *Total Marketing Services v Commission*, EU:C:2015:614, paragraph 26; and C-403/04 *Sumitomo Metal Industries v Commission*, paragraph 46.

[405] T-168/01 *GlaxoSmithKline Services Unlimited v Commission*, EU:T:2006:265, paragraphs 82-83.

[406] C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, paragraph 47. See also C-613/13 P *Keramag Keramische Werke*, EU:C:2017:49, paragraphs 52-55; T-56/99 *Marlines v Commission*, EU:T:2003:333, paragraph 28; *ICI v Commission*, paragraph 68; T44/02 P *Dresdner Bank v Commission*, EU:T:2006:271, paragraph 63; T-67/00 *JFE Engineering v Commission*, EU:T:2004:221, paragraph 180; T-56/99 *Marlines v Commission*, EU:T:2003:333, paragraph 28. See also *ICI v Commission*, paragraph 68; T44/02 P *Dresdner Bank v Commission*, EU:T:2006:271, paragraph 63; and T-67/00 *JFE Engineering v Commission*, EU:T:2004:221, paragraph 180. See, in the same vein, the EU Court of Justice in C-613/13 Keramag Keramische Werke, EU:C:2017:49: corroborating documentary evidence should not be required to satisfy, in itself, all the elements to constitute sufficient evidence of an infringement – by imposing that requirement, the EU General Court '*failed to consider whether the evidence, viewed as a whole, could be mutually supporting*' (paragraph 55).

[407] T-56/99 *Marlines v Commission*, EU:T:2003:333, paragraph 28. See also *ICI v Commission*, EU:C:1972:70, paragraph 68.

[408] T-141/94 *Thyssen Stahl v Commission*, EU:C:2003:527, paragraph 175.

[409] See, for example, *Durkan v OFT* [2011] CAT 6, paragraph 95, where the CAT noted that '*It is incumbent on the OFT to adduce precise and consistent evidence in order to establish the existence of an infringement. But it is sufficient, according to the caselaw, if the body of evidence relied on by the OFT, viewed as a whole, meets that requirement: see JJB, at paragraph 206*'

Application in this case

5.9 Consistent with the legal principles set out above, the CMA bases its conclusions on the Infringement on the body of available evidence, taken together and assessed as a whole.

5.10 This body of evidence establishing the Infringement comprises the conduct of the Parties, documentary evidence as well as *ex post* interview evidence.

5.11 In assessing this body of evidence, the CMA has placed the greater weight on the Parties own conduct and documents as this evidence is most likely to give an accurate picture of the arrangements between the parties at the relevant times.

5.12 In circumstances where the true meaning of documents is unclear, the CMA has evaluated their potential meanings (including any alternative explanations submitted by the Parties) having regard to the wider evidence base.

5.13 In relation to witness evidence, the CMA notes that in certain *ex post* interviews, witnesses from the Parties have denied the Infringement or provided accounts that are alleged to conflict with the CMA's case. When considering the credibility of evidence obtained from witnesses and resolving any conflicts between the 'natural meaning' of any documentary evidence and witness evidence the CAT has noted that, '*when considering the credibility of witnesses [it is essential] always to test their veracity by reference to the objective facts proved independently of their testimony, in particular by reference to the documents in the case, and also to pay particular regard to their motives and the overall probabilities. …where there is a conflict of evidence such as there was in the present case, reference to the objective facts and documents, to the witnesses' motives, and to the overall probabilities, can be of very great assistance … in ascertaining the truth.*'[410]

5.14 The CMA has applied this approach when considering the weight to place on witness evidence and any alleged conflicts between that evidence and the CMA's case.

5.15 Having done so and for the reasons set out in this Decision, the CMA has concluded on the balance of probabilities that based on the body of evidence taken together as a whole, each of the Parties committed or participated in the Infringement.

The Parties' representations on the burden and standard of proof

5.16 The burden and standard of proof in competition cases is well-established. However, the Parties have made a number of representations on the nature and

[410] *Tesco v OFT* [2012] CAT 31, paragraph 128 , quoting Robert Goff LJ in *Armagas Ltd v Mundogas SA* (The Ocean Frost) [1985] 1 Lloyd's Rep 1 at 57 (endorsed by the Privy Council in Grace Shipping v Sharp & Co [1987] 1 Lloyd's Rep 207 at 215).

application of the burden and standard of proof to the body of evidence in this case.

The standard of proof

5.17 Advanz and Cinven both submitted that the standard of proof that the CMA must meet is higher than the balance of probabilities.[411] In support, both Parties cite the judgment in *Napp Pharmaceutical Holdings v DGFT* (Napp), between them citing the CAT's references in that case to the need for '*strong and compelling evidence*', '*strong and convincing evidence*', '*the presumption of innocence*', and '*reasonable doubt.*' Both Parties also cite references in European case law, including for the need for an authority to reach a '*firm conviction*' that an infringement occurred, as supporting the conclusion that the CMA must meet a higher standard of proof. Cinven also refer to the '*quasi-criminal nature*' of competition law investigations in support of a heightened standard of proof.

5.18 The CMA is not required to meet a higher standard of proof than the balance of probabilities.

5.19 The Supreme Court has emphasised that there is one single civil standard of proof: the balance of probabilities.[412] That is the standard which applies here: see *Willis v OFT.*[413] The CMA recognises that allegations of infringements of the Act are serious. However the CAT has clarified that the seriousness of an allegation does not necessarily make it less likely that it is true: context is everything.[414]

5.20 In relation to Advanz and Cinven's references to the CAT judgment in *Napp*, in *JJB Sports v OFT* the CAT explained that its judgment in *Napp*:

> *'should not be interpreted as introducing the criminal standard through the back door … It also follows that the reference by the Tribunal to "strong and compelling" evidence at [109] of Napp should not be interpreted as meaning that something akin to the criminal standard is applicable to these proceedings. The standard remains the civil standard. The evidence must however be sufficient to convince the Tribunal in the circumstances of the particular case, and to overcome the presumption of innocence to which the undertaking concerned is entitled.[415]*

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[411] Advanz RSO, 1 August 2019 (URN: PRO-C5111), paragraphs 2.1 to 2.8; Advanz RDPS, 7 July 2021, paragraph 5.13 (URN: PRO-C7481); Cinven RSO, 15 August 2019, paragraphs 2.2, 2.6 to 2.18 (URN: PRO-C5132).

[412] *Re B* [2009] 1 AC 11 at paragraph 13.

[413] *AH Willis and Sons Limited v OFT* [2011] CAT 13, paragraphs 45-47.

[414] *Durkan Holdings Limited and Others v Office of Fair Trading* [2011] CAT 6, paragraph 94, citing opinion of Lady Hale in *In Re B* [2008] 3 WLR 1. Compare *Quarmby Construction v OFT* [2011] CAT 11, paragraphs 73-86.

[415] *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraphs 197-204. The CAT also stated that: '*In non-criminal proceedings facts are required to be proved on the balance of probability, that is to say that the court must be satisfied on the evidence, that the occurrence of the event is more likely than not. However, the principle is that the more serious the allegation, the stronger should be the evidence before the court concludes that the allegation is established on the*

5.21 Nor does the presumption of innocence affect the standard of proof. Rather, the presumption of innocence means simply that '*Any doubt in the mind of the Tribunal as to whether a point is established on the balance of probabilities must operate to the advantage of the undertaking alleged to have infringed the competition rules*'.[416]

5.22 The standard of proof applicable to the CMA is not affected by retained EU law, including any references in European case law. As noted in Council Regulation (EC) No 1/2003, EU law does not affect the '*national rules on the standard of proof*'[417]. In *Mastercard*,[418] the Supreme Court recognised that, while the '*nature of the evidence by which a finding of infringement can be secured or rebutted may be a question of EU law*',[419] depending on the substantive requirements of the specific case, '*questions as to the standard of proof are left to the law of the member state concerned.*'[420] In this case, therefore, such questions are to be decided on the basis of English law.

The CMA's use of inferences

5.23 In reaching this Decision the CMA has drawn certain inferences from the body of evidence in this case. Advanz and Cinven have objected to the CMA's use of inference. They both submit that the use of inferences must be limited to cases where cartels are '*secret and complex*,' operated in a '*clandestine manner*' and/or where the conduct is '*not governed by any formal rules,*'[421] which they submit is not the case here.[422] Cinven also criticise the number of inferences used by the CMA in light of the existence of '*written agreements*' between the Parties and the '*large volume of documentation*' on the CMA's file.[423]

5.24 The CMA uses inferences to support the finding of certain facts, on the balance of probabilities, on the basis of inductive or deductive reasoning applied to the available evidence. In some competition cases, courts have stressed the need to draw inferences because of the secret nature of the activity and the fragmentary evidence base. The EU Court of Justice has made clear that:

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balance of probabilities. Hence the civil standard provides for flexibility as to the cogency of the evidence required to satisfy the court of the facts' (paragraph 188). Any '*flexibility*' deriving from the seriousness of the allegation therefore relates to '*the cogency of the evidence*' and not the standard of proof (see also paragraph 199). These principles set out in the *JJB Sports v OFT* judgment were subsequently reaffirmed by the CAT in *Argos & Littlewoods v OFT* [2004] CAT 24 paras 164-166.

[416] *Tesco Stores v Office of Fair Trading* [2012] CAT 31, paragraph 88 (emphasis added).

[417] Council Regulation (EC) No 1/2003, OJ L 001, 04/01/2003, pages 0001 – 0025, Recital 5

[418] *Sainsbury's v Visa and Mastercard* [2020] UKSC 24.

[419] Paragraph 114.

[420] Paragraph 111.

[421] Advanz RSO, 1 August 2019, paragraph 2.18 (URN: PRO-C5111); Cinven RSO, 15 August 2019, paragraph 2.21 (URN: PRO-C5132).

[422] Advanz RSO, 1 August 2019 (URN: PRO-C5111), paragraphs 2.18 and 2.19; Cinven RSO, 15 August 2019, paragraph 2.22 and 2.23 (URN: PRO-C5132).

[423] Cinven RSO, 15 August 2019, paragraph 2.24 (URN: PRO-C5132).

> *'Even if the Commission discovers evidence explicitly showing unlawful contact between traders, such as the minutes of a meeting, it will normally be only fragmentary and sparse, so that it is often necessary to reconstitute certain details by deduction.*
>
> *In most cases, the existence of an anti-competitive…agreement must be inferred from a number of coincidences and indicia which, taken together, may, in the absence of another plausible explanation, constitute evidence of an infringement of the competition rules' [emphasis added].*[424]

5.25 However, there is no rule of law that the CMA may only draw inferences if certain preconditions are met.

5.26 In any event, in the present case, while certain terms of the Infringement were recorded in writing, a number were not. In addition, the existence and content of certain meetings between individuals involved in the Infringement were not recorded. These aspects of the Infringement were therefore secret or covert. Therefore, even if it were the case that the use of inferences must be limited to cases where cartels are 'secret and complex,' and/or operated in a 'clandestine manner' (which is not accepted), the CMA's use of inferences from the available evidence in these circumstances would still be appropriate.

The relevance of alternative explanations for conduct and evidence put forward by the Parties

5.27 Alliance, Cinven and Advanz have all submitted various alternative explanations for their conduct and for certain items of evidence. In their submissions these alternative explanations are sufficient to vitiate the CMA's case.

5.28 Advanz submitted that the '*requirement on the CMA to adduce precise and consistent evidence to give grounds for a firm conviction*' that the infringement took place is not satisfied '*where a plausible explanation can be given for those alleged infringements which rules out an infringement*'.[425] Advanz submitted that because the CMA does not rely on '*documentary evidence*' within the meaning of European

[424] C-204/00 *Aalborg Portland*, EU:C:2004:6, paragraphs 56 to 57 (emphasis added). The CAT stated in *Durkan Holdings Limited and Others v Office of Fair Trading* [2011] CAT 6, paragraph 96, that these comments apply equally to the OFT. Compare C-634/13 P *Total Marketing Services v Commission*, EU:C:2015:614, paragraph 26; and C-403/04 *Sumitomo Metal Industries v Commission*, EU:C:2007:52, in which the EU Court of Justice held that the evidence relied on by the Commission – a series of documentary indicia and market share tables – sufficed to prove the existence of a market exclusion agreement: '*where the Commission has succeeded in gathering documentary evidence in support of the alleged infringement, and where that evidence appears to be sufficient to demonstrate the existence of an agreement of an anti-competitive nature, there is no need to examine the question whether the undertaking concerned had a commercial interest in the agreement*' (paragraph 46).

[425] Advanz RSO, 1 August 2019, paragraphs 2.12-2.14 (URN: PRO-C5111); Advanz RDPS, 7 July 2021, paragraph 5.17 (URN: PRO-C7481).

case law (which is '*unambiguous'* and '*unequivocal'*), Focus is free to put forward a plausible explanation as an alternative to the one adopted by the CMA.[426]

5.29 Cinven submitted that because the CMA makes '*liberal'* use of inference, *'[w]here an undertaking can provide an alternative plausible explanation of the relevant facts, an infringement decision cannot be sustained*'.[427] Cinven submitted that this is of particular relevance in this case as Focus' conduct accords with normal business practices and industry standards. Cinven further submitted that the CMA must '*engage diligently and impartially with the plausible alternative explanations presented to it*'.[428]

5.30 Alliance submitted that the CMA failed to consider whether there were alternative explanations for the inferences the CMA made.[429] Alliance stated that the CMA must disprove any plausible explanation.

5.31 As explained above, the standard of proof applicable to this case is the balance of probabilities. The burden of proof falls on the CMA. Where there are potential alternative explanations for the conduct under consideration, the CMA will carefully consider all of the evidence in the round in order to decide whether the Infringement has been established, on the balance of probabilities. How much weight is to be given to potential alternative explanations will depend on all the circumstances, including the strength of the evidence supporting the infringement and the strength of the evidence supporting the alternative explanation. However, there is no rule of law to the effect that if any 'plausible' alternative explanation is advanced then the CMA must decide that there was no infringement.

5.32 Under EU law (which the parties rely on), where the European Commission's reasoning is based on the supposition that parallel behaviour cannot be explained other than by concerted action between undertakings, it is open to parties to rebut the inference of concerted action by advancing an alternative 'plausible explanation'.[430] However, where a fact or circumstance is established by the Commission using documentary evidence it is not sufficient for parties simply to provide a plausible alternative explanation for that fact or circumstance. Rather, the parties must engage with that evidence and demonstrate why it does not establish that fact or circumstance.[431] In the absence of such a demonstration it is not

[426] Advanz RSO, 1 August 2019, paragraphs 2.15, 3.104 to 3.105 (URN: PRO-C5111); Advanz RDPS, 7 July 2021, paragraphs 5.14 and 5.15 (URN: PRO-C7481).

[427] Cinven RSO, 15 August 2019, paragraphs 4.10-4.13 (URN: PRO-C5132).

[428] Cinven RSO, 15 August 2019, paragraph 4.14 (URN: PRO-C5132).

[429] Alliance RSO, 1 August 2019, paragraph 2.9 (URN: PRO-C5096).

[430] T-36/05 *Coats v Commission*, EU:T:2007:268, paragraph 72; also T-442/08 *CISAC v Commission*, EU:T:2013:188, paragraph 99.

[431] T-442/08 *CISAC v Commission*, EU:T:2013:188, paragraph 99 and case-law cited, C-239/11 *Siemens v Commission*, EU:C:2013:866, paragraphs 220 and 224, T-305/94 *Limburgse Vinyl v Commission*, EU:T:1999:80, paragraphs 727-728: where an authority's case '*is based not on a mere finding of parallel market conduct but on documents which show that the practices were the result of concerted action… the burden is on the applicants not merely to submit an alleged alternative explanation for the facts found by the [Authority] but to challenge the existence of those facts established on the basis of the documents produced by the [Authority]*'.

necessary to assess the plausibility of any alternative explanations advanced by the parties. The EU Court of Justice has held that where the '*evidence appears to be sufficient to demonstrate the existence of an agreement of an anti-competitive nature, there is no need to examine the question whether there is a plausible alternative explanation for the conduct*'.[432] This equally applies when the existence of an infringement is established '*by deduction from other facts, indirect evidence or non-documentary evidence*'.[433]

5.33 As a matter of EU law, to qualify as documentary evidence for these purposes, the content of the document must not be ambiguous or call for interpretation.[434] While the CMA considers that English law applies in this context, in response to the Parties' representations, the CMA has assessed the Parties' claims that certain items of evidence in this case are not 'documentary evidence' under the EU law approach - because they are ambiguous or call for interpretation - in context below. When assessing whether a document is ambiguous or calls for interpretation the CMA has carefully considered whether the natural meaning of the document, in the context of the factual background known to the parties at the time and the other evidence on the CMA's file,[435] is sufficiently clear. The CMA notes that simply because a Party is able to articulate a possible alternative meaning for a document does not make that document ambiguous or one that calls for interpretation. If, applying the approach above, and taking account of any alternative explanations submitted by the Parties, the CMA finds that the meaning of the document is sufficiently clear then, as noted above, under principles of EU law regarding the treatment of 'documentary' or unambiguous evidence, it will not be sufficient for the Parties to simply articulate a different explanation for any facts or circumstances established by the document.

5.34 In the present case, the CMA's Decision relies on a number of items of documentary (i.e. unambiguous) evidence[436] as well as the drawing of some inferences from the Parties' conduct when seen in context. Accordingly, if EU law were to apply to this issue, this would not be a case in which the CMA's conclusions could be rebutted simply by pointing to alternative plausible explanations. Further and in any event, when seen in the context of the evidence as a whole the alternative explanations advanced by the Parties are not sufficiently "plausible" to rebut the CMA's conclusions reached on the balance of probabilities. The position is therefore consistent under both English and EU law.

5.35 Alliance also submitted that where the undertaking has insufficiently substantiated its plausible explanation, the CMA must investigate further or find that the

[432] C-239/11P etc. *Siemens AG and others v Commission*, EU:C:2013:866, paragraph 220.

[433] C-239/11P etc. *Siemens AG and others v Commission*, EU:C:2013:866, paragraph 222.

[434] Case T-36/05 *Coats v Commission*, EU:T:2007:268, paragraph 74.

[435] Tesco v OFT [2012] CAT 31, paragraph 125 and 126.

[436] Not, as Advanz suggest in their representations, on a 'single piece of contemporaneous evidence' (Advanz RSO, 1 August 2019, paragraph 3.104 (URN: PRO-C5111)).

undertaking was not capable of providing the necessary information.[437] In *Phenytoin* the Court of Appeal held that there is a duty of fair evaluation upon the CMA in relation to evidence before it, but that it has discretion as to how it performs that duty, including as to the depth and intensity of its inquiry.[438] The extent of that duty to evaluate the evidence adduced by an undertaking is affected by the quality of that evidence as there is an important evidential burden upon an undertaking being investigated.[439] The CMA considers it has appropriately conducted such a fair evaluation in this case. The CMA has carefully considered all of the evidence and explanations provided by the Parties. It has pro-actively conducted interviews with a range of witnesses and sought relevant evidence from the Parties e.g. issuing a number of s.26 Notices to each Party. Each of the Parties has also had ample opportunity during the administrative phase of this case to corroborate any explanations they offered.

Legal and economic context

5.36 The CMA sets out in this section the legal and economic context within which the conduct has occurred (see paragraphs 5.37 to 5.114), namely consideration of:

5.36.1 the legal framework, including the legal framework relevant to potential competition; and

5.36.2 the application of the legal framework to the legal and economic context of the conduct under investigation, namely:

(a) the nature of the goods affected; and

(b) the real conditions of the functioning and structure of the market for the supply of Prochlorperazine POM in the UK, including: (i) the market conditions prior to the Market Exclusion Agreement; (ii) Alliance was an actual competitor in the supply of Prochlorperazine POM; and (iii) Lexon and Medreich, working together, were potential competitors of Alliance in the supply of Prochlorperazine POM.

[437] Alliance RSO, 1 August 2019, paragraph 2.10 (URN: PRO-C5096).

[438] *Flynn Pharma Ltd & Anr v CMA* [2020] EWCA Civ 339, paragraph 113, 270, 273.

[439] *Flynn Pharma Ltd & Anr v CMA* [2020] EWCA Civ 339, paragraph 114.

Legal framework

5.37 In order to determine whether an agreement objectively reveals a sufficient degree of harm such as to constitute a restriction of competition by object, regard must be had to the economic and legal context of which it forms a part.[440] This includes:

5.37.1 the nature of the goods affected; and

5.37.2 the real conditions of the functioning and structure of the relevant market.[441]

5.38 The economic and legal context also includes consideration of whether the Parties are actual or potential competitors at the time.[442]

Legal framework relevant to potential competition

5.39 The examination of conditions of competition on a given market must be based not only on existing competition between undertakings already present in the relevant market, but also on potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market and compete with established undertakings.[443]

5.40 In examining potential competition, the critical assessment is whether the potential entrant had *'real and concrete possibilities'* of entering the market:[444]

5.40.1 The assessment of this issue must be carried out having regard to *'the structure of the market and the economic and legal context in which [the*

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[440] Cinven submitted that the Statement of Objections did not consider *'the economic and legal context of which [the Alleged Infringements] forms a part.'* (Cinven RSO, 15 August 2019, paragraph 3.47 (URN: PRO-C5132)). The CMA disagrees. The CMA considered in detail in the Statement of Objections the economic and legal context of which the Market Exclusion Agreement forms a part (see SO, paragraphs 4.3 to 4.65, see also paragraphs 5.37 to 5.114 of this Decision).

[441] C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 53, citing C-32/11 *Allianz Hungária 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.

[442] See, for example, CMA decision in *Paroxetine* (CE-9531/11), sections 6.C.vi and vii. Contrary to a representation by Cinven (Cinven RSO, 15 August 2019, paragraphs 3.48 to 3.50 (URN: PRO-C5132), when considering the economic and legal context of which the Market Exclusion Agreement forms part, there is no requirement for the CMA to conduct a counterfactual assessment, and demonstrate whether, absent the Market Exclusion Agreement, Focus, Lexon and Medreich would have entered the market for the supply of Prochlorperazine POM any sooner (or that Alliance would have been willing to enter a supply agreement with Focus absent exclusivity, or that Focus would have been willing to sign the Focus-Lexon Heads of Terms without the profit share clause given that Focus could not agree to supply a product that was not yet for sale). The cases cited by Cinven concern the specific contexts of non-compete clauses and intellectual property rights and do not provide support for this contention.

[443] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 99; as upheld by the ECJ in C-591/16P *Lundbeck v Commission*, EU:C:2021:243, paragraphs 54-55; T-374/94 *European Night Services and Others v Commission*, EU:T:1998:198, paragraph 137; T-461/07 *Visa Europe and Visa International v Commission*, EU:T:2011:181, paragraph 68; and T-360/09 *E.ON Ruhrgas and E.ON v Commission*, EU:T:2012:332, paragraph 85.

[444] C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 54.

agreement] operates'.[445] This includes assessing whether an undertaking which is not able to enter a given market by itself may nonetheless still be classified as a potential competitor, where it has business partners (or the possibility of finding business partners) through which it can access that market.[446] The '*perception of the established operator*' – i.e., whether it perceived the potential entrant as a competitive threat - is a factor that is relevant to the assessment of the existence of a competitive relationship between the incumbent and the potential entrant since *'if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market'*.[447]

5.40.2 Against that background, the first key element to assess is whether the potential entrant had a *'firm intention and an inherent ability'* to enter the market at the time at which the relevant agreement was concluded. A *'firm intention and an inherent ability to enter the market'* is established where the potential entrant has taken *'sufficient preparatory steps to enable it to enter the market concerned within such a period of time as to impose competitive pressure'* on the incumbent.[448] These preparatory steps *'permit the conclusion that [an undertaking] has a firm intention and an inherent ability to enter the market'*.[449]

5.40.3 The second key element to assess is whether there were any insurmountable barriers to market entry;[450] and

5.40.4 Third, the finding that a potential entrant has a firm intention and an inherent ability to enter the market, if not called into question by the existence of insurmountable barriers to market entry, can be *'confirmed by additional factors'*.[451]

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[445] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 39.

[446] T-682/14 *Mylan Laboratories and Mylan v Commission*, EU:T:2018:907, paragraphs 87 and 88. See also T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraph 256.

[447] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 42.

[448] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 43 and the CAT's supplementary judgment in *Generics (UK) and others v CMA* [2021] CAT 9, paragraphs 11 and 12; C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraphs 56 and 57.

[449] C-307/18, *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 44. Cinven and Advanz submitted that it was necessary for the CMA to examine an undertaking's intention to enter a market when assessing whether it was a potential competitor. In accordance with the judgment of the EU Court of Justice in C-307/18 *Generics (UK) and others v CMA* EU:C:2020:52 and C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, the CMA has in this case assessed whether Lexon and Medreich, working together, had a firm intention and inherent ability to enter the market at the time the Market Exclusion Agreement was concluded.

[450] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 45; C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraphs 56 and 57.

[451] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 54 and the CAT's supplementary judgment in *Paroxetine II* [2021] CAT 9, paragraph 14; C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 57.

5.41 When examining whether an undertaking was a potential competitor, the analysis should be conducted principally on contemporaneous evidence.[452] 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.'*[453] Evidence relating to events subsequent to the conclusion of that agreement cannot be taken into consideration in order to assess and retrospectively to rebut the claim that the parties to that agreement were potential competitors at the time when it was concluded.[454]

Sufficient preparatory steps / firm intention and inherent ability to enter

5.42 As stated above, in order to determine whether an undertaking is a potential competitor in the market, it must be determined whether there are *'real and concrete possibilities [of that undertaking] joining that market and competing with [the incumbent]'*.[455]

5.43 In assessing this issue, it is necessary first to determine whether, at the time the agreement was concluded, the undertaking had taken *'sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure [on the incumbent]'* such as to permit the conclusion that the potential entrant in fact had a firm intention and an inherent ability to enter the market.[456]

5.44 In the pharmaceutical industry, taking into account any regulatory constraints or applicable intellectual property rights, these *'sufficient preparatory steps'* may include the measures taken by the undertaking to put itself in a position to have, within that period, the required administrative authorisations for the marketing of the relevant drug, and an adequate stock of that medicine either through its own production or through supply contracts with third parties. Such measures evidence a *'firm intention and an inherent ability'* to enter the market.[457]

5.45 For example, in *Lundbeck*, the EU General Court stated that a potential entrant requires only *'real concrete possibilities and the capacity to enter the market'* which *'is certainly the case when those undertakings had made significant investments in*

[452] 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.

[453] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 141, as confirmed by the EU Court of Justice in C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraphs 67 to 70.

[454] C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 68.

[455] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 36.

[456] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraphs 43 and 44.

[457] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraphs 43 and 44.

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.'[458]

5.46 The CAT has held that an undertaking which holds an MA *'with a declared intention of entering the market in the near future'* should be regarded as a potential competitor.[459]

5.47 Further, an undertaking can be a potential competitor before it has obtained an MA. The EU General Court explained that *'potential competition includes inter alia the activities of generic undertakings seeking to obtain the necessary MAs, as well as all the administrative and commercial steps required in order to prepare for entry to the market…'*. [460]

5.48 Specifically, in *Lundbeck*, Merck and Ranbaxy were considered potential competitors even though Merck did not hold an MA in every relevant market, and Ranbaxy did not hold an MA at all. In such circumstances, *'the path to obtaining such an MA, when it is taken by an undertaking which has for a long time been seriously preparing its market entry, constitutes potential competition, even though it may in fact take longer than envisaged by the interested parties.'*[461] Potential competition is likely to be exerted throughout the MA application process unless the applicant encounters *'objectively insurmountable difficulties'*.[462] For example, the EU General Court held in *Teva v Commission* that the delays it suffered in the grant of an MA were *'not enough, by themselves, to preclude the classification of the marketing authorisations applicants concerned by those delays as potential competitors'*.[463]

5.49 Similarly, and contrary to a representation made by Cinven[464] an undertaking can be a potential competitor before it has obtained stock. For example, in *Lundbeck*, Ranbaxy was found to be a potential competitor to Lundbeck without having either stock available to sell at the time of the agreement nor a MA, but the possibility to obtain the MA within a short period of time.[465] The EU General Court found that: *'it*

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[458] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 131. See also paragraph 157, which shows that the Commission also took into account the strength of the incumbent's process patents, the fact that one generic undertaking had actually entered, and the significant amounts the incumbent paid to the generic undertakings to keep them out of the market.

[459] *Lexon (UK) Limited v Competition and Markets Authority* [2021] CAT 5, paragraph 234.

[460] *Paroxetine I* [2018] CAT 4, paragraph 158, citing T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 171, as upheld by the EU Court of Justice in C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 83.

[461] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraphs 178 to 180, 230, 299, 314 and 320, as upheld by the EU Court of Justice in C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 84.

[462] T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 149: *'potential competition is likely to be exerted from the filing of a marketing authorisation application and for as long as efforts are made to obtain the marketing authorisation…'*

[463] T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 149.

[464] Cinven RSO, 15 August 2019, paragraph 3.38 (URN: PRO-C5132).

[465] The EU Court of Justice in *Generics (UK) and others v CMA* recognised this as well, stating that *'sufficient preparatory steps'* to enter the market within a short period of time as would impose competitive pressure on the incumbent included the measures taken by the generic manufacturer *'to put itself in a position to have, within that period, the required administrative authorisations for the marketing of a generic version of the medicine concerned and an*

must be stated that the steps necessary for obtaining MAs and preparing for market entry constitute potential competition, when they are carried out by generic undertakings which have made significant investments in terms of human and economic resources in order to launch their generic medicinal product'.[466] The fact that Ranbaxy also had begun to develop a process to produce the generic product and had the ability to sell its API to a customer who could then enter the market and who may have needed to vary its MA to do so was an expression of potential competition, upheld by the EU Court of Justice.[467]

5.50 Further, the EU General Court has held 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… 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'*.[468]

5.51 The position of a potential competitor also cannot depend on whether the 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.'*[469] There is *'no requirement'* to demonstrate *'with certainty'* that the undertaking *'will in fact enter the market concerned, and, a fortiori, that it will be capable, thereafter, of retaining its place there'*.[470]

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adequate stock of that generic medicine either through its own production or through supply contracts concluded with third parties.' See C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraphs 43 and 44. See also C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 86.

[466] T-460/13 *Sun Pharmaceuticals and Ranbaxy v Commission,* EU:T:2016:453, paragraph 77.

[467] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraphs 308 to 310, upheld by the EU Court of Justice in C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraphs 88 and 89 and in Case C-586/16 *Sun Pharmaceuticals and Ranbaxy v Commission* EU:C:2021:241, paragraph 44: *'Sun Pharmaceutical had, at the time when the agreement at issue was concluded, real and concrete possibilities of entering the market with its API within a sufficiently short period of time for it to be characterised as a potential competitor of Lundbeck, and did not meet any insurmountable barrier to entry.'*

[468] T-682/14 *Mylan Laboratories and Mylan v Commission*, EU:T:2018:907, paragraphs 87 and 88. See also T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraph 256.

[469] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 159 as upheld by the EU Court of Justice in C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 63; T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 91.

[470] C-307/18, *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 38; see also C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 63.

5.52 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.[471]

5.53 An 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 so also includes an examination of the timeframe for potential entry, i.e. whether entry was possible within *'such a period of time as would impose competitive pressure'*[472] on the incumbent. It may also include an assessment of whether entry was possible *'on the basis of costs which would have been economically viable'*.[473]

5.54 With respect to the timeframe within which potential entry could take place, it is only required to be capable of taking place *'with sufficient speed to form a constraint on market participants'*,[474] in, *'such a period of time as would impose competitive pressure'*[475] *'without fixing a specific limit in that respect.'*[476] 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"'*.[477]

5.55 The European Commission's Guidelines on Horizontal Cooperation Agreements explain that a potential competitor is able to enter the market *'within a short period of time'*. The Guidelines explain that where a potential competitor is a party to the agreement concerned, the Commission would normally consider a longer period of time to be a 'short period of time' than in a case where the potential competitor is a third party.[478] The Guidelines also state that both the R&D and Specialisation Block Exemption Regulations *'consider a period of not more than three years a 'short period of time'*.[479]

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[471] T-679/14 *Teva v Commission*, EU:T:2018:919, paragraphs 155 to 157.

[472] C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 57. See also T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 203 and C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 44.

[473] 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. Cinven submitted that it was necessary for the CMA to conduct an assessment of whether entry was an *'economically viable strategy'* and that the CMA has failed to do so in this case. (Cinven RSO, 15 August 2019, paragraph 3.46 (URN: PRO-C5132). However, an assessment of whether entry is economically viable does not import a different legal test, or a higher standard than that of *'real concrete possibilities'*. (See T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraphs 160-161). Further, in *Merck*, the EU Court of Justice found that the EU General Court was not required to have considered whether the routes to market available to Merck (as identified by the Commission in its decision) were economically viable. Case C-614/16 P *Merck KGaA v Commission*, EU:C:2021:246, paragraphs 44-48.

[474] T-461/07 *Visa Europe and Visa International Service v Commission*, EU:T:2011:181, paragraph 189.

[475] C-591/16P *Lundbeck v Commission,* EU:C:2021:243, paragraph 57 .

[476] *Paroxetine I* [2018] CAT 4, paragraph 155, citing T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 163.

[477] Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 226.

[478] In *Visa v Commission* (referred to by the CAT in *Paroxetine*), the EU General Court had referred to the previous set of Guidelines (in force at the time) as follows*: 'the Commission refers to a period of one year while stating that 'in individual cases longer time periods can be taken into account' (*emphasis added) (See *Paroxetine I* [2018] CAT 4, paragraphs 92 to 93, citing T-461/07 *Visa Europe and Visa International v Commission* EU:T:2011:181, paragraph 171).

[479] *Guidelines on the applicability of Article 101 of the Treaty on the Functioning on the European Union to horizontal co-operation agreements*, paragraph 10 and footnote 3 to that paragraph, which was in force at the time of the Market Exclusion Agreement. The CMA has had regard to these Guidelines on the basis of section 60A(3) of the Act.

5.56 Indeed, the EU General Court has also recognised that the timeframe over which competitive pressure may be exercised by a potential entrant may be longer, but this will depend on the company's objective ability to enter the market, even if it encounters delays in entering the market. Specifically, *'[t]he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place, particularly since… the cost and time necessary for entering a new product market may be considerable'*.[480]

5.57 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.[481]

Insurmountable barriers to entry

5.58 Where specific market characteristics exist that may have an impact on potential entry it is necessary to assess whether those characteristics form an '*insurmountable barrier*' to the potential entrant which '*rule out*' any potential competition.[482]

5.59 It is relevant, in this context, to assess whether there are any *'significant regulatory hurdles'* preventing a potential competitor from launching its product.[483]

Additional factors

5.60 A finding that a potential entrant has a firm intention and an inherent ability to enter the market, if not called into question by the existence of insurmountable barriers to market entry, can be *'confirmed by additional factors'*.[484]

5.61 In that regard, the *'conclusion of an agreement between a number of undertakings, operating at the same level in the production chain… constitutes a* ***strong indication*** *that a competitive relationship existed between those undertakings'* (emphasis added).[485] This additionally provides a strong indication that the market

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[480] 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'*.

[481] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 163.

[482] 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'*. The requirement to consider the existence of any insurmountable barriers to entry was confirmed in C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 56.

[483] Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 232.

[484] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 54; C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 74.

[485] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 55, citing, by analogy, C-373/14 P *Toshiba Corporation v Commission* EU:C:2016:26, paragraphs 33 and 34. See also C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 78.

in question is *'not impenetrable'*[486] and that the incumbent *'perceived those undertakings as a potential threat at the time the agreements at issue were concluded'*.[487]

5.62 A further such indication is the intention, made known and acted upon by the incumbent, to make *'transfers of value to a manufacturer of generic medicines in exchange for the postponement of the latter's market entry'. 'The greater the transfer of value, the stronger the indication.'*[488] Such transfers of value provide an indication of the incumbent's perception of the commercial threat that a potential entrant poses and therefore of a competitive relationship between them (even in a situation where there is a claim to a patent infringement).

5.63 As noted above, the CMA may *'rely inter alia on the perception of the undertaking present on the market in order to assess whether other undertakings are potential competitors'*.[489] 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.'*[490]

5.64 This is relevant to assessing the existence of a competitive relationship between an incumbent and an undertaking not on the market at that time as *'if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market.'*[491]

5.65 For instance, in *Lundbeck* itself, the fact that an incumbent transferred value under an agreement demonstrated that Lundbeck perceived the recipient as a potential competitor. This was particularly so given that the incumbent occupied a more informed position in the market and '*it would be surprising if an undertaking as experienced as Lundbeck would have decided to pay several million euros to the generic undertakings in exchange for their commitment not to enter the market during a certain period if the possibility that those generic undertakings could enter the market was purely theoretical*.'[492]

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[486] 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 EU Court of Justice in C-373/14 P *Toshiba v Commission*, EU:C:2016:26, paragraphs 30 to 35.

[487] 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.

[488] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 56.

[489] 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 *'[t]he purely theoretical possibility of [market entry] is not sufficient to establish the existence of [potential] competition'*.

[490] T-461/07 *Visa Europe and Visa International Service* v *Commission*, EU:T:2011:181, paragraph 169; and T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 102.

[491] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 42; see also C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 76.

[492] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 161.

Application of the legal and economic context legal framework to the Market Exclusion Agreement

5.66 In this section, the CMA summarises the application of the legal and economic context to the Market Exclusion Agreement, including:

5.66.1 the nature of the goods affected; and

5.66.2 the real conditions of the functioning and structure of the market for the supply of Prochlorperazine POM in the UK, including:

(a) the market conditions prior to the Market Exclusion Agreement;

(b) Alliance was an actual competitor in the supply of Prochlorperazine POM; and

(c) Lexon and Medreich, working together, were potential competitors of Alliance in the supply of Prochlorperazine POM.

5.67 This section should be read in conjunction with paragraphs 3.21 to 3.52 above.

The nature of the goods affected

5.68 Prochlorperazine POM is an important drug on which thousands of patients rely. The provision of Prochlorperazine POM to patients is funded by the NHS, and ultimately, the taxpayer.

5.69 As outlined in paragraphs 3.21 to 3.25 above, Prochlorperazine POM is a generic drug. During the Infringement Period, Prochlorperazine POM was not subject to any patent, brand or data exclusivity.

5.70 All forms of Prochlorperazine POM are bioequivalent: their effects in the body are identical. Prochlorperazine POM tablets are therefore homogenous, fungible commodities. Any generic supplier with the necessary resources could seek a product licence, start suppling Prochlorperazine POM and expect to win market share with a competitively priced generic product.

The real conditions of the functioning and structure of the market

5.71 This case involves the supply of unbranded, generic drugs. In the UK, as outlined in paragraphs 3.31 to 3.52, the suppliers of unbranded generic drugs are in principle free to set their prices as they choose. This is because it is assumed that competition will bring down prices, once generic competitors are free to enter the market and compete on price.[493]

[493] See https://www.gov.uk/government/publications/health-service-medical-supplies-costs/health-service-medical-supplies-costs-bill-factsheet accessed on 23 July 2021 (URN: PAD016).

5.72 This approach is generally believed to be an effective means of securing value for money for the NHS. For example, the British Generic Manufacturers Association 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.'*[494]

5.73 This model of relying on competition to drive down prices for generic drugs only works where competitors enter the market and compete on price. Effective market entry 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 collusion. These factors may result in entry being delayed or not occurring at all, shielding the drug from effective competition, and rendering it susceptible to significant price increases by suppliers.

5.74 As noted at paragraph 3.63 above, Alliance acquired Buccastem (the branded version of Prochlorperazine POM) in August 2009.[495] On 18 February 2011, Alliance varied its MA to allow it to market the generic version of Buccastem, Prochlorperazine POM.[496] However, as outlined in paragraph 3.114 above, Alliance did not de-brand 'Buccastem' and begin supplying Prochlorperazine POM until December 2013. During the period in which Alliance was selling Buccastem (the branded product), it was subject to the price and profit controls of the PPRS. In June 2013 the reimbursement price for Buccastem POM was £6.49.[497]

5.75 Under the UK regulatory regime, de-branding the drug meant that it was no longer subject to the price and profit controls of the PPRS or the statutory scheme for branded drugs. From December 2013, Prochlorperazine POM sold by Focus became a generic drug, outside price regulation.

5.76 Focus increased the price of Prochlorperazine POM to wholesalers dramatically in the following years, from £8 per pack in December 2013 to around £30 per pack in December 2017, having peaked at nearly £35 in June 2017.[498]

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[494] British Generics Manufacturers Association About generics, accessed on 28 July 2021 (URN: PAD005).

[495] Email [Alliance employee] to various recipients entitled *'Buccastem and Timodine'* dated 20 August 2009 (URN: PRO-E000801).

[496] Section 26 response of Alliance, part 2, paragraph 4, dated 16 November 2017, to CMA Notice of 16 October 2017 (URN: PRO-C0367).

[497] Section 26 response of NHSBSA dated 1 March 2018, to the CMA Notice of 2 February 2018, Annex 9 (URN: PRO-C1501).

[498] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 1 (URN: PRO-C3150).

The market conditions prior to the Market Exclusion Agreement

5.77 At the time the Parties entered into the Market Exclusion Agreement, Alliance was the sole supplier of Buccastem in the UK – a branded medicine which Alliance decided to 'debrand'.

5.78 Independent generic entry typically results in significant price erosion and loss of sales for the incumbent (see paragraph 3.40), and Alliance anticipated that the same would be the case in relation to the impact of independent generic entry in the supply of prochlorperazine POM (see for example paragraphs 3.175 and 3.187). If independent entry could be avoided, however, Alliance could expect to maintain its position as the sole supplier. Alliance therefore had an incentive to prevent or delay new entry into the market.

Actual and potential competition

5.79 The CMA finds that, at the time of entering into the Market Exclusion Agreement: (i) Alliance was active in the supply of Buccastem (and would later supply generic Prochlorperazine POM); and (ii) Lexon and Medreich, working together, were each potential competitors to Alliance in the supply of Prochlorperazine POM.

Alliance was an actual competitor in the supply of Prochlorperazine POM

5.80 At the time the Market Exclusion Agreement was entered into (that is most likely by 7 June 2013, and at the latest by 22 June 2013), Alliance was supplying Buccastem to a range of customers, including pharmacies and mainline wholesalers in the UK.[499] Alliance then supplied Prochlorperazine POM to Focus throughout the term of the Market Exclusion Agreement. Therefore, the CMA concludes that Alliance was an actual competitor in the supply of Buccastem / Prochlorperazine POM at the time the Market Exclusion Agreement was entered into (and that it remained an actual competitor throughout the term of that agreement).

Lexon and Medreich worked together to develop Prochlorperazine POM

5.81 As noted at paragraph 5.50, above, *'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'*.[500]

5.82 Pursuant to the terms of the Lexon-Medreich Agreement, Medreich was responsible for making the MA applications for the prochlorperazine products

[499] Section 26 response of Alliance, part 1, appendix 5, dated 2 November 2017, to CMA Notice of 16 October 2017 (URN: PRO-C0222).

[500] T-682/14 *Mylan Laboratories and Mylan v Commission*, ECLI:EU:T:2018:907, paragraphs 87 and 88.

jointly developed by Lexon and Medreich (hence the MAs for Prochlorperazine OTC and POM were applied for in Medreich's name). However, the Lexon-Medreich Agreement provided that [✂].[501] Further, pursuant to the terms of the Lexon-Medreich Agreement, Lexon was *'exclusively responsible for negotiating and setting the selling price for onward sales'*.[502]

5.83 As a result of the Lexon-Medreich Agreement, Lexon and Medreich could only have entered the market for the supply of prochlorperazine in the UK by working together. Whilst Medreich legally held the MAs for prochlorperazine, it could only supply the UK market through Lexon as a result of the exclusive rights Lexon held under the Lexon-Medreich Agreement. [✂].[503]

5.84 It follows, therefore, that Lexon and Medreich must be considered together for the purpose of determining whether they were potential competitors in the supply of Prochlorperazine POM.

Lexon and Medreich, working together, were potential competitors to Alliance in the supply of Prochlorperazine POM

5.85 For the reasons set out below, the CMA concludes that Lexon and Medreich, working together pursuant to the Lexon-Medreich Agreement, were potential competitors to Alliance in the supply of Prochlorperazine POM in the UK at the time the Market Exclusion Agreement was entered into (that is most likely by 7 June 2013, and at the latest by 22 June 2013):

5.85.1 Lexon and Medreich (working together) had taken '*sufficient preparatory steps'* to show their '*firm intention and inherent ability*' to enter the market (paragraphs 5.87 to 5.92);

5.85.2 There were no insurmountable barriers to Lexon and Medreich's entry (working together) (paragraph 5.93); and

5.85.3 Additional factors indicate the existence of potential competition (paragraphs 5.98 to 5.104).

5.86 The CMA also concludes that Lexon and Medreich (working together) remained potential competitors to Alliance during the term of the Market Exclusion Agreement (paragraphs 5.94 to 5.97).

[501] Document entitled *'Product Development and Profit Sharing Agreement Between Medreich PLC and Lexon (UK) Limited'*, 25 February 2008 (URN: PRO-E002374).

[502] Document entitled *'Product Development and Profit Sharing Agreement Between Medreich PLC and Lexon (UK) Limited'*, 25 February 2008, Article 4(2) (URN: PRO-E002374).

[503] Article 2.7 of the Lexon-Medreich Agreement notes [✂]. Further the Agreement [✂] (URN: PRO-E002374).

Lexon and Medreich, working together, had taken sufficient preparatory steps to enter the market to show a firm intention and inherent ability to do so

5.87 As set out at paragraph 3.55, in June 2010 Medreich applied (pursuant to the Lexon-Medreich Agreement) for MAs to market Prochlorperazine POM, Prochlorperazine OTC and prochlorperazine 5mg tablets in the UK. As at September 2011, Medreich and Lexon expected those licences to be granted, *'towards the end of 2012'.*[504] To enable the MA application to be made, it was agreed in the Lexon-Medreich Agreement that Medreich Limited (a company registered in India) would undertake formulation development, dossier compilation, bio-equivalence studies and the manufacture of validation batches for a range of pharmaceutical products (including prochlorperazine).[505] Due to the provisions of the Lexon-Medreich Agreement, even though the relevant MAs were legally held by Medreich, Lexon was *'exclusively responsible for negotiating and setting the selling price for onward sales'*[506] and presented itself as effectively being the MA-holder in commercial negotiations.[507]

5.88 In the course of 2012, Lexon and Medreich exchanged a number of emails about the anticipated commercialisation of the jointly developed Prochlorperazine POM and OTC in the UK (see paragraphs 3.56 to 3.59 above). Those emails show that Medreich: (i) expected the MAs to be granted shortly; (ii) had responded to all outstanding requests for information by the MHRA; and (iii) was considering what steps to take to commercialise the product. In late January 2013, Medreich had begun planning the production of validation batches and expected to order them between April and June 2013.[508]

5.89 Therefore, at the date the Market Exclusion Agreement was entered into, the CMA concludes that Medreich and Lexon had jointly invested the necessary resources to apply for MAs for Prochlorperazine POM and OTC, expected to receive those MAs imminently and were taking the necessary steps to plan the launch of the jointly developed product.

5.90 It is clear from the preparatory steps that Medreich and Lexon, working together, had taken that Lexon would have been able to launch the product within a reasonable period of the date on which the Market Exclusion Agreement was concluded, and that at the date the Market Exclusion Agreement was entered into,

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[504] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*RE: Lexon Project Status Aug-2011*' 9 September 2011 (URN: PRO-E002504).

[505] Document entitled *'Product Development and Profit Sharing Agreement Between Medreich PLC and Lexon (UK) Limited'*, 25 February 2008, Article 4(2) (URN: PRO-E002374).

[506] Document entitled *'Product Development and Profit Sharing Agreement Between Medreich PLC and Lexon (UK) Limited'*, 25 February 2008, Article 4(2) (URN: PRO-E002374).

[507] For example, the Focus-Lexon Heads of Terms refer to Lexon's MA. See document entitled *'Heads of Agreement'* dated 1 August 2013 (URN: PRO-E003834).

[508] Email [Medreich Director 2] to [Medreich employee] cc [Medreich employee] entitled '*Validation Batch Sizes*' 30 January 2013 (URN: PRO-E002570).

Lexon and Medreich, working together, had the possibility to enter the market within such a period of time as to impose competitive pressure on Alliance.

5.91 Contemporaneous documents indicate that Medreich had anticipated being in a position to enter the market in the short term. Shortly after the Market Exclusion Agreement was agreed between Alliance and Lexon, [Medreich Employee 1] emailed [Lexon Director 1] to provide an update on the grant of the Prochlorperazine POM MA, noting that, *'We have one 3 mg license [sic], [Medreich employee] spoke to the Assessor of the other 3 mg and the 5 mg. These are now also signed off, and we should receive the approval copies in August positively.'*[509] This is consistent with the CMA's conclusion that, at the time Lexon entered into the Market Exclusion Agreement, both Lexon and Medreich expected to obtain the MA for Prochlorperazine POM imminently and that they were potential competitors to Alliance.[510]

5.92 It is evident that, at the date the Market Exclusion Agreement was entered into, Medreich and Lexon (acting together) had taken sufficient preparatory steps to prepare for entry, entry was possible with '*sufficient speed to form a constraint on market participants*'.

There were no insurmountable barriers to Lexon and Medreich's entry (working together)

5.93 The CMA concludes that there were no '*insurmountable barriers*' to the entry of Lexon and Medreich, working together. There were no legal barriers to entry to the market for the supply of Prochlorperazine POM in the UK which would have precluded Lexon and Medreich's combined entry. This is consistent with Medreich having obtained an MA for prochlorperazine POM in January 2014 and, as set out below, with Medreich's conduct during the period leading up to the conclusion of the Market Exclusion Agreement during which it anticipated imminent entry even when there were setbacks that led to delay.

Lexon and Medreich, working together, remained potential competitors to Alliance during the term of the Market Exclusion Agreement

5.94 Medreich faced certain regulatory and manufacturing difficulties in the period from December 2014 until September 2015.[511] However, as set out below, those difficulties were each resolved in a timely manner and the CMA does not consider that any of them constituted an insurmountable barrier to entry such that Lexon

[509] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled '*Prochlorperazine*' 30 July 2013 (URN: PRO-E002619).

[510] The MA for Prochlorperazine POM was granted in January 2014, seven months after the Market Exclusion Agreement was concluded, thereby clearing the most important regulatory hurdle for market entry.

[511] See paragraphs 3.227 to 3.240 above.

and Medreich ceased being potential competitors to Alliance in the supply of Prochlorperazine POM in the UK.

5.95 On 4 February 2014, having received its MA for Prochlorperazine POM, Medreich informed Lexon that it was having difficulty securing a time to audit their prochlorperazine API supplier (see paragraph 3.208). However, this issue did not prevent Medreich from ordering API, receiving that API within a relatively short period of time (within two months of ordering),[512] and using that API to prepare batches of Prochlorperazine 5mg tablets which were supplied to Lexon in June 2015.[513] The fact that there was some delay in Medreich securing an audit slot, which was ultimately secured on 1 December 2015,[514] did not therefore prevent Medreich from using the API that could have been used to supply 3mg Prochlorperazine POM[515] and that was used to supply the 5mg product.[516] Accordingly, the CMA does not consider that the delay in Medreich obtaining API and securing an audit slot with its API supplier meant that Medreich faced an insurmountable barrier to entry, nor does it indicate that Medreich could not enter the market with *'sufficient speed to form a constraint on market participants'*.[517]

5.96 On 17 December 2014, the MHRA wrote to Medreich to inform it of an issue concerning its Prochlorperazine POM and OTC MAs (see paragraphs 3.227 to 3.228). The issue concerned the fact that the reference product Medreich had used in its MA application was itself a generic[518] and, on this basis, the MHRA required Medreich to re-submit its application relying on a different legal basis for approval.[519] Medreich immediately took steps to resolve this issue by submitting a revised application with the additional detail required by the MHRA by 27 February 2015.[520] The MHRA responded to the revised application on 15 September 2015 to

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[512] Medreich placed an order for API on 24 June 2014 which was to be delivered on 13 August 2014 (see paragraph 3.223).

[513] Medreich PLC placed an order with Medreich India for Prochlorperazine 5mg tablets on 21 March 2014. The first record Medreich has of receiving an order for Prochlorperazine 5mg tablets from Lexon is on 3 June 2015. Medreich supplied 5mg prochlorperazine tablets to Lexon on 4 June 2015 – See Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, paragraph 1.4 (URN: PRO-C3856).

[514] See paragraph 3.223.

[515] Medreich confirmed that the API used for the production of Prochlorperazine 5mg is the same as the API used for the 3mg product (Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, paragraph 1.1 (URN: PRO-C3856)).

[516] See Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, paragraph 1.4 (URN: PRO-C3856), which notes that Prochlorperazine 5mg tablets were delivered to Lexon on 4 June 2015.

[517] T-461/07 *Visa Europe and Visa International v Commission*, EU:T:2011:181, paragraph 189.

[518] Email [MHRA employee] to [Medreich employee] cc [MHRA employee] entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 17 December 2014 (URN: PRO-E002900).

[519] Medreich's MA was not revoked or suspended while this issue was resolved. Email [MHRA employee] to [CMA Official] cc various others at CMA and MHRA entitled '*Re: CMA Case no. 50511-2 - notice to MHRA with questions re specific licences and operation of sunset clause on a particular licence*' 29 March 2019 (URN: PRO-C3882). The MHRA stated that *'Medreich was still entitled to supply the product after the e-mail dated 17 December 2014. Their MA was not revoked or suspended and, therefore, they still held a valid MA after 17 December 2014 and could have marketed their product, if they wished. The MHRA would expect that a company which was notified of an error in the legal basis for an MAA would not place its product on the market once it was made aware of the error; however, MHRA could only legally prevent them from doing so by taking formal regulatory action'.*

[520] Email [[✂] employee] to [Medreich Employee 1] cc various others entitled '*Prochlorperazine – Information update submission to MHRA'* 27 February 2015 (URN: PRO-E002937).

inform Medreich that the issue had been resolved (paragraphs 3.239 and 3.240 above). Accordingly, less than nine months after the problem was raised, it was resolved. The CMA does not consider that this short delay undermines a finding of potential competition in this case.

5.97 Consistent with the CMA's findings about the Market Exclusion Agreement, Medreich did in fact supply one batch of Prochlorperazine POM in November 2017[521] in keeping with Lexon and Medreich's intention to produce a single batch of Prochlorperazine POM to avoid the application of the Sunset Clause (see paragraph 3.271 below). This provides further confirmation that, despite facing the regulatory and manufacturing issues described above, Medreich was able to take the steps necessary to resolve those difficulties and actually supply Prochlorperazine POM.

Additional factors which indicate the existence of potential competition

5.98 As noted at paragraph 5.40.4 above, a finding that a potential entrant has a firm intention and an inherent ability to enter the market, if not called into question by the existence of insurmountable barriers to market entry, can be *'confirmed by additional factors'*. [522]

Alliance perceived the product jointly developed by Lexon and Medreich to be a competitive threat

5.99 As set out below, the evidence demonstrates that Alliance perceived Lexon and Medreich (working together) to be a competitive threat at the time Alliance entered into the Market Exclusion Agreement.

5.100 Having been informed that Lexon's '*affiliate Medreich was in the process of obtaining a PL for prochlorperazine'*[523] and that Lexon intended to start supplying Prochlorperazine POM (see paragraphs 3.73 to 3.76), Alliance held numerous internal discussions about how to best respond to the threat of generic entry, including the possibility of either Alliance *'sell[ing] Lexon product in Alliance livery'* or Alliance agreeing to *'supply Lexon with generic product'*.[524]

5.101 In terms of timing for the grant of the MAs, Alliance reported internally on 14 March 2013 that the Lexon licence was expected in 6 weeks: *'[Alliance Employee 1] has*

[521] Section 26 response of Lexon dated 27 November 2018, to CMA Notice of 7 November 2018 (URN: PRO-C2977).

[522] C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraph 54; C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 74.

[523] Section 26 response of Alliance, part two, paragraph 17, dated 16 November 2017, to CMA Notice dated 16 October 2017 (URN: PRO-C0367).

[524] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

had discussions with contacts at Lexon on threat of generic prochlorperazine… Not approved yet, they have said coming out in 6 weeks."[525]

5.102 The decision by Alliance to adopt a '*defence strategy*' was prompted by the threat of entry by Lexon. As [Alliance Director 2] noted in an internal Alliance email of 21 March 2013, *'…unfortunately the Buccastem threat would appear to be real, and not a PI threat. We are working on our defence strategy accordingly and I'll keep you informed as this is pulled together.'* [526] By May 2013, Alliance was progressing a strategy to de-brand Buccastem in response to the threat posed by Lexon: see, for example, the minutes of the Alliance *'Community and Consumer Products Report'* held in May 2013 which noted that Alliance was, *'Progressing launch of generic Prochlorperazine to combat the anticipated launch of competitor product by Lexon…'* [527]

5.103 The CMA therefore finds that Alliance perceived the product jointly developed by Lexon and Medreich to be a competitive threat and that, therefore, Lexon and Medreich, working together, were perceived by Alliance to be potential competitors. As noted at paragraph 5.63 above, the CMA may *'rely inter alia on the perception of the undertaking present on the market in order to assess whether other undertakings are potential competitors.'* [528] The CMA therefore concludes that Alliance's perception of the product jointly developed by Lexon and Medreich provides strong indications that a competitive relationship existed between Alliance, on the one hand, and Lexon and Medreich on the other.

The existence of an agreement between Alliance and Lexon

5.104 Further, and for completeness, the very fact that an agreement was entered into between Alliance and Lexon (at a time when Lexon and Medreich, working together, were not yet supplying Prochlorperazine POM) provides a further strong indication that Lexon and Medreich, working together, were potential competitors to Alliance.[529] Had Lexon and Medreich not been potential competitors, there would have been no incentive for Alliance to transfer value to Lexon (indirectly via Focus) by exclusively supplying Focus with its Prochlorperazine POM, in return for which

[525] Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' meeting dated 14 March 2013 09:00 – 12:00, page 8 (URN: PRO-E000971)). A different document also entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' recording the minutes of the meeting held on 14 March 2013 (URN: PRO-E000979) records the minutes differently on page 5, noting that: *'[Alliance Employee 1] contact at Lexon has confirmed they have a product coming out in 6 weeks, not on Rama yet. All of Lexon's licenses are PLPI; this would be less of a threat. Options would be to do nothing, do a deal on Buccastem or launch Alliance generic (project Cobra); this would take 8-12 weeks. [Alliance Employee 2] and [Alliance Employee 1] will monitor closely and keep dialogue open with Lexon open.'*

[526] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*FW: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000988).

[527] Alliance report 'Community and Consumer Products Report' 13 May 2013, page 5 (URN: PRO-E001008).

[528] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 104 and case law cited.

[529] See C-307/18 *Generics (UK) and others v CMA*, EU:C:2020:52, paragraphs 55-57, citing, by analogy, Judgment of 20 January 2016, *Toshiba Corporation v Commission*, C-373/14 P, EU:C:2016:26, paragraphs 33 and 34. See also C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 78.

Lexon would not enter with the Prochlorperazine POM that it had jointly developed with Medreich.

Representations on the ability of Lexon/Medreich to launch Prochlorperazine POM

5.105 In its response to the SO, Cinven submitted that the CMA could not have concluded that Lexon and Medreich, working together, were potential competitors at the time the Market Exclusion Agreement was concluded.[530] Cinven submitted that Medreich (and consequently Lexon) had no ability to enter until either mid to late-2017, or in any case until at least September 2015, such that they did not have a real capacity to enter the market within a sufficiently short period:[531]

5.105.1 [✂] and, as a result, Medreich faced [✂] delays in obtaining the API it required. Medreich faced further challenges [✂].[532]

5.105.2 Medreich encountered [✂] difficulties in obtaining a valid and appropriately scoped MA, which contributed to a significant delay in its entry to the Prochlorperazine POM market.[533]

5.105.3 Medreich encountered multiple technical difficulties with its Prochlorperazine POM manufacturing process.[534]

5.105.4 Medreich continued to face production difficulties during 2016 and early 2017.[535]

5.106 Lexon also submitted that *'objectively, in hindsight'*, there were no real concrete possibilities of Lexon/Medreich being able to enter the market due to *'legal, technical and commercial barriers'* and therefore that Alliance and Lexon were not potential competitors.[536]

5.107 The CMA observes, first, that none of these points are relevant to the CMA's finding that, at the time the Market Exclusion Agreement was entered into, Lexon and Medreich (working together) were potential competitors to Alliance in the supply of Prochlorperazine POM. This is because the evidence Cinven and Lexon rely on relates to events that happened *after* the conclusion of the Market Exclusion Agreement, and there is no evidence that they were specifically anticipated at the time the agreement was entered into. As the EU Court of Justice held in *Lundbeck*, *'evidence which is unknown to the parties at the date of*

[530] Cinven RSO, 15 August 2019, paragraph 3.44 (URN: PRO-C5132).
[531] Cinven RSO, 15 August 2019, paragraph 3.40 (URN: PRO-C5132).
[532] Cinven RSO, 15 August 2019, paragraphs 3.40(a) and 4.115 to 4.119 (URN: PRO-C5132).
[533] Cinven RSO, 15 August 2019, paragraphs 3.40(b) and 4.120-4.122 (URN: PRO-C5132).
[534] Cinven RSO, 15 August 2019, paragraph 3.40(c) and 4.123-4.131 (URN: PRO-C5132).
[535] Cinven RSO, 15 August 2019, paragraphs 3.40(c) and 4.132-4.135 (URN: PRO-C5132).
[536] Lexon RSO, 31 July 2019, paragraphs 35, 40-41 (URN: PRO-C5091).

conclusion of the agreement at issue is not capable of having influenced their conduct on the market and, therefore, of shedding light on the existence or absence of a competitive relationship between the undertakings concerned at the time when that agreement was concluded.'[537]

5.108 Second, the CMA observes that Cinven's analysis of the impact of the difficulties it identifies is backward looking and refers to what it considers to be their cumulative impact. Consistent with the EU Court of Justice's comments concerning the significance of subsequent events to an analysis of the context at the time the agreement was entered into, any assessment that contemplates Lexon and Medreich's (working together) status as a potential entrant during the subsequent years must similarly consider only the situation as it existed at the time, and take account only of issues that were capable of having influenced their conduct on the market.

5.109 When considered on this basis, it is evident that none of the factors identified by Cinven, represented an insurmountable barrier to entry or prevented Lexon/Medreich (working together) from supplying its product within a sufficiently short period of time to exert competitive pressure on Alliance:

5.109.1 As set out at paragraph 5.95 above, the evidence demonstrates that the challenges regarding Medreich's API did not constitute insurmountable barriers to its entry and would not have prevented Medreich from supplying the 3mg product within a short period.

5.109.2 Similarly, and as set out at paragraph 5.96 above, the challenges that Medreich faced regarding its MA did not deter it from taking the steps needed to resolve the issues within nine months of them being identified.

5.109.3 The manufacturing issues referred to by Cinven relate to that fact that in May 2016 Medreich identified a discrepancy between the approved formula in its MA and the working formula to produce Prochlorperazine POM such that a batch variation application was made.[538] However, it is again apparent that the issues referred to by Cinven did not represent an insurmountable barrier to Lexon and Medreich's (working together) potential to supply Prochlorperazine POM, nor prevent them from supplying product at a later date. The issue was resolved in the following month, on 22 June 2016, when the MHRA approved the variation.[539]

[537] C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 69.

[538] Cinven RSO, 15 August 2019, paragraphs 4.123-4.131 (URN: PRO-C5132).

[539] Email [Medreich Director 2] to [Medreich employee], cc various others entitled *'FW: [SUSPECTED SPAM] Fwd: Qty Mismatch -Prochlorperazine 3mg Tablets-UK'* 22 June 2016 (URN: PRO-E003116).

5.109.4 Due to the technical issues referred to by Cinven, Medreich's first batch of Prochlorperazine POM (from December 2016) was unfit for shipment.[540] As a consequence, Medreich fulfilled Lexon's order for Prochlorperazine POM in November 2017.[541] Again, therefore, it is evident that the issues did not prevent Medreich from taking steps to supply the single batch required to satisfy the Sunset Clause, nor did they prevent Medreich from ultimately supplying that batch of product.[542] Medreich was able to apply, in December 2016 and April 2017, for extensions of the Sunset Clause of its Prochlorperazine POM MA.[543]

5.110 In conclusion, the CMA rejects Cinven's submissions in this regard. The delays experienced by Medreich cannot lead to the conclusion that Medreich did not maintain the potential to enter the market. Medreich continued taking sufficient preparatory steps to ensure that it maintained its licence and would be in a position to supply product, should it choose to do so. At the time each issue arose, none was significant enough to have prevented Lexon/Medreich (working together) from entering the market within a sufficiently short period of time. As set out above, Medreich actively addressed and overcame each difficulty and went on to produce Prochlorperazine POM.[544] It is also evident from the conduct of Focus (who continued to share their profits with Lexon) and Alliance (who enabled Focus to earn (and share with Lexon) significant profits on the supply of its product) that they continued to regard Lexon and Medreich (working together) as able to enter the market had the Market Exclusion Agreement been terminated.[545]

5.111 In its comments on the SO, Medreich also referred to the regulatory and manufacturing challenges considered at paragraphs 5.109 above and submitted that, while it did not suggest that such issues were insurmountable, they had had an impact on the extent to which competition was restricted in the supply of Prochlorperazine POM.[546] For the reasons outlined above, the CMA finds that none of the issues faced by Medreich undermine the CMA's finding that Lexon and Medreich (working together) were potential competitors in the supply of

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[540] Email [Medreich employee] to [Medreich employee] entitled *'RE: Prochlorperazine 8s and 50s'* 4 January 2017 (URN: PRO-E003227).

[541] Section 26 response of Lexon dated 27 November 2018, to CMA Notice of 7 November 2018 (URN: PRO-C2977).

[542] This provides further confirmation that, despite facing the regulatory and manufacturing issues described above, Medreich was able to take the steps necessary to resolve those difficulties and actually supply Prochlorperazine POM.

[543] Email [Medreich employee] to [MHRA email address] entitled *'Prochlorperazine Maleate 3mg Buccal Tablets-PL 21880/0122'* 22 December 2016 (URN: PRO-E003222); Email [MHRA email address] to [Medreich employee] *entitled 'Prochlorperazine Maleate 3mg Buccal Tablets-PL 21880/0122'* 5 January 2017 (URN: PRO-E003228); and Section 26 response of Lexon dated 27 November 2018, to CMA Notice of 7 November 2018 (URN: PRO-C2977).

[544] That unplanned delays do not negate potential competition has been confirmed by the EU General Court, who stated that *'[t]he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place'* (T-114/02 *BaByliss SA v Commission*, EU:T:2003:100, paragraph 102).

[545] As regards Focus, this is further confirmed by the Project Capital presentation, see Email [AMCo Employee 4] to various colleagues at AMCo entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) and its attachment presentation entitled *'Project CAPITAL BD Workstream'*, dated 20 June 2015, slides 15-17 (URN: PRO-E001636), as discussed in paragraph 5.497).

[546] Medreich RSO, 26 July 2019, paragraphs 2.7-2.26 (URN: PRO-C6253).

Prochlorperazine POM. Medreich's comments concerning their *ex post* effects are not relevant to this assessment.

Representations on the need to conduct a relevant market analysis

5.112 Advanz submitted that the CMA cannot draw a conclusion on whether potential competition existed between any of the Addressees in the absence of an analysis of the relevant market, its structure and real operating conditions.[547] Advanz submitted that the CMA has not established that branded and generic product should form part of the same market.[548]

5.113 The CMA does not accept that it is required to carry out a full market definition analysis in order to establish whether the Parties were potential competitors in these circumstances. This approach is consistent with the European Commission's decisions in *Lundbeck*[549] and *Fentanyl.*[550] In any case, that position is only reinforced in the particular circumstances of this case, which concerns the potential supply of *biologically equivalent* products[551] and where it is clear from the documentary evidence that Lexon expected to compete with Alliance in the supply of its product, and that (prior to the Market Exclusion Agreement) Alliance had regarded the potential entry of Lexon (working with Medreich) as a significant threat to its supply of Prochlorperazine POM (see also paragraph 4.3 where the CMA found that, for the purpose of this case, the relevant market as no wider than the supply of Prochlorperazine POM in the UK). It was also the case that Alliance could (and did) choose to supply generic product rather than retain its brand name. Finally, it is observed that the CMA has set out its findings as regards the real conditions of the functioning and structure of the market for the supply of Prochlorperazine POM in the UK in paragraphs 5.71-5.78 above.

Conclusion

5.114 In conclusion, for the reasons set out above, Lexon and Medreich, working together, had real concrete possibilities of entering the market and had taken '*sufficient preparatory steps'* to show their '*firm intention and inherent ability'* to do so at the time. By the time the Market Exclusion Agreement was entered into, they had made significant investments and taken '*sufficient preparatory steps'* to prepare for entry and entry was possible with '*sufficient speed to form a constraint on market participants*'*.* They were therefore potential competitors of Alliance.

[547] Advanz RSO, 1 August 2019, paragraphs 1.26, 1.32 and 5.4.1 (URN: PRO-C5111).

[548] Advanz RSO, 1 August 2019, paragraph 5.67 (URN: PRO-C5111).

[549] Commission decision of 19 June 2013 in Case 39226 *Lundbeck*.

[550] Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*.

[551] The MHRA confirmed Alliance's branded Buccastem product was part of the same MA as Prochlorperazine POM. Section 26 response of MHRA dated 2 November 2018, to CMA Notice of 12 October 2018, questions 3 and 4 (URN: PRO- C2737).

Market Exclusion Agreement

5.115 The CMA sets out in this section its assessment of whether the conduct in question amounted to an agreement and, if so, what were its terms, that is considering:

5.115.1 the law on what constitutes an agreement, including the legal framework for participation in an agreement;

5.115.2 the evidence of whether there was an agreement between Alliance and Lexon; comprising:

(a) documentary evidence from 2013 that Alliance would pay Lexon to stay out of the market;

(b) the entry into contractual agreements between Alliance and Focus and between Focus and Lexon;

(c) the subsequent conduct of each of Alliance, Lexon, Focus and Medreich;

(d) correspondence between Focus and Lexon in 2014 that refers to the supply of product;

(e) the CMA's assessment of the credibility of the Parties' submissions taken collectively and in the round; and

(f) a conclusion on whether the conduct in question amounted to an agreement between Alliance and Lexon.

Legal framework

5.116 The CMA sets out in this section the law on what constitutes an agreement, including the legal framework for participation in an agreement.

Legal Framework: Agreements for the purpose of the Chapter I prohibition

Agreements

5.117 The Chapter I prohibition prohibits agreements between undertakings which have as their object or effect the prevention, restriction or distortion of competition and which may affect trade within the UK.

5.118 Such agreements are illegal, unless exempt under section 9 of the Act.

5.119 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'*.[552]

5.120 The EU 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'.*[553]

5.121 Courts have also described the concept of an agreement as a *'common understanding'* between the parties - which has the same meaning as *'concurrence of wills'*. For example, in its judgment in Hitachi, the EU 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)'*.[554]

5.122 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.[555] That a party 'cheats' on the agreement also does not absolve it.[556] The CAT has confirmed that:

> *'An agreement, in our view, can be constituted by an "understanding" even if there is nothing to prevent either party from going back on, or disregarding, the understanding in question."*[557]

5.123 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'.[558]

5.124 The EU General Court has held that:

> *'the commitment of a group of producers not to enter a market reserved to the other* group *… is based on a simple concept which may be implemented easily. Similarly, its implementation does not require, in*

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[552] 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 and 97).

[553] T-7/89 *SA Hercules Chemicals NV v Commission*, EU:T:1991:75, paragraph 256.

[554] T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 272.

[555] *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 EU Court of Justice in 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 and 80.

[556] T-141/89 *Tréfileurope v Commission*, EU:T:1995:62, paragraphs 53 to 60.

[557] *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2004] CAT 24, paragraph 658.

[558] C-41/69 *ACF Chemiefarma NV v Commission*, EU:C:1970:71, in particular paragraphs 106 to 114. See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2004] CAT 24 at paragraph 658. See also Commission decision of 30 October 2002 in Cases 35.587, 35.706 and 36.321 *Video Games, Nintendo Distribution and Omega-Nintendo*, paragraph 247.

principle, interaction between the undertakings concerned. Consequently, such a commitment is perfectly capable of existing as an unwritten understanding, which also reduces the likelihood of its discovery'.[559]

5.125 An agreement therefore need not be articulated by the parties explicitly. It may not be necessary for the parties to refer in their discussions to their common understanding, which may *'go without saying' 'since the content of that understanding was understood, accepted and implemented by all the participants in the cartel without the need for any specific discussion on it.'*[560] This may be particularly likely where the common understanding consists of *'a mere commitment not to act'* – for example, not to enter a market.[561]

5.126 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 EU 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'.*[562]

Legal Framework: Participation in an infringement

5.127 In a number of cases the EU Courts have assessed whether an undertaking is liable for an infringement in its entirety even though it does not participate in the infringement in the same way or to the same extent as the other participants in that infringement.

5.128 The EU Courts have found that the following conditions need to be satisfied *'to find that an undertaking participated in an infringement and was liable for all the various elements comprising the infringement'*:

5.128.1 the existence of an overall plan pursuing a common objective;

5.128.2 the intentional contribution of the undertaking to the common objective pursued by all the participants; and

[559] T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 91. See also T-133/07 *Mitsubishi v Commission* EU:T:2011:345, paragraph 186. Upheld on further appeal in C-239/11, C-489/11 and C-498/11 *Siemens and Others v Commission*, EU:C:2013:866.

[560] T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraphs 141 and 269.

[561] T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 141.

[562] C-2&3/01 P *BAI and Commission v Bayer*, EU:C:2004:2, paragraph 100. See also T-168/01 *GlaxoSmithKline Services Unlimited v* Commission, EU:T:2006:265, paragraphs 82 and 83: the existence of an agreement may be established by *'indirect evidence, for example in the form of conduct'*.

5.128.3 the undertaking's awareness of the conduct planned or put into effect by other undertakings in pursuit of the same objectives, or that it could reasonably have foreseen it and was prepared to take the risk.[563]

5.129 The EU Courts have applied these conditions to find that an undertaking can be liable for an infringement in its entirety where the undertaking participates directly in only some of the anti-competitive conduct comprising the relevant infringement[564] or where the undertaking actively contributes to the restriction of competition by 'facilitating' the infringement.[565] It has also been found that, if these conditions are satisfied, an undertaking will be held liable for an infringement based on acts of a third party that acts on behalf of that undertaking. [566]

5.130 The conditions outlined at paragraph 5.128 were first set out in cases concerning single and continuous infringements[567] but have not been limited to that context.

5.131 The CMA has applied these conditions to this case to show that Focus and Medreich were liable for the Market Exclusion Agreement entered into by Alliance and Lexon by virtue of their participation in it.

The existence of an overall plan pursuing a common objective

5.132 It must be demonstrated that conduct has an 'identical' purpose or object to the anticompetitive aims allegedly being pursued, i.e. that conduct is *'part of a series of efforts made by the undertakings in question in pursuit of a single economic aim'*.[568] In other words, there must be evidence showing the *'existence of an overall plan pursuing a common objective'*.[569]

5.133 The common objective must be based on objective elements linking the various actions together, showing that they were indeed part of an overall plan in pursuit of the same common objective or single economic aim.[570] A competition authority should be guided by a combination of the relevant objective factors, rather than dependence on a single element. The objective will be a question of fact and characterisation based on the evidence gathered.

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[563] See T-204/08 *Team Relocations v Commission*, EU:T:2011:286, paragraph 37; T-180/15 *Icap and Others v Commission,* EU:T:2017:795, paragraph 100; and C-194/14 *AC-Treuhand v Commission*, EU:C:2015:717, paragraph 30 and the case-law cited.

[564] See Case T-204/08 *Team Relocations v Commission*, EU:T:2011:286.

[565] Case T-99/04 *AC-Treuhand v Commission* EU:T:2008:256; Case T-29/05 *Deltafina v Commission* EU:T:2010:355; Case T-27/10 *AC-Treuhand v Commission* EU:T:2014:59, upheld on appeal in Case C-194/14 P *AC-Treuhand v Commission* EU:C:2015:717; Case T-180/15 *Icap v Commission* EU:T:2017:795.

[566] See, for example, Case C-542/14 *VM Remonts and Others* EU:C:2016:578.

[567] See for example, C-49/92 P *Commission v Anic Partecipazioni*, EU:C:1999:356, paragraphs 82-83 and 203.

[568] C-49/92 P *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraphs 82 and 83. See also Case T-27/10 *AC Treuhand v Commission*, EU:T:2014:59, paragraph 239; and Case T-180/15 *Icap and Others v Commission* EU:T:2017:795, paragraph 205.

[569] T-204/08 *Team Relocations and Others v Commission*, EU:T:2011:286, paragraph 37.

[570] T-410/09 *Almamet v Commission,* EU:T:2012:676 , paragraphs 170 to 175.

5.134 To demonstrate a common objective, there must be more than a plan simply to distort competition in a particular market, since the distortion of competition is an element of any conduct covered by Article 101(1).[571] In one of the *Gas Insulated Switchgear* cartel appeals, the EU General Court found that the practices at issue shared a common objective, namely *'the establishment of a system for sharing the worldwide market for [gas insulated switchgear] projects and allocating those projects among the various participants'*. The EU Court of Justice ruled that such finding did not amount to a general reference to a distortion of competition in the relevant product market.[572]

5.135 The EU Court of Justice has confirmed that it is not necessary for the practices at issue to be complementary in nature to find a common objective.[573] Nevertheless, an authority must ascertain *'whether there are any elements characterising the various instances of conduct forming part of the infringement which are capable of indicating that the conduct in fact implemented by other participating undertakings does not have an identical object or identical anti-competitive effect, and, consequently, do not form part of an 'overall plan'*.[574]

5.136 It has been found that *'[m]embers may join or leave the cartel from time to time without its having to be treated as a new 'agreement' with each change in participation.'*[575]

Intentional contribution

5.137 It is necessary to establish that the relevant undertaking intentionally contributed, through its own conduct, to the common objective of the participants as a whole.[576]

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[571] T-101/05 *BASF and UCB v Commission*, EU:T:2007:380, paragraph 180.

[572] See T-113/07 *Toshiba v Commission*, EU:T:2011:343, paragraph 228, and C-239/11 *Siemens and Others v Commission*, EU:C:2013:866, paragraph 246. Similarly, in one of the *Power Cables* cartel appeals, the EU Court of Justice found that the EU General Court had determined the common objective by reference to the fact that smaller producers had reasons to share the cartel's single objective, which was *'the establishment of a system for sharing the worldwide market for power cable projects with the exception of the United States'* and not by a general reference to a distortion of competition on the markets concerned by the infringement. See Case C-607/18 P *NKT Verwaltungs and NKT v Commission*, EU:C:2020:385, paragraph 128 and Case T-447/14 *NKT Verwaltungs and NKT* v *Commission*, EU:T:2018:443, paragraph 121.

[573] Case C-239/11 P *Siemens v Commission*, EU:C:2013:866, paragraph 248: '*The General Court is not in fact required to examine such an additional condition of complementarity*'.

[574] Case C-239/11 P *Siemens v Commission*, EU:C:2013:866, paragraph 248.

[575] See, for example, Commission Decision of 21 October 1998 in Case C IV/35.691 *Pre-insulated pipes*, paragraph 134, as noted by the EU General Court in T-9/99, *HFB v Commission,* EU:T:2002:70 paragraph 234. See also CMA Decision in case 50507.2 *Nortriptyline (information exchange)*, Decision of 4 March 2020, paragraph 5.143 and CMA Decision in Case 50415 *Supply of groundworks products to the construction industry*, Decision of 17 December 2020, paragraph 5.132, footnote 771.

[576] C-49/92 P *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraphs 83 and 203; See also T-29/05 *Deltafina v Commission*, EU:T:2010:355, paragraph 62 and T-180/15 *Icap and Others v Commission*, EU:T:2017:795, paragraph 100.

5.138 The undertaking's intention to contribute to the overall objective pursued can be inferred from its participation in at least one element of the relevant conduct.[577]

5.139 In *Icap*, the EU General Court held that as, *'Icap knew of the existence of collusion between the banks concerned and…there was a very high degree of complementarity between the conduct of the banks concerned and that of Icap, it necessarily follows that Icap intended to contribute to the achievement of the common objectives pursued by those banks'.*[578]

5.140 The EU Court of Justice has noted that *'the mere fact that each undertaking takes part in the infringement in ways particular to it does not suffice to exclude its liability for the entire infringement, including conduct put into effect by other participating undertakings but sharing the same anti-competitive object or effect."*[579]

5.141 Further, the fact that an undertaking has not taken part in all aspects of an anti-competitive scheme, or that it played only a minor role in the aspects in which it did participate, is not material to the establishment of an infringement on its part.[580]

5.142 The EU Court of Justice has also held that an undertaking need not participate from the beginning of the infringement or have pursued the common objective in the same way as the other parties to the infringement: *'the condition concerning the intentional contribution to the common objectives pursued by all the participants… does not mean that the intentional contribution to those common objectives can be established only where the undertaking concerned has contributed to those common objectives since the start of the infringement or on condition that it pursued those objectives in ways identical to those put into effect when the infringement commenced."*[581]

Awareness of the offending conduct planned or put into effect by other undertakings in pursuit of the same objectives, or that it could reasonably have foreseen it and was prepared to take the risk

5.143 The authority must demonstrate that the undertaking in question was aware of the conduct planned or put into effect by the other parties in pursuit of the same objectives, or could reasonably have foreseen it and was prepared to take the risk.[582] Even if a particular undertaking did not directly participate in every aspect of

[577] In T-25/95 *Cimenteries CBR and Others* v *Commission*, EU:T:2000:77, paragraph 4123, a single and continuous infringement was found to exist on the ground that *'[e]ach party whose participation in the Cembureau agreement is established contributed, at its own level, to the pursuit of the common objective by participating in one or more of the implementing measures referred to in the contested decision'*.

[578] T-180/15 *Icap and Others v Commission*, EU:T:2017:795, paragraph 180.

[579] C-49/92 *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraph 80. See also T-29/05 *Deltafina v Commission*, EU:T:2010:355, paragraph 60.

[580] Cases C-204/00 P etc. *Aalborg Portland and Others v Commission*, EU:C:2004:6, paragraph 86. See also T-29/05 *Deltafina v Commission*, EU:T:2010:355, paragraph 61.

[581] C-444/11 P *Team Relocations v Commission*, EU:C:2013:464, paragraph 56.

[582] T-180/15 *Icap and Others v Commission*, EU:T:2017:795, paragraphs 100 and 113.

an infringement, it can still be found liable for the whole infringement if it was *'aware (proved or presumed) of the offending conduct of the other participants'*.[583]

5.144 The reasonable foreseeability of illicit acts by the other participants is deemed to fulfil this requirement.[584]

5.145 It is not necessary for each undertaking to be aware of the full detail of all the participants' activities, so long as each, *'could not have been unaware of the general scope and the essential characteristics of the cartel as a whole.'*[585]

5.146 The EU Court of Justice has held that this condition, *'does not require…that it be established that that undertaking was or should have been aware of the offending conduct of the initial participants in the infringement or that it adhered to that infringement from the outset. It also does not lay down that that condition of awareness can be established only if that undertaking contributed to the single and continuous infringement in a way identical to that initially put in place.'*[586]

5.147 The Parties made numerous representations challenging the legal framework applied by the CMA for participation in an infringement. The CMA rejects these arguments. The Parties' representations, together with the CMA's response, are set out in Annex A:.

Market Exclusion Agreement between Lexon and Alliance

5.148 The CMA sets out in this section its assessment of whether there was an agreement between Alliance and Lexon, comprising:

5.148.1 an overview of the evidence considered by the CMA in this section;

5.148.2 events leading to the Market Exclusion Agreement;

5.148.3 the documentary evidence from 2013 that Alliance would pay Lexon to stay out of the market;

5.148.4 the entry into contractual agreements between Alliance and Focus and between Focus and Lexon;

5.148.5 the subsequent conduct of each of Alliance, Lexon, Focus and Medreich;

[583] T-204/08 *Team Relocations v Commission*, EU:T:2011:286, paragraph 37.

[584] C-49/92 P *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraph 87.

[585] T-259/02 to T-264/02 and T-271/02 *Raiffeisen Zentralbank Österreich* v *Commission*, EU:T:2006:396, paragraph 193.

[586] C-444/11 P *Team Relocations and Others v Commission*, EU:C:2013:464, paragraph 54; see also T-82/13 *Panasonic and MT Picture Display v Commission*, EU:T:2015:612, paragraph 103.

5.148.6 the correspondence between Focus and Lexon in 2014 that refers to the supply of product;

5.148.7 the CMA's assessment of the credibility of the Parties' submissions taken collectively and in the round; and

5.148.8 its conclusion on the existence of the Market Exclusion Agreement between Alliance and Lexon.

Overview of the evidence

5.149 The CMA has found that a pay for delay or market exclusion agreement existed between Alliance and Lexon relating to Prochlorperazine POM (that is, the Market Exclusion Agreement), in which Focus, and subsequently Medreich, participated.

5.150 Under the terms of the Market Exclusion Agreement, Alliance and Lexon agreed that:

5.150.1 Alliance would indirectly (through Focus) transfer value to Lexon by exclusively supplying Focus with its Prochlorperazine POM, and Focus sharing the profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon; and

5.150.2 in return for that value transfer, Lexon would not supply the Prochlorperazine POM that it had jointly developed with Medreich in competition with Alliance.

5.151 The payments made to Lexon ultimately totalled £7.86 million (£4.96 million of which was retained by Lexon and £2.9 million was transferred by Lexon to Medreich). The agreement between Alliance and Lexon was most likely entered into by 7 June 2013[587] and lasted until 31 July 2018.

5.152 Focus and Medreich participated in the Market Exclusion Agreement:

5.152.1 Focus was aware of the common objective (that is, the implementation of the Market Exclusion Agreement) and the conduct of Alliance, Lexon and Medreich in pursuit of it, or could reasonably have foreseen it and was prepared to take the risk, and intentionally contributed to it by supplying the Alliance product and sharing the profits from doing so with Lexon.

5.152.2 Medreich was aware of the common objective (that is, the implementation of the Market Exclusion Agreement) and the conduct of Alliance, Lexon and Focus in pursuit of it, or could reasonably have foreseen it and was

[587] In any event, the agreement was entered into at the latest by 22 June 2013, that being the date of [Focus Director 1]'s email to [Focus Director 2] setting out what had been agreed between Alliance and Lexon and including the details of the profit share split under the proposed Focus-Lexon Heads of Terms. See Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

prepared to take the risk, and intentionally contributed to it by accepting payments as compensation for not supplying the Prochlorperazine POM it had jointly developed with Lexon.

5.153 The terms of the Market Exclusion Agreement between Alliance and Lexon were not recorded in a formal written contract. However, the existence and terms of the Market Exclusion Agreement can be established and inferred from the evidence at paragraphs 5.158 to 5.581, summarised at paragraph 5.154 below, including contemporaneous documentary evidence, the terms of the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms that implemented the terms of the Market Exclusion Agreement (the '**Implementing Agreements**'), from the Parties' subsequent conduct (including the substantial payments made from Focus to Lexon) and from further documentary evidence during the lifetime of the Market Exclusion Agreement.

5.154 The evidence in paragraphs 5.158 to 5.581 upon which the CMA relies in order to prove the existence of the Market Exclusion Agreement is summarised (non-exhaustively) below.

Documentary evidence of discussions relating to Prochlorperazine POM between Alliance and Lexon in the period prior to the Market Exclusion Agreement (see paragraphs 5.158 to 5.188 below)

5.154.1 Internal Alliance documentary evidence that Lexon had informed Alliance in early 2013 that it was preparing to enter the market with Prochlorperazine POM.[588,589]

5.154.2 Internal Alliance documentary evidence that, in response to Lexon's potential entry, Alliance decided to maintain a dialogue with Lexon as it formulated its 'defence' strategies.[590,591]

5.154.3 Internal Alliance documentary evidence and witness interview evidence relating to two meetings held between Alliance and Lexon, at which potential supply options relating to Prochlorperazine POM were discussed,

[588] Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' dated 14 March 2013 09:00 – 12:00, page 8 (URN: PRO-E000971).

[589] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

[590] Email [Alliance Employee 2] to [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 18 March 2013 (URN: PRO-E000976).

[591] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

the first on 12 April 2013, and the second in late May or early June 2013.[592,593]

5.154.4 Internal Alliance documentary evidence that, following the second meeting between Alliance and Lexon in late May or early June 2013, Alliance's thinking regarding its response to the Lexon threat significantly changed such that it no longer referred to the possibility of appointing Creo Pharma as a distributor but instead referred only to the supply of the product to Focus.[594,595]

The documentary evidence of an agreement that Alliance would pay Lexon (via Focus) to delay its market entry

5.154.5 The contemporaneous documentary evidence that by 7 June 2013 Alliance and Lexon had reached an agreement in principle that (i) Alliance would exclusively supply a de-branded version of its Buccastem POM (that is, would supply Prochlorperazine POM) to Focus, (ii) Lexon would enter into an agreement with Focus in relation to Prochlorperazine POM that would enable Focus to share the profits earned from the sales of Alliance's Prochlorperazine POM with Lexon (that is, Alliance would indirectly transfer value to Lexon through Focus), and (iii) in return, Lexon would not enter the market with the product that it had jointly developed with Medreich. This contemporaneous documentary evidence includes:

(a) [Alliance Director 1]'s 11 June 2013 notebook entry,[596] in which he recorded [Alliance Employee 1]'s Buccastem defence plan, pursuant to which Lexon would enter into an agreement with Focus, but then only supply it with an individual batch needed to sustain its marketing authorisation, whilst Alliance would supply de-branded Prochlorperazine POM (see paragraphs 5.191 to 5.194 and paragraphs 5.204 to 5.226 below).

(b) An internal Focus email dated 22 June 2013, in which [Focus Director 1] explained that Lexon and Alliance had agreed that Alliance would supply Focus with the newly de-branded Prochlorperazine POM at the same average selling price as it had sold the branded product to wholesalers and Focus would set the market price, as well as

[592] Interview [Alliance Employee 1], 4 October 2018, Part 1, page 93, lines 7-9 and pages 99-100 (URN: PRO-C2909); Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 44 (URN: PRO-C5092); Interview [Alliance Employee 2], 3 October 2018, page 22, lines 1-8 (URN: PRO-C2945).

[593] Alliance RSO, 1 August 2019, paragraph 3.12 (URN: PRO-C5096); Interview [Alliance Employee 1] Part 1 pages 27, line 20 to page 28, line 4 (URN: PRO-C2909).

[594] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled 'CCG switch and Buccastem defence' 7 June 2013 (URN: PRO-E001009). See paragraph 3.83.

[595] Email [Alliance Employee 2] to [Alliance employee] and others at Alliance entitled '*Buccastem'* 10 June 2013 (URN: PRO-E001010).

[596] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

recording the terms on which Focus would share the majority of the profits it earned from the supply of the Alliance product with Lexon[597] (see paragraphs 5.195 to 5.198 and paragraphs 5.227 to 5.247 below).

(c) Subsequent email exchanges, on 24 June 2013,[598] 10 July 2013[599] and 18 July 2013[600] which provide further evidential support that Alliance and Lexon had previously entered into the Market Exclusion Agreement (see paragraph 5.199 and paragraphs 5.248 to 5.268 below).

5.154.6 The contemporaneous documentary evidence relating to the agreement between Alliance and Lexon, as set out above, is consistent with subsequent documentary evidence from Lexon,[601] Medreich[602] and Focus[603] confirming that Lexon had committed not to supply Prochlorperazine POM other than the supply of the single batch necessary to avoid the Sunset Clause, and that Alliance and Lexon had agreed the terms on which Alliance would supply its product to Focus (see paragraphs 5.200 and 5.201 below).

The entry by Alliance and Lexon into the Implementing Agreements with Focus

5.154.7 The conduct of each of Alliance, Lexon and Focus, in entering into the Implementing Agreements that would enable Lexon to be paid from profits that Focus earned from the sale of the Alliance product, supports the finding that a pay for delay agreement been reached between Alliance and Lexon.

5.154.8 The Implementing Agreements were of an exceptional nature. They enabled Lexon (and Medreich) to be paid a significant share of the profits earned by Focus from the supply of Alliance product over five years. They

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[597] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[598] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood'* dated 24 June 2013 (URN: PRO-E000325).

[599] Email [Focus Director 1] to [Lexon Director 1] entitled *'Fwd: Rama as requested'* 10 July 2013 (URN: PRO-E000326).

[600] Email [Focus Director 1] to [Focus Director 2] entitled 'Prochlorperazine 3mg Tabs' 18 July 2013 (URN: PRO-E001478).

[601] Including email from [Lexon Director 1] to [Medreich Employee 1], entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750).

[602] Including '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich PLC Offices'* 29 June 2015 (URN: PRO-E002985), email [Medreich Director 2] to [Meiji employee] and [Medreich employee], cc various others at Medreich entitled *'RE: Follow up on the meeting in January'* 28 February 2017 (URN: PRO-E003257) and email [Medreich Director 2] to [Meiji employee], entitled *'RE: Prochlorperzaine --- profit sharing'* 21 July 2017 (URN: PRO-E003351).

[603] Including email [AMCo Employee 4] to various colleagues at AMCo entitled *'Project Capital – Ad Hoc PPRM_Agenda & Presentation'* 29 June 2015 (URN: PRO-E001635) attaching presentation entitled *'Project CAPITAL BD Workstream'* 30 June 2015 (URN: PRO-E001636) and email [Focus Employee 1] to [AMCo employee], entitled '*RE: Well Pharmacy price amendments – Focus lines*' 23 March 2017 (URN: PRO-E002030).

also involved Focus entering into supply agreements to become the exclusive supplier of both the Alliance and Lexon/Medreich products, yet agreeing to supply only the Alliance product.

5.154.9 Under the Alliance-Focus Agreement,[604] Alliance agreed to supply Focus at a fixed price that was equivalent to the price it had charged for branded Buccastem. Alliance agreed to this price despite at the same time opting to de-brand its product and remove it from the price and profit controls of the PPRS (see paragraphs 5.278 to 5.280). This enabled Focus to increase the price it charged for the Alliance product and to earn substantial profits from doing so, but ensured that Alliance itself could not profit from the price increases that it had enabled. Such conduct can be explained only on the basis of the Market Exclusion Agreement.

(a) In the absence of the price and profit controls of the PPRS, Focus implemented a series of price increases and earned gross profits of £14.4 million by July 2018 (see Figure 2 and Annex I:).

(b) The purpose of this margin transfer under the Alliance-Focus Agreement was to enable Focus to pay compensation to Lexon. Alliance's agreement to fix its own selling price, while at the same time enabling its distributor to increase its price and earn far greater returns, can credibly be explained only on the basis that Alliance had agreed to compensate Lexon, through Focus, for Lexon's agreement not to enter the market.

(c) The alternative explanations put forward by Alliance witnesses do not adequately explain the terms of the Alliance-Focus Agreement and the consequent margins afforded to Focus (see paragraphs 5.285 to 5.295 below).

5.154.10 Under the Focus-Lexon Heads of Terms,[605] Focus agreed to share with Lexon the majority of the profits Focus earned on the sale of Alliance's product, and such conduct can credibly be explained only on the basis of the Market Exclusion Agreement:

(a) The Focus-Lexon Heads of Terms required Focus to pay Lexon a significant percentage (initially 75%) of Focus' profits generated by the sale of Prochlorperazine POM from any source. This meant that Focus was obliged to pay the majority of its profits to Lexon even when supplying the Alliance product. By the end of July 2018, Focus had made payments totalling some £7.86 million to Lexon, £2.90

[604] Section 26 response of Alliance, part two, dated 16 November 2017, to CMA Notice dated 2 October 2017, Appendix 2, Alliance-Focus Agreement (URN: PRO-C0369).

[605] Document entitled *'Heads of Agreement'* signed 1 August 2013 (URN: PRO-E000429).

million of which Lexon passed to Medreich (see Annex I:), despite the fact that Lexon had not provided any product to Focus with the exception of a single batch (of [✂] packs, for which Lexon invoiced Focus £49,522.25[606] and which represented in volume less than 1% of Focus' total supply of the Alliance product to that point[607]) in March 2018.

(b) The alternative explanations put forward by Focus and Lexon witnesses as to why the profit share clause was included in the Focus-Lexon Heads of Terms, and as to why Focus was willing to continue to make payments to Lexon under the profit sharing clause over some four and a half years, despite the absence of any Prochlorperazine POM product apart from the single batch of March 2018, are not credible (see paragraphs 5.304 to 5.345 and paragraphs 5.532 to 5.555) below).

5.154.11 Focus entered into conflicting agreements, where it was appointed as the sole supplier of the Lexon product, yet was prohibited from supplying it as a result of the exclusivity provision under the Alliance-Focus Agreement. Such conduct can credibly be explained only on the basis of the Market Exclusion Agreement:

(a) Focus' willingness to sign up to incompatible exclusivity provisions under the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms further supports the finding of the Market Exclusion Agreement between Alliance and Lexon (see paragraphs 5.346 to 5.349 below).

(b) [Focus Director 1]'s claim that there was not an exclusivity obligation on Focus under the Alliance-Focus Agreement is not persuasive (see paragraph 5.351 below); similarly, his explanation of Focus' rationale for entry into the two agreements cannot be sustained (see paragraph 5.354).

[606] Section 26 response of Lexon dated 27 November 2018, to CMA Notice of 7 November 2018, questions 4(b) and 4(c) (URN: PRO-C2977): [✂].

[607] Focus had supplied over one million packs of the Alliance product to the end of February 2018 (see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150)).

Subsequent conduct and documentary evidence after the Implementing Agreements supporting the existence of the Market Exclusion Agreement – Alliance

5.154.12 The subsequent conduct and documentary evidence relating to Alliance provides further evidence of the existence of the Market Exclusion Agreement. It includes:

(a) Alliance's decision to de-brand Buccastem, while at the same time accepting the fixed price on its sales of the de-branded product to Focus which can credibly be explained only on the basis of the Market Exclusion Agreement.

(b) Internal Alliance documents in Spring/Summer 2013 which regularly referred to its concerns regarding Lexon's potential market entry. However, having entered into the Market Exclusion Agreement, such references came to an end. This is consistent with Alliance having considered that, pursuant to the Market Exclusion Agreement, the Lexon entry threat had been removed (see paragraph 5.408 below).

(c) Alliance's sale forecasts which demonstrate that, having entered into the Market Exclusion Agreement, Alliance did not expect that Lexon's product would be launched on to the market (see paragraphs 5.379 to 5.405 below).

Subsequent conduct and documentary evidence after the Implementing Agreements supporting the existence of the Market Exclusion Agreement – Lexon

5.154.13 The subsequent conduct and documentary evidence relating to Lexon provides further evidence of the existence of the Market Exclusion Agreement. It includes:

(a) Lexon documentation following the conclusion of the Focus-Lexon Heads of Terms which indicates anticipation of healthy returns[608] solely from Focus' sale of the Alliance product, without Lexon having to (or intending to) launch its own product (see paragraph 5.419 below).

(b) Lexon documentary evidence indicating that – in contrast to Lexon's commercial position for prochlorperazine 5mg tablets, which shared the same API – Lexon did not want Medreich to produce Prochlorperazine POM product. Specifically, [Lexon Director 1]'s

[608] Document entitled *'Lexon (UK) Limited Board Meeting Minutes'*, dated 12 September 2013, page 2 (URN: PRO-C0054).

response of 4 February 2014 to an email from [Medreich Employee 1] relating to commercialisation of prochlorperazine, in which [Lexon Director 1] had stated that: *'3mg POM is best left alone as we make far much [sic] more as it is. I have agree [sic] that we make a batch every 3 years and drift it into the Alliance stock… The 5mg … If we can make it work then happy to proceed'*[609] (see paragraph 5.422 below).

(c) Despite Medreich obtaining its Prochlorperazine POM licence on 9 January 2014, Lexon ordered on 23 June 2015 only the single batch required for the purposes of keeping the licence active[610] (see paragraph 5.434 below).

(d) The evidence that – despite Medreich not having supplied any product – in late June 2015 Lexon considered itself in a commercial position to cite to Focus Medreich's resistance of a renegotiation of the profit sharing arrangement in AMCo/Focus' favour until such time as AMCo had secured its own MA[611] (see paragraph 5.470 below).

Subsequent conduct and documentary evidence after the Implementing Agreements supporting the existence of the Market Exclusion Agreement – Focus

5.154.14 The subsequent conduct and documentary evidence relating to Focus provides further evidence of the existence of the Market Exclusion Agreement. It includes:

(a) Focus' internal forecasts which assumed that product would be ordered only from Alliance,[612] and the lack of any Focus forecasts to Lexon regarding ongoing product requirements, despite having entered into the Focus-Lexon Heads of Terms (see paragraphs 5.485 and 5.486 below).

(b) Following Focus' acquisition by AMCo in October 2014, and having secured a Prochlorperazine POM development of its own through its June 2015 acquisition of Primegen, AMCo's analysis[613] and use of the Primegen development as part of the second profit share

[609] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'Re: Products'* 4 February 2014 (URN: PRO-E002750).

[610] Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, question 2.2 (URN: PRO-C3856).

[611] Email [Focus Director 1] to [Focus Director 2] entitled *'Prochlorperazine 3mg'* 26 June 2015 (URN: PRO-E001634).

[612] See Email [Focus Director 1] to [Focus Director 2] entitled *'FW: other OLS for budget'* 14 November 2013 (URN: PRO-E003759).

[613] Email [AMCo Employee 4] to various colleagues at AMCo entitled *'Project Capital – Ad Hoc PPRM_Agenda & Presentation'* 29 June 2015 (URN: PRO-E001635) attaching presentation entitled *'Project CAPITAL BD Workstream'* 30 June 2015 (URN: PRO-E001636).

renegotiation with Lexon supports the CMA's finding that an agreement had been reached between Alliance and Lexon under which profit would be shared with Lexon as compensation for not entering the market (see paragraphs 5.490 to 5.507 below). In particular:

i. The second profit share renegotiation between Focus and Lexon was prompted by the grant of the Primegen licence (consistent with the existence of the Market Exclusion Agreement), rather than by any failure by Lexon to supply product[614] (see paragraph 5.500).

ii. Evidence from June 2015[615] shows that AMCo was aware that launching its own Primegen product would prompt Lexon's market entry, and demonstrates that AMCo regarded Lexon's decision not to supply its product as a consequence of the Market Exclusion Agreement rather than an inability to supply product (see paragraphs 5.497 to 5.499).

iii. AMCo used the Primegen licence as leverage in profit share re-negotiations with Lexon, pursuant to the Market Exclusion Agreement, rather than to launch its own (cheaper) product (see paragraphs 5.314 to 5.324 and paragraphs 5.501 to 5.504).[616]

(c) Focus continued to make payments to Lexon over the course of four and a half years despite the lack of receipt of any product (other than a single batch in March 2018), as compensation for Lexon's non-entry into the market.

i. Focus ultimately paid Lexon a total of £7,861,912.90 despite failing to receive any product from Lexon under the Focus-Lexon Heads of Terms except for a single batch of product in March 2018 (see paragraph 5.524 below), which itself was provided for under the Market Exclusion Agreement to avoid the application of the Sunset Clause.

ii. Focus did not revisit or question that it should make profit share payments to Lexon despite the lack of product (see paragraph 5.526 below).

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[614] Email [Focus Director 1] to [Lexon Director 1] entitled *'prochlorperazine 3mg Tabs'* 26 June 2015 (URN: PRO-E003877).

[615] Email [AMCo Employee 4] to various colleagues at AMCo entitled *'Project Capital – Ad Hoc PPRM_Agenda & Presentation'* 29 June 2015 (URN: PRO-E001635) attaching presentation entitled *'Project CAPITAL BD Workstream'* 30 June 2015 (URN: PRO-E001636).

[616] Email [AMCo Director 2] to [Focus Employee 1], entitled *'Re: Prochlorperazine Buccal Tabs'* 8 February 2016 (URN: PRO-E001757).

iii. Alternative explanations for Focus' and AMCo's continued willingness to pay profit share payments to Lexon, despite the absence of product received, as put forward by witnesses, cannot credibly explain their conduct (see paragraphs 5.314 to 5.340 and paragraphs 5.532 to 5.555 below).

(d) Later documentary evidence from Focus / AMCo provides further evidence of the existence of the Market Exclusion Agreement. In an email of 23 March 2017, [Focus Employee 1] observed to [AMCo employee] that Focus generally sold Prochlorperazine POM to mainline wholesalers (which would not include Lexon) but stated that, by way of exception, Focus did sell to Lexon in its wholesaler capacity. By way of explanation, [Focus Employee 1] stated: *'The only reason that Lexon gets Prochlorperazine Buccal Tablets is because they helped set up the supply agreement with Alliance Pharma (who also make our Aspirin EC 300mg).'*[617] In other words it was Focus' understanding that: (i) rather than receiving Prochlorperazine POM tablets from Lexon (as contemplated by the Focus-Lexon Heads of Terms), Focus in fact supplied Prochlorperazine POM to Lexon (in its capacity as a wholesaler); and (ii) the 'only reason' that Focus supplied Lexon with Prochlorperazine POM was because Lexon, '*helped set up the supply agreement with Alliance*' (see paragraph 5.556 below).

Subsequent conduct and documentary evidence after the Implementing Agreements supporting the existence of the Market Exclusion Agreement – Medreich

5.154.15 The subsequent conduct and documentary evidence relating to Medreich provides further evidence of the existence of the Market Exclusion Agreement. It includes:

(a) Evidence from Medreich in early 2014, and after being briefed by [Lexon Director 1], showing that Medreich considered that its future annual budgets could be based on Medreich's share of the profits earned from Focus supplying the Alliance product, rather than on the basis of Medreich/Lexon launching their own Prochlorperazine POM product[618] (see paragraph 5.567 below).

(b) The fact that, in respect of prochlorperazine 5mg tablets, following the receipt of written instructions to proceed from Lexon in February 2014,

[617] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030).

[618] Email from [Medreich Employee 1] to [Medreich Director 1] entitled *'RE: Prochlorperazine 3 mg x 50 Focus'* 28 March 2014 (URN: PRO-E002787) attaching Excel Spreadsheet entitled *'Prochlorperazine 2014 budget'* (URN: PRO-E002788).

Medreich proceeded to launch prochlorperazine 5mg, as evidenced by Medreich plc (the commercial arm) placing an order with Medreich Ltd (the manufacturing arm) for prochlorperazine 5mg tablets on 21 March 2014 and then producing a validation batch for prochlorperazine 5mg tablets in September/October 2014:[619] by contrast, Medreich did not take any such internal actions in relation to Prochlorperazine POM tablets until June 2015 (see paragraph 5.565).

(c) Evidence from Medreich in March 2014 showing that Medreich was aware of Alliance's involvement in relation to the Prochlorperazine POM arrangement that had been negotiated by Lexon and which involved Focus, and which Medreich described as a '*clever arrangement*'[620] (see paragraph 5.569).

(d) Evidence from Medreich in June 2015 showing Medreich's understanding that [Lexon Director 1]'s order of a single batch was for the purpose of keeping the licence active[621] (see paragraph 5.573 below).

(e) Later documentary evidence from Medreich in which Medreich employees outlined the essential features of the Market Exclusion Agreement, from Medreich's perspective, to Medreich's new owners, Meiji. First, [Medreich Director 2] explained in an internal email of February 2017 that Prochlorperazine POM was a product that had not been ordered despite being approved, adding that: '*When we do profit share deals, there is no written agreement, it is gentleman [sic] word and invoices are raised based on off the record workings*.'[622] Second, in a further email on 21 July 2017, [Medreich Director 2] explained Medreich's understanding that: *'3mg has never been manufactured or supplied .. Profit share comes from 3mg only. There is a deal in place that for Medreich Not [sic] to bring 3mg in market we get royalty…'*[623] (see paragraphs 5.575 to 5.577).

5.155 The CMA has taken account of the witness evidence and the Parties' representations in relation to the evidence set out above; the documentary

[619] Medreich submission of 8 November 2021, in response to CMA questions of 22 October 2021, paragraphs 2.2, 2.3 and 3.1 (URN: PRO-C7817).

[620] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002803).

[621] '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich PLC Offices'* 29 June 2015 (URN: PRO-E002983 and PRO-E002985).

[622] Email [Medreich Director 2] to [Meiji employee] and [Medreich employee], cc various others at Medreich entitled *'RE: Follow up on the meeting in January'* 28 February 2017 (URN: PRO-E003257).

[623] Email [Medreich Director 2] to [Meiji employee], entitled *'RE: Prochlorperzaine --- profit sharing'* 21 July 2017 (URN: PRO-E003351).

evidence, witness evidence and the associated representations of the Parties are addressed in detail below.

Correspondence between [Focus Director 1] and [Lexon Director 1] in 2014

5.156 The CMA has also considered in detail as part of its analysis correspondence in the form of three email exchanges between [Focus Director 1] and [Lexon Director 1] in 2014 that refers to the supply of product, but that do not specify whether any such supply would be limited to the single batch of product needed to avoid the application of the Sunset Clause or to a plan to supply commercial volumes of the product (see paragraphs 5.582 to 5.620).

5.157 The CMA does not rely on these documents to establish the existence of the Market Exclusion Agreement. However, it finds that these emails do not support the Parties' claims that they are evidence of Lexon's intention to supply or Focus' intention to order commercial volumes of Prochlorperazine POM. With regard to these email exchanges, when considered in the round and in the context of the surrounding documentary evidence and the Parties' conduct, the CMA finds that:

5.157.1 they are not explained by an expectation on the part of Lexon and/or Focus of the supply by Lexon to Focus of commercial volumes of Prochlorperazine POM; and

5.157.2 they can each plausibly be explained by one or more interpretations that do not involve an expectation on the part of Lexon or Focus of the supply by Lexon to Focus of commercial volumes of Prochlorperazine POM product (see further Annex F:).

Events leading to the Market Exclusion Agreement

Introduction and section summary

5.158 Based on the evidence set out below in this section, the CMA finds that, in the period February 2013 to June 2013:

5.158.1 Lexon, a potential competitor, and Alliance, the incumbent supplier, were in direct contact with each other in relation to the supply of prochlorperazine; and

5.158.2 the discussions related to both the P and POM products. Those discussions included a potential supply arrangement between Alliance and Lexon, pursuant to which only one of the suppliers' POM products would have been marketed.

The documentary evidence of discussions relating to Prochlorperazine POM in the period prior to the Market Exclusion Agreement

5.159 Internal Alliance documentary evidence demonstrates that Lexon and Alliance were in contact in relation to the Prochlorperazine POM product in early 2013.

5.160 The minutes of an Alliance *'UK Review & Planning Meeting'* on 14 March 2013, record that, *'[Alliance Employee 1] has had discussions with contacts at Lexon on threat of generic prochlorperazine'*.[624] These minutes followed an internal Alliance email on 27 February 2013 from [Alliance Employee 2] to [Alliance employee] entitled '*rama*' indicating that [Alliance Employee 1] had been informed that the entry threat was imminent; specifically, that email had stated: *'Can you please do a quick check on Rama for Buccastem/Prochlorperazine. [Alliance Employee 1] has mentioned a competitor is due to bring out another line in a few weeks'.*[625]

5.161 The minutes of the 14 March 2013 meeting also recorded that, in the face of Lexon's potential entry, Alliance was considering how to respond and that further communication with Lexon should take place. Alliance's defence options, which concerned its POM product,[626] were recorded *as 'Do nothings [sic], deal on branded or launch generic'*. It is inferred that the 'do nothings' option involved Alliance not taking any positive action; the 'deal on branded' was, most likely, a potential 'brand equalisation' deal; and 'launch generic' would have involved Alliance launching a generic product and competing with the new entrant. The minutes of the meeting also record that Alliance would remain in contact with its potential competitor Lexon: '*Keep dialogue open. Keep very close eye on'.*

5.162 An internal Alliance email written by [Alliance Employee 2] entitled *'Buccastem/Prochlorperazine generic threat'* on 18 March 2013 recorded that Lexon had communicated its intention to launch a generic version of Buccastem and that, after reviewing the other products in the Lexon portfolio, Alliance considered that Lexon may only have a parallel import licence. Alliance considered the prospect of a parallel import licence was *'not as bad as if they are launching a straight generic as the prices are likely to still be quite high.'*[627] The email also confirmed that Alliance proposed to continue to communicate with its potential

[624] Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' dated 14 March 2013 09:00 – 12:00, page 8 (URN: PRO-E000971).

[625] Email [Alliance Employee 2] to [Alliance employee] entitled *'rama'* 27 February 2013 (URN: PRO-E000969). 'Rama' is a subscription service managed by the MHRA providing licensing information about products authorised in the UK. A hard copy notebook obtained by the CMA during its inspection at Alliance (CXH007) contained an entry on page 1 dated 1 March 2013 recording '*Buccastem – Potential generic threat -> switch to generic packaging – Lexon?*' (URN: PRO-E003981).

[626] The terminology of '*deal on branded or launch generic*' relates to the supply of prescription only medicines.

[627] Email [Alliance Employee 2] to [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 18 March 2013 (URN: PRO-E000976).

competitor noting that [Alliance Employee 1] would *'make contact with Lexon again to keep dialogue open and try to gain further information'.*[628]

5.163 By 21 March 2013, it is evident that Alliance had gained further information from Lexon which confirmed that Lexon's product would be generic prochlorperazine, that it would be sourced from India with a low supply price, and that it would not be a parallel import of its own product. An internal Alliance email from [Alliance employee] to [Alliance Employee 2], [Alliance Employee 1] and [Alliance Director 2] set out *'a summary of the meeting yesterday and update on the latest situation',*[629] recording that *'Lexon have communicated they have a generic license [sic] for both the 8s and 50s buccal prochlorperazine 3mg'* and that the *'product is coming from India with low CoGS [cost of goods]'*.[630]

5.164 The [Alliance employee] 21 March 2013 email summarising the meeting records that Alliance was, at that time, considering three potential responses to the information that it had received from its potential competitor, two of which related to Lexon and Alliance co-operating to supply only one of their two products. Both arrangements (involving Lexon supplying Alliance or Alliance supplying Lexon) would have enabled the suppliers to share in the monopoly profits earned from supplying one of the products, and would have avoided competition between the two undertakings. The other option that was considered was to de-brand Alliance's product, to launch the generic product and '*name price*'. The email records that these options had been discussed at an internal Alliance meeting on 20 March 2013, and that [Alliance Employee 1] and [Alliance Employee 2] would discuss the supply options further with Lexon:

> *'The options for Alliance now are as follows:*
>
> *'1) De-brand Buccastem, launch generic prochlorperazine in to Category A and name price. ['**Option 1**']*
>
> *2) De-brand Buccastem and gain supply of generic from Lexon, launch into Category A with an increase in price due to an increase in CoGS. Sell*

[628] Email [Alliance Employee 2] to [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 18 March 2013 (URN: PRO-E000976).

[629] In an interview with the CMA, [Alliance Employee 1] accepted that the email was a summary of an earlier meeting. Interview [Alliance Employee 1] Part 1 page 96, lines 11-16 (URN: PRO-C2909).

[630] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986). Although [Alliance Employee 1] could not remember how this information was received from Lexon, he stated in his interview with the CMA that *'that shows that that information had been communicated then'.* Interview [Alliance Employee 1], 4 October 2018, part 1, page 96, line 23 to page 97, line 4 (URN: PRO-C2909). [Alliance Employee 2] also confirmed that she believed the information contained in the extract was communicated from Lexon. Interview [Alliance Employee 2], 3 October 2018, page 79, lines 14-22 (URN: PRO-C2945). In an interview with the CMA [Alliance Director 2] also surmised that there must have been further contact between Alliance and Lexon between the 18 March 2013 and 21 March 2013 emails stating *'…I can only surmise that they've had a meeting and they've said, "No, it's a straight generic", but that's supposition putting those two together...'.* Interview [Alliance Director 2], 5 October 2018, page 78, lines 21-23 (URN: PRO-C2941).

*Lexon product in Alliance livery. The problem with this option is there are 2 years' worth of Buccastem M stock already manufactured. ['**Option 2**']*

*3) Alliance to supply Lexon with generic product. ['**Option 3**']*

[Alliance Employee 2] and [Alliance Employee 1] will be meeting with Lexon in Gloucester on the 12th April to discuss supply further'.[631]

5.165 It is evident that the information Alliance had received from Lexon included the Prochlorperazine POM product and that it was considering options in respect of that product:

5.165.1 the 21 March 2013 email refers explicitly to Lexon having communicated that it would have a generic licence for '*both the 8s and 50s buccal prochlorperazine 3mg*', that is including the Prochlorperazine POM Product;

5.165.2 [Alliance Employee 2] told the CMA that she understood that the references to the *'threat of generic prochlorperazine'* in the 14 March 2013 meeting minutes was a reference to the POM product rather than the P Product;[632]

5.165.3 the options being discussed by Alliance in the emails are specific to the supply of prescription medicines, rather than to over-the-counter supply. [Alliance Director 2] confirmed that the references to de-branding Buccastem and launching the generic product into Category A of the Drug Tariff was relevant only to the supply of prescription medicines;[633]

5.165.4 in early 2013, in parallel to exploring supply options with Lexon, Alliance had also been exploring the option of launching its own generic Prochlorperazine POM (i.e. Option 1) and using Creo Pharma (a company described by Alliance, alongside Focus, as a '*specialty generics compan[y]*'[634]) to distribute that product. Creo Pharma told the CMA that it had first discussed the potential distribution of Prochlorperazine POM (as well as a number of other products) with Alliance at a meeting on 28 February 2013;[635] and

[631] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*RE: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

[632] Interview [Alliance Employee 2], 3 October 2018, page 54, line 20 to page 55, line 3 (URN: PRO-C2945).

[633] [Alliance Director 2] told the CMA that the discussion in the 21 March 2013 email could not be about an OTC product *'because it's an A'*; Interview [Alliance Director 2], 5 October 2018, page 81, lines 9 – 14 (URN: PRO-C2941). See also Interview [Alliance Employee 1] Part 1, page 102, lines 2 – 15 (URN: PRO-C2909).

[634] Section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017 paragraph 12 (URN: PRO-C0367).

[635] Section 26 response of Creo Pharma dated 17 October 2018, to CMA Notice of 4 October 2018, question 2(a) (URN: PRO-C2624).

5.165.5 following the initial contact with Creo Pharma in February 2013, on 9 April 2013, three days before an in-person meeting between Alliance and Lexon (referred to below at paragraph 5.168), [Alliance Employee 1] again contacted Creo Pharma to discuss the possibility of Creo Pharma distributing Alliance's Prochlorperazine POM: '*I would also like to pick your brains regarding options for prochlorperazine now that Lexon are coming with a generic for both the 50 pack and the 8 pack in the 3mg'*.[636]

5.166 Following the 14 March 2013 UK Review & Planning Meeting and the 21 March 2013 email, neither [Alliance Employee 1], [Alliance Director 2] nor [Alliance Director 1] expressed any concern about the competition law implications of [Alliance Employee 1] and [Alliance Employee 2] meeting on multiple occasions with a potential competitor to discuss such agreements, or with seeking further information concerning its entry. There is no evidence in the 14 March 2013 UK Review & Planning Meeting minutes of [Alliance Director 1] expressing any concern about Alliance's intention to keep open the dialogue with Lexon. In his reply to the email of 21 March 2013 setting out the three options cited above, [Alliance Employee 1] responded that *'it would be prudent to expedite a move to a generic version… to give flexibility of options'*.[637] Similarly, [Alliance Director 2] emailed [Alliance Director 1] on 21 March 2013 to inform him that *'…unfortunately the Buccastem threat would appear to be real, and not a PI threat. We are working on our defence strategy accordingly and I'll keep you informed as this is pulled together.'*[638]

5.167 Following the initial contact in February 2013 between Lexon and Alliance regarding the anticipated launch of Lexon prochlorperazine products, there is evidence of two further in-person meetings between Lexon and Alliance in relation to the product.[639]

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[636] Email [Alliance Employee 1] to [Creo Pharma employee] entitled *'Meeting 22nd'* 9 April 2013 (URN: PRO-E000991).

[637] Email [Alliance Employee 1] to [Alliance employee] and [Alliance Employee 2] cc [Alliance Director 2] entitled '*RE: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000987).

[638] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*FW: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000988). In his witness statement, [Alliance Director 2] stated that he would have '*encouraged meeting with them [Lexon] for verification purposes, i.e. to ensure that the news of impending competition was (and remained) genuine and there was therefore good reason as to why APL [Alliance] should continue to consider debranding its product'* (Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 3.10(a) (URN: PRO-C5098)).

[639] In his witness statement, [Lexon Director 1] accepted that two meetings took place but stated that the first meeting was held towards the end of February 2013 and the second meeting was the meeting held on 12 April 2013; [Lexon Director 1] denied that a further meeting took place after the meeting on 12 April 2013 ([Lexon Director 1] witness statement paragraph 46 (URN: PRO-C5092)). This claim is addressed in paragraphs 5.183 to 5.187 below and, for the reasons set out, is not accepted by the CMA.

5.168 The first meeting took place on 12 April 2013 (the '**First Meeting**'), at a hotel in Gloucester, and was attended by [Alliance Employee 1], [Alliance Employee 2] and [Lexon Director 1], each of whom recalled this meeting taking place.[640]

5.169 The scheduling of the First Meeting was referred to in the 21 March 2013 email referred to in paragraph 5.164 above. Having set out the possible Alliance 'defence' options for its POM product, the email concludes that *'[Alliance Employee 2] and [Alliance Employee 1] will be meeting with Lexon in Gloucester on the 12th April to discuss supply further'*.

5.170 The contemporaneous documents demonstrate that Alliance continued actively to explore the possibility of de-branding its Prochlorperazine POM following the First Meeting, and considered supplying its de-branded product to Creo Pharma who would then distribute it to pharmacies and wholesalers (which is consistent with 'Option 1' in the 21 March 2013 email (see paragraph 5.164 above)). Specifically:

5.170.1 On 8 May 2013, [Alliance Employee 1] emailed [Creo Pharma employee] to inform him that it *'[l]ooks like we are going to launch prochlorperazine as a generic so there is potential to add this into the mix in a few months.'*[641]

5.170.2 On 13 May 2013, internal Alliance meeting notes record that, in relation to Prochlorperazine POM, [Alliance Employee 1] was *'[p]rogressing launch of generic Prochlorperazine to combat the anticipated launch of competitor product by Lexon… Planning split batch of Buccastem and Prochlorperazine. Collaborating with **[Alliance Employee 1]** to progress this and submit to Cat A. Prochlorperazine 3mg will potentially be marketed/traded through Creo Pharma'*.[642]

5.170.3 On 23 May 2013, [Alliance Employee 1] informed colleagues at Alliance that he was *'reviewing a contract regarding supply of a number of our generic portfolio to a specialist company (Creo)… The first product is … (others are expected to follow – … – prochlorperazine as and when)…'*.[643]

5.171 According to [Alliance Employee 1] in interview and based on Alliance's written information provided to the CMA, a second in-person meeting took place between [Alliance Employee 1] and [Lexon Director 1] after the First Meeting on 12 April 2013 (the '**Second Meeting**'). Based on the evidence provided by Alliance and [Alliance Employee 1], and the fact that [Alliance Director 2] subsequently referred

[640] Interview [Alliance Employee 1] part 1, page 93, lines 7-9 and pages 99-100 (URN: PRO-C2909); Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraphs 44 and 45 (URN: PRO-C5092); Interview [Alliance Employee 2], 3 October 2018, page 22, lines 1-8 (URN: PRO-C2945).

[641] Email [Alliance Employee 1] to [Creo Pharma employee] entitled *'RE: Indapamide'* 8 May 2013 (URN: PRO-E000995).

[642] Community and Consumer Products Report, dated 13 May 2013, page 5 (URN: PRO-E001008).

[643] Email [Alliance Employee 1] to various recipients at Alliance entitled '*Supply of stock to third party distributor'* 23 May 2013 (URN: PRO-E001005).

on 7 June 2013 to [Alliance Employee 1] having worked up a 'plan' (see paragraph 5.172 below), which appears to have differed from the options previously considered within Alliance, the CMA finds that the timing of the Second Meeting is most likely to have been in late May or early June 2013. As outlined further below, [Alliance Employee 1] told the CMA that at that meeting, in Alliance's words, [Lexon Director 1] *'proposed a supply agreement in relation to the POM'.*[644]

5.172 Following the Second Meeting, Alliance's thinking regarding its response to the Lexon threat saw a significant change. As discussed in more detail in Annex B:, Alliance's internal documents no longer referred to the possibility of appointing Creo to supply Prochlorperazine POM (see paragraph 5.283 below) and proceeded instead to refer only to the appointment of Focus, on terms that would allow Focus to determine its own selling price and to earn a profit margin over and above an agreed transfer price of £5.65 (see paragraph 5.278) and that could (and did) enable Focus to retain a far greater share of the profits earned on supplying the product than would (based on Alliance's arrangements with Creo in relation to other products (see paragraph 5.283 below)) have been retained by Creo had it been supplied instead. The conclusion of a defence plan involving Focus was recorded internally within Alliance:

5.172.1 [Alliance Employee 1] presented a proposed defence plan to senior colleagues within Alliance. On 7 June 2013, after the Second Meeting, [Alliance Director 2], to whom [Alliance Employee 1] reported, emailed [Alliance Director 1] [✂] and [Alliance Director 3], explaining that [Alliance Employee 1] had developed a defence plan that [Alliance Director 2] was comfortable with: *'Buccastem Defence plan [Alliance Director 1] and [Alliance Director 3] – [Alliance Employee 1] has worked up a plan which I'm comfortable with but I'd also like him to take you through his thoughts'*.[645]

5.172.2 On 10 June 2013, three days after [Alliance Director 2]'s email of 7 June 2013, an internal Alliance document records, for the first time in 2013, the option of Alliance supplying Prochlorperazine POM through Focus rather than Creo Pharma. [Alliance Employee 2] emailed colleagues at Alliance to inform them that: *'We have a project ongoing to plan to react to the threat of a generic Prochlorperazine 3mg buccal entrant into the UK market. One of the options we are reviewing would be to cease*

[644] Alliance RSO, 1 August 2019, paragraph 3.12 (URN: PRO-C5096); Interview [Alliance Employee 1] part 1, page 26 lines 20 to 24 and page 27, line 18 to page 28, line 4 (URN: PRO-C2909).

[645] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*CCG switch and Buccastem defense [sic]*' 7 June 2013 (URN: PRO-E001009).

manufacturing the branded 50s pack and drive all sales to a generic pack produced by Alliance but sold by another partner eg Focus.'[646]

5.173 The only prior agreement that Alliance had with Focus related to the supply of Aspirin 300mg E/C, but did not concern a situation in which Focus was appointed to improve Alliance's ability to compete with the anticipated entry of a rival. To the contrary, and as outlined in further detail below (see paragraph 5.284), under that agreement, Alliance sold its product to Focus (who was the only other MA holder and supplier of Aspirin 300mg E/C), Focus earned a considerable margin on re-selling Alliance's de-branded Aspirin 300mg E/C, and Focus committed not to supply its product on to the market such that Alliance's 300mg E/C would be the only product on the market.[647] Pursuant to the Aspirin Agreement, therefore, Alliance retained a monopoly in the supply of Aspirin 300mg E/C.

5.174 In conclusion, it is apparent from the documentary evidence that there was contact between Lexon and Alliance concerning the supply of Prochlorperazine POM. Such contact included the initial communication between [Lexon Director 1] and [Alliance Employee 1] (see paragraph 5.160) and the First Meeting. [Alliance Employee 1]'s reference to a Second Meeting after the First Meeting of 12 April 2013 is not itself referred to in the documentary evidence, and its existence and content is the subject of conflicting witness evidence, as discussed below. Following the Second Meeting referred to by [Alliance Employee 1], Alliance's documents record an abrupt change to Alliance's proposed strategy and refer only to the appointment of Focus.

The witness evidence regarding the timing and content of discussions between Alliance and Lexon

5.175 As set out in paragraphs 5.159 to 5.165 above, it is clear that at the time of the First Meeting Alliance was aware that Lexon had informed Alliance about its Prochlorperazine POM product. [Alliance Employee 1] told the CMA in interview that the reason for attending the First Meeting was to find *'out more information about … this product he [Lexon Director 1] said he was going to get licensed'*.[648] He accepted that the subject matter of the meeting had already been communicated to Alliance in advance of the meeting, and said that, although he could not speak for Lexon, he assumed the reason Lexon had divulged this

[646] Email [Alliance Employee 2] to [Alliance employee] cc [Alliance Employee 1] and [Alliance employee] entitled '*Buccastem'* 10 June 2013 (URN: PRO-E001010).

[647] An Alliance internal strategy presentation for a meeting that took place the week prior to the Aspirin Agreement being concluded described how Alliance and Focus were currently each supplying into the market but that, following the conclusion of the agreement, Alliance expected to: (i) hold a monopoly in the supply of the product; (ii) see an increase in the drug tariff price for the product; (iii) supply Focus at a fixed price that would enable it to earn a significant margin on the supply of the Alliance product; and (iv) significantly increase its own profits (*'[f]rom November 2011 Alliance will supply the complete UK market […]k pks via Focus @ […] – tariff increases to £9.90. This equates to an additional £13,140 profit per month or £158k pa / £170k pa gross'*) (Alliance presentation entitled '*Strategy Meeting EPBU [Alliance employee]'* 29/30 June 2011, slide 49 (URN: PRO-E000932)).

[648] Interview [Alliance Employee 1], 4 October 2018, part 1, page 22, lines 17-18 (URN: PRO-C2909).

information was because Lexon wanted *'something more specific, yes, to get some supply against his product licence…'*.[649]

5.176 [Alliance Employee 1] recalled attending the First Meeting but was unable to recall when the discussion of the POM product came up within Alliance.[650] [Alliance Employee 1] confirmed no decisions were made at the First Meeting[651] and that it was left for Alliance to go back and discuss the matters raised at the First Meeting.

5.177 [Alliance Employee 2] confirmed that both the P (i.e. OTC) Product and the POM Product were discussed at the First Meeting[652] and told the CMA that:

> *'[Lexon Director 1] indicated that they had been approached by a company called Medreich, to -- with a, generic licence for prochlorperazine on the POM and also on the P.'*[653]

5.178 [Alliance Employee 2]'s recollection that the First Meeting included discussion of the Prochlorperazine POM product is consistent with the 21 March 2013 email discussed above (see paragraph 5.164 above), which envisaged that discussions relevant to that product would take place.

5.179 In relation to the Second Meeting, [Alliance Employee 1] told the CMA that he recalled that the purpose of the Second Meeting was *'discussing if there was any option for supply with the POM'*.[654] In this regard, he told the CMA that he recalled having discussed the option of Alliance supplying Lexon with its product, and that he indicated that he would discuss that option with his colleagues at Alliance before reverting to [Lexon Director 1]:

> *'[Alliance Employee 1]: All I can remember is talking about some supply and me thinking I can't supply them. So, I said – pretty sure I would have said I need to go back, discuss this and if there is something we can do, we'll get in touch. …*
>
> *CMA: Did he put any other options to you at that point other than taking supply from Alliance?*
>
> *[Alliance Employee 1]: Sorry, I can't remember there being any other options.*
>
> *CMA: So, following that second meeting, what's your recollections of what happened back at Alliance following that?*

[649] Interview [Alliance Employee 1], 4 October 2018, part 1, page 22, line 20 to page 23 line 17 (URN: PRO-C2909).
[650] Interview [Alliance Employee 1], 4 October 2018, part 1, page 25, lines 25-26 (URN: PRO-C2909).
[651] Interview [Alliance Employee 1], 4 October 2018, part 1, page 25, line 14 (URN: PRO-C2909).
[652] Interview [Alliance Employee 2], 3 October 2018, page 31, lines 14-20 (URN: PRO-C2945).
[653] Interview [Alliance Employee 2], 3 October 2018, page 22, lines 24-26 (URN: PRO-C2945).
[654] Interview [Alliance Employee 1], 4 October, part 1, page 27, line 24 to page 28, line 4 (URN: PRO-C2909).

[Alliance Employee 1]: So, back at Alliance, I think … it was discussed and I think there were a few meetings to discuss. This was a – a threat for the … POM presentation. So, I think we'd realised with the P the risk was minimal. For the POM, clearly there's a desire for generic prescribing. So, if a competitor did come along, you would – you would lose a big proportion of your market share. So, as a result of that, I think there were a number of meetings to discuss potential defence strategies'.[655]

5.180 [Alliance Employee 1]'s recollection that the POM product was discussed at the Second Meeting is consistent with the evidence attributed to him by Alliance in a section 26 response and in its response to the Statement of Objections.[656]

5.181 [Alliance Employee 1]'s recollection of a meeting that included discussion of the supply of Prochlorperazine POM is supported by the evidence that [Alliance Director 1] *initially* provided to the CMA. Although in his witness statement [Alliance Director 1] now states that he has no recollection of *'any arrangement or possible arrangement with Lexon',*[657] he previously informed the CMA that Lexon and Alliance had discussed an agreement with Lexon (the nature of which is discussed further below) concerning the supply of Prochlorperazine POM. He stated that Lexon:

'invited [Alliance Employee 1] to a meeting to say that they had one in development or they were expecting, they didn't have a development, they were going to somehow access to it from another company and because of the established supply chain that we have, that they would, they would prefer to take ours. So we set a different arrangement up there, because we had to manufacture the consumer product, therefore we needed to keep manufacturing relationship going, therefore we took responsibility for the manufacturing of the product and we [Alliance] entered into a distribution agreement with Lexon and Lexon had, Lexon passed on that, some of the ongoing business relationship to Focus, so for Focus to sell the product into the generic market and I'm not sure why, how that occurred or why that occurred'.[658]

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[655] Interview [Alliance Employee 1], 4 October, part 1, page 33, line 23 to page 34, line 26 (URN: PRO-C2909). Consistent with this, Alliance told the CMA that *'At the second meeting in May 2013 [Lexon Director 1] proposed a supply agreement in relation to the POM'* (Alliance RSO, 1 August 2019, paragraph 3.12 (URN: PRO-C5096)).

[656] Alliance informed the CMA that, following the First Meeting: *'[Alliance Employee 1] and [Alliance Employee 2] reported back to Alliance and [Alliance Employee 1] recalls that Alliance was not interested in an agreement to supply the M product because that was a promoted product and had brand value. At a subsequent meeting with Lexon, he communicated to Lexon the decision of the Alliance business in relation to the M product. Lexon broached the possibility of supply of the 50 pack POM product. Again, [Alliance Employee 1] does not recall any other details of that meeting.'* Section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 18 (URN: PRO-C0367).

[657] Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraph 2.10 (URN: PRO-C5097).

[658] Interview [Alliance Director 1], 3 November 2017, part 2, page 30, lines 8 to 19 (URN: PRO-C1148).

5.182 [Alliance Director 1] also agreed with the proposition put to him that *'Lexon used…the Medreich forthcoming product as leverage to get [Alliance] to consider a deal with Focus'.*[659]

5.183 In a witness statement provided with Lexon's response to the Statement of Objections, [Lexon Director 1] submitted that there was no meeting with [Alliance Employee 1] after the 12 April 2013 meeting, and that any discussions with [Alliance Employee 1] were limited to the P product. [Lexon Director 1] stated that:

5.183.1 he was *'certain that there was no meeting with [Alliance Employee 1] in May 2013'*;[660]

5.183.2 the final meeting between him and [Alliance Employee 1] was the April meeting and that that meeting concerned the P product;[661]

5.183.3 [Alliance Employee 1] had, given the passage of time, confused the meetings and that it was in fact at their discussions in February 2013 that they initially discussed a supply arrangement for the P product with further (inconclusive) discussions held on that subject in April;[662] and

5.183.4 he does not recall any discussions having taken place with Alliance regarding the POM product.[663]

5.184 The CMA has considered these competing versions of events with reference to the objective facts and documents and to the overall probabilities. For the reasons set out below, the CMA rejects [Lexon Director 1]'s claims that (i) there were no discussions with Alliance concerning the POM product; and (ii) there was no Second Meeting after the meeting of 12 April 2013, for the reasons below.

5.185 First, [Lexon Director 1]'s claim that he and [Alliance Employee 1] only ever discussed the P product is contradicted by the following:

5.185.1 the contemporary Alliance documentary evidence cited above, all of which proceeds on the basis that Alliance had been informed by Lexon that it was expecting to launch Prochlorperazine POM and that meetings were held to discuss a supply arrangement in relation to Prochlorperazine POM (see paragraphs 5.160 to 5.165 above);

5.185.2 [Lexon Director 1]'s statement in an interview with the CMA that his discussions with [Alliance Employee 1] at the Healthcare Distributors' Association (HDA) event were about the OTC licence because he knew

[659] Interview [Alliance Director 1], 3 November 2017, part 2, page 33, lines 9 - 13 (URN: PRO-C1148).
[660] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 46 (URN: PRO-C5092).
[661] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraphs 46 and 47 (URN: PRO-C5092).
[662] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraphs 47 and 48 (URN: PRO-C5092).
[663] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 49 (URN: PRO-C5092).

that [Alliance Employee 1] *'was aware of the 50 [POM product] by then..'*.[664] However, in the absence of a discussion with [Alliance Employee 1] regarding the Prochlorperazine POM product being launched by Lexon, there is no credible way that [Lexon Director 1] could have known that [Alliance Employee 1] was aware of the POM product; and

5.185.3 there is no clear reason why, if [Lexon Director 1] considered it legitimate at that time to refer to his anticipated OTC licence, he would not have reached the same view regarding the POM licence. In fact, beyond referring to *'a bit of arrogance',*[665] [Lexon Director 1] failed to explain why he informed his competitor, Alliance, of his commercial strategy.[666]

5.186 Second, although [Lexon Director 1] states in his witness statement provided after issuance of the Statement of Objections that he can now be '*certain*' there was no meeting after 12 April 2013, when interviewed by the CMA he was very unsure as to the timing of his discussions with [Alliance Employee 1] and has provided no explanation as to why he was subsequently (in July 2019) able to recall the timing of the meetings in 2013 with far greater clarity than he had been at the time of his interview in September 2018. When asked in interview about whether he could recall the timing of his discussions with [Alliance Employee 1] he answered as follows:

> *'CMA: Would that have been, those discussions can you just help us in terms of the timeframe for those.*
>
> *[Lexon Director 1]: I can't remember to be blatantly honest.*
>
> *CMA: Would it have been around the same time as this correspondence [24 June 2013]?*
>
> *[Lexon Director 1]: I'm sure it would be I'm sure it would be.*
>
> *CMA: So we're talking so this correspondence is mid-2013, June 2013.*
>
> *[Lexon Director 1]: Yeah I'm guessing I can't remember so … whether it was before or afterwards … I can't remember I'm sorry apologies'*. [667]
> …
>
> *'[Lexon Director 1]: Again just to reiterate what I've said to yourself was I can't remember'.*[668]

[664] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 38, lines 20-22 (URN: PRO-C3192).
[665] Interview [Lexon Director 1], 10 September 2018, part 1, CD 1, page 26, lines 8-9 (URN: PRO-C3187).
[666] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 40, lines 12 to 17 (URN: PRO-C3192).
[667] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 39, lines 2 to 14 (URN: PRO-C3192).
[668] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 41, line 24 (URN: PRO-C3192).

5.187 By contrast, [Alliance Employee 1]'s evidence that there was a Second Meeting after the 12 April 2013 meeting and that discussions between Lexon and Alliance related to both the P and POM products is consistent with the documentary record and the conduct of Alliance:

5.187.1 [Alliance Employee 1] himself proactively volunteered in his interview with the CMA the fact that there had been a second meeting with [Lexon Director 1] after the meeting of 12 April 2013:

'[Alliance Employee 1]: So …. as you know, there was a meeting afterwards.

CMA: With [Lexon Director 1]?

[Alliance Employee 1]: With [Lexon Director 1].

CMA: A second in-person meeting?

[Alliance Employee 1]: Second meeting, yes.

CMA: Okay. Involving?

[Alliance Employee 1]: Just me. … Because I think it was more about the POM.'[669]

5.187.2 [Alliance Employee 1]'s evidence on the existence and content of the Second Meeting as provided in his interview was clear and confident, and the CMA sees no reason why [Alliance Employee 1] might have wished to mislead the CMA as to the existence of such a second meeting with [Lexon Director 1].

5.187.3 As set out at paragraphs 5.161 to 5.165 above, a number of internal Alliance documents proceed on the basis that Alliance had been informed by Lexon that their planned entry concerned both the POM and P products.

5.187.4 The existence of the Second Meeting, and its having included discussion of an agreement between Lexon and Alliance concerning Prochlorperazine POM, is consistent with Alliance's conduct in: (i) abruptly changing its strategy in the period shortly after the Second Meeting was thought to have occurred; (ii) the evidence cited in the section below that documents the nature of the agreement entered into by Alliance and Lexon.

[669] Interview [Alliance Employee 1], 9 October 2018, part 1, page 25, line 25 to page 26, line 16 (URN: PRO-C2909).

Conclusion

5.188 Taken together, the documentary and witness evidence demonstrate that in the period February to June 2013 Lexon, the potential entrant, and Alliance, the incumbent supplier, were in direct contact with each other in relation of the supply of prochlorperazine P and POM products. The Second Meeting included the discussion of a potential supply arrangement between Alliance and Lexon in relation to the POM product.

Documentary Evidence in June and July 2013 of the commencement of the Market Exclusion Agreement

Introduction and section summary

5.189 Based on the evidence set out in this section below, the CMA finds that the contemporary documents from June and July 2013 demonstrate that Alliance and Lexon had agreed that:

5.189.1 Alliance would exclusively supply its debranded generic Prochlorperazine POM to Focus at a fixed price;

5.189.2 Lexon would enter into an agreement with Focus in relation to Prochlorperazine POM that would enable Focus to share the profits earned from the sales of Alliance's Prochlorperazine POM with Lexon (that is, Alliance would indirectly transfer value to Lexon through Focus); and

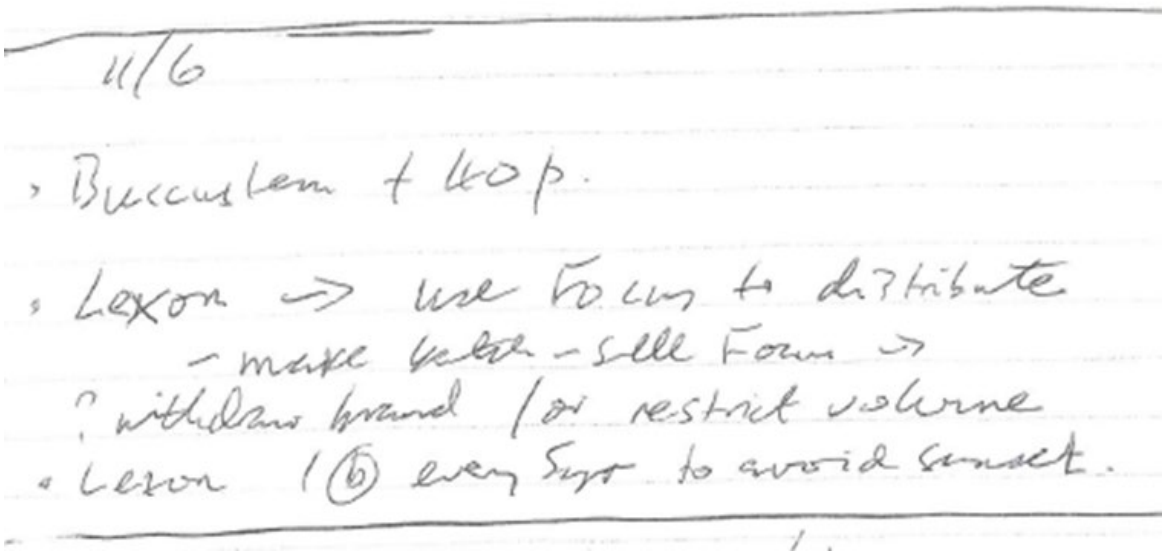
5.189.3 in return, Lexon would not supply commercial volumes of the product that it had jointly developed with Medreich.

The documentary evidence of the agreement between Alliance and Lexon

5.190 On 7 June 2013, after the Second Meeting between Alliance and Lexon, [Alliance Director 2], to whom [Alliance Employee 1] reported, emailed [Alliance Director 1], [✂], and [Alliance Director 3], [✂], about the '*Buccastem defence plan*'. [Alliance Director 2] explained that [Alliance Employee 1] had '*worked up a plan which I'm comfortable with*', adding '*but I'd also like him to take you through his thoughts […] Either way we need a direction by end of play next Thursday*' (14 June 2013).[670]

[670] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*CCG switch and Buccastem defense [sic]*' 7 June 2013 (URN: PRO-E001009).

5.191 On 11 June 2013, [Alliance Director 1] recorded a handwritten entry in his notebook:



'11/6

- *Buccastem + 40p*
- *Lexon → use Focus to distribute*

  - make batch – sell Focus →

  ? withdraw brand / or restrict volume
- *Lexon 1 [batch][671] every 5yr to avoid Sunset'*.[672]

5.192 In an interview with the CMA on 8 October 2018, [Alliance Director 1] accepted that the notebook entry could have recorded a discussion he had had with [Alliance Employee 1].[673] [Alliance Employee 1] similarly said in an interview with the CMA on 9 October 2018 that it was '*possible*' that the notebook entry recorded a meeting he had with [Alliance Director 1]. [Alliance Employee 1] also accepted he would have been the most likely person within Alliance to have briefed [Alliance Director 1] on the '*Buccastem defence plan*'.[674]

[671] During an interview with the CMA on 8 October 2018, [Alliance Director 1] confirmed that the 'b' within a circle was his shorthand for 'batch'. See Interview [Alliance Director 1], 8 October 2018, page 87, lines 9-12 (URN: PRO-C2944).

[672] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

[673] Interview [Alliance Director 1], 8 October 2018, page 80, lines 19-20 (URN: PRO-C2944). In his witness statement dated 29 July 2019, [Alliance Director 1] confirmed it was 'likely' he had been briefed in relation to Prochlorperazine POM on 11 June 2013 and that his notebook entry 'may' represent his note of a briefing by [Alliance Employee 1] in relation to Alliance's strategy for Prochlorperazine POM. Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraphs 2.12 and 6.3 (URN: PRO-C5097).

[674] Interview [Alliance Employee 1], 9 October 2018, part 2, page 7, line 24 to page 9, line 18 (URN: PRO-C2910). and part 1, page 64, line 26 to page 65, line 4 (URN: PRO-C2909).

5.193 The CMA concludes that [Alliance Director 1]'s notebook entry records a briefing that [Alliance Employee 1] gave to [Alliance Director 1] on 11 June 2013 about the '*Buccastem defence plan*' on the basis of these explanations: the closeness in time of the notebook entry to [Alliance Director 2]'s email of 7 June 2013, the fact that [Alliance Director 1]'s 11 June 2013 notebook entry clearly refers to '*Buccastem*' and the absence of any other explanation for [Alliance Director 1]'s notebook entry.

5.194 The plain reading of [Alliance Director 1]'s notebook entry is as follows:

5.194.1 The first line contemplates Alliance increasing the price of its Buccastem product by 40p.

5.194.2 The second and third lines record that Lexon would use Focus to distribute its product but then refer, in a sub-bullet, to Lexon manufacturing an individual '*batch*' and selling that to Focus.

5.194.3 The fourth line questions whether Alliance would either de-brand its Buccastem product entirely or restrict the volume of branded product that it would supply. This question can apply only to Alliance as Lexon had no brand to withdraw.

5.194.4 Continuing from the third line, which noted that Lexon would '*make*' an individual '*batch*', the fifth line records that Lexon would supply only one batch of product every five years[675] as a means of avoiding the Sunset Clause applicable to its marketing authorisation.

5.195 Consistent with the content of [Alliance Director 1]'s notebook entry of 11 June 2013 as set out above, [Focus Director 1] emailed [Focus Director 2] on 22 June 2013 a summary of the '*agreement [Lexon Director 1] made*' concerning the terms on which Focus would purchase Alliance's (that is Lexon's potential competitor's) supply of generic Prochlorperazine POM. The email also recorded the terms on which Focus would share the profits from its sales of Alliance's Prochlorperazine POM with Lexon.

> *'[Focus Director 2]*
>
> *In case [Alliance Employee 1] rings you , the agreement [Lexon Director 1] made was we initially buy at 25% off thier [sic] current trade price for the initial stock to allow us to open generic bins etc . When Alliance discontinue brand we purchase from them at current trade less 12.5% ie they keep the current asp and Focus sell the generic pack.*
>
> *Generic Pricing [sic] will depend on market and Focus will set !*

[675] The reference to five years in the notebook entry is an error as a Sunset Clause operates after a failure to make sales of the relevant product from three years of the grant of the marketing authorisation.

Deal between Focus and [Lexon Director 1]. 25/75 % profit share in Lexon favour (as it is his licence)

Volumes look higher on ethics line[676] *than I thought !*

We can have a chat on Monday . I am waiting on [Alliance Employee 1] ringing me back , but have [Lexon Director 1] chasing to see what is happening…'[677]

5.196 In considering [Focus Director 1]'s email of 22 June 2013, it is also relevant to take account of the following correspondence involving [Focus Director 1] in the succeeding weeks of June and July 2013.

5.196.1 Following on from [Focus Director 1]'s statement in his email of 22 June 2013 (above) that he was waiting to hear back from [Alliance Employee 1] in relation to Prochlorperazine POM, two days later, on 24 June 2013, [Lexon Director 1] and [Focus Director 1] exchanged emails: [Focus Director 1] informed [Lexon Director 1] that he had '*still not heard back from **[first name of Alliance Employee 1]***', to which [Lexon Director 1] replied that he would '*chase **[first name of Alliance Employee 1]** in the morning*'.[678]

5.196.2 On 10 July 2013, [Focus Director 1] forwarded [Lexon Director 1] a copy of a RAMA report[679] listing all product licences containing the active substance prochlorperazine maleate, commenting, '*I take it the Medrich [sic] licence is yours exclusively before I send this to **[Alliance Employee 1]***'.[680]

5.196.3 On 18 July 2013, [Focus Director 1] emailed [Focus Director 2] regarding Focus' anticipated monthly profits from the sale of Alliance's Prochlorperazine POM. The figures were based on the assumption that Alliance's '*brand is discontinued*', Focus would '*get all the prescriptions*' and supply all of Alliance's Prochlorperazine POM,[681] and Alliance '*agree to sell to [Focus] at their current ASP of trade less 12.5%*'.[682] [Focus

[676] The CMA understands that the reference to 'ethics line' refers to sales of prescription-only medicines (POM).

[677] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476). It is clear from the contents of the email that the *'[first name of Alliance Employee 1]'* referred to is [Alliance Employee 1] and the *'[first name of Lexon Director 1]'* is [Lexon Director 1]. This is also apparent from the CMA's interview with [Focus Director 1], see Interview [Focus Director 1], 2 October 2018, pages 109-138 (URN: PRO-C3294) and was not disputed as regards the content of this email by [Focus Director 1] or the Parties in their representations.

[678] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood'* dated 24 June 2013 (URN: PRO-E000325).

[679] RAMA is a subscription service managed by the MHRA providing licensing information about products authorised in the UK.

[680] Email [Focus Director 1] to [Lexon Director 1] entitled *'Fwd: Rama as requested'* 10 July 2013 (URN: PRO-E000326).

[681] [Focus Director 1]'s email of 18 July 2013 sets out a monthly volume of Prochlorperazine POM of 25,250 packs – equivalent to an annual volume of 303,000 packs; this volume would account for the entirety of annual demand (see Table 1) even allowing for some stock build by Focus in the first year.

[682] Email [Focus Director 1] to [Focus Director 2] entitled 'Prochlorperazine 3mg Tabs' 18 July 2013 (URN: PRO-E001478).

Director 1]'s calculations recorded that Focus envisaged raising the price it charged to wholesalers for Alliance's Prochlorperazine POM from £8 to £11.20 whilst retaining '*25%*' of the profits – that is the majority of the profits would not be retained by Focus. [Focus Director 1]'s email of 18 July 2013 does not mention Lexon, or any prospect of Focus obtaining product from Lexon.

5.197 The plain reading of [Focus Director 1]'s 22 June 2013 email is unambiguous, reporting that:

5.197.1 [Lexon Director 1] had agreed with Alliance that:

(a) Alliance would sell its de-branded Prochlorperazine POM to Focus;

(b) Focus would purchase Alliance's de-branded Prochlorperazine POM at a fixed price, determined by reference to a specified percentage discount to its current list price (initially 25%, before moving to 12.5%); and

(c) following the discontinuation of their branded product, Alliance would sell its Prochlorperazine POM to Focus at the same average selling price ('asp') per pack that it had sold its Buccastem POM to wholesalers.

5.197.2 Focus would then set the price at which it would sell Alliance's Prochlorperazine POM into the market.

5.197.3 Focus and Lexon had agreed that Focus would pass the majority of its profits (75%) from the sale of Alliance's Prochlorperazine POM to Lexon, on the basis that Lexon had (with Medreich) a marketing authorisation for the same product.

5.197.4 [Focus Director 1] was waiting to hear back from [Alliance Employee 1] but, in the meanwhile, [Focus Director 1] had '*[Lexon Director 1] chasing to see what is happening*'. When read in the context of the rest of his email, it can be inferred that this final sentence refers to [Lexon Director 1] making contact with [Focus Director 1] to find out what progress Focus had made in implementing the agreement that [Lexon Director 1] had negotiated in principle with Alliance.

5.198 [Focus Director 1]'s email of 22 June 2013 makes no reference to Focus either purchasing or selling any product from Lexon. Further, in the paragraph of the email setting out the profit share split under the Focus-Lexon Heads of Terms, [Focus Director 1] justified the proportion of the profit share split payable to Lexon by explaining to [Focus Director 2] that the split was '*in Lexon favour (**as it is his***

licence *)*' (emphasis added).[683] Had [Focus Director 1] actually anticipated Focus supplying Prochlorperazine POM sourced from Lexon, he would not have needed to explain specifically to [Focus Director 2] why the product manufacturer would retain a proportion of the profits from the sale of their product, as such an outcome would have been entirely normal. In contrast, the proposal to share the majority of Focus' profits from the sale of one supplier's (Alliance's) Prochlorperazine POM with another supplier (Lexon) would clearly require the type of explanation advanced by [Focus Director 1].

5.199 The plain reading of [Focus Director 1]'s 22 June 2013 email is supported by his further emails of 24 June 2013, 10 July 2013 and 18 July 2013.

5.199.1 In the email exchange on 24 June 2013, [Focus Director 1] informed [Lexon Director 1] that he was still yet to hear from '*[first name of Alliance Employee 1]*', to which [Lexon Director 1] responded that he would chase '*[first name of Alliance Employee 1]*' the next day.[684] In light of the proximity of this email to [Focus Director 1]'s 22 June 2013 email and the fact that there is no credible alternative '*[first name of Alliance Employee 1]*' to which [Focus Director 1] could have been referring (see further at paragraphs 5.248 to 5.253 below), the CMA understands that [Focus Director 1] was referring to [Alliance Employee 1]. The email exchange of 24 June 2013 is supportive of the CMA's interpretation of [Focus Director 1]'s email of 22 June 2013 for the following reasons.

(a) Absent any prior role for [Lexon Director 1] in agreeing with Alliance the terms on which Alliance would supply its Prochlorperazine POM to Focus, [Lexon Director 1] would have had no reason to '*chase*' [Alliance Employee 1] in regard to Alliance's proposed supply of Prochlorperazine POM to Focus.

(b) This is consistent with the plain reading of [Focus Director 1]'s email of 22 June 2013 – that is, two days prior to the email of 24 June 2013 – which recorded that an agreement had been reached between Alliance and [Lexon Director 1] as to the terms on which Alliance would supply its Prochlorperazine POM to Focus, that [Focus Director 1] was '*waiting*' for [Alliance Employee 1] to contact him in relation to that supply agreement, and that [Lexon Director 1] was '*chasing*' [Focus Director 1] to ascertain what progress had been made on implementing that supply agreement.

5.199.2 On 10 July 2013, [Focus Director 1] sought to confirm with [Lexon Director 1] that the '*Medrich [sic] licence*' for Prochlorperazine OTC listed in the

[683] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[684] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood'* dated 24 June 2013 (URN: PRO-E000325).

attached RAMA report was '*yours exclusively*' before [Focus Director 1] sent the RAMA report to '*[Alliance Employee 1]*'.[685]

(a) It can be inferred from [Focus Director 1]'s email of 10 July 2013 that [Lexon Director 1] knew in July 2013 that Focus was in discussion with Alliance in relation to the supply of Prochlorperazine POM.

(b) Further, it can be inferred that [Lexon Director 1] not only understood in July 2013 that Alliance would supply Focus its Prochlorperazine POM to Focus, but he also understood why: (i) Lexon's contractual status as regards Medreich's licence for Prochlorperazine POM[686] would be relevant to Alliance and (ii) that the status of the Prochlorperazine OTC licence would be informative in this respect such as to be worth providing to Alliance, and (iii) that this information was relevant to Alliance's decision to supply the Prochlorperazine POM product to Focus. The briefness of, and lack of explanation in, [Focus Director 1]'s email demonstrates that [Focus Director 1] assumed he did not need to explain to [Lexon Director 1] why he would send the RAMA report to Alliance, nor why he intended to confirm that Medreich's marketing authorisation for prochlorperazine was Lexon's '*exclusively*'. [Focus Director 1] clearly expected [Lexon Director 1] to understand why Focus would want to inform Alliance that Lexon had exclusive access to Medreich's marketing authorisation, i.e. to assure Alliance that a transfer of value to Lexon would be effective in delaying entry of a new Medreich Prochlorperazine POM product by confirming that the product was Lexon's '*exclusively*' and could not therefore reach the market from other sources.

(c) [Focus Director 1]'s email of 10 July 2013 is consistent with the plain reading of his 22 June 2013 email, which recorded that: [Lexon Director 1] had agreed with Alliance the terms on which Alliance would supply Focus, and therefore would have expected Focus to be in discussion with Alliance in relation to the supply of Prochlorperazine

[685] Email [Focus Director 1] to [Lexon Director 1] entitled *'Fwd: Rama as requested'* 10 July 2013 (URN: PRO-E000326).

[686] Although the RAMA report [Focus Director 1] proposed to share with [Alliance Employee 1] listed Medreich's licence for its Prochlorperazine OTC product, the CMA concludes that [Focus Director 1] intended to share this information to confirm that Lexon would be likely to obtain a Prochlorperazine POM licence (given these were the same product, albeit differently packaged) and to assure Alliance that the transfer of value would prevent that Prochlorperazine POM product entering the market as it was Lexon's '*exclusively*' and could not reach the market from other sources. It has never been suggested by any witness or undertaking that Focus had any interest or involvement in the Prochlorperazine OTC product. [Focus Director 1] would have had no interest in passing this to [Alliance Employee 1] unless Lexon's 'exclusivity' could also be taken as relevant to Prochlorperazine POM. Further, [Lexon Director 1] was aware that Focus did not have expertise in supplying OTC products. See Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 25 (URN: PRO-C5092). [Alliance Director 2] has also confirmed that Lexon and Medreich's obtainment of a marketing authorisation for Prochlorperazine OTC confirmed that they *'were genuine in their claim to be seeking a generic product'*. (Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 3.10(e) (URN: PRO-C5098)).

POM; and Focus and Lexon had agreed that Focus would share the majority of its profits from the sale of Alliance's Prochlorperazine POM with Lexon on the basis that Lexon – '*exclusively*' – had (with Medreich) a marketing authorisation for the same product.

5.199.3 In his email to [Focus Director 2] dated 18 July 2013, [Focus Director 1] set out Focus' anticipated profits from the sale of Alliance's Prochlorperazine POM. Despite again making no reference to the purchase or sale of Lexon and Medreich's Prochlorperazine POM, and instead implicitly contemplating purchasing the entire market demand from Alliance, [Focus Director 1] anticipated retaining '*25%*' of Focus' profits from the sale of Alliance's Prochlorperazine POM over time as Focus increased the price of the product in the market – that is, meaning that 75% of the profits would *not* be retained by Focus.[687] This is consistent with the plain reading of [Focus Director 1]'s 22 June 2013 email which recorded that Focus would share 75% of its profits from the sale of Alliance's Prochlorperazine POM with Lexon '*(as it is his [[Lexon Director 1]'s] licence)*'.

5.200 The plain reading of [Alliance Director 1]'s 11 June 2013 notebook entry and of [Focus Director 1]'s 22 June 2013 email is also consistent with subsequent documentary evidence (see further at paragraphs 5.358 to 5.581 below), confirming that Lexon had committed not to enter the market other than through the supply of the single batch necessary to avoid the Sunset Clause, and that Alliance and Lexon had agreed the terms on which Alliance would supply its product to Focus, including the following key evidence:[688]

5.200.1 The email from [Lexon Director 1] to [Medreich Employee 1] dated 4 February 2014 in which [Lexon Director 1] responds to a suggestion from Medreich that it should get ready to introduce its Prochlorperazine POM product by stating that:

(a) the product would be '*best left alone*' as Lexon and Medreich '*make far much [sic] more as it is*'; and

(b) [Lexon Director 1] had agreed to supply a single batch of Prochlorperazine POM every three years and '*drift it into the Alliance stock*' (see further at paragraph 5.422 below).[689]

[687] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

[688] The CMA considers in paragraphs 5.582 to 5.620 the three email exchanges between [Focus Director 1] and [Lexon Director 1] in 2014 that the Parties have suggested would undermine any conclusion that there was a Market Exclusion Agreement and that Focus participated in it.

[689] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750). The CMA's analysis of [Lexon Director 1]'s evidence in respect of this email is set out in paragraphs 5.426 to 5.432.

5.200.2 The minutes of Medreich plc's Executive Committee meeting held on 24 June 2015 which recorded that Medreich had placed an internal order (for the first time[690]) for '*the 1 batch required in order to keep the license [sic] active*' for Prochlorperazine POM.[691]

5.200.3 The email from [Focus Employee 1] dated 23 March 2017 in which [Focus Employee 1] explains that Lexon was involved in establishing the exclusive supply agreement between Alliance and Focus for Prochlorperazine POM (see further at paragraph 5.556 below).[692]

5.200.4 The email from [Medreich Director 2] to [Meiji employee] dated 21 July 2017 in which [Medreich Director 2] explained that:

(a) Medreich (and Lexon) have never '*manufactured or supplied*' Prochlorperazine POM due to a '*deal*' under which Medreich receives '*royalty*' as compensation for not bringing its Prochlorperazine POM to market; and

(b) Medreich must produce one batch of Prochlorperazine POM to avoid the application of the Sunset Clause (see further at paragraph 5.577 below).[693]

5.201 The plain reading of [Alliance Director 1]'s 11 June 2013 notebook entry and [Focus Director 1]'s 22 June 2013 email is also consistent with the conduct that Alliance, Lexon and Focus went on to pursue, most notably:

5.201.1 Alliance appointed Focus as the exclusive supplier of its de-branded product and supplied on the pricing terms envisaged in [Focus Director 1]'s 22 June 2013 email (see further at paragraphs 5.277 to 5.284 below).

5.201.2 Lexon appointed Focus as the exclusive distributor of its Prochlorperazine POM product (see further at paragraphs 5.296 and 5.302).[694]

5.201.3 For the duration of the Market Exclusion Agreement, Lexon supplied Focus with only a single batch of Prochlorperazine POM, manufactured to

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[690] See paragraph 5.573.

[691] '*Minutes of the Meeting of the Executive Committee of Medreich plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich plc Offices'* 29 June 2015, page 3 (URN: PRO-E002985). The CMA's analysis of [Lexon Director 1]'s evidence in respect of this email is set out in paragraph 5.463.

[692] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030). The CMA's analysis of [Focus Employee 1]'s evidence in respect of this email is set out in paragraphs 5.558 to 5.561.

[693] Email [Medreich Director 2] to [Meiji employee], entitled *'Re: Prochlorperazine --- profit sharing'* 21 July 2017 (URN: PRO-E003351). [Medreich Director 2]'s own commentary on the contents of his email of 21 July 2017 are set out in paragraph 5.578. The Parties' representations on the significance of [Medreich Director 2]'s email of 21 July 2017, and the CMA's consideration of them, are set out in paragraphs 5.579 to 5.581.

[694] See document entitled *'Heads of Agreement'* signed 1 August 2013 (URN: PRO-E000429).

avoid the application of the Sunset Clause to Medreich's Prochlorperazine POM marketing authorisation (see paragraph 3.273).

5.201.4 Between January 2014 and July 2018, Focus paid Lexon £7.86 million under the Focus-Lexon Heads of Terms despite Lexon supplying only one batch of Prochlorperazine POM to Focus in that period (see further at paragraph 5.524 below).

5.202 The documentary evidence from June and July 2013 therefore demonstrates that:

5.202.1 Lexon had agreed with Alliance that Lexon would supply only one batch of its product every five years to avoid the application of the Sunset Clause.[695]

5.202.2 Lexon had agreed with Alliance the terms on which Alliance would supply Focus, in circumstances in which Focus would share its profits from supplying Alliance's Prochlorperazine POM with Lexon.

5.203 The CMA has been provided during its investigation with witness evidence and representations from the Parties that contest the CMA's interpretation of the documentary evidence cited above. In the sections that follow, the CMA considers this evidence and these representations for each of the documents relied on as described above.

Witness evidence and Parties' representations on the [Alliance Director 1] notebook entry 11 June 2013

[Alliance Director 1]'s evidence on his notebook entry

5.204 Notwithstanding the plain reading of the notebook entry, and its consistency with subsequent emails and conduct, [Alliance Director 1] provided an account of his 11 June 2013 notebook entry[696] that is at odds with its plain reading.

5.205 By way of context for [Alliance Director 1]'s account of his 11 June 2013 notebook entry, it is relevant to recall that in his initial interview with the CMA on 3 November 2017, which was held at the start of the CMA's investigation and before the CMA had provided Alliance with detailed information on the nature of the allegations against it,[697] [Alliance Director 1] recalled that Alliance had entered into an agreement with Lexon for the distribution of Prochlorperazine POM and that Focus was appointed as the distributor of the product.

[695] In his email of 4 February 2014, [Lexon Director 1] explained to Medreich that the agreement related to production of one batch every three years, which is the period relevant to the application of the sunset clause provision (Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750)).

[696] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

[697] See the note of state of play call with Alliance on 17 July 2018 (URN: PRO-C2369).

5.205.1 Specifically, [Alliance Director 1] recollected that, after learning that Lexon had a generic version of Prochlorperazine POM in development, Alliance had *'entered into a distribution agreement with Lexon'* and *'Lexon passed on that, some of the ongoing business relationship to Focus, so for Focus to sell the product into the generic market'*. [Alliance Director 1] further explained that Alliance's *'discussion started with Lexon, and then Focus ended up having an agreement with [Alliance] for the distribution'*.[698]

5.205.2 When asked later in the same interview whether *'Lexon used … the Medreich forthcoming product as leverage to get [Alliance] to consider a deal with Focus'*, [Alliance Director 1] replied: *'That's how it ended up. … Yes I'm not sure of, you know whether Focus were the, a distribution partner for Lexon I don't know. … I just know that that conversation started with Lexon, and ended with Focus that's all I know'*.[699]

5.206 In his second interview with the CMA, carried out a year into the CMA's investigation after the CMA had provided Alliance with further information on the nature of the allegations against it,[700] [Alliance Director 1] was asked by the CMA to explain his notebook entry of 11 June 2013. In that second interview, he explained that the notebook entry detailed Alliance's proposed response to Lexon's anticipated entry. In respect of the last line relating to the line '*1 [batch] every 5yr to avoid Sunset*' he explained multiple times that the final line related to Alliance's proposal to retain the Buccastem brand, which necessitated the production of product every three or five years:

> *'So if you wanted to keep the brand viable, you would make a batch, and, if you like, keep it technically available but you're not pushing it out commercially, so that, you maintain the viability of that Buccastem labelling, and you, you need to show that you've produced a batch, I think it's every five years, I've written here. I thought it might have been three, but it looks like five, to avoid what's known as a sunset clause. So if, if you have a product licence or marketing authorisation, if you don't use it, you'll eventually lose it. So that's what it means there, to avoid the sunset clause. … So to avoid the sunset clause and keep the brand available, it would have to be labelled up as Buccastem, whereas up above we're talking about making generic prochlorperazine. … If we want to keep the brand alive, we do it in this way, that we manufacture a batch every five years,*

[698] Interview [Alliance Director 1], 3 November 2017, part 2, page 30, lines 16-19 and page 32, lines 7-8 (URN: PRO-C1148). Alliance subsequently submitted that [Alliance Director 1]'s reference in his first interview to Alliance having a distribution agreement with Lexon was '*a mistake – an accidental confusion of the parties more than four years after the event and nothing more*' which had been corrected on behalf of [Alliance Director 1] in an email to the CMA when [Alliance Director 1] commented on his transcript (Alliance RSO, 1 August 2019, paragraph 4.85(b) (URN: PRO-C5096)).

[699] Interview [Alliance Director 1], 3 November 2017, part 2, page 33, lines 9-23 (URN: PRO-C1148).

[700] See note 697 above.

and, avoid the sunset clause. I mean, if we want to, and I don't know what we did.'[701]

5.207 In the CMA's Statement of Objections, the CMA set out its provisional view that [Alliance Director 1]'s explanation regarding the need to supply branded product for this reason was erroneous from a regulatory perspective, because the branded Buccastem POM product was on the same licence as the generic Prochlorperazine POM product, and therefore it would not have been necessary to produce a batch of the branded product periodically.[702] This was subsequently accepted by [Alliance Director 1] in his witness statement provided in response to the Statement of Objections, when he stated that:

> *'I am told now that in fact it would not be necessary to do that under applicable regulations since APL has a single marketing authorisation for both the branded and generic products and supply of the generic would prevent application of the sunset rule. I am not an expert on the regulatory regime and may not have known that then, or may have made a mistake. These are likely rough ideas that cropped up during a brief discussion.'*[703]

5.208 Notwithstanding his acceptance that such a reading of the notebook would entail a regulatory mistake, [Alliance Director 1] stated in his witness statement that all of the proposed actions listed in his notebook entry of 11 June 2013 were attributable to Alliance and that his notebook entry records, or might recall, a discussion with [Alliance Employee 1] concerning Alliance's potential de-branding of its Buccastem product in reaction to the threat of entry from Lexon.[704] He has submitted that:[705]

5.208.1 the notebook entry should be read as: '*in reaction to the news from Lexon, [Alliance] will sell batches of prochlorperazine to Focus as a distributor and either withdraw the branded product or make small amounts of the branded product to avoid the application of the sunset rule*';

5.208.2 the first '*Lexon*' in the second line provides context and is 'shorthand' for the threat of competition Lexon posed to Alliance's Buccastem product;

5.208.3 the remainder of the line indicates Alliance's intention to use Focus to supply its de-branded Prochlorperazine POM product;

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[701] Interview [Alliance Director 1], 8 October 2018, page 82, lines 18-26, page 91, lines 8-10 and page 96, line 26 to page 97, line 3 (URN: PRO-C2944).

[702] Statement of Objections, paragraph 4.178(b).

[703] Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraph 6.4(d) (URN: PRO-C5097).

[704] Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraphs 6.3 and 6.4 (URN: PRO-C5097).

[705] Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraph 6.4 (URN: PRO-C5097). [Alliance Director 1] did not provide in his witness statement any commentary on the first line ('*Buccastem + 40p*').

5.208.4 although he cannot '*specifically remember*', the second '*Lexon*' on the fifth and final line is likely incomplete text '*jotted down*' and '*not continued*';

5.208.5 the second reference to 'Lexon' is not connected to any other text, since there is a large space (a caesura) before the rest of the wording in the last line; and

5.208.6 the remainder of the text other than 'Lexon' under the second line:

(a) records Alliance's plans to either withdraw or restrict the volume of sale of Buccastem;

(b) in relation to the last line, the wording '*1 [batch] every 5yr to avoid Sunset*' flows from the wording in the previous line relating to '*?withdraw brand/or restrict volume*'; and

(c) 'likely' relate to his (mistaken) understanding that Alliance would need to produce at least one batch of Buccastem every five years to avoid the application of a Sunset Clause to Alliance's Buccastem marketing authorisation and ensure its brand was kept 'alive'.

5.209 [Alliance Director 1] has stated that this reading is consistent with the fact that the references to brand withdrawal in the fourth line can only have been relevant to Alliance, submitting that *'[f]or this reason alone, the CMA's interpretation is implausible'*.[706]

The Parties' representations on the [Alliance Director 1] notebook entry

5.210 Alliance criticised the CMA's reliance on [Alliance Director 1]'s notebook entry on the basis that it was a *'scribbled, shorthand note'* that was *'hastily jotted down by [Alliance Director 1] at or after his meeting with [Alliance Employee 1]'* that the CMA had sought to elevate into a '*minute of the meeting*'.[707]

5.211 Alliance argued in favour of [Alliance Director 1]'s explanation (as author of the entry) on the basis that it was implausible that [Alliance Director 1] would not have referred to Alliance's plans to appoint Focus to distribute its Prochlorperazine POM as this was the '*very transaction which had been under discussion within Alliance*' and that this interpretation '*makes most sense*' given that the wording of the entry clearly refers to a '*branded product*'. Alliance noted that this explanation was consistent with the '*fact that the brand [Buccastem] was of the utmost importance*' to [Alliance Director 1] and Alliance.[708]

[706] Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraph 6.4(c) (URN: PRO-C5097).

[707] Alliance RSO, 1 August 2019, paragraphs 1.15(a), and 4.18-4.19 (URN: PRO-C5096).

[708] Alliance RSO, 1 August 2019, paragraphs 4.19 to 4.21 (URN: PRO-C5096).

5.212 Alliance submitted that [Alliance Director 1]'s interpretation of the notebook entry was consistent with [Alliance Director 2]'s email of 7 June 2013,[709] providing the context and purpose for the 11 June 2013 meeting, and [Alliance Employee 2]'s email of 10 June 2013[710] in which she explained that one of the options Alliance was reviewing to '*react to the threat of a generic Prochlorperazine 3mg buccal entrant into the UK market*' was to '*cease manufacturing the branded 50s pack and drive all sales to a generic pack produced by Alliance but sold by another partner eg Focus'*.[711]

5.213 Advanz, although stating that [Alliance Director 1]'s explanation of the notebook was perfectly credible, also noted that the entry '*Lexon → use Focus to distribute*' might also refer to a recommendation from Lexon to Alliance to appoint Focus as its distributor of Prochlorperazine POM.[712]

5.214 Cinven disputed the CMA's interpretation of the notebook entry, pointing out further that it did not explicitly record Lexon's commitment not to enter the market and that the CMA had provided no explanation of the first line of [Alliance Director 1]'s notebook entry, '*Buccastem + 40p*' which did not seem to reflect any agreement with Lexon.[713]

The CMA's assessment of [Alliance Director 1]'s witness evidence and the Parties' associated representations on the [Alliance Director 1] notebook

5.215 The CMA does not accept [Alliance Director 1]'s explanation for his notebook entry and the Parties' representations in support of that interpretation.

5.216 First, [Alliance Director 1]'s explanation is inconsistent with a plain reading of the document, which clearly attributes the relevant actions in the second and final lines of the notebook entry to Lexon. In this respect, the CMA rejects Alliance's related submission (see paragraph 5.210 above) that the casual nature of the document points against the CMA's interpretation and reliance on it: to the contrary, the CMA's interpretation accords with the notebook entry on its face.

5.217 Second, read as suggested by [Alliance Director 1], the third line of the notebook entry – '*make batch – sell Focus*' – would record Alliance's plan to manufacture and supply a single batch of Prochlorperazine POM to Focus, which makes no

[709] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*CCG switch and Buccastem defense [sic]*' 7 June 2013 (URN: PRO-E001009).

[710] Email [Alliance Employee 2] to [Alliance employee] and others at Alliance entitled '*Buccastem'* 10 June 2013 (URN: PRO-E001010).

[711] Alliance RSO, 1 August 2019, paragraphs 4.18 to 4.20 (URN: PRO-C5096).

[712] Advanz RSO, 1 August 2019, paragraph 3.123.3(e) (URN: PRO-C5111). Advanz made a similar representation with regard to the interpretation of the [Focus Employee 1] email of 23 March 2017 which stated that *'[t]he only reason that Lexon gets Prochlorperazine Buccal Tablets is because they helped set up the supply agreement with Alliance Pharma'* (Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030)): see paragraph 5.560.

[713] Cinven RSO, 15 August 2019, paragraph 4.71, footnote 216 (URN: PRO-C5132).

sense in the context of its plans at that time to debrand Buccastem and supply all its de-branded Prochlorperazine POM to Focus.[714]

5.217.1 Alliance would not have anticipated supplying – and did not in fact supply – just a single batch of the product to Focus,[715] but anticipated appointing Focus as its distributor of generic Prochlorperazine POM going forward.

5.217.2 Alliance also did not request its manufacturing company, Dales Pharmaceuticals (the manufacturing arm of Dechra Pharmaceuticals), to 'make' a single batch of Prochlorperazine POM, but instructed it on 3 July 2013 to *'pack the majority of Buccastem 50's in the new Generic Prochlorerpazine [sic] livery from the next order'*[716] – consistent with an understanding that Prochlorperazine POM would be supplied in generic form going forward.

5.217.3 There is no contemporaneous documentary evidence suggesting that Alliance considered at this stage that it would:

(a) seek to have a single batch of Prochlorperazine POM – which is an identical product to Buccastem POM – manufactured or 'made';

(b) order only a single batch of generic Prochlorperazine POM from Dales Pharmaceuticals; or

(c) supply only a single batch of Prochlorperazine POM to Focus.[717]

5.217.4 In contrast, the third line of [Alliance Director 1]'s notebook entry ('*make batch – sell Focus'*) is consistent with the fifth line of the notebook entry (*'1 [batch] every 5yr to avoid Sunset'*) and with Lexon's subsequent correspondence (see further at paragraph 5.422 below) and conduct (see further paragraph 5.434 below), in which Lexon envisaged supplying, and

[714] See, for example, Email [Alliance Employee 2] to [Alliance employee] and others at Alliance entitled '*Buccastem'* 10 June 2013 (URN: PRO-E001010), in which she explains that Alliance was reviewing an option in which it would *'cease manufacturing'* Buccastem and *'drive **all sales** to a generic pack produced by Alliance but sold by another partner eg Focus'* (emphasis added).

[715] See email from [Focus Director 1] to [Alliance Employee 1] entitled '*RE: Meeting Summary*' 21 August 2013 and subsequent email [Alliance Employee 1] to [Alliance Employee 3] cc various others at Alliance entitled '*RE: Prochlorperazine initial orders*' (both shown in URN: PRO-E001057) in which Focus envisages three '*initial orders*' with Alliance for Prochlorperazine POM, and email from [Focus employee] to [Alliance employee], cc [Alliance Employee 1] and [Focus Director 1] entitled '*FW: PO 9164959 to 9164961*' 22 August 2013 (URN: PRO-E001047) attaching Focus' three purchase orders for Prochlorperazine POM for November 2013, December 2013 and January 2014.

[716] Email [Alliance employee] to [Dechra Pharmaceuticals Manufacturing employee] cc [Dechra Pharmaceuticals Manufacturing employee] entitled *'Buccastem/Generic Prochlorerpazine [sic] Version Packing'* 3 July 2013 (URN: PRO-E004782). See also email [Alliance employee] to [Dechra Pharmaceuticals Manufacturing employee] entitled '*Buccastem (Prochlorperazine) Forecast and Order*' 5 July 2013 (URN: PRO-E004787) in which he attaches a *'new forecast'* anticipating future orders of Prochlorperazine POM (URN: PRO-E004788) and the *'first Prochloperazine [sic] order'* and email [Alliance employee] to [Alliance Director 2], [Alliance Employee 2], [Alliance Employee 1] and others (Alliance) entitled '*Buccastem/Prochloperazine [sic]*' 5 July 2013 (URN: PRO-E004789) in which [Alliance employee] confirms that he had *'just placed the first order for Prochloperazine [sic] (generic Buccastem) as advised by [Alliance Employee 1] & [Alliance Employee 2]*'.

[717] See note 716 above.

actually supplied, only a single batch of Prochlorperazine POM to Focus.[718]

5.218 Third, notwithstanding [Alliance Director 1]'s extensive commentary in his second interview that production of a single batch of branded Buccastem POM would be necessary to maintain the licence for the branded product,[719] Alliance's plan to de-brand Buccastem would not have required the production of one batch of Buccastem every three years (or five years) to prevent the application of any Sunset Clause that would preclude Alliance from retaining the option of supplying Buccastem POM. Further, it is not credible that [Alliance Director 1] (and Alliance) would have misunderstood this in 2013 and that [Alliance Director 1] would have continued in that mistaken belief until 2018.

5.218.1 The MHRA has confirmed that Alliance's Buccastem POM was part of the same marketing authorisation as Prochlorperazine POM and that sales of either product – including the generic product – would prevent the application of the Sunset Clause to that marketing authorisation.[720] This point was subsequently accepted by [Alliance Director 1], with an explanation that he was not an expert on the regulatory regime and may not have known that then, or may have made a mistake, and that the notebook recorded *'rough ideas that cropped up during a brief discussion'*.[721]

5.218.2 There is no contemporaneous documentary evidence supporting [Alliance Director 1]'s suggestion that in June 2013 he or Alliance considered (mistakenly) that it would or might need to continue to produce a single batch of the Buccastem POM to avoid the application of the Sunset Clause.[722]

5.218.3 Further, it is highly unlikely that Alliance would in 2013 have been unaware or unsure whether de-branding Buccastem POM would require a new

[718] The CMA rejects Cinven's submission that [Alliance Director 1]'s notebook does not explicitly record Lexon's agreement not to enter the market for Prochlorperazine POM: this is evident from the entry: '*1 [batch] every 5yr to avoid Sunset*', which summarises Lexon's willingness to limit its supply of Prochlorperazine POM to a single batch, supplied solely to '*avoid*' the application of the Sunset Clause to its licence rather than to produce commercial volumes of Prochlorperazine POM.

[719] Interview [Alliance Director 1], 8 October 2018, page 82, lines 18-26, page 91, lines 8-10 and page 96, line 26 to page 97, line 3 (URN: PRO-C2944).

[720] Section 26 response of MHRA dated November 2018, to CMA Notice of 12 October 2018, pages 2-5 (URN: PRO-C2737).

[721] Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraph 6.4(d) (URN: PRO-C5097).

[722] Alliance RSO, 1 August 2019, Annex 1, Witness Statement of [Alliance Director 1], paragraph 6.4(d) (URN: PRO-C5097).

marketing authorisation (subject to a separate Sunset Clause) for the generic Prochlorperazine POM given the following points.

(a) The fact that Alliance had by June 2013 de-branded a number of other products, including Deltacortril[723] in 2009 and NuSeals (aspirin)[724] in 2011, such that Alliance and its staff would have been well aware of the associated regulatory processes.

(b) The fact that Alliance had in February 2011 varied its Buccastem POM licence to include the generic Prochlorperazine POM name on it.[725]

(c) The level of planning that had occurred by 11 June 2013 for the proposed de-branding of Buccastem POM: (i) In his witness statement dated 31 July 2019, [Alliance Director 2] set out the various elements of the '*complex, multi-stage process*' of de-branding – including '*discussing regulatory matters with internal colleagues and potentially the regulatory agency*'.[726] (ii) [Alliance Director 2] stated that he did '*not expect*' that Alliance '*would have given the go-ahead to debrand unless*' these elements '*had been planned and described to the management*' or [Alliance Employee 1] had '*at least […] assured'* Alliance's management team that *'each was satisfactorily accounted for*'.[727] (iii) [Alliance Director 2]'s statement indicates that [Alliance Employee 1] would have been well-prepared for his briefing to [Alliance Director 1] on Prochlorperazine POM, including engagement with Alliance's regulatory team who had submitted the '*variation to get the Prochlorperazine name on the Buccastem 3mg license [sic]*' by 17 February 2011[728] and received approval for the addition on 22 March 2011.[729] (iv) This level of planning by [Alliance Employee 1] is reflected in [Alliance Director 2]'s email of 7 June 2013 in which he

[723] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 2.5 (URN: PRO-C5098).

[724] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.1 (URN: PRO-C5098).

[725] Section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 4 (URN: PRO-C0367).

[726] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 3.13 (URN: PRO-C5098).

[727] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraphs 3.13-3.14 (URN: PRO-C5098).

[728] Email [Alliance employee] to Established Products BTU (Alliance), entitled *'Prochlorperazine submission – Project Cobra'* 17 February 2011 (URN: PRO-E000876).

[729] Email [Alliance employee] to Regulatory Team (Alliance) and others, entitled *'Approval of Prochlorperazine name on Buccastem license [sic] (10-432)'* 23 March 2011 (URN: PRO-E000903).

commented that [Alliance Employee 1] had '*worked up a plan which I'm comfortable with*'.[730]

(d) It is not credible that, having worked on, as Alliance claimed, a de-branding plan, [Alliance Employee 1] would have made (and communicated to Alliance's [✂], [Alliance Director 1]) a regulatory mistake of such central importance to the defence plan. The CMA concludes that, given that level of planning within Alliance, it is likely that [Alliance Director 1] would have been advised that the Prochlorperazine POM had already been added to the MA for Buccastem POM and that there was no requirement for a new marketing authorisation (subject to a separate Sunset Clause) for the generic product.

(e) Such a fundamental mistake about the steps that were required to retain the Buccastem POM brand is clearly irreconcilable with Alliance's argument that [Alliance Director 1]'s interpretation of his notebook was consistent with the fact that the brand was of '*the utmost importance*' to [Alliance Director 1] and Alliance (paragraph 5.211 above): if it had been of such importance, Alliance would have been unlikely to make such a careless regulatory error after having carried out the extensive planning described by [Alliance Director 2] (above).

5.218.4 Notwithstanding the implausibility of [Alliance Director 1]'s (and Alliance's) claimed regulatory mistake in June 2013, it is not credible that any such mistaken view of [Alliance Director 1] would have persisted over the five years between the time of his notebook entry in June 2013 and the time of his second interview in October 2018, in which he stated: *'If we want to keep the brand alive, we do it in this way, that we manufacture a batch every five years, and, avoid the sunset clause'*,[731] not least given that:

(a) the CMA understands that Alliance did not produce a batch of Buccastem POM in the way that [Alliance Director 1] claimed would have been necessary; and

(b) furthermore, Alliance had had experience in the intervening period with the debranding of another product, Symmetrel/Amantadine (see paragraph 5.290), further reducing the likelihood of [Alliance Director 1] continuing to hold that mistaken view over this extended period of time.

[730] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*CCG switch and Buccastem defense [sic]*' 7 June 2013 (URN: PRO-E001009).

[731] Interview [Alliance Director 1], 8 October 2018, page 96, line 26 to page 97, line 3 (URN: PRO-C2944).

5.219 Fourth, [Alliance Director 1]'s suggestion that the second reference to '*Lexon*' may have been an incomplete note is unlikely, given:

5.219.1 the position of the word 'Lexon' clearly on the same line as the remainder of the bulleted sentence, '*1 [batch] every 5yr to avoid Sunset*';

5.219.2 the reference to producing a single batch of Prochlorperazine POM to avoid the Sunset Clause would have had no relevance to Alliance's plans to de-brand Buccastem POM, but is consistent with the interpretation of the third line (which is positioned as a sub-bullet to the second line that also starts with 'Lexon') as relating to Lexon – namely: '*make batch – sell Focus*'; and

5.219.3 the fact that Lexon planned to, and did, supply a single batch of its Prochlorperazine POM to avoid the application of the Sunset Clause to its marketing authorisation (see further at paragraphs 5.422, 5.434 and 5.463 below).

5.220 Finally, [Alliance Director 1]'s statements in relation to the content of his notebook entry on 11 June 2013 are at odds with his initial evidence given in his first interview with the CMA on 3 November 2017, in which he recalled that Alliance had entered into an agreement with Lexon for the distribution of Prochlorperazine POM and that Focus was appointed as the distributor of the product:[732] see paragraph 5.205 above. Although Alliance submitted that this was simply a mistake by [Alliance Director 1] in terms of mixing up the parties more than four years after the event, [Alliance Director 1]'s initial, unvarnished recollection in his first interview is closer to the plain reading of his notebook entry than his subsequent evidence to the CMA in his second interview and his witness statement.

5.221 The CMA has considered the additional representations made by the Parties in respect of [Alliance Director 1]'s interpretation of his notebook entry, but does not find them persuasive for the reasons set out below.

5.222 [Alliance Director 1]'s comment, as endorsed by Alliance, that the fourth line entry of his notebook ('*? withdraw brand / or restrict volume*') can only have referred to Alliance given Lexon did not have a branded product, are accepted – but do not prove the wider point that the entirety of the notebook entry refers to the intended actions of Alliance. Withdrawal of the Alliance branded Buccastem POM product, or at least a restriction in the volume of branded product made available, was necessary if Focus was to be able to raise prices and therefore generate profits to be used to compensate Lexon for not supplying commercial volumes of product and making only one batch periodically to avoid the Sunset Clause. By way of distinction, unlike the fourth line entry that refers to Alliance, the entries in the second and third lines reading '*use Focus to distribute – make batch sell Focus ->*'

[732] Interview [Alliance Director 1], 3 November 2017, part 2, page 30, lines 16-19 (URN: PRO-C1148).

and in the fifth line reading '*1 [batch] every 5yr to avoid Sunset*' are both preceded by the word 'Lexon' on the same line and therefore plainly relate to Lexon.

5.223 The CMA rejects Alliance's submission that it was clear from [Alliance Director 2]'s email to [Alliance Director 1] of 7 June 2013[733] that the purpose of [Alliance Employee 1]'s meeting with [Alliance Director 1] was to brief [Alliance Director 1] on Alliance's plans to de-brand Buccastem POM and to use Focus to distribute that de-branded product. [Alliance Director 2]'s email refers to a '*Buccastem Defence plan*' but does not refer to Alliance appointing Focus or to any imperative to preserve the Buccastem POM brand: on the contrary, [Alliance Director 2]'s email is oblique about the nature of the 'plan' that had been worked-up by [Alliance Employee 1]. Similarly, the CMA finds that [Alliance Employee 2]'s email of 10 June 2013[734] does not provide support for [Alliance Director 1]'s explanation of the notebook entry – and fails to account for the entry '*make batch – sell Focus'* (see paragraph 5.217) above.

5.224 The CMA finds Advanz's submission that the entry '*Lexon → use Focus to distribute*' might refer to Lexon's having 'recommended' to Alliance that it should appoint Focus as Alliance's distributor of Prochlorperazine POM not to be credible. Absent the existence of the Market Exclusion Agreement (i.e. consistent with the CMA's interpretation of the notebook entry), it is entirely unclear why Lexon would be offering advice on how its rival should compete with it at its expense, nor why Alliance would rely on a competitor for advice on how best to maximise its sales.

5.225 Cinven submits that the CMA has not explained fully the first line of the notebook entry apparently relating to a proposed price ('*Buccastem + 40p*'). However, this entry is not inconsistent with the CMA's interpretation of the notebook (given that the Market Exclusion Agreement did indeed foresee price increases for Prochlorperazine POM following debranding by Alliance) and is not more obviously explained through [Alliance Director 1]'s alternative explanation: on the contrary, to the extent that Alliance envisaged having to compete with a generic Lexon product, this would be expected to result in price *decreases* rather than any increase.

5.226 Subject to its review of the wider evidence base, the CMA considers that [Alliance Director 1]'s notebook entry of 11 June 2013 constitutes the first record of the terms of the agreement reached between Alliance and Lexon:

5.226.1 The second line – '*Lexon → use Focus to distribute*' – records Alliance's understanding of Lexon's intention to enter into an agreement to appoint Focus as its distributor (see further at paragraphs 5.296 and 5.297 below).

[733] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*CCG switch and Buccastem defense [sic]*' 7 June 2013 (URN: PRO-E001009).

[734] Email [Alliance Employee 2] to [Alliance employee] cc [Alliance Employee 1] and [Alliance employee] entitled *'Buccastem'* 10 June 2013 (URN: PRO-E001010).

5.226.2 The third and final lines – '*make batch – sell Focus / […] Lexon 1 [batch] every 5yr to avoid Sunset*' – record Lexon and Alliance's agreement that Lexon would not commercialise its (and Medreich's) Prochlorperazine POM, but supply only one batch to avoid the application of the Sunset Clause to Medreich's Prochlorperazine POM MA.

5.226.3 The fourth line – '*? withdraw brand /or restrict volume*' – records Alliance's intention to de-brand Buccastem POM (or restrict sales volumes) (see further at paragraphs 5.359 to 5.362 below).

Witness evidence and parties' representations on [Focus Director 1]'s 22 June 2013 email

[Focus Director 1]'s, [Focus Director 2]'s and [Lexon Director 1]'s evidence on the 22 June 2013 email

5.227 [Focus Director 1], [Focus Director 2] and [Lexon Director 1] have submitted that the meaning of the Focus 22 June 2013 email[735] (as well as the meanings of the Focus/Lexon 24 June 2013 email exchange,[736] the Focus/Lexon 10 July 2013 email[737] and the Focus 18 July 2013 email[738]) are different to their plain reading, as articulated above (see paragraphs 5.195 to 5.199 above). Each of these documents is therefore discussed below, starting with the Focus email of 22 June 2013.

5.228 [Focus Director 1], [Focus Director 2] and [Lexon Director 1] have suggested that the CMA has misunderstood the meaning of the first and final lines of [Focus Director 1]'s email dated 22 June 2013.[739]

5.229 In relation to the first line, '*In case [Alliance Employee 1] rings you , the agreement [Lexon Director 1] made was […]*':

5.229.1 [Focus Director 1] has told the CMA that he thinks he '*mixed up the name*' that he included and suggested that he intended to refer to '*the agreement [Alliance Employee 1] made*'.[740] [Focus Director 1] proposed that his

[735] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[736] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood'* dated 24 June 2013 (URN: PRO-E000325).

[737] Email [Focus Director 1] to [Lexon Director 1] entitled *'Fwd: Rama as requested'* 10 July 2013 (URN: PRO-E000326).

[738] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

[739] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[740] Advanz and Cinven both represented that the typo was understandable given the email was an understandable human error in a '*holiday note*' or '*handover note*' '*dashed off*' by [Focus Director 1] '*on a Saturday morning before he went on holiday*' and that [Focus Director 1] would have had [Lexon Director 1] '*front of mind*' when writing the email as he referred to [Lexon Director 1] in the next paragraph of his email and because [Focus Director 1] was '*being chased by*' [Lexon Director 1] (Advanz RSO, 1 August 2019, paragraph 3.106 (URN: PRO-C5111); Advanz RLF, 22 April 2021, paragraphs 4.42.4 and 4.43.2 (URN: PRO-C7112)). [Focus Director 1]'s purported error is consistent with the '*large*

reference to '*[Lexon Director 1]*' was a '*typo*' prompted by his later reference in the same email to [Lexon Director 1] and the timing of the email (sent on a Saturday), which he '*probably*' wrote '*before*', '*after*' or '*during*' a vacation.[741]

5.229.2 [Focus Director 2], the recipient of [Focus Director 1]'s 22 June 2013 email, told the CMA in an interview (held after [Focus Director 2] had seen the CMA's Statement of Objections setting out the CMA's provisional findings in relation to the Market Exclusion Agreement, including as regards the 22 June 2013 email) that, although he did not recall receiving the email, he would have '*assumed*' that [Focus Director 1] meant '*the agreement that […] he's [Focus Director 1's] made with [Alliance Employee 1]*' as it would not '*make sense*' for [Alliance Employee 1] to telephone [Focus Director 2] about '*something he's [[Alliance Employee 1]] already agreed with [Lexon Director 1]*'.[742]

5.229.3 [Lexon Director 1] has told the CMA that he thinks that [Focus Director 1]'s explanation of the first line of his email dated 22 June 2013 '*is correct*' as the email '*makes perfect sense*' when read on this basis as [Focus Director 1] is '*informing [Focus Director 2] of the terms of the supply agreement that he had just negotiated with Alliance*' as set out in the '*first paragraph of the email*'.[743]

number of other typos in the email' that '*bear out the rushed nature of the email*', which appears to have been '*sent from [Focus Director 1]'s phone*' (Cinven RSO, 15 August 2019, paragraph 4.151 (URN: PRO-C5132)). Cinven argued that [Focus Director 1]'s email '*reads more easily*' with the first line referring to the 'agreement *[Alliance Employee 1]* made' rather than the '*agreement [Lexon Director 1] made*' (Cinven RLF, 22 April 2021, paragraph 2.84 (URN: PRO-C7107)).

[741] Interview [Focus Director 1], 2 October 2018, page 110, line 5 to page 111, line 3; page 113, lines 3 to 19; page 113, line 26 to page 114, line 10; page 118, line 22 to page 119, line 3 (URN: PRO-C3294). Advanz submitted that [Focus Director 1]'s email of 22 June 2013 therefore showed that Focus was seeking to become – '*separately*' – the distributor of both Alliance and Lexon's Prochlorperazine POM (Advanz RSO, 1 August 2019, paragraph 3.25 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraph 4.42.2 (URN: PRO-C7112)) and that the email should be read in '*two parts*'; the first provides an update on the status of [Focus Director 1]'s '*dealings*' with Alliance, the second on his '*dealings*' with Lexon (Advanz RSO, 1 August 2019, paragraph 3.106 (URN: PRO-C5111)). Cinven also endorsed this interpretation of the email (Cinven RSO, 15 August 2019, paragraph 4.152 (URN: PRO-C5132)) as did Alliance (Alliance RSO, 1 August 2019, paragraph 1.15(b) and 4.22(a)(ii) (URN: PRO-C5096)).

[742] Interview [Focus Director 2], 8 January 2020, page 51, line 18 to page 52, line 23; page 55, lines 1-27 and page 58, lines 9-10 (URN: PRO-C5886). Advanz also cited [Focus Director 2]'s commentary that [Focus Director 1] was '*not the best with email*' and '*used to, sort of … just, dump a lot of stuff down*' when he was '*going away*' (Advanz RLF, 22 April 2021, paragraph 4.43.1 (URN: PRO-C7112)).

[743] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 57 (URN: PRO-C5092).

5.230 In relation to the final line, '*I am waiting on [Alliance Employee 1] ringing me back , but have [Lexon Director 1] chasing to see what happening*':

5.230.1 [Focus Director 1] has made two inconsistent claims as to what he meant by this phrase in his email.

(a) [Focus Director 1] initially stated that [Lexon Director 1] was chasing to '*find out […] what's happened to his licence because he, obviously, thought [..] he'd have it granted […] by then*'.[744]

(b) Later in the same interview, however, [Focus Director 1] suggested he had informed [Lexon Director 1] that Focus had *'another option'* or an *'alternative source'* for sourcing Prochlorperazine POM and that [Lexon Director 1] was therefore chasing him (i.e. [Focus Director 1]) to confirm whether [Focus Director 1] had this *'alternative source'* of Prochlorperazine POM.[745]

5.230.2 [Focus Director 2] told the CMA he did not know what [Focus Director 1] meant by the final line of his email, but said that he would '*imagine*' [Focus Director 1] was referring to [Lexon Director 1] '*chasing*' to formalise '*his deal*' with Focus for the supply of Prochlorperazine POM.[746]

5.230.3 [Lexon Director 1] maintains that he had no awareness of a potential agreement between Focus and Alliance at that time, and that [Focus Director 1] had '*said nothing*' to [Lexon Director 1] '*about the possibility of Focus being supplied by Alliance until September 2013*'.[747] [Lexon Director 1] has said that he does not recall chasing [Focus Director 1] at that time, but speculated that he may have chased [Focus Director 1] to '*get the [Focus-Lexon Heads of Terms] signed*'.[748]

The Parties' representations on the 22 June 2013 email

5.231 Alliance supported [Focus Director 1]'s explanation of the 22 June 2013 email based partly on the timing of Alliance and Focus' negotiations, which Alliance said

[744] Interview [Focus Director 1], 2 October 2018, page 115, lines 12-14 (URN: PRO-C3294).

[745] Interview [Focus Director 1], 2 October 2018, page 121, lines 4-18; page 122, line 8-17; page 125, line 8 to page 126 line 4; and page 127, line 18 to page 130, line 2 (URN: PRO-C3294). [Focus Director 1]'s evidence on this point was not consistent, however. When asked at one point in the interview about this possible meaning of the comment in his email, [Focus Director 1] had also said that [Lexon Director 1] was *not* chasing him to find out what Focus planned with its alternative source (Interview [Focus Director 1], 2 October 2018, page 121, line 20 to page 122, line 4 (URN: PRO-C3294)).

[746] Interview [Focus Director 2], 8 January 2020, page 61, lines 8 to 24 (URN: PRO-C5886).

[747] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraphs 30 and 57 (URN: PRO-C5092); see also Lexon RSO, 31 July 2019, paragraph 21 (URN: PRO-C5091).

[748] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 57 (URN: PRO-C5092).

were *'at a reasonably advanced stage of negotiation'* on 22 June 2013 but '*not in a near-final stage until late July 2013*'.[749]

5.232 Advanz[750] and Cinven[751] have variously submitted that, by contrast, the CMA's explanation that the plain reading of the 22 June 2013 email shows that [Lexon Director 1] was involved in determining the terms of the Alliance-Focus Agreement is implausible given:

5.232.1 the terms of the Alliance-Focus Agreement were '*identical*' to those in a pre-existing distribution agreement between Alliance and Focus for Aspirin;[752]

5.232.2 it is not clear why [Alliance Employee 1] would have *'wanted or needed to contact [Focus Director 2]'* had he already agreed the terms on which Alliance would supply Focus with [Lexon Director 1];[753]

5.232.3 [Lexon Director 1] could not plausibly have limited his involvement to the '*benign terms*' set out in [Focus Director 1]'s email, but would have also been involved in setting the price that Focus would charge for the Alliance product given that Lexon '*directly benefitted from the profits made by Focus on the sale of Alliance's product*';[754] relatedly, the fact that [Focus Director 1]'s email '*makes clear that Focus considered itself entirely free to set its own price*' is inconsistent with the Market Exclusion Agreement between Alliance and Lexon;[755]

5.232.4 [Focus Director 1] would have been expected to explain the profit share allocation between Focus and Lexon by reference to what had been '*agreed between Alliance and Lexon*' rather than on the basis that: '*it is his [[Lexon Director 1]'s] licence*';[756] and

5.232.5 there were no further communications with Lexon on the terms of the Alliance-Focus Agreement, including any '*final sign off by Lexon on the terms*'.[757]

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[749] Alliance RSO, 1 August 2019, paragraphs 4.22(b)(ii) and 4.22(b)(iii) (URN: PRO-C5096).

[750] Advanz RSO, 1 August 2019, paragraph 3.106 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraphs 4.42.4 and 4.43.2 (URN: PRO-C7112).

[751] Cinven RLF, 22 April 2021, paragraph 2.84 (URN: PRO-C7107).

[752] Advanz RSO, 1 August 2019, paragraph 3.106 (URN: PRO-C5111).

[753] Cinven RLF, 22 April 2021, paragraph 2.84(a) (URN: PRO-C7107).

[754] Advanz RSO, 1 August 2019, paragraph 3.106 (URN: PRO-C5111) and Cinven RLF, 22 April 2021, paragraph 2.84(a) (URN: PRO-C7107). Advanz submitted that the fact that Lexon had no control over or ability to influence the price at which Focus sold the product is noteworthy given that Lexon would directly benefit from an increase in Focus' revenues through the profit share term (Advanz RSO, 1 August 2019, paragraph 3.170.4 (URN: PRO-C5111)).

[755] Cinven RLF, 22 April 2021, paragraph 2.84(a) (URN: PRO-C7107).

[756] Cinven RSO, 15 August 2019, paragraph 4.154 (URN: PRO-C5132); Cinven RLF, 22 April 2021, paragraph 2.84(b) (URN: PRO-C7107).

[757] Advanz RSO, 1 August 2019, paragraph 3.106 (URN: PRO-C5111).

5.233 Alliance has submitted that the CMA's interpretation of [Focus Director 1]'s email is inconsistent with the CMA's interpretation of [Alliance Director 1]'s 11 June 2013 notebook entry, as the CMA has understood that [Alliance Director 1] noted that Lexon would appoint Focus as the distributor of its Prochlorperazine POM product.[758]

5.234 Cinven and Advanz submitted that it is '*unsurprising*' that [Focus Director 1]'s email did not make any reference to Focus purchasing any product from Lexon as Medreich did not at this point have a marketing authorisation for Prochlorperazine POM. Cinven and Advanz claimed that, in any case, no inference can be drawn from this omission as [Focus Director 1]'s email '*also makes no reference to purchasing Prochlorperazine POM from Alliance*', which Cinven has suggested would necessarily lead the CMA to conclude on the same logic that Focus did not intend to purchase any Prochlorperazine POM from Alliance. Advanz also pointed out that the 22 June 2013 email makes no mention of a Sunset Clause on the basis that Advanz submitted that Focus believed Lexon would be actively commercialising its Prochlorperazine POM.[759]

5.235 Advanz submitted that the CMA misrepresented [Focus Director 1]'s email of 22 June 2013 on the basis that the email did not discuss an ability on the part of Focus significantly to increase the price: Advanz pointed out that the email stated that the pricing would '*depend on market*', that price increases were rational commercial behaviour and that it would be of concern if Focus, as a distributor, did not have the ability to determine its price.[760]

The CMA's assessment of the witness evidence and the associated Parties' representations on the 22 June 2013 email

5.236 The CMA rejects the claims of [Focus Director 1], [Focus Director 2] and [Lexon Director 1] in relation to the interpretation of the 22 June 2013 email.

5.237 In relation to the first line of [Focus Director 1]'s email dated 22 June 2013, the CMA rejects the claim that '*the agreement [Lexon Director 1] made*' should have read as '*the agreement [Alliance Employee 1] made*'.

5.237.1 In all other respects, and although drafted in an informal style, [Focus Director 1]'s email accurately records the nature of the arrangements that Focus would enter into with Alliance and Lexon, and there is consequently little reason to doubt the accuracy of [Focus Director 1]'s reference to '*[Lexon Director 1]*'; this reasoning applies irrespective of whether [Focus

[758] Alliance RSO, 1 August 2019, paragraph 4.22(c) (URN: PRO-C5096).

[759] Advanz RSO, paragraph 3.163 (URN: PRO-C5111); see also Cinven RSO, 15 August 2019, paragraph 4.155 (URN: PRO-C5132).

[760] Advanz RSO, 1 August 2019, paragraph 3.170 (URN: PRO-C5111).

Director 1]'s email was rushed, was written before or during a holiday, or contained spelling errors.

5.237.2 Contrary to [Focus Director 2] and [Lexon Director 1]'s comments, it *would* make sense for [Alliance Employee 1] to contact Focus to discuss the implementation of a supply agreement between Alliance and Focus that [Alliance Employee 1] had at that time only agreed in principle with Lexon. In contrast, it would make less sense for [Focus Director 1] to be expecting an imminent call from [Alliance Employee 1] if he had already just negotiated with Alliance the terms of that supply agreement.

5.237.3 Within [Focus Director 1]'s email of 22 June 2013, the wording '*the agreement [Lexon Director 1] made*', makes linguistic sense. His proposed alternative formulation allowing for a typo, '*the agreement [Alliance Employee 1] made*', would by contrast be an unusual construction – even within [Focus Director 1]'s informal writing style – to describe an agreement between himself and [Alliance Employee 1], as it appears to exclude (or at least diminish) [Focus Director 1]'s own role in making that agreement: the sentence would then read '*[i]n case [Alliance Employee 1] rings you , the agreement [Alliance Employee 1] made was we initially buy …*', which is a strange construction; if [Focus Director 1] had intended this, it would have been far quicker, and more natural, simply to write '*[i]n case [Alliance Employee 1] rings you , the agreement we made was …*'.

5.237.4 Moreover, [Focus Director 1]'s subsequent correspondence indicates that, notwithstanding the agreement in principle reached between Alliance and Lexon at that point, and Focus' willingness to participate in that agreement, Focus had not yet bilaterally confirmed with Alliance the terms of their supply agreement by 22 June 2013:

(a) On 22 June 2013, [Focus Director 1] explained to [Focus Director 2] that '*the agreement [Lexon Director 1] made*' was for Focus to '*initially buy at 25% of thier [sic] current trade price*' and then to '*purchase from them at current trade less 12.5%*' once Alliance had '*discontinue[d] [their] brand*'.

(b) On 18 July 2013, [Focus Director 1] told [Focus Director 2] that he was *'[j]ust doing the preparation for meeting with [Alliance Employee 1]*' and shared some anticipated monthly profit forecasts, which he had calculated '*[a]ssuming the brand is discontinued and we get all the prescriptions , and Alliance agree to sell to us at their current ASP of trade less 12.5%*' (emphasis added).[761] [Focus Director 1]'s need to assume that Alliance would '*sell to us at their current ASP of trade*

[761] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

less 12.5%' demonstrates that, although an agreement in principle had been reached between Alliance and Lexon, the content of which was communicated by Lexon to Focus, [Focus Director 1] had not yet directly confirmed '*the agreement [Lexon Director 1] made*' with [Alliance Employee 1] and Alliance.

(c) On 25 July 2013, [Focus Director 1] thanked [Alliance Employee 1] for '*meeting [him] earlier this week*' and provided a summary of their discussion. In relation to Prochlorperazine POM, [Focus Director 1] recorded that he and [Alliance Employee 1] had '*agreed an exclusive supply agreement*' (emphasis added) as well as the price per pack that Focus would purchase Prochlorperazine POM from Alliance.[762] [Focus Director 1]'s email of 25 July 2013 records that Focus had directly agreed with Alliance the terms of the supply of Prochlorperazine POM between 18 and 25 July 2013, and not before 22 June 2013 (see further at paragraph 5.237.5 below).

5.237.5 Alliance's suggestion that it offers in support of [Focus Director 1]'s submission that its negotiations with Focus were '*reasonably advanced*' but not '*near-final stage*' on 22 June 2013 is not supported by documentary evidence showing any discussion or negotiation between Alliance and Focus in relation to the supply of Prochlorperazine POM prior to 22 June 2013;[763] in fact, Focus confirmed the supply arrangement with Alliance at a meeting held during the week commencing 22 July 2013 (see further at paragraph 5.237.4 above).

5.237.6 Contrary to the claims of [Focus Director 2] and [Lexon Director 1], it also does not make sense to read the email of 22 June 2013 on the basis that it contained a typo and ought to have referred to '*[Alliance Employee 1]*' instead of '*[Lexon Director 1]*' given the broader context of the agreements that Focus would enter into with Alliance and Lexon. An arrangement that contemplates the originator supplier debranding its product, yet imposing upon itself a fixed price (see further at paragraphs 5.281 to 5.284 below), a distributor paying most of its profits to a supplier that provides no product in return (see further at paragraphs 5.298 to 5.300 below), and a potential competitor receiving monthly cash payments despite retaining no plans to enter the market (see further at paragraphs 5.422 and 5.434), makes most sense when considered as part of an agreement between Alliance and Lexon.

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[762] Email [Focus Director 1] to [Alliance Employee 1] entitled *'Meeting summary'* 25 July 2013 (URN: PRO-E003735).

[763] [Alliance Employee 1] stated in interview in respect of his meeting with [Focus Director 1] in July 2013 that *'during the meeting, this is where we bashed out the deal. Prior to that, it must have been a discussion about meeting up to talk about the option of this. I don't know when that was but clearly we -- I don't think I would have landed the whole prochlorperazine thing on him when we met'* (Interview [Alliance Employee 1], 4 October 2018, page 138, lines 1-5 (URN: PRO-C2909)).

5.237.7 Furthermore, [Lexon Director 1]'s involvement – as described in [Focus Director 1]'s email of 22 June 2013 – in agreeing the terms on which Alliance would supply Focus Prochlorperazine POM is consistent with other contemporaneous documentary evidence (see paragraphs 5.194 and 5.200 above) and is clearly confirmed by subsequent documentary evidence, including [Focus Employee 1]'s email of 23 March 2017: *'The only reason that Lexon gets Prochlorperazine Buccal Tablets is because* ***they helped set up the supply agreement with Alliance Pharma*** *…'* (emphasis added).[764]

5.237.8 Lastly, had [Focus Director 1] intended to write '*the agreement **[Alliance Employee 1]** made*' and had his email summarised two wholly separate agreements Focus had made with each of Alliance and Lexon as claimed by the witnesses and the Parties' representations, it would have been expected that [Focus Director 1] would have needed to warn [Focus Director 2] that the negotiations Focus was conducting with each of Alliance and Lexon were to be kept separate and not mentioned to the other party.

(a) Under the Focus-Lexon Heads of Terms, Lexon would receive profit share payments from Focus based on Focus' sale of the Alliance product. Lexon would therefore financially benefit from Focus having reached an agreement with Alliance – and would necessarily discover the existence of the arrangement once it started receiving profit share payments from Focus.

(b) Given this, it would have been natural for [Focus Director 2] to have assumed that [Focus Director 1] would have kept [Lexon Director 1] abreast of (or at least made mention of) the status of the negotiations between Focus and Alliance; it would therefore have been particularly important – if the negotiations were being kept distinct – for [Focus Director 1] to have warned [Focus Director 2] not to mention the negotiations with Alliance to [Lexon Director 1].

(c) Despite the fact that [Focus Director 1] stated that he had not informed Lexon about Focus' potentially obtaining supplies from Alliance at this point,[765] and that he claimed that both deals were kept separate until after terms had been agreed,[766] [Focus Director 1]'s

[764] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030).

[765] [Lexon Director 1] also claimed in his witness statement that [Focus Director 1] said nothing to him about the possibility of Focus being supplied by Alliance until September 2013 (Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 30 (URN: PRO-C5092)).

[766] Interview [Focus Director 1], 2 October 2018, page 64, line 6 to page 65, line 14 (URN: PRO-C3294).

email to [Focus Director 2] of 22 June 2013 contained no such warning.

(d) Whilst [Focus Director 2] (as the recipient of [Focus Director 1]'s email of 22 June 2013) stated that he was aware that the deals were separate and should not be discussed with the other company,[767] the CMA finds that this explanation is not credible given that [Focus Director 2]:[768] (i) initially stated he was unsure as to whether [Focus Director 1] was keeping the deals separate or whether they could be discussed with the other party;[769] (ii) stated that there were no other situations where Focus had been negotiating separate distribution deals with different marketing authorisation holders;[770] (iii) did not recall being told by [Focus Director 1] that the two agreements should be kept separate and should not be discussed;[771] and (iv) said he would not have known what [Lexon Director 1] knew about the Alliance agreement in July 2013.[772]

5.238 In relation to the final line of [Focus Director 1]'s email dated 22 June 2013, [Focus Director 1], [Focus Director 2] and [Lexon Director 1]'s suggestions of what and whom [Lexon Director 1] was '*chasing*' are inconsistent, incompatible and therefore unreliable. Further, none of [Focus Director 1], [Focus Director 2] or [Lexon Director 1] has provided a credible alternative explanation of whom or what [Lexon Director 1] would be chasing – and why he would be chasing at that point in time if his chasing were not connected to the implementation of the Market Exclusion Agreement:

5.238.1 As set out in paragraph 5.230 above, [Focus Director 1]'s comments in interview to explain this phrase were in themselves contradictory and unclear. He claimed, first, that [Lexon Director 1] was chasing for an update on the status of his marketing authorisation for Prochlorperazine POM, and, second, that [Lexon Director 1] was chasing him ([Focus Director 1]) to confirm whether [Focus Director 1] had secured an alternative source of the product.

5.238.2 In relation to [Focus Director 1]'s first explanation – that [Lexon Director 1] was chasing a third party about the status of his licence – it is not explicable why [Focus Director 1] would in June 2013 have been

[767] Interview [Focus Director 2], 8 January 2020, page 64, line 22 to page 65, line 5 (URN: PRO-C5886).

[768] The CMA additionally observes that [Focus Director 2]'s evidence was provided in an interview with the CMA held after he had reviewed the CMA's Statement of Objections and Advanz's response to the Statement of Objections. Interview [Focus Director 2], 8 January 2020, page 4, line 23 to page 5, line 1; page 10, line 23 to page 11, line 3; page 11, lines 14-15; page 52, lines 4-17 (URN: PRO-C5886).

[769] Interview [Focus Director 2], 8 January 2020, page 64, lines 13 to 18 (URN: PRO-C5886).

[770] Interview [Focus Director 2], 8 January 2020, page 65, lines 7 to 12 (URN: PRO-C5886).

[771] Interview [Focus Director 2], 8 January 2020, page 66 lines 6 to 12 (URN: PRO-C5886).

[772] Interview [Focus Director 2], 8 January 2020, page 78, lines 8 to 12 (URN: PRO-C5886).

particularly concerned about getting [Lexon Director 1] to do this ([Focus Director 1] wrote '*I am waiting on [Alliance Employee 1] ringing me back , but **have** [Lexon Director 1] chasing'*[773] (emphasis added) as opposed to writing '*[Lexon Director 1] is chasing*'). At this point, Focus was seeking a supply arrangement with Alliance which would enable Focus to obtain product and raise prices in the market; on this basis, there is no clear reason as to why [Focus Director 1] would have got [Lexon Director 1] to chase to obtain the Medreich licence as matter of urgency. [Focus Director 1] has not explained why he would wish to get [Lexon Director 1] to chase about the Medreich licence. In addition, [Lexon Director 1] interpreted the sentence in [Focus Director 1]'s email as referring to him ([Lexon Director 1]) chasing [Focus Director 1];[774] [Lexon Director 1] did not refer to his '*chasing*' the status of Medreich's Prochlorperazine POM licence (either with Medreich or the MHRA).[775]

5.238.3 On [Focus Director 1]'s second interpretation – that [Lexon Director 1] was chasing him about an alternative source of supply – [Focus Director 1]'s evidence was equivocal: earlier in the same interview, [Focus Director 1] had also told the CMA that [Lexon Director 1] was *not* chasing him to find out what [Focus Director 1] would do with his alternative source (see paragraph 5.230 above). In any event, on this interpretation of the phrase, to the extent that [Lexon Director 1] was chasing [Focus Director 1] about Focus obtaining product from Alliance, this is consistent with the Market Exclusion Agreement. In fact, [Focus Director 1][776] and [Lexon Director 1][777] have stated that [Focus Director 1] had not informed [Lexon Director 1] of the '*possibility of Focus being supplied by Alliance*' at the date of the email of 22 June 2013 and did not do so until September 2013. This therefore undermines this second interpretation put forward by [Focus Director 1] given that, in June 2013, there was no other licence holder at that time other than Alliance (let alone any product being manufactured by a third party): hence, it is not clear why [Lexon Director 1] would exhibit any urgency in this respect.

5.238.4 Both of [Focus Director 1]'s explanations are contradicted by [Focus Director 2]'s evidence who, like [Lexon Director 1], suggested that [Lexon

[773] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[774] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 57 (URN: PRO-C5092).

[775] Lexon did not question the CMA's interpretation of the phrase. See the submission of Lexon dated 10 December 2019, in response to CMA questions of 26 November 2019, question 2 (URN: PRO-C5477).

[776] Interview [Focus Director 1] 2 October 2018, page 64, lines 6-25 (URN: PRO-C3294).

[777] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 30 (URN: PRO-C5092).

Director 1] was chasing [Focus Director 1] to finalise the Focus-Lexon Heads of Terms[778] (discussed in paragraph 5.238.5 below).

5.238.5 [Focus Director 2] and [Lexon Director 1]'s suggestion that [Lexon Director 1] was chasing [Focus Director 1] to finalise the Focus-Lexon Heads of Terms is itself not consistent with the remaining text of the 22 June 2013 email or the wider context:

(a) the other text of the 22 June 2013 email shows that the deal between Focus and Lexon had been reached: what was outstanding was bilateral confirmation between Alliance and Focus of the terms that had been agreed in principle between Alliance and Lexon: this explains why [Focus Director 1] was waiting for a phone call back from [Alliance Employee 1];

(b) the reference in the 22 June 2013 email to [Lexon Director 1] chasing is part of the same sentence as [Focus Director 1]'s comment that he was waiting to hear back from [Alliance Employee 1], and is drafted to suggest the two propositions are linked: '*I am waiting on [Alliance Employee 1] ringing me back , **but** have [Lexon Director 1] chasing to see what is happening…*' (emphasis added); this connection clearly suggests that [Lexon Director 1]'s chasing of [Focus Director 1] is linked to the fact that [Focus Director 1] was waiting to hear back from [Alliance Employee 1]; to the extent that [Lexon Director 1] was simply chasing to finalise the Focus-Lexon Heads of Terms, there would have been no need or basis for [Focus Director 1] to have linked this to hearing back from [Alliance Employee 1] and this explanation does not, in any event, account for [Focus Director 1]'s choice of words '*chasing to see **what is happening***' (emphasis added); and

(c) in any event, given that Medreich had not at that point received its marketing authorisation for Prochlorperazine POM, which was approved on 9 January 2014, and Lexon was therefore some time away from being able to supply Focus with any Prochlorperazine POM product, there was no apparent cause for [Lexon Director 1] to 'chase' [Focus Director 1] about the status of the Focus-Lexon Heads of Terms at that point; nor is there further evidence of [Lexon Director 1] 'chasing' to conclude the Focus-Lexon Heads of Terms, which was not documented until some time later.

5.238.6 On the basis of the above, and consistent with the surrounding contemporaneous evidence, the CMA finds that the 22 June 2013 email

[778] Interview [Focus Director 2], 8 January 2020, page 61, lines 11-13 (URN: PRO-C5886) and page 61, lines 7-9 (URN: PRO-C5887).

should be given its natural meaning: [Lexon Director 1] was chasing [Focus Director 1] to establish what progress Focus and Alliance had made in implementing the agreement that had already been reached in principle between Lexon and Alliance.

5.239 The CMA has considered the various further representations made by the Parties about the interpretation of [Focus Director 1]'s 22 June 2013 email.

5.240 The CMA rejects Alliance's representation that the CMA's reading of the 22 June 2013 email is inconsistent with the CMA's interpretation of [Alliance Director 1]'s 11 June 2013 notebook entry. These interpretations are corroborative rather than conflicting: [Alliance Director 1]'s notebook entry set out that Lexon would appoint Focus to distribute its product, but that Lexon would limit its supply of Prochlorperazine POM to '*1 [batch] every 5yr to avoid Sunset*'.[779] This is fully consistent with [Focus Director 1]'s 22 June 2013 email, in which he explains that the '*deal*' between Focus and Lexon consisted of the share of profits (from the sale of Alliance's Prochlorperazine POM) in '*Lexon [sic] favour*' and makes no reference to purchasing any product from Lexon.[780]

5.241 The CMA rejects Cinven's submission that it is implausible that [Lexon Director 1] had agreed the terms on which Alliance would supply Focus its Prochlorperazine POM on the basis that it was unclear why [Alliance Employee 1] would have contacted [Focus Director 2] about an agreement that had already made between Alliance and Lexon. By 22 June 2013, Focus had agreed with Lexon to participate in the agreement between Alliance and Lexon in relation to the supply of Prochlorperazine POM, but had not at that point discussed with Alliance how those terms would be implemented. That [Focus Director 1] met with [Alliance Employee 1] during the week commencing 22 July 2013 and agreed an '*exclusive supply agreement*' on the same terms as previously agreed by Lexon explains why [Alliance Employee 1] would have been in contact with Focus about the practical implementation of the agreement already made in principle between Alliance and Lexon.[781]

5.242 The CMA does not accept Advanz's submission that [Lexon Director 1] could not have agreed the terms on which Alliance would supply Prochlorperazine POM to Focus as these terms were '*identical*' to Alliance and Focus' pre-existing agreement to supply Aspirin. Most obviously, the terms were not identical. The key pricing terms for Prochlorperazine POM were added separately to that agreement as an addendum and amendment to the Aspirin Agreement.[782]

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[779] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

[780] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[781] Email [Focus Director 1] to [Alliance Employee 1] entitled *'Meeting summary'* 25 July 2013 (URN: PRO-E003735).

[782] Section 26 response of Alliance, part two, dated 16 November 2017, to CMA Notice dated 16 October 2017, Appendix 2, Alliance-Focus Agreement, page 10 (URN: PRO-C0369).

5.243 The CMA does not accept Cinven's submission that, had there been an agreement between Alliance and Lexon as to the terms on which Alliance would supply Focus Prochlorperazine POM, [Focus Director 1] would have explained the profit-share split between Focus and Lexon by reference to what had been '*agreed between Alliance and Lexon*' rather than '*as it is his [[Lexon Director 1]'s] licence*'. This is because the CMA does not find that Alliance was aware of, or agreed to, the precise terms of the profit-sharing agreement reached by Focus and Lexon. Alliance did not need to be aware of the profit share split between Focus and Lexon: provided that Lexon was compensated for and therefore refrained from entering the market such that Alliance's sales volumes and its prior price were protected (consistent with the 22 June 2013 email), the precise commercial terms agreed between Lexon and Focus would not themselves have a commercial impact on Alliance.[783]

5.244 The CMA rejects the related submission that [Lexon Director 1] could not plausibly have limited his involvement to the terms on which Alliance would supply Focus without agreeing the price at which Focus sold Alliance's Prochlorperazine POM into the market. Lexon would have had no need to specify, control or agree with Alliance (or indeed Focus) the price at which Focus sold Alliance's Prochlorperazine POM into the market given that Focus and Lexon would both benefit from price increases in this respect: the profit share meant their incentives were aligned and it is also clear from contemporary evidence that Lexon anticipated price rises by Focus on the basis that Lexon was expecting in late 2013 '*healthy returns*'[784] from its receipt of profit share under the Focus-Lexon Heads of Terms (see paragraph 5.419).

5.245 The CMA does not find Advanz's submission that [Lexon Director 1] could not have agreed the terms that Alliance would supply Focus Prochlorperazine POM due to the absence of further communications with Lexon on the terms of the Alliance-Focus Agreement, including any '*final sign-off*', persuasive. There is no basis to assert that an additional formal step would have been necessary for [Lexon Director 1] to have 'signed-off' the agreement between Alliance and Focus (which was in fact implemented on the terms agreed between Lexon and Alliance). Later evidence indicates that [Lexon Director 1] was aware that the arrangements between Alliance and Focus had progressed,[785] resulting in [Lexon Director 1]

[783] Alliance's submission (Alliance RSO, 1 August 2019, paragraph 4.22 (URN: PRO-C5096)) that [Focus Director 1]'s reference to a '*deal*' between Focus and Lexon does not implicate Alliance is, however, incorrect. Alliance had agreed with Lexon that Lexon would limit its supply of product to a single batch of Prochlorperazine POM to avoid the application of the Sunset Clause in exchange for a transfer of value made via Focus' sales of Alliance's Prochlorperazine POM (see further at paragraphs 5.190 to 5.202 above).

[784] Document entitled *'Lexon (UK) Limited Board Meeting Minutes'*, dated 12 September 2013, page 2 (URN: PRO-C0054).

[785] On 10 July 2013, [Focus Director 1] emailed [Lexon Director 1] forwarding a copy of a RAMA report and stating, '*I take it the Medrich [sic] licence is yours exclusively before I send this to [Alliance Employee 1]*' (Email [Focus Director 1] to [Lexon Director 1] entitled '*Fwd: Rama as requested*' 10 July 2013 (URN: PRO-E000326)); this email is addressed in detail at paragraph 5.199.2 above and paragraphs 5.254 to 5.263 below). On 12 September 2013, [Lexon Director 1] reported to the Lexon board that *'Prochlorperazine is due to be launched next month from which healthy returns are*

being sent profit share reconciliation statements from 3 January 2014,[786] showing that [Lexon Director 1] had been made aware that the Alliance-Focus Agreement had been implemented on the terms he had agreed.

5.246 The CMA rejects Cinven's and Advanz's explanation as to why [Focus Director 1] made no reference to purchasing Prochlorperazine POM from Lexon in his email. Whilst it is correct that Lexon/Medreich did not have a Prochlorperazine POM marketing authorisation at this point, and Focus could therefore not have guaranteed receiving product from a particular date, [Focus Director 1]'s email does not contemplate Focus (either immediately or subsequently) purchasing Prochlorperazine POM at all from Lexon, and makes no suggestion that the arrangement he is describing is expected to be short-lived or pending the grant of Medreich's licence.[787]

5.247 The CMA rejects Advanz's submission that [Focus Director 1]'s email does not signify an ability on Focus' part significantly to increase price. [Focus Director 1]'s language ('*Generic Pricing [sic] will depend on market and Focus will set!*') must be read in context, namely that [Focus Director 1] refers to the discontinuation of the brand in the previous sentence, meaning that, unlike the branded product, the generic product would not be price constrained by the PPRS scheme. Further, in terms of his comment that pricing would '*depend on market*', [Focus Director 1] would have been aware that Focus would be the only supplier of Prochlorperazine POM in the UK at that point.[788]

Witness evidence and Parties' representations on the 24 June 2013 correspondence between [Focus Director 1] and [Lexon Director 1]

[Lexon Director 1]'s and [Focus Director 1]'s evidence on the 24 June 2013 correspondence

5.248 As regards [Focus Director 1]'s and [Lexon Director 1]'s email exchange on 24 June 2013,[789] [Focus Director 1] and [Lexon Director 1] have both provided evidence that is inconsistent with the CMA's reading of that email as set out above (see paragraph 5.199.1).

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expected', see document entitled *'Lexon (UK) Limited Board Meeting Minutes'*, dated 12 September 2013, page 2 (URN: PRO-C0054); this evidence is addressed in detail at paragraph 5.419.

[786] Email [Focus Director 1] to [Lexon Director 1] cc [Focus employee] entitled *'FW: Prochlorperazine Reconciliation December 2013'* 3 January 2014 (URN: PRO-E000346) and attachment entitled '*Prochlorperazine Reconciliation December 2013*', 3 January 2014 which showed the cost of goods being deducted from a net revenue figure to generate profit, with *'75% Profit Share owed to Lexon'* (URN: PRO-E000347).

[787] Cinven's related submission that the 22 June 2013 email makes no reference to Focus purchasing product from Alliance is inaccurate given that this is the subject of the first paragraph of the 22 June 2013 email.

[788] The CMA recognises that distributors set sales prices and may have a unilateral incentive to increase price: however, these points do not undermine the relevance of [Focus Director 1]'s recognition that Focus would be able to increase price as a result of being appointed distributor of the de-branded Alliance product whilst not facing a competitive constraint from the Lexon/Medreich product, and that the contemporary evidence shows that Focus did actually forecast being able to increase prices (see paragraph 5.196.3 above).

[789] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood'* dated 24 June 2013 (URN: PRO-E000325).

5.248.1 [Focus Director 1] told the CMA that his comment that he had '*still not heard back from [first name of Alliance Employee 1]*' referred to [Co-op employee] and to [Co-op employee]'s attendance at Pinewood Healthcare's annual golf day held that year on 26 June 2013 at Dundrum Golf Club in Ireland, rather than to [Alliance Employee 1].[790]

5.248.2 [Lexon Director 1]'s evidence has differed between that given in his interview and that given in his subsequent witness statement:

(a) During an interview with the CMA, when reviewing the exchange of 24 June 2013, [Lexon Director 1] assumed that [Focus Director 1] was referring to [Alliance Employee 1], commenting that he was '*struggling*' as to '*why [he] would be chasing [Alliance Employee 1]*'. [Lexon Director 1] explained that, although [Co-op employee] went '*on golf trips*', he did not think that [Co-op employee] attended Pinewood Healthcare's annual golf days.[791]

(b) In his later witness statement which accompanied Lexon's Statement of Objections representations, received after [Lexon Director 1] had had access to [Focus Director 1]'s interview transcript, [Lexon Director 1] contradicted his statements in interview and submitted that he and [Focus Director 1] were referring to [Co-op employee] who was '*due to play golf*' with [Lexon Director 1] and [Focus Director 1] at Pinewood Healthcare's golf day that year. [Lexon Director 1] added that he and [Focus Director 1] '*were contacting [Co-op employee] to replace*' him as he '*could not play the match*'.[792]

The Parties' representations on the 24 June 2013 correspondence

5.249 By way of support for the explanation put forward by [Focus Director 1] in interview and by [Lexon Director 1] in his witness statement (but not his initial interview),

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[790] Interview [Focus Director 1] 2 October 2018, page 98, line 26 to page 100 line 8 (URN: PRO-C3294). [Lexon Director 1] provided details of that year's Pinewood Healthcare golf event in his witness statement dated 31 July 2019, see Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 58 (URN: PRO-C5092).

[791] Interview [Lexon Director 1], 10 September 2018, part 1, CD2, page 34, line 18 to page 35, line 25 (URN: PRO-C3192). Cinven has submitted that [Lexon Director 1] had said that he was '*unsure*' which '*[first name of Alliance Employee 1]*' was referred to in the email exchange, that it '*could be*' [Co-op employee], and that [Lexon Director 1] had told the CMA that he had attended '*a few golf tournaments with [Co-op employee]*' (Cinven RLF, 22 April 2021, paragraph 2.91(a) (URN: PRO-C7107)). However, Cinven's representations do not take account of the fact that [Lexon Director 1] was initially relatively positive in his interview that the reference was to [Alliance Employee 1], and only discussed the potential for this to refer to [Co-op employee] when asked (Interview [Lexon Director 1], 10 September 2018, part 1, CD2, page 33, line 20 to page 35, line 4 (URN: PRO-C3192)). Cinven's representations also do not account for [Lexon Director 1]'s specific response, when asked in interview, that he did *not* think [Co-op employee] did go on any of the Pinewood trips.

[792] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 58 (URN: PRO-C5092). Cinven has submitted that the evolution of [Lexon Director 1]'s evidence in relation to his email exchange with [Focus Director 1] on 24 June 2013 was because [Lexon Director 1] had been able to '*consider the email more fully*' (Cinven RLF, 22 April 2021, paragraph 2.91(b) (URN: PRO-C7107)); however, the CMA does not accept this given that [Lexon Director 1] has not provided any basis or explanation for his alleged enhanced recollection in this respect.

Advanz submitted[793] that [Focus Director 1] had explained in an interview with the CMA that he would have been in '*contact with other individuals in the sector who were known to attend to golf* events *to see if they wanted to join a golf excursion to Ireland*'. Advanz said that [Co-op employee] was a '*known golf player*' who '*regularly attended other golf events*' such as the '*PIGS Tour*' held for Parallel Importers Generic Suppliers and would have been contacted to '*see if he could be persuaded to attend a golf event in Ireland*'.[794]

5.250 In terms of the evidence obtained from [Co-op employee] (summarised in paragraph 5.252 below), Advanz and Cinven have stated that the CMA should prefer the sworn witness evidence of [Focus Director 1] and [Lexon Director 1], also given that their interview evidence was accompanied by a signed statement of truth.[795] By contrast, they criticised the CMA's '*informal*' record of its '*short*' call with [Co-op employee], described the CMA's questions during the call to be '*manifestly inadequate*',[796] noting also that [Co-op employee] reviewed but was not asked to '*corroborate his statements*', '*swear that his statements were truthful*' or '*check his internal records*'.[797] Advanz also stated that although [Co-op employee] had confirmed to the CMA that he had never attended or been invited to a Pinewood golf event, he also confirmed that he had played golf in Ireland.[798]

5.251 Advanz also observed that [Focus Director 1] and [Lexon Director 1]'s email exchange of 24 June 2013 makes '*no mention of Prochlorperazine POM, Alliance or any contemplated distribution or other business arrangements*'.[799]

The CMA's assessment of the witness evidence and the associated Parties' representations on the 24 June 2013 correspondence

5.252 In relation to [Focus Director 1] and [Lexon Director 1]'s email exchange on 24 June 2013, the CMA does not find the witness evidence given by [Focus Director 1] and (subsequently) by [Lexon Director 1] to be persuasive for the following reasons:

5.252.1 [Focus Director 1]'s statement that he and [Lexon Director 1] were referring to [Co-op employee] in their email exchange of 24 June 2013 has been undermined by evidence given by [Co-op employee] himself. [Co-op employee] informed the CMA that he has never attended, never been

[793] Advanz RLF, 22 April 2021, paragraphs 4.4 to 4.9 (URN: PRO-C7112).
[794] Advanz RLF, 22 April 2021, paragraph 4.8 (URN: PRO-C7112).
[795] Cinven RLF, 22 April 2021, paragraph 2.93 (URN: PRO-C7107).
[796] Advanz RLF, 22 April 2021, paragraphs 4.6 and 4.9 (URN: PRO-C7112).
[797] Cinven RLF, 22 April 2021, paragraphs 2.91-2.93 (URN: PRO-C7107).
[798] Advanz RLF, 22 April 20201, paragraph 4.6 (URN: PRO-C7112).
[799] Advanz RLF, 22 April 2021, paragraph 4.2 (URN: PRO-C7112).

invited to attend and never been asked about attending a golf event in Ireland organised by Pinewood Healthcare.[800]

5.252.2 [Co-op employee]'s evidence is consistent with [Lexon Director 1]'s initial view expressed in interview that [Co-op employee] did not attend Pinewood Healthcare's annual golf days held in Ireland.[801]

5.252.3 By contrast, [Co-op employee]'s evidence contradicts [Lexon Director 1]'s later submission in his witness statement[802] – provided after Lexon had been provided with access to [Focus Director 1]'s interview transcript – that [Co-op employee] was '*due to play golf*' with him and [Focus Director 1] at the Pinewood Healthcare golf day that year and that he and [Focus Director 1] had contacted [Co-op employee] to replace [Lexon Director 1] who '*could not play the match*'.

5.252.4 Although [Lexon Director 1] did provide evidence that he had informed Pinewood Healthcare on 18 June 2013 that he would not be able to attend the golf event that year,[803] [Lexon Director 1] has not provided any evidence supporting his assertion in his witness statement that [Co-op employee] was '*due to play golf*' at the Pinewood Healthcare golf day in Ireland or that he and [Focus Director 1] '*were contacting*' [Co-op employee] to '*replace*' [Lexon Director 1],[804] or provided any explanation as to why his evidence on this point has changed between interview and witness statement.

5.252.5 While [Co-op employee]'s evidence was provided via a telephone call with the CMA, he confirmed the accuracy of the call note in writing and the CMA is aware of no reason why [Co-op employee] would wish to conceal or mislead the CMA in regards to whether he had been invited to attend a Pinewood Healthcare golf event in Ireland in 2013, in particular given that the CMA had made clear to [Co-op employee] at the start of the call that he was not under investigation.[805]

5.252.6 [Focus Director 1]'s and [Lexon Director 1]'s explanation for the 24 June 2013 email is also difficult to reconcile with the wording of [Focus Director

[800] Meeting note between CMA and [Co-op employee], 16 January 2020 (URN: PRO-C5768). In this respect, the fact that [Co-op employee] played golf and has played golf in Ireland is neither disputed nor relevant given [Co-op employee]'s lack of ambiguity regarding the Pinewood event.

[801] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 35, line 12 (URN: PRO-C3192).

[802] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 58 (URN: PRO-C5092).

[803] Email [Lexon Director 1] to [Pinewood Healthcare employee] no subject 18 June 2013 (page 83 of URN: PRO-C5089).

[804] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 58 (URN: PRO-C5092).

[805] Meeting note between CMA and [Co-op employee], 16 January 2020 (URN: PRO-C5768). When the CMA first contacted [Co-op employee] to set up the call, it had expressly stated that '*neither you [[Co-op employee]] nor the Lincolnshire Co-operative Group are under investigation in this matter, and our queries are not with a view to scoping you or the Lincolnshire Co-operative Group into an investigation*' (Email [CMA Official] to [Co-op employee] entitled '*Competition and Markets Authority – Query [Co-op employee]*' 9 January 2020 (URN: PRO-C5703)).

1]'s original email itself: *'I take it you are not going to pinewood ? Also I have still not heard back from [first name of Alliance Employee 1]'*.[806] [Focus Director 1]'s wording suggests that he believes [Lexon Director 1] would not be attending the Pinewood event, but is uncertain: hence the question being posed to [Lexon Director 1]. It is inherently unlikely, given this uncertainty and that [Lexon Director 1] was yet to confirm to [Focus Director 1] whether or not he would attend, that [Focus Director 1] would already (that is, by 24 June 2013) have approached [Co-op employee] to replace [Lexon Director 1] and would '*still*' be waiting to hear back from him.

5.253 The CMA regards Advanz's submission that [Focus Director 1] and [Lexon Director 1]'s email exchange on 24 June 2013 made no reference to '*Prochlorperazine POM, Alliance or any contemplated distribution or other business arrangements*'[807] as misconceived given that it is clear from [Focus Director 1]'s email, '***Also*** *I have* ***still*** *not heard back from [first name of Alliance Employee 1]*' (emphasis added), that:[808]

5.253.1 [Focus Director 1] was changing the subject from his initial enquiry as to whether [Lexon Director 1] was planning on attending the Pinewood Healthcare golf event in Ireland ('*Also*'); and

5.253.2 [Focus Director 1] and [Lexon Director 1] had very recently in their correspondence of 22 June 2013 discussed the fact that [Focus Director 1] was waiting to hear back from [Alliance Employee 1] ('*I am waiting on [Alliance Employee 1] ringing me back*'[809]); this explains the language in the email of 24 June 2013 ('***still*** *not heard back from [first name of Alliance Employee 1]*' (emphasis added)) and the fact that [Focus Director 1] assumed – correctly, given [Lexon Director 1]'s response – that [Lexon Director 1] did not need any further context to understand which *[first name of Alliance Employee 1]* he was referring to or why [Focus Director 1] was expecting to '*hear back*' from him.

[806] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood'* dated 24 June 2013 (URN: PRO-E000325).

[807] Advanz RLF, 22 April 2021, paragraph 4.2 (URN: PRO-C7112).

[808] Email [Focus Director 1] to [Lexon Director 1] entitled '*Pinewood'* dated 24 June 2013 (URN: PRO-E000325).

[809] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

Witness evidence and Parties' representations on [Focus Director 1]'s 10 July 2013 email

[Focus Director 1]'s and [Lexon Director 1]'s evidence on the 10 July 2013 email

5.254 In relation to [Focus Director 1]'s email to [Lexon Director 1] on 10 July 2013,[810] [Focus Director 1] and [Lexon Director 1] have both provided evidence that is inconsistent with the CMA's reading as set out above (see paragraph 5.199.2 above).

5.254.1 [Focus Director 1] told the CMA he believed that he was seeking to confirm to [Alliance Employee 1] that Medreich's marketing authorisation for Prochlorperazine OTC listed on RAMA was Lexon's *'licence'* for the product after [Alliance Employee 1] had asked him *'who was going to sell the Medreich product'*. [Focus Director 1] said that he had told [Lexon Director 1] that [Alliance Employee 1] had *'been asking about product*' as Alliance was *'expecting somebody to launch'*.[811] [Focus Director 1] also said that [Lexon Director 1] did not know at that time about the proposed agreement between Alliance and Focus for the supply of Prochlorperazine POM and was unable to explain how he expected [Lexon Director 1] to understand that the '*[first name of Alliance Employee 1]*' referred to in his email was [Alliance Employee 1], stating '*I think that was me putting it down without any thought process rather than it being specific*'.[812]

5.254.2 [Lexon Director 1]'s evidence has differed between that given in interview and that given in his subsequent witness statement:

(a) In an interview with the CMA, [Lexon Director 1] said that [Focus Director 1] intended to send the RAMA report to [Alliance Employee 1] '*[a]s evidence that the licence has been granted*'. [Lexon Director 1] explained that [Focus Director 1] had '*agreed to take some stock off*' Alliance, but [Alliance Employee 1] '*wouldn't supply stock […] until the licence has been granted*' because there would be '*no need if [Alliance] weren't going to have any competition*' if Focus had not '*got a product*'. [Lexon Director 1] also said that he was '*happy*' for [Focus Director 1] to '*take stock*' from Alliance '*as long as [he] got [his] share of the profit*'.[813]

[810] Email [Focus Director 1] to [Lexon Director 1] entitled *'Fwd: Rama as requested'* 10 July 2013 (URN: PRO-E000326).

[811] Interview [Focus Director 1], 2 October 2018, page 100, line 18 to page 104, line 15; page 107, lines 7-24 (URN: PRO-C3294).

[812] Interview [Focus Director 1], 2 October 2018, page 104, line 17 to page 106, line 23; page 108, line 21 to page 109, line 4 (URN: PRO-C3294).

[813] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 43, line 23 to page 46, line 22 (URN: PRO-C3192).

(b) In contrast, in his witness statement, [Lexon Director 1] said that he did not recall seeing the email or believe that he had replied to it, did not see why [Focus Director 1] would mention [Alliance Employee 1] to him and did not understand why the RAMA report was relevant to Focus given it listed Medreich's licence for Prochlorperazine OTC rather than Prochlorperazine POM.[814] [Lexon Director 1] also said in his witness statement that he had no idea that Focus was contemplating entering into a supply agreement for Prochlorperazine POM with Alliance until September 2013.[815]

The Parties' representations on the 10 July 2013 email

5.255 Advanz and Cinven disputed the CMA's reliance on [Focus Director 1]'s email of 10 July 2013 on the basis that it related to public information concerning the ownership of Medreich's MA for Prochlorperazine OTC, and that no inference regarding Prochlorperazine POM could be drawn from that.[816] Cinven further submitted that [Focus Director 1]'s email did not mention a transfer of value or delay in the entry of the Lexon and Medreich's Prochlorperazine POM and that:[817]

5.255.1 it is unclear why Alliance would have sought any such assurances about the effectiveness of a transfer of value from Focus, rather than Lexon directly, and why any such reassurances would not have been asked about Prochlorperazine POM specifically; and

5.255.2 any need for Focus to assure Alliance that Lexon had exclusive rights to Medreich's marketing authorisation would suggest that Alliance was '*uninformed*' about Lexon's relationship with Medreich.

5.256 Cinven questioned the CMA's reliance[818] on [Alliance Director 2]'s view that the grant of the Prochlorperazine OTC licence confirmed to Alliance that Lexon and Medreich were '*genuine in their claim to be seeking a generic product*'[819] to show that Lexon's exclusive access to Medreich's Prochlorperazine OTC MA was relevant to Alliance and Lexon's agreement in relation to Prochlorperazine POM, suggesting that [Alliance Director 2]'s statement contains a '*different rationale to that relied upon by the CMA*' and the CMA has relied on '*different (conflicting)*

[814] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 65 (URN: PRO-C5092).

[815] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 30 (URN: PRO-C5092).

[816] Advanz RLF, 22 April 2021, paragraphs 4.21 – 4.32 (URN: PRO-C7112). Cinven RSO, 15 August 2019, paragraphs 7.12, 7.13(b) and 7.14 (URN: PRO-C5132); Cinven RLF, 22 April 2021, paragraphs 2.78 to 2.82 (URN: PRO-C7107).

[817] Cinven RLF, 22 April 2021, paragraph 2.81 (URN: PRO-C7107).

[818] See note 686 above.

[819] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 3.10(e) (URN: PRO-C5098).

narratives' to support its interpretation of [Focus Director 1]'s email of 10 July 2013.[820]

5.257 From Focus' perspective, Cinven disputed that [Focus Director 1]'s email of 10 July 2013 shows Focus' awareness of the Market Exclusion Agreement[821] given that [Focus Director 1] had explained to the CMA in interview that Focus was seeking to obtain market information on Prochlorperazine OTC in order to respond to a request from Alliance[822] and it is '*plausible*' that Focus would be '*willing to provide a piece of ad hoc market colour to Alliance to please its potential supplier*'.[823]

5.258 Alliance submitted that the email did not provide evidence of Alliance's involvement in the Market Exclusion Agreement on the basis that it showed Focus checking with Lexon that the licence was indeed connected with the Lexon product such that Focus could then '*inform Alliance, thereby indicating the imminence of a third party generic threat, in order for Focus to secure the exclusive agreement to distribute Alliance's product which Focus was negotiating with Alliance at the time*'.[824]

The CMA's findings on the witness evidence and Parties' representations regarding the 10 July 2013 email

5.259 Neither [Focus Director 1] nor [Lexon Director 1] has been able to provide a credible alternative explanation as to why, on 10 July 2013, [Focus Director 1] requested information about the Medreich Prochlorperazine OTC marketing authorisation from Lexon before providing it to [Alliance Employee 1].

5.259.1 [Lexon Director 1]'s initial evidence given in interview[825] with the CMA supports the CMA's finding that [Lexon Director 1] knew in July 2013 that Focus was in discussion with Alliance in relation to the supply of Prochlorperazine POM: [Lexon Director 1] stated that in sending that email, [Focus Director 1] was seeking to confirm to Alliance that Focus had got a product; this is consistent with the CMA's finding that [Focus Director 1] considered confirmation of Lexon's 'exclusivity' would be relevant to Alliance and that [Focus Director 1] – accurately – expected [Lexon Director 1] to understand the relevance of that 'exclusivity' without the need for further explanation or context in the email of 10 July 2013.

5.259.2 [Lexon Director 1]'s subsequent evidence provided in a witness statement accompanying Lexon's Statement of Objections representations merely

[820] Cinven RLF, 22 April 2021, paragraph 2.81(d) (URN: PRO-C7107). Also, Advanz RLF, 22 April 2021, paragraph 4.31 (URN: PRO-C7112).

[821] Cinven RLF, 22 April 2021, paragraph 2.79 (URN: PRO-C7107).

[822] Cinven RLF, 22 April 2021, paragraphs 2.79 and 2.82 (URN: PRO-C7107).

[823] Cinven RLF, 22 April 2021, paragraph 2.82 (URN: PRO-C7107).

[824] Alliance RLF, 30 November 2021, paragraph 3.12 (URN: PRO-C7914).

[825] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 45, line 10-23 (URN: PRO-C3192).

asserts that [Lexon Director 1] does not recall seeing the email and does not provide any alternative explanation of its contents.[826]

5.259.3 Similarly, [Focus Director 1]'s statement in interview[827] that he was providing this information to Alliance so that Alliance would understand that Lexon was the exclusive *'marketer'* of the Medreich licence is supportive of the CMA's interpretation of the 22 June 2013 email. The CMA acknowledges that the fact of the grant of the Medreich marketing authorisation for Prochlorperazine OTC would have been public knowledge, but the additional information that [Focus Director 1] proposed to provide to Alliance was that this product would be marketed exclusively by Lexon[828] – and that fact would have been of relevance to Alliance, and understood by Lexon as the email recipient to be of relevance to Alliance, only to the extent that Alliance had formed an agreement with Lexon which would be implemented through Focus.[829] Were that not the case, there was no basis upon which Focus could have assumed that Lexon would be wiling for Focus to share such information with Lexon's competitor (Alliance), nor any basis on which Lexon should have understood why [Focus Director 1] would wish to provide information on the distribution of the Medreich product to Alliance.

5.259.4 [Focus Director 1] was, however, unable to explain credibly why he would have expected [Lexon Director 1] to understand why he intended to send the information about Medreich's marketing authorisation to Alliance or how [Lexon Director 1] would have known that the '*[first name of Alliance Employee 1]*' referred to in his email was [Alliance Employee 1].[830] This lack of credible explanation as regards [Focus Director 1]'s email to [Lexon Director 1] is particularly relevant in light of [Focus Director 1]'s and [Lexon Director 1]'s submission that [Lexon Director 1] did not at this point know of the proposed supply agreement between Alliance and Focus.[831] Given these representations, [Lexon Director 1] might reasonably have been expected to have been baffled upon receiving [Focus Director 1]'s email of

[826] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 65 (URN: PRO-C5092).

[827] Interview [Focus Director 1], 2 October 2018, page 101, lines 7-13 and page 103, line 3 (URN: PRO-C3294).

[828] For this reason, the CMA does not accept Cinven's representation that [Focus Director 1]'s email of 10 July 2013 showed that Alliance was '*uninformed*' about Lexon's relationship with Medreich: the key information that was being confirmed ('*I take it the Medrich [sic] licence is yours exclusively before I send this to [Alliance Employee 1]*') was the exclusivity between Medreich and Lexon relating to Prochlorperazine OTC (and by implication also Prochlorperazine POM). In any event, whether Alliance already knew that the licence for the Lexon product would be held by Medreich was not relevant as to the reason why [Focus Director 1] wished to provide the assurance of exclusivity to Alliance.

[829] For this reason, the CMA rejects the Parties' arguments around the fact that the Medreich OTC licence was public knowledge: this point is irrelevant.

[830] Interview [Focus Director 1], 2 October 2018, page 104, line 17 to page 105, line 21 and page 108, line 21 to page 109, line 4 (URN: PRO-C3294). For this reason, the CMA rejects Cinven's representation that it is plausible that Focus was '*willing to provide a piece of ad hoc market colour to Alliance*' on Alliance's request. This explanation disregards [Focus Director 1]'s failure to provide a credible explanation of the email he sent to Lexon.

[831] Interview [Focus Director 1], 2 October 2018, page 64, lines 15 to 25 (URN: PRO-C3294). Witness Statement of [Lexon Director 1] 31 July 2019, paragraph 30 (URN: PRO-C5092).

10 July 2013 without any other explanation. Ultimately, [Focus Director 1] concluded in relation to his 10 July 2013 email: *'As I've said, I … think that was me putting it down without any thought process rather than it being specific'*:[832] the CMA does not find this credible.

5.260 The CMA does not find persuasive the Parties' representations focused on the fact that the licence was for Prochlorperazine OTC. Simply put, Medreich's success in obtaining a licence for Prochlorperazine OTC demonstrated it would be able to obtain a licence for Prochlorperazine POM (the same product, but differently packaged).[833] The provision of the information from Focus to Alliance would therefore demonstrate to Alliance that, as [Lexon Director 1] recognised in his interview, Lexon would be able to enter the market for the supply of Prochlorperazine POM.[834]

5.261 Given Focus' lack of interest or expertise in Prochlorperazine OTC products (as understood by Lexon)[835] the information being provided by Focus to Alliance was not relevant unless Lexon's 'exclusivity' could also be taken as relevant to Prochlorperazine POM. The witnesses and the Parties have not provided any credible alternative explanation as to why Focus would wish to pass on information about the ownership status of Prochlorperazine OTC to Alliance at this point – and why Lexon would understand[836] the provision of such information by Focus to Alliance.

5.262 Cinven's submission that it is unclear why Alliance would have sought assurances that a transfer of value would have been effective from Focus, rather than Lexon itself, is immaterial. Given that Alliance would implement its Market Exclusion Agreement with Lexon via a supply agreement for Prochlorperazine POM with Focus, it clearly could have sought this assurance from either party. It would also be unsurprising if, having agreed that the Market Exclusion Agreement would be implemented through the two bilateral agreements between Alliance and Focus on the one hand and Focus and Lexon on the other, Alliance would avoid further direct contact with Lexon (its competitor) in this respect rather than obtaining the information from its contractual counterpart, Focus.

5.263 The CMA does not accept Alliance's submission that the 10 July 2013 email was designed to confirm Lexon's involvement with the Medreich licence such that

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[832] Interview [Focus Director 1], 2 October 2018, page 109, lines 3-4 (URN: PRO-C3294).

[833] Given the fact that the product is identical in both formulations, the CMA rejects Cinven's representation in relation to the CMA's reliance on [Alliance Director 2]'s evidence in this respect: it is unsurprising that Alliance would regard the Prochlorperazine OTC licence as evidence of Lexon/Medreich's forthcoming Prochlorperazine POM licence.

[834] Interview [Lexon Director 1], 10 September 2018, part 1, CD 2, page 44, line 16 to page 46, line 12 (URN PRO-C3192).

[835] See the Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 25 (URN: PRO-C5092).

[836] The fact that [Focus Director 1]'s email of 10 July 2013 does not provide any contextual information or explanation to [Lexon Director 1] demonstrates that [Lexon Director 1] would understand the relevance of the provision of the information. For this reason, the CMA rejects Cinven's representation that the fact that the email did not spell out the notion of value transfer undermines the CMA's reliance on it.

Focus could then pass that information to Alliance to secure the agreement to distribute Alliance's product; this is because (as noted above – see paragraph 5.259.3) it is unclear why Alliance would have needed to know that the Medreich product would be marketed by Lexon exclusively, and because (as noted above – see paragraph 5.259.4) it is unclear how [Lexon Director 1] would have known that the '*[first name of Alliance Employee 1]*' referred to in [Focus Director 1]'s email was [Alliance Employee 1], particularly in light of [Focus Director 1]'s and [Lexon Director 1]'s submissions that [Lexon Director 1] did not at this point know of the proposed supply agreement between Alliance and Focus.[837]

Witness evidence and parties' representations on [Focus Director 1]'s 18 July 2013 email

[Focus Director 1]'s and [Focus Director 2]'s evidence about the 18 July 2013 email

5.264 In relation to [Focus Director 1]'s email dated 18 July 2013,[838] [Focus Director 1] and [Focus Director 2] have both provided evidence that is inconsistent with the CMA's reading of that email as set out above (see paragraph 5.199.3).

5.264.1 [Focus Director 1] explained in an interview with the CMA that his email set out Focus' '*proposal*' to Alliance, including his proposed purchase price for Alliance's Prochlorperazine POM.[839] [Focus Director 1] further explained that his anticipated retention of 25% of the profits Focus would make on the sale of Alliance's Prochlorperazine POM was on the assumption that Focus would be '*honouring the Lexon agreement*'.[840]

5.264.2 [Focus Director 2], the recipient of [Focus Director 1]'s email, told the CMA in an interview that the email '*describes what [Focus [✂]] is thinking in terms of launching Prochlorperazine [POM]*' ahead of a meeting with [Alliance Employee 1] and observed that [Focus Director 1]'s email of 18 July 2013 set out the '*same terms*' as those that followed the wording '*the agreement [Lexon Director 1] made*' in [Focus Director 1]'s email of 22 June 2013. [Focus Director 2] maintained that [Focus Director 1]'s need to assume in his email of 18 July 2013 that Alliance would '*agree to sell*' Prochlorperazine POM to Focus at the specified price was not at odds with his – and [Focus Director 1]'s – submission that [Alliance Employee 1] (rather than [Lexon Director 1]) had '*made*' this agreement with Focus

[837] Interview [Focus Director 1], 2 October 2018, page 64, lines 15 to 25 (URN: PRO-C3294). Witness Statement of [Lexon Director 1] 31 July 2019, paragraph 30 (URN: PRO-C5092).

[838] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

[839] Interview [Focus Director 1], 2 October 2018, page 94, line 19 to page 96, line 10 (URN: PRO-C3294).

[840] Interview [Focus Director 1], 2 October 2018, page 93, lines 16-22 (URN: PRO-C3294).

before 22 June 2013 (see paragraph 5.229 above) as there was a '*process of negotiation*' between these dates.[841]

The Parties' representations on the 18 July 2013 email

5.265 Advanz[842] and Cinven[843] disputed that the CMA could draw any inference from [Focus Director 1]'s email of 18 July 2013 given that Lexon was not mentioned in the email, and there was no reference to or inference of Focus being a *'mechanism'* for a transfer of value, or of Lexon not supplying Prochlorperazine POM in return for the same. The fact that [Focus Director 1]'s 18 July 2013 email did not contemplate Focus purchasing product from Lexon was explained by the fact that Lexon/Medreich did not have a marketing authorisation for Prochlorperazine POM at 18 July 2013, but discussions with Lexon regarding the supply of Prochlorperazine POM were sufficiently progressed at this point, meaning it was sensible for Focus to build payments to Lexon into its assumptions.

5.266 Cinven further submitted that [Focus Director 1]'s 18 July 2013 email shows '*nothing more*' than [Focus Director 1]'s preparation for a meeting with Alliance, in which he used a '*set of assumptions to calculate the upper bound of potential Focus profits from sales*' of Alliance's Prochlorperazine POM,[844] and the fact that [Focus Director 1] was making '*assumptions*' was itself inconsistent with the suggestion that the 22 June 2013 email demonstrates Focus' awareness of there already being a Market Exclusion Agreement between Alliance and Lexon.

The CMA's assessment of the witness evidence and the associated Parties' representations on the 18 July 2013 email

5.267 The CMA finds that the witness evidence of [Focus Director 1] and [Focus Director 2], and the Parties' representations on [Focus Director 1]'s email dated 18 July 2013, are not persuasive.

5.267.1 [Focus Director 1]'s explanation that his email summarised his own intended '*proposal*'[845] to Alliance in relation to the supply of Prochlorperazine POM is inconsistent with his email of 22 June 2013 which – as written – states that an agreement had already been '*made*' by [Lexon Director 1] or – as submitted by [Focus Director 1] – by [Alliance Employee 1] by 22 June 2013; this language is simply not compatible with the notion of a '*process of negotiation*'[846] between Alliance and Focus as described by [Focus Director 2]. Equally, there would have been no need

[841] Interview [Focus Director 2] 8 January 2020, page 72, line 3 to page 74, line 22 (URN: PRO-C5886).
[842] Advanz RSO, 1 August 2019, paragraph 3.179 and 3.224 (URN: PRO-C5111).
[843] Cinven RSO, 15 August 2019, paragraphs 4.102 and 4.163-4.168 (URN: PRO-C5132).
[844] Cinven RSO, 15 August 2019, paragraphs 4.163-4.168 (URN: PRO-C5132).
[845] Interview [Focus Director 1], 2 October 2018, page 95, line 6 (URN: PRO-C3294).
[846] Interview [Focus Director 2], 8 January 2020, page 73, line 12 (URN: PRO-C5886).

for [Focus Director 1] to merely '*assum[e]*' in his 18 July 2013 email that Alliance would agree to implement the supply terms that had been set out in his email of 22 June 2013: that agreement would, on his interpretation of the 22 June 2013 email, already have been reached between them.[847]

5.267.2 [Focus Director 1]'s 18 July 2013 email is, however, consistent with Alliance having made an in principle agreement with Lexon prior to 22 June 2013 on the terms on which Alliance would supply Focus, albeit that [Focus Director 1] had not on 18 July 2013 yet directly confirmed the implementation of the precise details of that agreement with [Alliance Employee 1].

5.267.3 [Focus Director 1] has provided no credible explanation of why in July 2013 he was already anticipating, as he put it in interview, '*honouring the Lexon agreement*'[848] by sharing 75% of Focus' profits from the sale of Alliance's Prochlorperazine POM with Lexon, when Focus did not have at that time any contractual obligation to share any profits from the sale of Prochlorperazine POM with Lexon (see further at paragraph 5.275 below).

5.268 The CMA rejects the Parties' representations in relation to the CMA's reliance on [Focus Director 1]'s 18 July 2013 email.

5.268.1 Although Lexon is not mentioned by name in [Focus Director 1]'s email, it is not disputed by [Focus Director 1] that his modelled retention of 25% of profits is based on the fact that Focus would be paying 75% of its profits to Lexon.

5.268.2 Whilst it is correct that Lexon/Medreich did not have a Prochlorperazine POM licence at this point, and Focus could therefore not have guaranteed receiving Lexon/Medreich product from a particular date, it is significant that [Focus Director 1]'s email makes no mention whatsoever of any future purchasing of product from Lexon: [Focus Director 1]'s profit modelling is based entirely around obtaining supply from Alliance, increasing the price to wholesalers over time, whilst paying the majority of Focus' profits to Lexon: a position consistent with the Market Exclusion Agreement. To the extent that Focus had genuinely expected this position to be of a short term nature, it would have been natural for [Focus Director 1] to have reflected this, by providing for the expectation that in the medium to long

[847] For this reason, the CMA rejects Cinven's representation that the fact that [Focus Director 1] was making assumptions in the 18 July 2013 email undermines the CMA's finding that an agreement had been reached between Alliance and Lexon. This agreement had been reached in principle between [Alliance Employee 1] and [Lexon Director 1] but its implementation remained dependent upon [Alliance Employee 1] giving effect to that agreement in a formal agreement with Focus: hence the need for [Focus Director 1] to make assumptions at this point. In fact, the Alliance-Focus Agreement did reflect the terms agreed in principle between Alliance and Lexon.

[848] Interview [Focus Director 1], 2 October 2018, page 93, lines 16-22 (URN: PRO-C3294).

term Focus would receive product from Lexon: but any mention of that is entirely absent in [Focus Director 1]'s email.

CMA's consideration of the June and July 2013 documentary evidence

5.269 The CMA concludes that the contemporaneous documents from June and July 2013 as cited above demonstrates that Alliance and Lexon had reached an agreement in principle by 7 June 2013 that Lexon would not commercialise the Prochlorperazine POM product that it had developed with Medreich, and that in return it would be compensated through receipt of some of the profits earned by Focus from its exclusive supply of Alliance's debranded Prochlorperazine POM product. While the witnesses have advanced alternative explanations for the interpretation of these documents, the CMA finds their evidence to be inconsistent and/or unpersuasive.

5.270 Based on their plain reading, and when assessed in the context of the surrounding documents and subsequent conduct:

5.270.1 The [Alliance Director 1] notebook entry of 11 June 2013[849] is evidence that Alliance understood that Lexon would not enter the market, other than with the single batch of product necessary to prevent the application of the Sunset Clause.

5.270.2 At the same time, notwithstanding that there would only be one batch of Lexon/Medreich Prochlorperazine POM product to distribute, the [Alliance Director 1] notebook entry demonstrates that Alliance was aware that Lexon would enter into an agreement with Focus in relation to Prochlorperazine POM.

5.270.3 The 22 June 2013 email from [Focus Director 1][850] demonstrates that Lexon and Alliance had agreed in principle the terms on which Alliance would supply Focus with a de-branded version of its Buccastem POM product (that is, would supply Prochlorperazine POM), including that Alliance would discontinue its Buccastem POM product and would supply Focus with its de-branded Prochlorperazine POM at a specified fixed price.

5.271 It is evident that Lexon's commitment not to commercialise the product it had developed with Medreich reflected a common understanding that, in exchange for

[849] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

[850] Email [Focus Director 1] to [Focus Director 2] entitled 'Fwd: *Prochlorperazine IMS*' dated 22 June 2013 (URN: PRO-E001476).

doing so, it would receive compensation from the profits earned from Focus' supply of the Alliance Prochlorperazine POM product:

5.271.1 First, it is clear that, absent a common understanding that it would receive sufficient compensation from Alliance, Lexon had no reason to deny itself the opportunity to profit from the sale of its newly developed product. Its commitment not to enter the market can therefore only have been communicated to Alliance on the basis that it received assurances that it would receive compensation for doing so. Consistent with this, the fact that the [Alliance Director 1] notebook entry of 11 June 2013 refers to an agreement between Lexon and Focus, despite Lexon intending to supply only one batch of product, is evidence that Lexon and Alliance had agreed that Lexon would be paid from the profits earned by Focus.

5.271.2 Second, [Lexon Director 1]'s involvement in the negotiation of the terms on which Alliance would supply Focus (what [Focus Employee 1] later referred to as Lexon *'help[ing] set up'* the exclusive agreement between Alliance and Focus[851]) is credibly explained only on the basis that Lexon and Alliance understood that that arrangement was of relevance to Lexon's own profitability and Lexon wished to ensure that the agreed pricing and volume terms would enable Focus to fund compensation payments of a sufficient level. Indeed, [Focus Director 1]'s 22 June 2013 and 18 July 2013 emails[852] explain precisely how that arrangement was expected to function, with Focus being able to set an inflated price across the supply of Alliance's de-branded product, and with the majority of the resulting Focus profit margins being shared with Lexon. There is no other credible explanation for the involvement of Lexon (a potential competitor) in agreeing the terms on which Alliance (the incumbent) would proceed to supply its Prochlorperazine POM to Focus.

5.272 The CMA does not find that the documentary evidence from June and July 2013 shows that Alliance was aware of, or agreed to, the precise terms of the profit-sharing agreement reached by Focus and Lexon. This does not, though, detract from the CMA's finding that the [Alliance Director 1] notebook entry and [Focus Director 1]'s 22 June 2013 email demonstrate that Alliance and Lexon had a common understanding that, in return for Lexon's commitment not to enter, Focus would compensate Lexon out of the profits earned from the sale of the Alliance product. It was, in fact, unnecessary for Alliance to be aware of, or to have agreed to, the precise terms of that arrangement between Focus and Lexon. This is

[851] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030). The CMA's analysis of [Focus Employee 1]'s evidence and the Parties' associated representations on this email are set out in paragraph 5.556 to 5.561 below.

[852] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476) and Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

because, provided that Lexon was compensated for and therefore refrained from entering the market such that Alliance's sales volumes and its prior price were protected (consistent with the terms of [Focus Director 1]'s 22 June 2013 email), the precise commercial terms agreed between Lexon and Focus would not themselves have a commercial impact on Alliance.

The Implementing Agreements: Alliance, Focus and Lexon concluded agreements that enabled Lexon to be paid for not entering the market

Introduction and section summary

5.273 The CMA sets out in this section the evidence that, shortly after the evidence of Alliance and Lexon having reached an agreement by which Lexon would be paid (via Focus) not to enter the market, Alliance and Focus entered into the Alliance-Focus Agreement and Focus and Lexon entered into the Focus-Lexon Heads of Terms. The CMA finds that these Implementing Agreements were intended to provide for a value transfer from Alliance to Lexon, in compensation for Lexon's agreement not to enter the market:

5.273.1 Alliance agreed to supply Focus on terms that would enable Focus to retain substantial profits from the supply of the Alliance product;

5.273.2 Focus agreed to pay the majority of the profits earned on the sale of Alliance's product to Lexon; and

5.273.3 Focus agreed to become the exclusive supplier of both products, yet under the Alliance-Focus Agreement committed to supply only the Alliance product.

5.274 The conduct of each of Alliance, Lexon and Focus, in putting into place the Implementing Agreements that would enable Lexon to be paid from profits earned from the sale of the Alliance product, supports the finding that a pay for delay agreement of the type described above had been reached between Alliance and Lexon.

5.275 As outlined above, shortly after the Alliance internal meeting of 11 June 2013 that resulted in the [Alliance Director 1] notebook entry, both Alliance and Lexon were in discussions with Focus. As is made clear by the 22 June 2013 Focus email cited above (see paragraph 5.197), the key terms of the two agreements were understood by all relevant parties within two weeks of the meeting at which [Alliance Employee 1] had briefed [Alliance Director 1] about his plan. Subsequent evidence shows that the Alliance-Focus Agreement was finalised by 25 July 2013

(see paragraph 3.100), while the Focus-Lexon Heads of Terms had likely been adopted by 1 August 2013[853] (see paragraph 3.106).

5.276 Those agreements were of an exceptional nature. They enabled Lexon (and, indirectly, Medreich) to retain a significant share of the profits earned from the supply of Alliance product by Focus over five years. They also involved Focus entering into supply agreements to become the exclusive supplier of both products, yet agreeing to supply only the Alliance product. As set out in detail below, the CMA finds that:

5.276.1 Alliance supplied Focus on terms that would enable Focus to retain substantial profits from the supply of the Alliance de-branded product, and such conduct can be explained only on the basis of the Market Exclusion Agreement; the agreement between Alliance and Focus was clear on its face that Focus was only to purchase and supply the Alliance Prochlorperazine POM product;

5.276.2 under the Focus-Lexon Heads of Terms, Focus agreed to share the majority of the profits earned on the sale of any Prochlorperazine POM product with Lexon, including Alliance's product; Focus' willingness to agree that clause, and to continue to make payments under it despite the absence of product from Lexon, can be explained only on the basis of the Market Exclusion Agreement; and

5.276.3 Focus entered into conflicting agreements, in that the Alliance-Focus Agreement did not permit Focus to purchase and sell the competing Lexon Prochlorperazine POM product; Focus' conduct in this respect can be explained only on the basis of the Market Exclusion Agreement.

Alliance supplied Focus on terms that would enable Focus to retain substantial profits from the supply of the Alliance product

5.277 For the reasons set out below, the CMA finds that:

[853] Specifically, [Focus Director 1] emailed [Lexon Director 1] on 8 August 2014 to request that he re-sign the Focus Lexon Heads of Terms. Email [Focus Director 1] to [Lexon Director 1] entitled '*FW: Emailing: 20140808172223*' 8 August 2014 (URN: PRO-E000426) attaching PDF document entitled '*20140808172223.pdf*' (URN: PRO-E000427), as per the comment of [Focus Director 1] (Interview [Focus Director 1] page 166, lines 3 to 14 (URN: PRO-C3294)). The copy of the Heads of Terms attached by [Focus Director 1] had been dated 1 August 2013. This demonstrates that [Focus Director 1] considered that the Focus-Lexon Heads of Terms was most likely entered into no later than 1 August 2013. The fact that AMCo treated the Focus-Lexon Heads of Terms as having expired on 1 August 2018 is consistent with the CMA's conclusion that the agreement was entered into by 1 August 2013. See Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 3(b) (URN: PRO-C3149). The Focus-Lexon Heads of Terms was later emailed by [Focus Director 1] to [Lexon Director 1] on 12 September 2013 (Email [Focus Director 1] to [Lexon Director 1] entitled '*Heads of agreement for Prochlorperazine 3mg Tabs*' 12 September 2013 (URN: PRO-E000329)).

5.277.1 the Alliance-Focus Agreement provided for a significant value transfer[854] from Alliance to Focus (which in turn, could then be shared with Lexon pursuant to the Market Exclusion Agreement); and

5.277.2 the purpose of that transfer was to enable Focus to pay compensation to Lexon for its agreement not to enter the market.

The Alliance-Focus Agreement provided for a significant value transfer from Alliance to Focus

5.278 Under the terms of the Alliance-Focus Agreement, Alliance agreed to supply Prochlorperazine POM to Focus at an initial transfer price of £4.85 for the first batch supplied, increasing to a fixed price £5.65 for subsequent orders (see paragraph 3.100 above).[855] Having purchased product from Alliance at a price of £5.65, Focus was free to determine a selling price of its choosing. This is because Alliance had de-branded its Buccastem POM product such that it was no longer subject to the price and profit controls of the PPRS or any other regulatory constraint.

5.279 Alliance[856] and Focus[857] understood that, once the product was de-branded, it would be possible significantly to increase the price of Prochlorperazine POM.[858] Focus proceeded to set a price to mainline wholesalers of £8 per pack in

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[854] Whilst a value may be transferred through the provision of a cash payment, in other cases it may be made *'through a more covert transfer of value'* which *'cannot be adequately explained by, or which considerably exceeds, the value to the originator undertaking of any counter-performance of the [potential entrant]'* Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 660.

[855] The supply price was subject to re-negotiation in January 2015 (see paragraph 3.175), when Focus and Alliance agreed an increased supply price of £6.10 per pack.

[856] The evidence shows that Alliance had expected to increase the price of the product had it continued to supply it to wholesalers. For example, as early as 2010, Alliance described the *'opportunity'* of de-branding as follows*: 'increase profit stream from x to y as a result of genericising the 50's pack, enabling a price increase strategy to be deployed. How much money can we make and how quickly?'* (Email [Alliance employee] to [Alliance employee] cc [Alliance employee] entitled '*Buccastem: Uk generic opportunity*' [sic] 8 April 2010 (URN: PRO-E000806) (see paragraph 3.65). See also comparable reasoning in relation to the Aspirin E/C product in Email [Alliance employee] to [Alliance employee] entitled '*Re: Meeting Follow-up*' 21 June 2011 (URN: PRO-E000926) in which [Alliance employee] had commented: *'… ideally generic pack so they can get the tariff increase … its our NHS price holding the Cat A generic down. … they would sort the tariff out and gain from it – they would like a 2 year deal with us and then after 2 years we could trigger NuSeals 300mg back in again ? generic would be a lot higher – in the region of £8 per pk'* (see paragraph 3.69). Further, following the approach from Lexon in 2013, Alliance's internal documentation from March 2013 had listed de-branding as an option: *'De-brand Buccastem, launch generic prochlorperazine in to Category A and name price'* Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

[857] See for example an email in which [Focus Director 1] states that *'Generic pricing will depend on market and Focus will set!'* Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476) and Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478), which sets out a table of anticipated price increases.

[858] Alliance was aware of the scope for the drug tariff price to be increased significantly on Alliance's generic products that were distributed by Focus. By the time of the amendment of the existing contact relating to Aspirin 300mg E/C to include Prochlorperazine POM in July 2013, the reimbursement price for Aspirin 300mg E/C (pack size 100s) had increased by 79% from £6.64 (in July 2011, when Alliance entered into the agreement with Focus) to £11.89 (source: Prescription Cost Analysis (PCA) data (https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data) which shows national prescription data dispensed in the community in England at presentation level. Reimbursement price calculated as (Net Ingredient Cost (p) [from tab 1] + Net Ingredient Cost (p) [from tab 2])/(Quantity [from tab 1] + Quantity [from tab 2])/100 [to convert in £] * pack size). The reimbursement price for Aspirin 300mg E/C (pack size 100s) plus NuSeals 300mg E/C (pack size 100s) increased 82% from £6.53 in July 2011 to £11.88 in July 2013.

December 2013, and to increase its price to around £30 in December 2017 (with the price reaching nearly £35 in June 2017).[859]

5.280 Accordingly, having de-branded Buccastem POM and agreed to supply Prochlorperazine POM to Focus, Alliance was, in effect, providing Focus with the ability to retain the substantial profits that could be earned on the monopoly supply of Prochlorperazine POM over and above the agreed transfer price. By the end of July 2018, Focus had earned gross profits of £14.4 million on its sales of Prochlorperazine POM, a significant proportion of which were shared with Lexon (and, in turn, Medreich). Apart from one increase to the transfer price (see paragraph 3.175 above), Alliance made no attempt to secure a greater share of the overall profits made on the supply of its product.

The purpose of the margin transfer was to enable Focus to pay compensation to Lexon

5.281 For the reasons set out below, the CMA finds that, in agreeing to de-brand its product and at the same time adopt its fixed selling price, Alliance's intention was to transfer value from Alliance to Focus to enable Focus to compensate Lexon for its agreement not to enter the market.

5.282 First, by entering into a fixed price distribution contract, and at the same time de-branding its product, Alliance denied itself the opportunity to profit from any price increases that could be realised by de-branding and removing the product from the constraints of the PPRS, and instead enabled Focus to realise the benefit of those price increases. As outlined above, the implication of the fixed sales price to Focus was that, while Alliance retained profits of £5.3 million (see Figure 5) during the Infringement Period, Alliance had enabled Focus to earn profits of £14.4 million on merely distributing Alliance's own product to wholesalers. Alliance adopted this pricing structure despite the fact that it was Alliance that retained the product licence and the associated IP, and Focus' role was limited simply to selling-on the Alliance product to wholesalers. Such conduct, in denying itself the opportunity to implement price increases and to profit from its own decision to de-brand, is credibly explained only on the basis that Alliance's intention was to compensate Lexon for not entering the market.

5.283 Second, it is evident that the huge margins that Alliance permitted Focus to earn on the distribution of its product were far greater than would ordinarily be afforded to other suppliers appointed to distribute its product, and are consistent with Alliance and Focus having intended that the margins be used to compensate Lexon for its agreement not to enter the market:

[859] Based on the Focus' average selling price to wholesalers (see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150)).

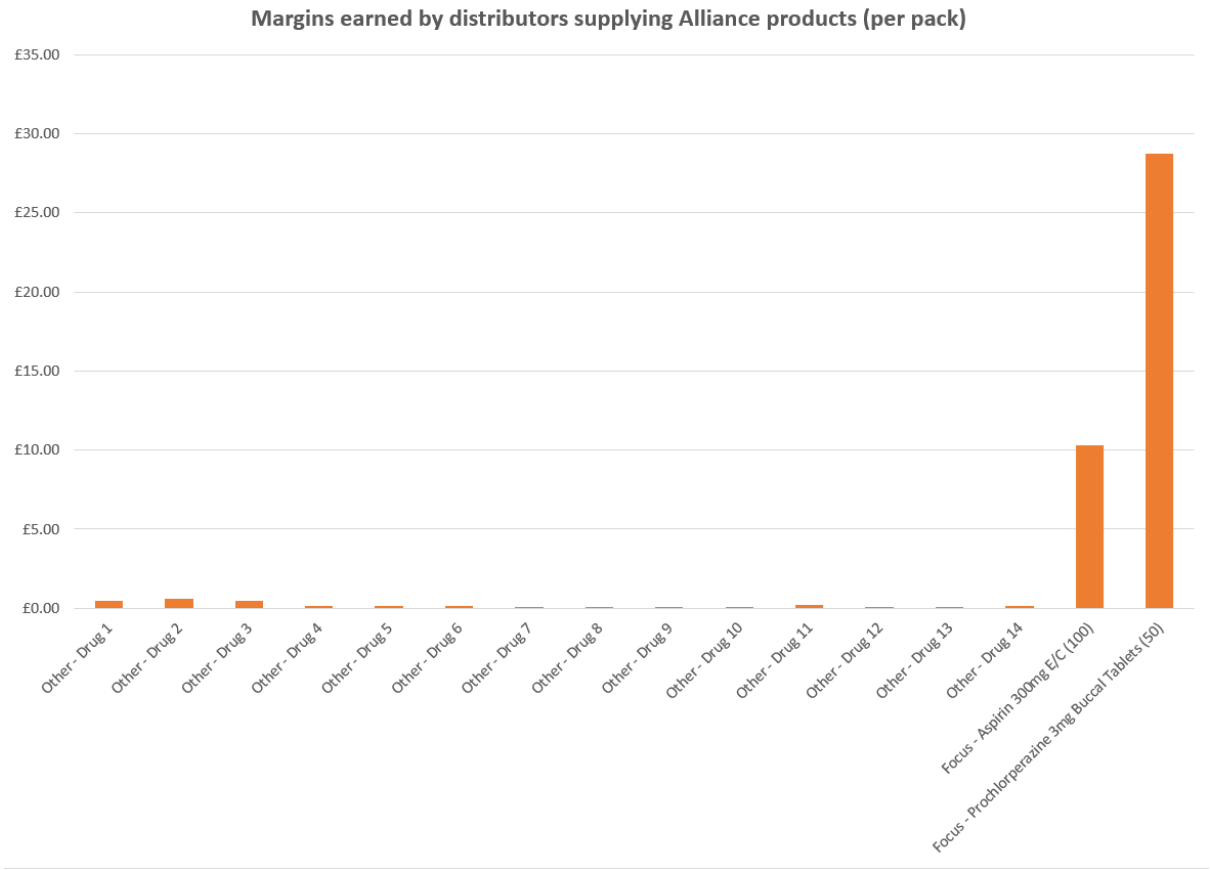
5.283.1 The Alliance margin data gathered by the CMA reveals that Alliance typically permits its distributors, including Creo Pharma (with whom Alliance had had discussions regarding the distribution of Prochlorperazine POM (see paragraph 5.170), to earn margins that are a fraction of those earned by Focus on the supply of Prochlorperazine POM. In a response to a section 26 Notice, Alliance provided margin data for those products that Alliance sold in the UK which currently faced generic competition[860] or that had faced such competition in the last seven years, and for which Alliance had entered into agreements with distributors and was not itself selling the products direct to wholesalers. Alliance also provided margin data for a branded formulation that it supplied to a distributor with the intention of benefitting from an exemption to the price constraints of the PPRS.[861] The distribution margins earned by these distributors on the supply of these products are illustrated in Figure 4 below. The data in the graph covers four medicines (that together have 14 different formulations) and compares the relevant margins with those earned on the supply of Prochlorperazine POM and Aspirin 300mg E/C (the other drug supplied by Alliance to Focus):[862]

[860] Section 26 response of Alliance, phase two, dated 7 December 2018, to CMA Notice of 11 October 2018, question 1 and 2 (URN: PRO-C3054).

[861] The CMA's section 26 request had asked Alliance for information concerning the margins earned on products sold through distributors and that had faced (in the last 7 years), or continued to face, generic competition. In response, Alliance submitted data for 4 products, but went on to state at footnote 63 of its RSO that the inclusion of one such product was in error given that it does not face generic competition and was in fact included in a distributions agreement *'to allow Alliance to benefit from a PPRS exemption'* (Alliance RSO, 1 August 2019, paragraph 3.25(d)(v) (URN: PRO-C5096)). The CMA has nevertheless retained the relevant product in its analysis on the basis that it provides evidence of the margins that Alliance afforded to its appointed distributors.

[862] Data for sales of other drugs by other distributors is based on the section 26 response of Alliance dated 24 April 2019, to CMA Notice of 10 April 2019 (URN: PRO-C3884, URN: PRO-C3885, URN: PRO-C3886). The distributor margin is calculated as at the time of the highest selling point of the relevant drug in the period from the first sale of that drug by that distributor up to 30 June 2018. Data for Focus – Aspirin 300mg E/C tablets is based on the transfer price from Alliance to Focus for June 2017 as set out in the email from [Focus Director 1] to [Alliance Employee 1] entitled *'New Transfer Costs'* 28 January 2015 (URN: PRO-E003860) and assuming Focus sold at a standard industry discount against the Drug Tariff. Data for Prochlorperazine POM is based on the average Focus wholesaler sales price in June 2017 (see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150) and a transfer price from Alliance to Focus of £6.10 per pack, and does not deduct 'Rebates and Manuals' as set out in the reconciliation spreadsheets.

Figure 3: Margins earned by distributors supplying Alliance products in the UK



Source: CMA analysis based on data from the parties

5.283.2 For drugs 1 to 14 (Aspirin 300mg E/C is considered separately below), the far smaller margins observed are the outcome of the modest percentage discounts that are conventionally afforded by MA holders to their distributors in the supply of prescription medicines in the UK. The margins which Alliance allowed its distributors to earn were [✂]% for Creo Pharma[863] and a smaller percentage for the other distributor. In contrast to these medicines, Focus retained a margin of 39%[864] from the commencement of the Alliance-Focus Agreement, which increased significantly over time to 82% by June 2017.[865] In cash terms, the distributors of the 'other drugs' 1 to 14 in Figure 3 above earned per pack margins of no more than 60 pence, while Alliance supplied Focus on terms

[863] Alliance paid Creo Pharma a margin of [✂]% on all drugs that Creo Pharma distributed apart from one formulation of one of the drugs Creo Pharma distributed where Creo Pharma was paid a slightly higher margin. The margin was calculated by reference to Creo's net sales value of the relevant products.

[864] That is, a Focus margin of £3.15 as against an average Focus sales price of £8 and an Alliance price to Focus of £4.85 (for the initial 40,000 packs: see paragraph 3.100) in December 2013; see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150).

[865] That is, a Focus margin of £28.71 as against an average Focus sales price of £34.81 and an Alliance price to Focus of £6.10 in June 2017; see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150). This figure does not deduct 'Rebates and Manuals' as set out in the reconciliation spreadsheets.

that enabled Focus to retain £3.15[866] from the outset of their agreement and £28.71 by June 2017.[867]

5.283.3 Very modest percentage discounts are also afforded to wholesalers used by Alliance (and other suppliers) to distribute prescription medicines to pharmacy customers.[868] While their role is different to Focus's role in the supply of Prochlorperazine POM (in that wholesalers used their distribution infrastructure to supply product to a vast number of pharmacy customers, whereas Focus' role involved the supply of Prochlorperazine POM to a far smaller number of customers),[869] it is relevant that the margins they received from Alliance were also determined on a percentage discount basis, and saw them typically retain only a modest percentage of the relevant drugs' list price.

5.284 Third, of the agreements referred to above, the only other instance of Alliance adopting a fixed selling price, and permitting its distributor to earn a substantially higher margin (see Figure 3 above), related to Alliance's other agreement with Focus (the Aspirin Agreement) and to an agreement that resulted in the only other MA holder (Focus itself in that case) agreeing not to supply its product on to the market. The agreement therefore resulted in the two MA holders earning margin on the supply of the Alliance product, and did not involve the appointment of a distributor being used by Alliance to enable it better to compete with suppliers of generic alternatives. Accordingly, the Aspirin 300mg E/C distribution margin does not suggest that the margin provided for in the supply of Prochlorperazine POM was in any way conventional, and instead represents further evidence that such

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[866] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150).

[867] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150). This figure does not deduct 'Rebates and Manuals' as set out in the reconciliation spreadsheets.

[868] Evidence received from Alliance demonstrates that the fixed price term in the agreement between Alliance and Focus, and that enabled Focus to retain a substantial share of the profits earned on the product, was not typical of its wholesale arrangements for other prescription medicines. Alliance provided data to the CMA in response to question 1 of the section 26 Notice dated 26 November 2019 (see section 26 response of Alliance dated 19 December 2019, to CMA Notice of 26 November 2019 (URN: PRO-C5591 and PRO-C5592) showing that, in January 2013, none of the 37 products supplied by Alliance to the leading UK wholesalers was sold at a fixed price. Rather, Alliance generally adopted discounts of [✂]% that were in line with the typical distribution margins provided for in this sector (as recorded in the OFT Medicines Distribution market study, wholesalers would typically expect to purchase branded drugs at a 12.5% discount to the list price and to sell drugs to pharmacies at a discount of (on average) 10.5%, thereby retaining (on average) 2% of the list price (see in this respect the OFT Medicines Distribution market study December 2007, paragraphs 2.35-2.36 ((PAD088))). See also the revised section 26 response of Alliance dated 7 December 2018, to the CMA Notice of 11 October 2018, page 2 (URN: PRO-C3054)) and the typical distributions fees recorded.

The CMA acknowledges that the agreements are of a different nature to the Alliance-Focus Agreement (Alliance RLF, 29 April 2021, paragraph 2.17 (URN: PRO-C7118)). The relevant wholesalers were not appointed by Alliance as the exclusive distributors of its medicines and the wholesalers provide a different role to Focus in that they use their significant logistics infrastructure to distribute product across the UK. The CMA considers, though, that the widespread adoption of percentage discounts, and the significantly more modest terms on which distributors are reimbursed (despite the provision of large-scale distribution and the fact that they were not granted exclusivity for a product), further supports the CMA's findings that the terms of the Alliance-Focus Agreement were highly exceptional and represent further evidence of the Market Exclusion Agreement.

[869] Source: Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150) showing Focus' sales to wholesalers and hospitals.

margins are associated with agreements that involve a competing product no longer being marketed.

5.284.1 As outlined above, the Aspirin Agreement was the agreement that was amended to include Prochlorperazine POM on 22 August 2013 (see paragraph 3.104 above). Prior to the inclusion of Prochlorperazine POM, it concerned only the supply of Aspirin 300mg E/C and involved Focus purchasing de-branded Alliance product at a fixed price, while committing not to supply its own Aspirin 300mg E/C product. Consistent with the supply of Prochlorperazine POM, the Aspirin Agreement also enabled Focus to earn margins that were far in excess of those more conventionally earned by distributors. The Aspirin Agreement does not therefore suggest that the huge margins that Alliance enabled Focus to earn in relation to the supply of Prochlorperazine POM are typical of agreements in which Alliance expected to compete with a rival or that they are reflective of a conventional relationship between a supplier and a distributor. Rather, the Aspirin Agreement confirms only that such terms are present where a rival product is prevented from entering the market.

5.284.2 The relevant background to the Aspirin Agreement (which was subsequently amended to include Prochlorperazine POM (see paragraph 3.103 above) is as follows:

(a) In 2011, Alliance and Focus concluded an agreement whereby Alliance would supply Focus with Aspirin 300mg E/C tablets at a fixed price, and Focus accepted a restriction on its ability to supply its own Aspirin 300mg E/C tablets.[870] In the case of both Prochlorperazine POM and Aspirin 300mg E/C tablets, therefore, the agreement reached between Alliance and Focus resulted in Focus becoming the exclusive supplier of the Alliance product.[871]

(b) Although Alliance has informed the CMA that *'current Alliance employees do not know the commercial rationale for entering into the [Aspirin 300mg E/C] distribution agreement'*[872] it is clear that an arrangement that prevented the supply of the only other Aspirin 300mg E/C product was also not made with the commercial rationale of enabling Alliance to compete with generic versions of its medicine.

[870] At the time of entering into the agreement to supply Alliance's Aspirin 300mg E/C tablets, Focus held an MA, allowing Focus to supply the same product independently of Alliance. In response to a section 26 notice from the CMA, Alliance stated that *'at the time of entry into the distribution agreement Focus Pharmaceuticals Limited had an aspirin 300mg licence and was supplying the product …. Alliance has established that there was some knowledge at the time that Focus was supplying Aspirin 300mg to the UK market.'* Section 26 response of Alliance, phase two, dated 7 December 2018, to CMA Notice of 11 October 2018, question 4 (URN: PRO-C3054).

[871] Section 26 response of Alliance, phase two, dated 7 December 2018, to CMA Notice of 11 October 2018 (URN: PRO-C3054).

[872] Section 26 response of Alliance, phase two, dated 7 December 2018, to CMA Notice of 11 October 2018 (URN: PRO-C3054).

This is further confirmed by an Alliance internal strategy presentation for a meeting that took place the week prior to the Aspirin Agreement being concluded, which described how Alliance and Focus were currently each supplying into the market but that, following the conclusion of the agreement, Alliance expected to: (i) hold a monopoly in the supply of the product; (ii) see an increase in the drug tariff price for the product; (iii) supply Focus at a fixed price that would enable it to earn a significant margin on the supply of the Alliance product; and (iv) significantly increase its own profits (*'[f]rom November 2011 Alliance will supply the complete UK market […]k pks via Focus @ […] – tariff increases to £9.90. This equates to an additional £13,140 profit per month or £158k pa / £170k pa gross'*[873]).

5.284.3 Following the Aspirin Agreement's implementation, Focus was able to earn a significant margin for the supply of tablets – initially an estimated 49% in May 2012 (when Focus started making sales[874]) increasing to estimated 63% in June 2017.[875] As shown in Figure 3, Focus was able to earn a margin of over £10 per pack by June 2017, far exceeding the margins of no more than 60 pence on drugs 1 to 14 in Figure 3 above.

[Alliance Employee 1]'s and [Alliance Director 2]'s explanations of the margins afforded to Focus

5.285 [Alliance Employee 1] and [Alliance Director 2] state that Alliance's decision to adopt its fixed sales price, and enable only Focus to realise the price and profit increases that could be implemented after de-branding, was motivated by its view that it represented Alliance's best commercial response to the entry by Lexon that they state they still expected at that time.

5.286 During an interview with the CMA, [Alliance Employee 1] stated that one of the reasons for not seeking a higher price from Focus, and to limit Alliance's own selling price to its prior level of the branded product, was to protect Alliance's reputation.[876] [Alliance Director 2] made similar observations regarding his concerns with the high pricing that could result from de-branding, noting that *'there could be reputational risks for APL in any scenario where a distributor sold a*

[873] Alliance presentation entitled '*Strategy Meeting EPBU [Alliance employee]*' 29/30 June 2011, slide 49 (URN: PRO-E000932).

[874] See in this respect the Alliance Established Product Business Team Meeting minutes 11 August 2011, page 2 (URN: PRO-E000944).

[875] CMA estimates based on Alliance transfer price to Focus as set out in the presentation entitled '*Alliance Strategy Meeting EPUBU'* dated 29 and 30 June 2011 (URN: PRO-E000932) and the email from [Focus Director 1] to [Alliance Employee 1] entitled *'New Transfer Costs'* 28 January 2015 (URN: PRO-E003860), reimbursement prices in May 2012 and June 2017 (source: Prescription Cost Analysis (PCA) data (https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data) which shows national prescription data dispensed in the community in England at presentation level. Reimbursement price calculated as Net Ingredient Cost (p) / Quantity); and also assuming Focus sold at a standard industry discount against the Drug Tariff. It is notable that Focus was still able to increase its margin despite the fact that the transfer price from Alliance to Focus also increased during this period.

[876] Interview [Alliance Employee 1], 9 October 2018, part 2, page 51 (URN: PRO-C2910).

debranded APL product at what might be perceived as an excessive price. High pricing contradicted the business model which I was keen for [Alliance] to follow'.[877]

5.287 In his witness statement, [Alliance Director 2] stated that the following factors were also relevant to Alliance's decision to adopt in the agreement with Focus the fixed price it had earned previously for the branded product, while at the same time de-branding its product to provide for price increases on the part of Focus:

5.287.1 Alliance anticipated that Focus would increase its price in the period prior to Lexon's anticipated market entry, such that the resulting price erosion would start from a higher price point. However, Alliance did not want to benefit from any price increases, as it wanted to avoid the volatility of a price increase being followed by price decreases. A fixed price would grant Alliance a 'reprieve' from a genericised market as it would maintain earlier revenue for as long as volumes held up.[878]

5.287.2 A fixed price is not unusual. Within Alliance, [✂] included a fixed price as opposed to a percentage discount that can vary with the distributors selling price.[879]

5.287.3 Where a fixed price is not adopted, it will be due to the particular circumstances of the agreement itself. A percentage discount was used in Alliance's distribution agreement with Creo Pharma (see paragraph 5.283) because the products were already exposed to generic competition and because Creo Pharma would tend to be reactive in responding to purchase requests, whilst Focus would be expected to be more successful in maintaining volumes against generic competition.[880] [Alliance Director 2] also referred to the CMA's analysis of the revenue share distribution arrangement that Alliance had with another distributor, which had been included as part of the CMA's analysis in Figure 3 above: as regards that medicine and the associated formulations, [Alliance Director 2] stated that they *'do not face generic competition'* and that the relevant distributor is the *'seller of record'* to allow for that medicine's sales to count towards the distributors sales *'for PPRS/Voluntary Scheme reasons'.* [Alliance Director 2] explained that the intention of the arrangement *'is to allow APL to benefit from an available regulatory exemption'*.[881]

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[877] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 2.9 (URN: PRO-C5098). See also Alliance RSO, 1 August 2019, paragraph 3.23(a) (URN: PRO-C5096).

[878] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(a) and (b) (URN: PRO-C5098). See also Alliance RSO, 1 August 2019, paragraph 3.21 (URN: PRO-C5096).

[879] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(c) (URN: PRO-C5098). Alliance RSO, 1 August 2019, paragraph 3.25(d) (URN: PRO-C5096).

[880] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(d)(i) (URN: PRO-C5098).

[881] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(d)(ii) (URN: PRO-C5098).

5.287.4 The pre-existing Aspirin Agreement with Focus already included a flat sales price, and as such it was more convenient to amend the same agreement and again adopt a fixed price.[882]

5.288 The factors described by [Alliance Employee 1] and [Alliance Director 2] do not credibly explain the adoption of the terms described above in the Alliance-Focus Agreement for Prochlorperazine POM.

5.289 Regarding [Alliance Employee 1]'s claim that it would have been reputationally damaging for Alliance to share in the price increase, it is noted that by de-branding its product while retaining the company name on its pack,[883] Alliance itself enabled the price of its product to be inflated whilst allowing that inflated price to be associated with Alliance and its product, and that would itself entail the reputational damage that [Alliance Employee 1] submitted was of concern. However, adopting a fixed price, within a confidential commercial distribution agreement, would appear a largely futile measure in containing the potential reputational harm that Alliance had itself created on de-branding its product and providing an appointed distributor with the freedom to determine the price of Alliance branded product.[884]

5.290 [Alliance Director 2]'s arguments concerning his and Alliance's apparent distaste for high pricing are similarly unconvincing:

5.290.1 Had Alliance retained an aversion to high pricing, the most effective course of action would have been to retain the product within the PPRS and thereby to prevent the observed price inflation occurring in the first place. As set out in more detail below (see paragraph 5.361), such an approach would also have had the added benefit of enabling Alliance to protect the significant proportion of its sales from competition in the event of Lexon's entry, and to avoid the need to lower its price to maintain those sales.

5.290.2 There appears to be no particular reason why Alliance would have been averse to a price that was above the supply price it had realised while Buccastem was subject to the PPRS, having adopted prices above that point on a number of other drugs and/or taken steps to enable it do so: (i) [Alliance Director 2] has explained that the aim of one of the distribution agreements included within Figure 3 was to enable it to price outside of the constraints of the PPRS (and, inevitably therefore, to increase price

[882] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(e) (URN: PRO-C5098).

[883] Alliance confirmed that the de-branded Prochlorperazine POM product sold by Focus was sold in Alliance livery (see section 26 response of Alliance dated 12 December 2019, to CMA notice of 26 November 2019, question 1 (URN: PRO-C5491)).

[884] Consistent with this, [Alliance Director 2] referred to Alliance's hope that Focus would implement only a modest price increase, as Alliance was concerned about the reputational impact on Alliance of a larger price increase being implemented in relation to its product (Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(b) (iii) (URN: PRO-C5098)).

above the level that would otherwise be permitted);[885] (ii) the evidence cited at paragraph 5.284 regarding Aspirin 300mg E/C demonstrates that Alliance expected to realise a price that was double the price it had sustained in relation to its branded pack (while also enabling Focus to realise a significant margin over and above its price); and (iii) in relation to its Amantadine product, Alliance supplied de-branded product to the other company that had obtained a licence for the same product (who agreed to become the distributor of the Alliance product), concluded a profit share arrangement, and benefited from a significant price increase.[886] In this regard, [Alliance Employee 1] commented on 9 February 2016, in his 2015 appraisal, that the product had '*exceed[ed] margin by 89% (£0.9m)*'[887] and this margin was referred to as evidence that the associated arrangement had been *'very beneficial to the business'*, with no concern that Alliance was benefitting from prices that exceeded the level previously permitted under the PPRS.

5.290.3 According to slides presented at the Alliance *'Strategy Meeting 2014'*, the *'ideal asset'* for Alliance would be *'non PPRS'*, the benefit of which is that such an 'asset' could be priced above and beyond the level permitted by the PPRS.[888]

5.290.4 As set out paragraphs 5.163 to 5.166, it is evident from [Alliance employee]'s email to [Alliance Employee 2] dated 21 March 2013,[889] that set out the options that Alliance could pursue in response to Lexon's potential entry, that both Alliance and [Alliance Director 2] were open to options that would result in a substantial increase in the price that Alliance itself charged for Prochlorperazine POM. Two of the options (options 1 and 2) that were discussed at the meeting would have involved an increase to the Alliance price, and on receipt of the email recording those options none of [Alliance Employee 1], [Alliance Director 2] nor [Alliance

[885] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(d)(ii) (URN: PRO-C5098).

[886] After entering into an agreement with Auden Mckenzie in June 2014 that included a profit share, the '**Amantadine Agreement**'), the reimbursement price of Amantadine was increased significantly. In May 2014 the reimbursement price of Symmetrel 100mg capsules (56 pack) was £3.30, and the price for Symmetrel 50mg/5ml Syrup was £6.66. By May 2016, the reimbursement price for the de-branded versions of those products was £41 for the 100mg capsules (56 pack) and £137.20 for the syrup (source: Prescription Cost Analysis (PCA) data (https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data) which shows national prescription data dispensed in the community in England at presentation level. Reimbursement price calculated as (Net Ingredient Cost (p) [from tab 1] + Net Ingredient Cost (p) [from tab 2])/(Quantity [from tab 1] + Quantity [from tab 2])/100 [to convert in £] * pack size). Under the terms of its agreement with Auden Mckenzie, Alliance earned a percentage of the Auden Mckenzie sales revenue (see document entitled '*Alliance Pharmaceuticals Limited and Auden Mckenzie (Pharma Division) Limited Fostering Agreement'*, dated 12 June 2014 (URN: PRO-C6448)), and was able therefore to realise a significant increase in the per unit income generated from selling the product (see also the pricing data recorded in the 'Sales price monitor' tab of the Alliance forecasting spreadsheet for July 2016 (URN: PRO-E004694)).

[887] [Alliance Employee 1] 2015 appraisal '*Form 12 month 2015 [Alliance Employee 1] Post Appraisal (002).doc*', 9 February 2016, page 15 (URN: PRO-E001244).

[888] Alliance presentation entitled *'Strategy Meeting 2014'*, dated 9 June 2014, slide 31 (URN: PRO-C7143).

[889] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

Director 1] expressed any concern about these options or the prospect of Alliance increasing its price for the product (see paragraph 5.166).[890]

5.291 [Alliance Director 2]'s suggestion that the fixed price was motivated by a desire to avoid the volatility associated with Focus temporarily inflating the price prior to generic entry and price erosion,[891] is not borne out by Alliance's own forecasts (see paragraphs 5.379 to 5.405 below). At the outset of the arrangement, Alliance in fact forecasted that Lexon would not enter the market in the coming years and that Alliance would remain the exclusive supplier of the product. Accordingly, there was no expectation of a temporary period in which Focus could inflate its price prior to competition emerging and, instead, only the expectation of the continued monopoly supply of the Alliance product. [Alliance Employee 1]'s claims that the fixed price was designed to avoid volatility are further contradicted by the following:

5.291.1 Any such concerns with volatility did not preclude Alliance from concluding percentage discount arrangements in its other distribution agreements, except those for Prochlorperazine POM and Aspirin. It adopted such terms both in agreements where it did face generic competition and may have foreseen price erosion, and also in cases where it does not currently face generic competition and there was potential for prices to be increased (for example (i) Amantadine;[892] and (ii) the medicine that [Alliance Director 2] observes was supplied by a distributor as a means of benefting from a PPRS exemption).[893]

5.291.2 In the event of generic entry, a fixed supply price would not have protected Alliance from volatility in the manner that [Alliance Director 2] implies. A fixed price would require re-negotiation in the event that the market price was no longer profitable for Focus.[894]

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[890] See: (i) email [Alliance Employee 1] to [Alliance employee] and [Alliance Employee 2] cc [Alliance Director 2] entitled '*RE: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000987); and (ii) email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*FW: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000988).

[891] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(b)(iii) (URN: PRO-C5098).

[892] In June 2014 Alliance entered into a profit-sharing agreement with Auden McKenzie in relation to its Amantadine product (see document entitled '*Alliance Pharmaceuticals Limited and Auden Mckenzie (Pharma Division) Limited Fostering Agreement'*, dated 12 June 2014 (URN: PRO-C6448)). In relation to that agreement, [Alliance Employee 1] commented on 9 February 2016 in his 2015 appraisal (URN: PRO-E001244) that the product had '*exceed[ed] margin by 89% (£0.9m)*', suggesting that significant additional margin obtained as a result of a profit share provision in relation to a generic drug was viewed as a positive within Alliance ([Alliance Employee 1] 2015 appraisal '*Form 12 month 2015 [Alliance Employee 1] Post Appraisal (002).doc*' 9 February 2016, page 15 (URN: PRO-E001244)). It is evident that the higher price was liable to attract further entry such that these inflated prices would not be sustained (see also, in this regard, Email [Alliance Employee 1] to [Alliance Director 2] entitled '*EP Strategy Numbers*' 28 May 2015 (URN: PRO-E001180)).

[893] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 4.6(d)(ii) (URN: PRO-C5098).

[894] [Alliance Employee 1] and [Alliance Director 2] both stated in interview that, if the market price declined, there was scope for renegotiation of the Alliance to Focus transfer price (see Interview [Alliance Employee 1], 4 October 2018, part 1, page 63, lines 21-24 (URN: PRO-C2909) and Interview [Alliance Director 2], 5 October 2018, page 53, lines 17-23 (URN: PRO-C2941)).

5.291.3 At around the same time as the fixed price deal was being entered into, Alliance demonstrated that it was willing to be exposed to significant profit share fluctuations in respect of revenue from another of its major generic drugs, by entering into the Amantadine Agreement.[895] As outlined above, the significant revenue and margin increases for Alliance on that product were viewed positively within Alliance, and the associated commentary made no mention of concerns that it could have resulted in volatility should generic competition later emerge. This suggests that significant additional margin obtained as a result of a profit share provision in relation to a generic drug was viewed as a positive within Alliance.

5.291.4 Prochlorperazine – in both its OTC and POM forms – represented less than 5% of Alliance's turnover at the time,[896] such that price fluctuations in relation to Prochlorperazine POM would in any case have a limited impact on Alliance's overall performance. It is also difficult to see why volatility would be of significant concern for Prochlorperazine POM but not for a product such as Amantadine[897] given that Amantadine was, like prochlorperazine, regarded as a key niche generic product for Alliance and generated comparable profits for Alliance to those generated by Prochlorperazine POM.[898]

5.291.5 Finally, and when seen in the context of the substantial price increases that Alliance benefited from and welcomed in the supply of Amantadine, Alliance's claim that it only expected Focus to implement a 'modest' price increase[899] serves to further undermine the notion that its decision to adopt a fixed price on de-branding Prochlorperazine POM was motivated by a desire to preserve stability in favour of increased profits.

5.292 [Alliance Director 2]'s submissions concerning the number of fixed price agreements across the Alliance business, in relation to other product types or countries, do not address the points made above that Alliance's adoption of a fixed

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[895] Document entitled '*Alliance Pharmaceuticals Limited and Auden Mckenzie (Pharma Division) Limited Fostering Agreement*', dated 12 June 2014 (URN: PRO-C6448).

[896] [Alliance Director 2]'s witness statement evidence states that Prochlorperazine, whilst *'significant'*, was just one of Alliance's established products at that time and accounted for *'no more than 5% of [Alliance's] turnover'* in both its OTC and POM form (see Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, paragraph 3.1 (URN: PRO-C5098)).

[897] At paragraph 2.16 of its response to the Letter of Facts, Alliance noted that in May 2013 Buccastem POM was ranked third in Alliance's sales revenue forecasts for the year to December 2013 and that [Alliance Director 2] would have been mindful of Alliance's overall aversion to volatility (Alliance RLF, 29 April 2021, paragraph 2.16 (URN: PRO-C7118)). The CMA observes that Alliance's conduct regarding Amantadine contradicts this claimed aversion to volatility, and demonstrates that Alliance was willing to risk such volatility (by accepting a significant increase in its income per unit) and that such conduct was pursued in relation to another major product for Alliance.

[898] See [Alliance Employee 1] 2015 appraisal '*Form 12 month 2015 [Alliance Employee 1] Post Appraisal (002).doc*' 9 February 2016 (URN: PRO-E001244). Page 15 of [Alliance Employee 1]'s appraisal refers to Amantadine as a *'key product'* and refers to its margin having increased from £1 million to £1.9 million between 2014 and 2015. Alliance's documents attribute comparable returns to Prochlorperazine, recording margins of around £1.6 milion in each of 2014 and 2015 (see, for example, the 'gross margin' tab of URN: PRO-E004693).

[899] Alliance RSO, 1 August 2019, paragraph 3.21 (URN: PRO-C5096).

price was exceptional given that (i) it had at the same time de-branded its product and provided for prices increases that would be unconstrained by the PPRS and that would enable *Focus* to retain far higher margins that those earned by its other distributors; (ii) Alliance has referred the CMA to a number of distribution and wholesaler agreements for the UK supply of *prescription medicines* that, with the exception only of its agreement with Focus, have adopted percentage discounts and provided the appointed distributor with margins that are significantly lower (with the exception of its Aspirin Agreement). The analysis presented by [Alliance Director 2] merely confirms the CMA's assessment.

5.292.1 Of the UK POM arrangements listed in his witness statement, only those with Focus involved a fixed selling price.

5.292.2 The fixed price arrangements that [Alliance Director 2]'s statement refers to are of a very different nature and are limited to cross-border supply arrangements and to three UK agreements that do not concern the supply of prescription medicines.[900] The existence of other fixed price agreements in other parts of Alliance's business does not therefore impact upon the observation that Alliance's standard practice concerning the supply of prescription medicines was to adopt percentage discounts, and that distributors were otherwise provided with margins of less than 60 pence (see Figure 3 above).

5.292.3 The evidence submitted by [Alliance Director 2] refers to two agreements (as part of the list in Exhibit 6 to [Alliance Director 2]'s witness statement) that concern the supply of prescription medicines and that were not covered by the analysis presented in Figure 3 above. Alliance stated that both of these agreements include a percentage discount rather than a fixed supply price.

5.293 As regards the agreements that are the subject of Figure 3 above, [Alliance Director 2] commented that one (the agreement with Creo Pharma) uses percentage discounts because generic competition was already in existence, whereas the other used a percentage discount where no such competition exists. It is not clear why, in the intermediate case of a drug that does not face competition but (it is claimed) was expected to do so imminently, a fixed price would be considered desirable. As regards the distinction that [Alliance Director 2] seeks to draw between Focus and Creo Pharma, it is unclear why Focus' supposed relationships with pharmacies would insulate it from price competition in the supply of a homogenous product such that a fixed price could be sustained in the face of lower priced competitors. Indeed, it is noted that [Alliance Director 2] himself stated

[900] Alliance RSO, 1 August 2019, Annex 2, Witness Statement of [Alliance Director 2] of 31 July 2019, rows 15, 38 and 67 of Exhibit 6 (URN: PRO-C5098).

that following generic entry prices would have declined, and [Alliance Employee 1] also assumed the same outcome.[901]

5.294 Finally, it is observed that the practicalities of inserting a percentage pricing clause into the pre-existing Focus agreement would appear unlikely to explain Alliance's willingness to allow Focus to earn such inflated margins on its product or to adopt prices that were expected to significantly reduce the sales volumes that Alliance could secure on the market. Indeed, the addendum agreed between Alliance and Focus in August 2013 did provide for the amendment of various clauses of the original 2011 agreement.[902]

Conclusion regarding the Alliance-Focus value transfer

5.295 Having considered the evidence described above, and Alliance's representations (see Annex C:), the CMA finds that:

5.295.1 the Alliance-Focus Agreement provided for a significant value transfer[903] from Alliance to Focus (which in turn, could then be shared with Lexon pursuant to the Market Exclusion Agreement); and

5.295.2 the purpose of that transfer was to enable Focus to pay compensation to Lexon for its agreement not to enter the market.

Focus agreed to share the majority of the profits earned on the sale of Alliance's product to Lexon, and that transfer can credibly be explained only on the basis of the Market Exclusion Agreement

5.296 The Focus-Lexon Heads of Terms were agreed between Focus and Lexon by 1 August 2013 (see paragraph 5.275 above). They required Focus to pay Lexon a significant proportion (initially 75%) of Focus' profits generated by the sale of Prochlorperazine POM from any source, i.e. product sourced from suppliers *other than Lexon*, without requiring Lexon to supply Focus with any Prochlorperazine POM (see paragraph 3.106). That is, under the Focus-Lexon Heads of Terms, Lexon was paid *irrespective* of whether it supplied Focus with Prochlorperazine POM.

5.297 By the end of July 2018, Focus had made payments totalling some £7.86 million to Lexon, £2.90 million of which Lexon passed to Medreich (see Annex I:). In return,

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[901] Interview [Alliance Director 2], 5 October 2018, page 50, lines 2-3 (URN: PRO-C2941): '… *the price should come down.The price should come down as soon as that .. hits that tipping point I've talked about*.' Interview [Alliance Employee 1], 4 October 2018, part 1, page 63, line 10 (URN: PRO-C2909): '*I would envisage that with competition it [the price] would decline*'.

[902] Section 26 response of Alliance, part two, dated 16 November 2017, to CMA Notice dated 2 October 2017, Appendix 2, Alliance-Focus Agreement (URN: PRO-C0369).

[903] Whilst a value may be transferred through the provision of a cash payment, in other cases it may be made *'through a more covert transfer of value'* which *'cannot be adequately explained by, or which considerably exceeds, the value to the originator undertaking of any counter-performance of the [potential entrant]'* Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 660.

Focus received a single batch of product including [✂] packs (as envisaged in the [Alliance Director 1] notebook – see paragraph 5.194 above) [✂].[904]

The purpose of the payment was to compensate Lexon for not entering the market

5.298 The CMA finds that the exceptional nature of such a term, involving Focus exposing itself to significant payments to Lexon, without any guarantee of product supply in return, is explicable only on the basis of the common understanding reached between Alliance and Lexon that, in exchange for compensation, Lexon would not enter the market.

5.299 The existence of the profit share clause in the Focus-Lexon Heads of Terms as the means by which Focus would transfer value from Alliance to Lexon was identified in the 22 June 2013 email between [Focus Director 1] and [Focus Director 2], in which, after a description of the terms on which Focus would purchase product from Alliance, it was then stated: *'Deal between Focus and [Lexon Director 1]. 25/75% profit share in Lexon favour (as it is his licence)'*.[905] The fact that the profit share to be paid to Lexon was compensation for Lexon not entering the market is supported by the fact that [Focus Director 1] justified the ratio of the profit share split between Focus and Lexon to his colleague, [Focus Director 2], as being '*as it is his licence*'; that is, Lexon was entitled to a significant proportion of the profit share split because it was the Lexon/Medreich product that was not being sold onto the market. Such an explanation would not have been necessary or appropriate in the event that [Focus Director 1] were contemplating the profit share based on supply of the Lexon product itself, as it would have been perfectly obvious to [Focus Director 2] as recipient of the email why the product manufacturer (Lexon) would obtain a share of profits, and this would not have needed to be spelt out.

5.300 In considering Focus' willingness to pay (and to continue to pay) Lexon pursuant to the profit share term, it must be borne in mind that Focus was aware that Lexon could have terminated the agreement at any point by giving six months' notice.[906] This raised the risk for Focus that Lexon – having received profit share payments from Focus – could subsequently give notice and be free of any contractual obligation towards Focus under the Focus-Lexon Heads of Terms. The fact that Focus continued to pay profit share to Lexon despite not having any guarantee that Lexon would not terminate the Focus-Lexon Heads of Terms provides further

[904] Section 26 response of Lexon dated 27 November 2018, to CMA Notice of 7 November 2018, questions 4(b) and 4(c) (URN: PRO-C2977).

[905] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[906] Interview with [Focus Director 1], 2 October 2018, page 204, line 15 to page 205, line 2 (URN: PRO-C3294).

evidence that the profit share payments were compensation for Lexon not entering the market with the product it had developed with Medreich.

5.301 Although the Focus-Lexon Heads of Terms required Focus to pay Lexon a significant proportion (initially 75%) of Focus' profits generated by the sale of Prochlorperazine POM from any source, it is recognised that it did not make clear on the face of the written document that the intention was that these profit share payments would be made to Lexon as compensation for its agreement with Alliance not to enter the market.

5.302 This omission of the purpose of the profit share payments, alongside the presentation of terms that otherwise envisaged the supply of product once available, when viewed in the context of evidence indicating that Lexon had agreed not to enter the market (see paragraphs 5.190 to 5.202 above) and the absence of credible bases upon which Focus would otherwise agree to share the majority of its profits from supplying the Alliance product with Lexon (as discussed below), is explained by caution on the part of Focus and Lexon regarding what they put into writing. The inclusion of any such clause would have immediately revealed its true nature to the CMA in any Competition Act investigation, to any business interested in the acquisition of Focus (which was a live issue at the time[907]), and/or to any one carrying out any corporate or audit scrutiny of the arrangement. Accordingly, the Parties were plainly incentivised not to include any such term in the Focus-Lexon Heads of Terms.[908]

[907] In early 2013, Focus had appointed Catalyst with a view to getting the business ready for sale (Advanz RSO paragraph 3.171 (URN: PRO-C5111)). Such a sale would likely have involved (and indeed, did involve) due diligence being carried out by the buyer's representatives over Focus' contracts and accounts, potentially raising the question as to why Focus was making profit share payments to Lexon for no product. [Focus Director 1] and [Lexon Director 1] may therefore have seen benefits in limiting the risk that a business contemplating the acquisition of Focus at that time (or the business' legal, financial, and/or accountancy advisers) was alerted to the real motivation of those 'compensation payments'; and [Focus Director 1] and [Lexon Director 1] may have seen benefits that within the Focus-Lexon Heads of Terms written document there was: (i) no record of the actual basis on which payments were to be made by Focus to Lexon notwithstanding the absence of product being supplied; and (ii) instead, a contractual basis for those payments to be made by Focus to Lexon notwithstanding the absence of product being supplied.

[908] Advanz submitted that the CMA's reasoning as regards the omission of the purpose of the profit share payments on the face of the Focus-Lexon Heads of Terms, in so far as it related to reduced likelihood of discovery in due diligence, was inconsistent with a finding that profit share clauses were highly uncommon in such distribution agreements (Advanz RLF 30 November 2021 paragraph 2.24 (URN: PRO-C7917)). However, Advanz's claim of inconsistency as regards the discovery risk in due diligence is not made out: whilst the obligation to pay profit share irrespective of source of product cannot be regarded as 'standard' (see paragraphs 5.311 to 5.313 below), it did not reveal the underlying nature of clause and enabled Focus and Lexon to present different justifications for its inclusion; by contrast, any statement on the face of the Focus-Lexon Heads of Terms document that the purpose of the profit share payments was compensation for Lexon/Medreich not entering the market would have been highly likely to attract attention on even the most basic level of review. On this basis also, the CMA does not accept Advanz's submission that it is not credible to suggest that the vendors of Focus would have been prepared to take the risk of jeopardising the prospects for the sale of Focus to Mercury Pharma Group on 1 October 2014 by entering into an illegal arrangement (Advanz RSO, 1 August 2019, paragraph 3.205 (URN: PRO-C5111)).

The witness evidence on the rationale for the inclusion of the profit share clause in the Focus-Lexon Heads of Terms, and Focus' willingness to make payments under the clause in the absence of product from Lexon

5.303 In the course of interviews with the CMA, [Focus Director 1], [AMCo Director 2] and [Lexon Director 1] provided a variety of explanations for the rationale for the inclusion of the profit share clause in the Focus-Lexon Heads of Terms – and specifically the fact that the profit share was payable to Lexon irrespective of the source of the product supplied – and Focus' and AMCo's continued willingness to honour that clause and make profit share payments to Lexon. The CMA considers in the sections that follow:

5.303.1 [Lexon Director 1]'s and [Focus Director 1]'s suggestion that the clause was inserted to protect Lexon's interests and served as an alternative to a non-compete clause.

5.303.2 [Focus Director 1]'s suggestion that the clause was 'standard'.

5.303.3 [Focus Director 1]'s and [AMCo Director 2]'s suggested motivations for Focus' agreement to include the clause, and then for Focus and AMCo agreeing to honour it and make payments under it, namely:

(a) Focus' aim of obtaining access to a Lexon/Medreich Prochlorperazine POM product that would be cheaper than the product sourced from Alliance;

(b) the expected short term nature of the arrangement and Focus' expectation that the arrival of the Lexon/Medreich Prochlorperazine POM product was 'imminent'; and

(c) Focus' aim of obtaining access to Lexon's pipeline of other products.

5.303.4 [Focus Director 1]'s claim that the agreement between Focus and Lexon was reached long before the Alliance-Focus Agreement, such that the conclusion of the two agreements could not be motivated by the Market Exclusion Agreement.

5.303.5 Additional representations made by the Parties on the rationale for inclusion of the clause.

The profit-sharing clause as an alternative to a non-compete clause

5.304 [Focus Director 1] stated in interview that the profit share clause was intended by Lexon to ensure that Focus would not disadvantage Lexon's supply of product to

Focus.[909] In this respect, [Lexon Director 1] suggested that the profit sharing clause was an alternative to an exclusivity or a non-compete clause (ie a clause prohibiting Focus from selling Prochlorperazine POM other than that sourced from Lexon).[910] Cinven described the clause as a *'quasi-exclusivity'* clause in its representations.[911]

5.305 In his witness statement, [Lexon Director 1] commented on this point further, stating that as Lexon was agreeing to supply Focus exclusively, Lexon was effectively seeking equivalent contractual protection from Focus. [Lexon Director 1] stated that the clause *'was agreed between [Focus Director 1] and myself purely as a mechanism to ensure that Focus would purchase the Product from Lexon and not from a third party'*;[912] however, [Lexon Director 1] also stated that *'reciprocal exclusivity was not a solution since we [Lexon] would not be able to supply until Medreich got the licence'*.[913] On that basis, [Lexon Director 1] stated that it was agreed between Focus and Lexon that if Focus bought Prochlorperazine POM from third parties, Lexon would be entitled to the same profit share as if Lexon had supplied the product. [Lexon Director 1] stated that he agreed these terms with [Focus Director 1] in June/July 2013 on the basis that the agreement would take effect from 1 August 2013 and he expected that he would be able to supply product by the end of 2013.[914] [Lexon Director 1] subsequently informed the CMA that *'Focus wanted exclusivity but at the same time wanted to be free to buy from third parties if Lexon was unable to supply. Accordingly, a straightforward non-compete clause would not have worked.'*[915]

5.306 The CMA does not consider that it is credible that the profit share clause was included in the Focus-Lexon Heads of Terms as an alternative to a *'non-compete'* or that it *'worked as a natural exclusivity clause'*[916] for the following reasons.

5.307 First, considering the impact of the clause from Focus' perspective, the clause cannot credibly be seen as an effective non-compete clause given that:

5.307.1 the profit share clause worked in a very different way to a standard '*non-compete*' clause. Rather than preventing Focus from supplying Prochlorperazine POM sourced from an undertaking other than Lexon, the

[909] Interview [Focus Director 1], 2 October 2018, page 76, line 18-23 (URN: PRO-C3294), as cited by Advanz's RSO, 1 August 2019, paragraph 6.15 (URN: PRO-C5111).

[910] Interview [Lexon Director 1], 10 September 2018, part 1, CD 3, page 26, lines 9 to page 27, line 11 (URN: PRO-C3188).

[911] Cinven RSO, 15 August 2019, paragraph 4.37 (URN: PRO-C5132) and Cinven RLF, 22 April 2021, paragraph 2.15 (URN: PRO-C7107).

[912] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 122 (URN: PRO-C5092). See also Cinven RSO, 15 August 2019, paragraphs 4.39 (URN: PRO-C5132): '*Lexon wanted to ensure that so long as it had Prochlorperazine POM available to supply, Focus would have every incentive to buy that product'.*

[913] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 27 (URN: PRO-C5092).

[914] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 27 (URN: PRO-C5092).

[915] Lexon RLF, 21 April 2021, paragraph 59 (URN: PRO-C7104).

[916] Cinven RSO, 15 August 2019, paragraphs 4.92 (URN: PRO-C5132).

clause envisaged that Focus could do so, and that, if Focus did, it would then share the profits from any associated sales with Lexon;

5.307.2 at approximately the same time as negotiating the Focus-Lexon Heads of Terms with Lexon, Focus was also negotiating to secure supply of the Alliance Prochlorperazine POM, and was committing in the Alliance-Focus Agreement not to supply Prochlorperazine POM sourced from any supplier other than Alliance (including Lexon) (see paragraph 3.104). Focus was therefore actively negotiating with the incumbent supplier that it would *only* supply the *Alliance* product going forward – that outcome being the antithesis of what [Lexon Director 1] stated in his witness statement that he was seeking to achieve through the clause;[917] it is therefore not credible that the clause had been designed specifically to incentivise Focus to purchase product from Lexon when it was available;[918]

5.307.3 in November 2013, Focus prepared its budget for 2014 (covering the period January 2014 to December 2014), which forecast that its purchases of Prochlorperazine POM would be made exclusively from Alliance;[919] this is consistent with an expectation and intention on the part of Focus not to purchase volumes of Prochlorperazine POM from Lexon, and contradicts any suggestion that the profit share clause can be seen as equivalent to a non-compete clause; further, according to the documents obtained by the CMA, and as confirmed to the CMA in interview by [Focus Director 1],[920] Focus never provided any forecast to Lexon in terms of ordering Prochlorperazine POM from it; and

5.307.4 it is difficult to regard the profit share clause as equivalent to a non-compete on Focus given that Focus did not make any purchases of Prochlorperazine POM from Lexon under the Focus-Lexon Heads of Terms with the exception of a single batch of Prochlorperazine POM on 29 March 2018[921] consisting of [✂] packs (as compared to Focus' total sales of Prochlorperazine POM of 1,043,925 packs between December 2013 and July 2018).[922]

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[917] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 27 (URN: PRO-C5092).

[918] Cinven RLF, 22 April 2021, paragraph 2.25 (URN: PRO-C7107).

[919] See Email [Focus Director 1] to [Focus Director 2] entitled *'FW: other OLS for budget'* 14 November 2013 (URN: PRO-E003759). This assumes that all purchases would be made at the supply price specified in the Alliance-Focus Agreement, as shown by the fact that the cost of goods (CoG) in the email chain was £5.65 (the price at which Focus purchased product from Alliance) for each month in 2014.

[920] See Interview [Focus Director 1], 2 October 2018, page 197, lines 13-15 (URN: PRO-C3294). [Focus Director 1] explained that this was *'because he [Lexon Director 1] couldn't make it'*.

[921] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 2 (URN: PRO-C3149).

[922] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 2 (URN: PRO-C3149).

5.308 Second, considering the clause from Lexon's perspective, the clause cannot credibly be seen as equivalent to a non-compete restriction.

5.308.1 It is not clear why [Lexon Director 1] would have been concerned about Focus purchasing Prochlorperazine POM from other suppliers.

(a) The only other supply route potentially open to Focus at that time (that is, other than Lexon/Medreich) was to purchase product from the sole licence holder, the incumbent supplier, Alliance. Alliance had been supplying its branded (Buccastem) POM product onto the market itself for many years at that point (without needing a distributor). Absent the Market Exclusion Agreement, there was no basis as to why [Lexon Director 1] would or should have been concerned about Alliance deciding to start supplying Focus, and [Lexon Director 1] has claimed that Lexon knew nothing about the prospect of Alliance supplying Focus at the time of the conclusion of the Focus-Lexon Heads of Terms.[923]

(b) As regards [Lexon Director 1]'s explanation in his witness statement that he was concerned about Focus purchasing product elsewhere, he explained that this was based on the fact that *'there were rumours in the market that other companies were applying for a Licence'*,[924] although he did not provide any further evidence or support for this or provide further details relating to such 'rumours'; in fact, other evidence in [Lexon Director 1]'s witness statement undermines any suggestion that he considered that such entry by other parties was imminent (such that Focus would be able to purchase stock from them): he stated that his assumption in June 2013 was that *'[t]here were other companies who were likely to obtain POM Product Licences* ***within the next 2/3 years****, notably Morningside Healthcare and Primegen'* (emphasis added)[925] – although in fact competition took even longer than this to appear, with Primegen obtaining its licence in 2016 and Morningside Healthcare in 2017.

5.308.2 [Lexon Director 1]'s explanation as to why a reciprocal non-compete clause could not be included in the Focus-Lexon Heads of Terms was that Lexon would not be able to supply until after Medreich had obtained its

[923] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 30 (URN: PRO-C5092).

[924] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 27 (URN: PRO-C5092).

[925] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 60(f) (URN: PRO-C5092).

licence.[926] However, the CMA finds that this explanation does not credibly explain the inclusion of the clause.

(a) First, any straightforward non-compete clause on Focus could have been drafted to take effect only once Lexon started supplying product to Focus, whilst leaving Focus open to purchase from other suppliers in the meantime. [Focus Director 2], when asked at interview, stated that he was not aware of concerns regarding Lexon's ability to supply at the time of Focus' negotiations with Lexon,[927] indicating that such a clause could have been included from Focus' perspective.[928]

(b) Second, as set out above, there were no other Prochlorperazine POM suppliers available to Focus at this point, other than Alliance; as stated above, absent the Market Exclusion Agreement, there was no reason for [Lexon Director 1] to have been concerned about supply by Alliance to Focus at this time.

5.309 What is clear, and very straightforward, is that the inclusion of the clause would inevitably impact upon *Lexon's* ongoing incentives to supply product to Focus, given that Lexon was in any event guaranteed 75% of Focus' profits on the sale of any Prochlorperazine POM.

5.310 The CMA therefore finds that the design and inclusion of the profit share clause in the Focus-Lexon Heads of Terms, where Lexon was paid profit share on Focus' sales of the Alliance product, cannot credibly be explained as having been included as an alternative to a non-compete clause.

The profit-sharing clause as being 'standard'

5.311 [Focus Director 1] described the inclusion of such a clause as *'standard'*,[929] and *'frequent in these types of arrangements'*.[930] Advanz further represented that the

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[926] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 27 (URN: PRO-C5092).

[927] Interview [Focus Director 2], 8 January 2020, page 101, lines 2-6 (URN: PRO-C5886).

[928] The CMA rejects Cinven's representation that Focus would not have agreed to an exclusivity clause that prevented it from taking supply from elsewhere in the event that Medreich was unable to meet Focus' requirements based on a Focus concern about Medreich's *ongoing* ability to ensure security of supply and concern about *'future supply outages'* (see Cinven RSO, 15 August 2019, paragraphs 4.40 and 4.92 (URN: PRO-C5132) and Cinven RLF, 22 April 2021, paragraphs 2.15 and 2.26(b) (URN: PRO-C7107)).There is no contemporaneous evidential support for this proposition and it is irreconcilable with Focus' assumed contractual exclusivity obligation to Alliance under the Alliance-Focus Agreement: that obligation is not consistent with Cinven's portrayal of the position as being that Focus would always be able to take the cheapest available product, without any interruptions in its ability to supply (Cinven RLF, 22 April 2021, paragraph 2.26(a) (URN: PRO-C7107)). Indeed, the [Focus Director 1] interview extract cited by Cinven on this point suggests that a non-compete clause that took effect upon Lexon supplying product would have been a viable alternative: *'…I [was] never 100% comfortable with Indian supplier product because it is very, very hit and, hit and miss through the release procedure. So, until we would know that that product was just – was consistently being – actually being released, then we would've dumped the Alliance [product]'* (Interview [Focus Director 1], 2 October 2018, page 72, lines 19-25 (URN: PRO-C3294)).

[929] Interview [Focus Director 1], 2 October 2018, page 75, line 4-7 (URN: PRO-C3294).

[930] Email [Morgan Lewis Partner] to [CMA Official] entitled '*RE: Case 50511-2 – Interview with [Focus Director 1] – draft transcript'* 14 January 2019 (URN: PRO-C3289) attaching [Focus Director 1] statement entitled *'letter for Morgan Lewis 13-1-19'* (URN: PRO-C3290).

profit share arrangement *'is not uncommon in the pharmaceutical sector'*,[931] and the fact that Lexon (together with Medreich) was the manufacturer explained why it would receive a higher share of the margin.[932]

5.312 In considering the validity of this claim, it is important to emphasise first that the CMA's finding in this respect does not relate to the mere existence of a profit share between distributor and manufacturer, nor to the fact that Lexon (as manufacturer) would receive a higher share of any such profits. Rather, the significance of the clause in this context is the obligation on a distributor to pay a share of its profits to another manufacturing undertaking *that was not providing the distributor with any products or services.* The notion that such a clause is 'standard' and should be considered legitimate in these circumstances is undermined by the following evidence:

5.312.1 During an interview with the CMA, [Focus Employee 1] (the [✂] for Focus) was asked if she was aware of any other agreements that Focus had entered into where it paid a profit share to a company which was not supplying Focus with a product. [Focus Employee 1] stated that she was not aware of any other agreements of this type.[933]

5.312.2 [Lexon Director 1] stated in his witness statement that the Focus-Lexon Heads of Terms was *'unusual'* in that it included a provision that if Focus purchased the product otherwise from Lexon, it would pay Lexon 75% of the net profit in the same way as if Lexon had supplied the product.[934]

5.312.3 In response to a Section 26 Notice asking specifically about this point, Advanz was not able to provide evidence of any other agreements that had been entered into by Focus where profits were shared with a company *that was not actually supplying any products to Focus*. Two other agreements entered into by members of the AMCO group, as referenced by Advanz, did provide for the payment of profit share, but where the payments reflected the use of know-how or technology in very specific, prescribed circumstances. In contrast, the profit share payments received by Lexon were not made in exchange for any know-how or technology provided by Lexon or Medreich, and the profit share was payable to Lexon irrespective of the reasons why it was not supplying product to Focus.[935]

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[931] Advanz RSO, 1 August 2019, paragraphs 3.180.2 and 6.14 (URN: PRO-C5111).

[932] Advanz RSO, 1 August 2019, paragraph 3.180.2 (URN: PRO-C5111).

[933] Interview [Focus Employee 1], 7 February 2019, page 41, line 17 to page 42, line 19 (URN: PRO-C3826).

[934] Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 122 (URN: PRO-C5092). In the Lexon RLF, 21 April 2021 (URN: PRO-C7104) [Lexon Director 1] confirmed that he had never suggested that the profit sharing clause in the Focus-Lexon Heads of Terms be considered as *'standard'* or *'frequently used'* but it was freely negotiated and agreed (see paragraph 60).

[935] See section 26 response of Advanz dated 20 February 2019, to the CMA Notice of 6 February 2019, Annex 4 (URN: PRO-C3806). Of the 10 agreements referred to in Advanz's response of 20 February 2019, six were agreements entered

5.312.4 Following representations made by Advanz in its oral hearing, the CMA requested that Advanz produce five examples of agreements in which Advanz was required to make milestone payments in advance of an MA being granted, and where those milestone payments were contractually linked to the profits Advanz earned from the sales of another undertaking's, or Advanz's own, product. Although Advanz did produce five agreements in response to the CMA's request:[936]

(a) None of the milestone payments payable pursuant to these agreements were contractually linked to the profits Advanz earned from the sales of another undertaking's, or Advanz's own, product.

(b) In contrast to the Focus-Lexon Heads of Terms, these agreements contained claw-back mechanisms requiring the milestone payments to be repaid in the event there was no supply agreement or a failure to supply and/or if the seller failed to provide adequate registration documents to the buyer or subsequently failed to obtain an MA or had it withdrawn. Certain of the agreements also allowed the buyer to retain and use any MAs and registration documentation generated by the seller if the agreement terminated due to the seller's material breach.

5.313 The CMA therefore finds that the profit-sharing clause agreed between Focus and Lexon cannot be considered 'standard'. The unusual nature of the clause is

into by Focus. None of those agreements involved Focus being paid, or Focus paying, a profit share in circumstances where Focus was not supplied, or was not supplying, products. The other four agreements referred to in the response were agreements entered into by other members of the AMCo Group. Of those four agreements only two were described as involving *'Profit sharing irrespective of source of relevant product'*. In the first of those two agreements (see Annex 5.3A of the response (URN: PRO-C3810)), the AMCo Group company which entered into the agreement was required, under certain circumstances, pursuant to clause 4.6, to pay a *'royalty of [✂]%'* of the *'net selling price'* if the AMCo Group company used the *'Know How and/or Dossier to investigate and develop an alternative third party supply of the Product'*. In those specific circumstances, the royalty payment appears to be a payment made in return for the use of the *'Know How and/or Dossier'*. Such an agreement is clearly distinguishable from the payments made by Focus to Lexon under the Focus-Lexon Heads of Terms. Advanz submitted that *'without even inquiring into the ownership of the dossier and know-how, it is not possible for the CMA to dismiss this profit sharing provision as it does'* (Advanz RSO, 1 August 2019, paragraph 3.180.4, footnote 312 (URN: PRO-C5111)). However, Advanz did not provide any further reasoning to doubt the CMA's conclusion that, on the face of the agreement, the royalty payment reflects the use of the *'Know How and/or Dossier'*. In the second such agreement (see Annex 5.7 of the response (URN: PRO-C3815)), pursuant to clause 11.1, in the event that the supplier was unable to supply the product *'as a result of… patent infringements… Force Majeure… or because an agreement on prices for PRODUCT…can not be reached'* then the AMCo Group company could *'have the right to manufacture PRODUCT itself or through third parties …'*. If the AMCo Group company exercised this option, then the AMCo Group company was permitted to *'purchase PRODUCT from a third party or are free to manufacture'* and would be required to *'pay a royalty of [✂] percent ([✂]%) of NET SELLING PRICES'*. Again, in those circumstances, the royalty is payable on the use of the technology which would allow manufacturing by the AMCo Group or a chosen third party and is clearly distinguishable from the payments made by Focus to Lexon under the Focus-Lexon Heads of Terms. In its representations on the SO, Advanz pointed to the fact that the AMCo Group company was *'free to purchase PRODUCT from a third party'* (clause 11.2) provided that the stipulated profit share was paid to the supplier (Advanz RSO, 1 August 2019, paragraph 3.180.4, footnote 312 (URN: PRO-C5111)). However, whether the AMCo Group company manufactured the product itself or purchased product from a third party, it is clear from clause 11.1 and clause 11.2 that such payments reflect the use of the supplier's technology, as evident from the fact that under clause 11.2 the AMCo Group company is required to purchase the API exclusively from the supplier.

[936] Advanz submission of 9 January 2020 in response to CMA questions of 26 November 2019 (URN: PRO-C5705-PRO-C5710) and email [Morgan Lewis employee] to [CMA Official] entitled *'RE: CMA - Case 50511-2 - Oral hearing transcript / follow-up questions / Competition Act 1998 section 26 notice'* 10 January 2020 (URN: PRO-C5716).

credibly explained only on the basis that the payments of profits by Focus on the sale of the Alliance product served to compensate Lexon/Medreich for their agreement not to enter the market.[937]

Focus' motivations for agreeing to the profit share clause and making payments to Lexon: access to a cheaper Lexon/Medreich Prochlorperazine POM product

5.314 In his interview with the CMA, [Focus Director 1] explained that a key motivation for entering into the Focus-Lexon Heads of Terms and agreeing to make profit share payments to Lexon whilst waiting for product from it was based on the prospect of securing access to the Lexon/Medreich Prochlorperazine POM product which would have had a cheaper cost of goods than the product sourced from Alliance.[938] [Focus Director 1] stated that he *'always anticipated that Lexon would ultimately supply [Focus] with Prochlorperazine [POM] and then at a price much lower than the price at which [Focus] was purchasing Prochlorperazine [POM] from [Alliance]'*.[939] Similarly, in his interview with the CMA, [AMCo Director 2] suggested that AMCo's rationale for continuing to make profit share payments reflected his desire to preserve *'optionality'* over different sources of supply, including a potentially lower cost source of supply in Lexon than represented by Alliance.[940]

5.315 It is clear, however, that, on the basis that the supply from Lexon to Focus in this situation would be made pursuant to the provisions of the Focus-Lexon Heads of Terms, this could not have been the basis on which Focus originally agreed to make, and subsequently persisted in making, payments to Lexon.

5.315.1 Alliance and Focus had – in line with the agreement made between Alliance and Lexon, as reflected in [Focus Director 1]'s email of 22 June 2013[941] (see paragraph 5.195 above) – agreed in the Alliance-Focus Agreement to a supply price of £5.65 (see paragraph 3.100 above).

5.315.2 By contrast, Focus would pay to Lexon (based on the Focus-Lexon Heads of Terms) a cost per pack plus the payment of the profit share; therefore, when considering the comparative cost of the product from different supply

[937] Cinven stated in its representations on this point that Focus expected to receive supplies of the Lexon-Medreich product within a reasonable period of time (Cinven RSO, 15 August 2019, paragraphs 4.94 (URN: PRO-C5132)). This reasoning does not make the clause any less unusual: but in any event, this point is considered (and rejected) in paragraphs 5.325 to 5.329 below.

[938] Interview [Focus Director 1], 2 October 2018, page 72, lines 7-9 (URN: PRO-C3294).

[939] Email [Morgan Lewis Partner] to [CMA Official] entitled '*RE: Case 50511-2 – Interview with [Focus Director 1] – draft transcript'* 14 January 2019 (URN: PRO-C3289) attaching [Focus Director 1] statement entitled *'letter for Morgan Lewis 13-1-19'* (URN: PRO-C3290).

[940] See Interview [AMCo Director 2], 7 January 2020, page 20, lines 20-23 (URN: PRO-C5994). Advanz subsequently described this in its representations as a *'hedging strategy which involved AMCo pursuing all options then available to it'* (Advanz RLF, 22 April 2021, paragraph 4.112 (URN: PRO-C7112)). Cinven described it as Focus putting itself in a commercially advantageous position whereby it would always be able to take the cheapest available product, without any interruptions in its ability to supply (Cinven RLF, 22 April 2021, paragraph 2.16 (URN: PRO-C7107)). These representations are undermined by the fact that, as set out in this section, the Lexon product would not be the cheapest product available given the profit share payable to Lexon.

[941] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' dated 22 June 2013 (URN: PRO-E001476).

sources, Focus would need to calculate the Lexon supply price factoring in the profit share payment, which was a function of Focus' own selling price.

5.315.3 Focus' expectation at the time of entering into the Focus-Lexon Heads of Terms was clearly that it would increase prices: on 18 July 2013, [Focus Director 1] emailed [Focus Director 2] setting out the predicted profitability of Focus' supply of Alliance's Prochlorperazine POM, in which [Focus Director 1] anticipated increases to the Focus price to wholesalers up to £11.20:[942]

Below is based on an initial Trade price for Focus of £10 rising to £12 and then £14 and allowing 20% for wholesale to get our ASP

Monthly Volume	Focus COG	Focus ASP	Focus monthly profit (25%)
25,250	£5.68	£8.00	£14,645
25,250	£5.68	£9.60	£24,745
25,250	£5.68	£11.20	£34,845

5.315.4 [Focus Director 1] stated in interview to the CMA that his proposal to Alliance would have involved moving the price of Prochlorperazine POM product up to the pro rata price of the P product, at £18.[943]

5.316 As a result of the fact that Focus did, as anticipated, increase prices, for the large part of the period in which Focus made profit share payments to Lexon, the equivalent supply price payable to Lexon (taking account of the profit share payments) would have been far higher than the supply price that Focus was paying to Alliance. For example, in contrast to the Alliance price of £5.65 until March 2015 (see paragraph 3.104) and then £6.10 (from April 2015, see paragraph 3.175), the

[942] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478). The CMA's analysis of the witness evidence and Party representations on this email is set out in paragraphs 5.264 to 5.268 above.

[943] Interview [Focus Director 1], 2 October 2018, page 47, lines 10-17 (URN: PRO-C3294).

equivalent supply price payable to Lexon based on Focus' prevailing prices sold to wholesalers was as follows:

Table 2: Equivalent supply price payable by Focus to Lexon

Date	Focus average selling price to wholesalers[944]	Lexon's cost per pack[945]	Profit share split applicable	Profit share payable per pack	Total equivalent supply price[946]
December 2014	£9.91	[✂]	75%	[£5-£10]	[£5-£10]
December 2015	£21.20	[✂]	50% above £10.50 / 75% below £10.50	[£10-£15]	[£10-£15]
December 2017	£31.14	[✂]	50%	[£15-£20]	[£15-£20]

5.317 Nor can it credibly be argued that Focus' expectation was that prices would subsequently fall after an initial increase. Although [Focus Director 1] did claim in his interview that Focus was expecting entry by other generics within a year,[947] Focus' internal documents around the time of the Focus-Lexon Heads of Terms record its expectation, as outlined above, that its selling prices would increase and that it would purchase only from Alliance; they did not assess the timing or expected impact of other competitors entering the market, or contemplate any such entry reducing the market price for Prochlorperazine POM.[948] Such unfettered price increases by Focus are not consistent with an expectation of imminent competition from other generic entrants. Consistent with this:

5.317.1 Focus' forecasting in April 2014 does not incorporate any loss of volume to competitors;[949]

[944] Source: Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150) showing Focus' selling price to wholesalers.

[945] Source: Excel spreadsheet entitled 'exon Medreich generics new line forcasts.xlsx' by [Lexon Director 1] 31 May 2012 (URN: PRO-E002539), showing a Lexon cost per pack of [✂]. In fact, the CMA notes that, when the single batch of Prochlorperazine POM was delivered from Medreich to Lexon in November 2017, the cost of the product was quoted as [✂] (see section 26 response of Lexon dated 27 November 2018, to CMA Notice of 7 November 2018, question 4(a) (URN: PRO-C2977)).

[946] Cost of Lexon product + Profit share: Equivalent supply price payable by Focus to Lexon.

[947] Interview [Focus Director 1], 2 October 2018, page 48, lines 11-14 (URN: PRO-C3294), as cited by Cinven in its representations on the Statement of Objections paragraph 4.34 and paragraph 4.98 (URN: PRO-C5132).

[948] For this reason the CMA rejects Cinven's submission that *'[w]hile cancelling the F-L Heads of Terms would result in an initial large gain for Focus, once the Lexon-Medreich product was launched, it would be reasonable to expect Focus' profits from supplying the Alliance product to be lower than if it supplied the Lexon-Medreich product given the lower Lexon-Medreich cost'* (Cinven RLF, 22 April 2021, paragraph 2.29 (URN: PRO-C7107)).

[949] *Focus Prochlorperazine Forecast – 04 04 14*' 4 April 2014 (URN: PRO-E001117).

5.317.2 [Focus Director 1] only raised the prospect of losing share with Alliance in late 2015 as a possibility for mid-2016;[950]

5.317.3 Focus forecasts did at no stage contemplate purchasing product from Lexon; and

5.317.4 Focus' internal documents do not record any assessment of whether the prospect of purchasing from Lexon could justify payments that totalled £7.86 million by July 2018.

5.318 Subsequent evidence from after Focus had been purchased by AMCo in October 2014, and AMCo had purchased Primegen in June 2015, further undermines the suggestion that the profit share payments were made to enable AMCo/Focus to access cheaper product from Lexon. Specifically, AMCo's decision to continue to supply the Alliance product, whilst making profit share payments to Lexon, rather than launch the Prochlorperazine POM product that was being developed by Primegen, further illustrates why the Focus payments to Lexon cannot have been motivated by a desire to obtain cheaper product from Lexon. In February 2016 at the time of the grant of the Primegen licence and the conclusion of the revised profit share renegotiation with Lexon (see paragraphs 3.156 to 3.158):

5.318.1 Focus paid Alliance a fixed price of £6.10 (having increased from £5.65 in April 2015 (see paragraph 3.175)).

5.318.2 Having purchased Primegen in June 2015, which had its own development project for Prochlorperazine POM, AMCo had the potential to source product at a significantly lower cost – which was subsequently adjusted during 2016 to €[✂] (equivalent to £[✂][951]) – from [✂] (the Primegen contract manufacturer).[952]

[950] Email [Focus Director 1] to [Alliance Employee 1] entitled '*RE: Update forecasts and PO's*' 1 September 2015 (URN: PRO-E001196).

[951] Based on Bank of England daily spot exchange rate of £1:€1.2898 as at 1 June 2016.

[952] See email from [AMCo employee] to [AMCo Director 2], cc [AMCo employee] entitled '*FW: [✂]/AMCO meeting minutes*' 25 April 2016 (URN: PRO-E001802) and email [AMCo employee] to [AMCo Director 2] and [AMCo Employee 4], cc [AMCo employee] (all AMCo) entitled '*RE: Amco- [✂]: Telecom – Prochlorperazine UK Launch*' 27 June 2016 (URN: PRO-E001853) showing that the Primegen cost of goods from [✂] was increased from €[✂] to €[✂] in April 2016 and then to €[✂] by June 2016. Advanz submitted that the [✂] cost of €[✂] should be seen in the context of [✂] having raised prices by around 700% without good reason (to AMCo's frustration), excluding API cost (which can be material), as being for one year only (such that further increases were possible) and seen in the context of [✂] (Advanz RLF, 22 April 2021, paragraph 4.134.4 (URN: PRO-C7112)). However, the quoted price of €[✂] in [AMCo employee]'s email of 27 June 2016 (URN: PRO-E001853) is stated to be [✂]'s '*final supply price (with API included)*', and, in any event, the CMA finds that these issues raised by AMCo do not detract from the fundamental point that AMCo had available its own supply line at a low manufacturing cost, and that the issues raised by Advanz were not insurmountable in a situation in which AMCo committed to pursuing the Primegen product: instead, AMCo did not make the Primegen product a priority for [✂] (Excel spreadsheet entitled '*PPRM Report – December 2016*' (URN: PRO-E002007) and see further paragraph 5.505 below).

5.318.3 The Lexon/Medreich product would, in contrast, have involved a cost per pack of [✂][953] plus the payment of the profit share to Lexon, which by the start of 2016 had been adjusted to 50% above £10.50 and which was then subsequently adjusted in February 2016 to 50% on all profits applicable from April 2016 (paragraph 3.158). Given that AMCo's market price was around £21.20[954] at that time, the Lexon equivalent supply price would therefore have been £[10-15][955] going forward based on the 50% revised profit share agreed between AMCo and Lexon (and would have been £[10-15] based on the profit share split prior to the amendment: see Table 2 above).

5.318.4 AMCo nevertheless chose to continue to supply the Alliance product and to make substantial payments to Lexon, even though it was apparent that the Lexon product would not have been cheaper than either the Alliance product that AMCo purchased, or the [✂] product that AMCo could have taken steps to supply. The Lexon 'option' is not therefore capable of justifying the payments AMCo continued to make to Lexon.

5.319 Further, it was not the case that AMCo management were concerned that prices would fall quickly to such an extent that the Lexon product could (on the basis of the profit share arrangement) soon be cheaper than the Alliance product. In its assessments of whether to launch its own product in competition with Lexon and Alliance, AMCo modelled in June 2015 that its average selling price of £14 per pack would be sustained at this level for the following five years notwithstanding the presence of multiple competitors.[956] However, at this pricing level, and even on the basis of the amended profit share in Focus' favour to 50% on all profits, AMCo would have faced a higher equivalent supply price from Lexon (£[5-10][957]) than it paid to Alliance (£6.10) (or could potentially have obtained for the Primegen product through [✂] (€[✂] / £[✂])), such that AMCo would again have had no

[953] See Excel spreadsheet entitled '*exon Medreich generics new line forcasts.xlsx*' by [Lexon Director 1] dated 31 May 2012 (URN: PRO-E002539), showing a Lexon cost per pack of [✂] as modelled by [Lexon Director 1]. In fact, the CMA notes that, when the single batch of Prochlorperazine POM was delivered from Medreich to Lexon in November 2017, the price of the product was quoted as [✂] (see section 26 response of Lexon, dated 27 November 2018, to CMA Notice of 7 November 2018, question 4(a) (URN: PRO-C2977)).

[954] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150) showing Focus' average selling price to wholesalers in February 2016 was approximately £21.20 per pack.

[955] That is, on the basis of the Focus-Lexon Heads of Terms and the amended profit share (see paragraph 3.158), the cost of goods sold of [✂], plus a 50% share of the margin between the £21.20 selling price and [✂] (see the Excel spreadsheet entitled '*exon Medreich generics new line forcasts.xlsx*' by [Lexon Director 1] 31 May 2012 (URN: PRO-E002539), showing a Lexon cost per pack of [✂]).

[956] Slide 16 of the Project CAPITAL BD Workstream presentation dated 30 June 2015 (URN: PRO-E001636). For this reason the CMA rejects Cinven's submission that AMCo was anticipating new market entry, which could have resulted in prices falling below the £14 level (Cinven RLF, 22 April 2021, paragraph 2.73 (URN: PRO-C7107)).

[957] That is on the basis of the Focus-Lexon Heads of Terms and the amended profit share (see paragraph 3.158), the cost of goods sold of [✂], plus a 50% share of the margin between a £14 selling price and [✂] (see the Excel spreadsheet entitled '*exon Medreich generics new line forcasts.xlsx*' by [Lexon Director 1] 31 May 2012 (URN: PRO-E002539), showing a Lexon cost per pack of [✂]).

prospect of recouping the payments that it was making to Lexon on securing the Lexon product.

5.320 Given the availability of product that would be significantly cheaper to source than Lexon's, AMCo's decision to continue to make payments to Lexon cannot be explained by a commercial analysis that the Lexon product would be cheaper or (as [AMCo Director 2] suggested in his interview[958]) by a commercial wish for AMCo to preserve *'optionality'* in relation to different Prochlorperazine POM supply sources. Given that Focus already had access to a cheaper and reliable source of supply provided by the incumbent (Alliance), there was no reason to continue to make substantial payments to preserve the option of securing the Lexon product at a later date.[959] Focus' conduct cannot credibly be explained, as Cinven claimed, to be based on maximising its own profits now while continuing to pursue the option of a lower cost product to supply in the future.[960]

5.321 Nor is it credible that [AMCo Director 2] decided to retain access to the Lexon/Medreich product given [✂] and a desire to retain commercial flexibility.[961] First, the Lexon/Medreich product was, effectively, more expensive than the Alliance product (see paragraphs 5.316 to 5.319 above). Second, the Lexon/Medreich product could itself hardly be regarded as certain given that, on the evidence of [AMCo Director 2], Lexon/Medreich's failure to produce product was the consequence only of its own inability to supply and in no way attributable to existence of the Market Exclusion Agreement. Third, [✂] arose *after* AMCo's decision to use the Primegen licence as leverage (see paragraph 5.518 below).

5.322 The claim that Focus' profit share payments to Lexon were aimed at securing access to a cheaper Prochlorperazine POM product than that available from Alliance is also inconsistent with evidence that there was the potential for a renegotiation of the Prochlorperazine POM price that Focus paid to Alliance under certain circumstances.[962] The prospect of re-negotiating the Alliance price further undermines any suggestion that the Lexon product would necessarily have been cheaper, let alone so much cheaper that it could justify the payment of the profit

[958] Interview [AMCo Director 2], 7 January 2020, page 33, lines 13-17; page 193, lines 1-5; page 194, line 22 to page 195, line 4 (URN: PRO-C5994).

[959] The CMA rejects Cinven's submission that the CMA should have quantified the '*excess amount*', as Cinven terms it, that Focus was paying Lexon under the Focus-Lexon Heads of Terms beyond that which would have been acceptable (see Cinven RLF, 22 April 2021, paragraph 2.19 (URN: PRO-C7107)) on the basis that, if the Lexon product was more expensive than the product that Focus could source from Alliance, then there is no basis why Focus should pay profit share to keep open the possibility of obtaining the Lexon product, in particular given that it has never been suggested that the Lexon supply route would be more reliable than that provided by Alliance.

[960] Cinven RLF, 22 April 2021, paragraph 2.56 (URN: PRO-C7107).

[961] Cinven RLF, 22 April 2021, paragraph 2.72 (URN: PRO-C7107).

[962] Cinven claimed in its representations that Focus considered that the Alliance product would always have a price floor greater than the cost of good from Lexon-Medreich (see Cinven RLF, 22 April 2021, paragraph 2.22(a) and 2.30(c) (URN: PRO-C7107)). However, the CMA is not aware of any evidence of any specific *'price floor'* (as seen from Focus' perspective) in this respect – and in any event, such a *'price floor'* would have to be offset against the need for Focus to pay 75% of profits to Lexon.

share payments by enabling Focus to recoup the profit share it was paying to Lexon.

5.322.1 In this regard there was a limited amendment in terms of the transfer price from Alliance to Focus from £5.65 to £6.10 and [Focus Director 1] thought that this could be negotiated down again: *'Cost of good s [sic] is now £6.10 from Alliance (was £5.65 but we gave them a little upside) – I may try to get this back down when i [sic] see him next'*.[963]

5.322.2 [Alliance Employee 1][964] and [Alliance Director 2][965] both stated in interview that, if the market price declined, there was scope for renegotiation of the Alliance to Focus supply price, and the CMA sees no reason to doubt their evidence in this respect. The Alliance witnesses' position reflects the commercial reality that there would have been no point in Alliance trying to tie Focus to purchase at a fixed price level in circumstances where the market price had fallen below this, given that the Alliance-Focus Agreement did not require Focus to purchase minimum volumes of product each year.

5.323 The CMA does not accept Advanz's submission that the scope for renegotiation of the transfer price depended on Focus having access to the Lexon product and that *'a potential renegotiation with Alliance could only be possible if AMCo/Focus had access to cheaper product from Lexon'*.[966] The comments of [Alliance Employee 1] and [Alliance Director 2] are clear that Alliance would have considered renegotiation of the transfer price to Focus where this was commercially required given market conditions: this could have been as a result of Focus having access to another product, or, as they envisaged, by another product entering the market. In any event, even if it were correct that Focus/AMCo would have benefited from commercial leverage in any such negotiations with Alliance, AMCo's ownership of the Primegen MA could have provided AMCo with this leverage from the time of the acquisition of Primegen in June 2015 – without having to make profit share payments to Lexon.[967]

5.324 The CMA rejects Cinven's submission that the CMA's finding that there may have been scope for renegotiation of the price payable by Alliance to Focus is

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[963] Email [Focus Director 1] to [Focus Director 2] entitled *'Prochlorperazine 3mg'* 26 June 2015 (URN: PRO-E001633). Advanz stated in response to the Statement of Objections that *'It is also clear that both Focus and Alliance considered the terms of the Alliance-Focus … Agreement to be open to renegotiation. This is clear from the fact that, in January 2015, Focus and Alliance negotiated an increase to the transfer price from £5.65 to £6.10 and from the fact that Focus in turn thought that this new price could be negotiated down again.*' (Advanz RSO, 1 August 2019, paragraph 3.203 (URN: PRO-C5111)).

[964] Interview [Alliance Employee 1], 4 October 2018, part 1, page 63, lines 21-24 (URN: PRO-C2909).

[965] Interview [Alliance Director 2], 5 October 2018, page 53, lines 17-23 (URN: PRO-C2941).

[966] Advanz RLF, 22 April 2021, paragraph 4.217 (URN: PRO-C7112).

[967] Advanz's representation is also undermined by its statement in response to the Statement of Objections as cited in note 963 above, which does not make any reference to dependence on the Lexon product for renegotiation of the Alliance to Focus supply price.

inconsistent with its finding that there existed a binding exclusivity obligation on Focus under the Alliance-Focus Agreement.[968] Whilst both Focus and Alliance contemplated the potential for price adjustment (see paragraph 5.322 above) the Alliance witnesses did not contemplate a situation in which Alliance would allow Focus to sell other competing products to its own and – in contrast to a possible price amendment to allow Focus to remain competitive in the market – there would have been no commercial rationale for Alliance in agreeing to such a request against its own interests.

Focus' motivations for agreeing to the profit share clause and making payments to Lexon: the expected short term nature of the arrangement and Focus' expectation that the Lexon/Medreich product was 'imminent'

5.325 In respect of his motivation for accepting the profit share clause in the Focus-Lexon Heads of Terms, [Focus Director 1] explained that *'I didn't think it was going to go on for as long as it did. I thought it's probably a few months'*.[969] He also commented that, going forward, Lexon's Prochlorperazine POM was continually expected to be just about to arrive in the market, and that fact explained Focus' willingness to continue to make payments to Lexon.[970]

5.326 The CMA does not find [Focus Director 1]'s explanation that he expected the profit share payments on sale of the Alliance product to go on for only '*a few months*' to be credible.

5.326.1 At the time of the agreement of the clause (in June/July 2013), Medreich did not have an MA for the Prochlorperazine POM product and only obtained an MA for the Prochlorperazine P product on 9 July 2013; the Prochlorperazine POM licence was obtained only in January 2014, and then there would have been a gap prior to any successful manufacturing.

5.326.2 In addition, [Focus Director 1] agreed in July 2013 a five year exclusive agreement with Alliance for sale of its product under which Focus would be contractually prohibited from selling Prochlorperazine POM sourced from anyone other than Alliance.[971]

5.326.3 [Focus Director 1]'s expectations in relation to Prochlorperazine POM pricing, as communicated to [Focus Director 2] on 18 July 2013, are premised on Focus' continued supply of the Alliance product as prices

[968] Cinven RLF, 22 April 2021, paragraph 2.22(b) (URN: PRO-C7107).

[969] Interview [Focus Director 1], 2 October 2018, page 76, lines 23-26 and page 77, line 1 (URN: PRO-C3294) as cited by Advanz in its representations on the Statement of Objections paragraph 6.16 (URN: PRO-C5111).

[970] Interview [Focus Director 1], 2 October 2018, page 169, lines 19-22 and page 177, lines 19-22 (URN: PRO-C3294).

[971] Whilst Advanz submitted in its representations (Advanz RSO, 1 August 2019, paragraph 6.106.2 (URN: PRO-C5111)) that Focus did not intend to be bound by the non-compete clause in the Alliance-Focus Agreement and did not consider itself bound by it, for the reasons set out in Annex C: the CMA has found that Advanz's representations in this respect are not sustained.

increased over time, rather than on purchase of any of the Lexon product:[972]

Below is based on an initial Trade price for Focus of £10 rising to £12 and then £14 and allowing 20% for wholesale to get our ASP

Monthly Volume	Focus COG	Focus ASP	Focus monthly profit (25%)
25,250	£5.68	£8.00	£14,645
25,250	£5.68	£9.60	£24,745
25,250	£5.68	£11.20	£34,845

5.326.4 Having entered into the Focus-Lexon Heads of Terms, Focus forecasted in November 2013 in its budget for 2014, covering the period January 2014 to December 2014, that its purchases of Prochlorperazine POM would be made exclusively from Alliance;[973] this is consistent with an expectation and intention not to purchase commercial volumes of Prochlorperazine POM from Lexon. Further, according to the documents obtained by the CMA, and as confirmed to the CMA in interview by [Focus Director 1],[974] Focus never provided any forecast to Lexon in terms of ordering Prochlorperazine POM from it, even after receipt of the single batch of product from Lexon in March 2018.

5.327 Nor does the CMA find it credible that – having entered into the Focus-Lexon Heads of Terms and started to make profit share payments to Lexon – [Focus Director 1] expected the Lexon/Medreich product to be just about to arrive or imminent such that this would explain Focus' continued willingness to pay profit share to Lexon. [Focus Director 1] commented in interview, in relation to [Lexon Director 1]'s email statement to Focus on 14 April 2014 that Lexon (and implicitly, Lexon's manufacturer partner, Medreich) had been *[✂]*,[975] that it would take between [✂] from a manufacturer's receipt of API before it was able to start producing product.[976] On the basis of this comment, [Focus Director 1] himself – who said that he considered he had the right to terminate the Focus-Lexon Heads

[972] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478). Whilst Cinven noted that Medreich did not have its Prochlorperazine POM MA at this point, and therefore could not supply Focus (Cinven RSO, 15 August 2019, paragraphs 4.102 and 4.167 (URN: PRO-C5132)) it would not have made sense for [Focus Director 1] to have communicated an expectation on profitability to [Focus Director 2] which were likely to be wholly undermined by expected short term developments or based on assumptions which would quickly be overtaken by events (namely, expected supply by Lexon). The CMA's analysis of the witness evidence and Party representations on this email is set out in paragraphs 5.264 to 5.268 above.

[973] See Email [Focus Director 1] to [Focus Director 2] entitled *'FW: other OLS for budget'* 14 November 2013 (URN: PRO-E003759). This assumes that all purchases would be made at the supply price specified in the Alliance-Focus Agreement, as shown by the fact that the cost of goods (CoG) in the email chain was £5.65 (the price at which Focus purchased product from Alliance) for each month in 2014.

[974] See interview [Focus Director 1], 2 October 2018, page 197, lines 13-15 (URN: PRO-C3294). [Focus Director 1] explained that this was '*because he [Lexon Director 1] couldn't make it*'.

[975] Email [Lexon Director 1] to [Focus Director 1] entitled *'Prochlorperazine 3mg'* 14 April 2014 (URN: PRO-E003794).

[976] Interview [Focus Director 1], 2 October 2018, page 206, lines 7-10 (URN: PRO-C3294).

of Terms[977] – in April 2014 would have been uncertain as to the date and in any case could not have been expecting product from Lexon before late 2014 at the earliest.[978,979]

5.328 Subsequent evidence relating to AMCo's ownership period of Focus also undermines the suggestion that Focus (and AMCo) expected the Lexon/Medreich Prochlorperazine POM product to be about to arrive imminently, such that this could credibly explain the continued payments of profit share to Lexon.

5.328.1 As regards [Focus Director 1], in his correspondence with [Lexon Director 1] discussing the potential second amendment of the profit share split in the Focus-Lexon Heads of Terms in anticipation of AMCo obtaining its own Primegen licence for Prochlorperazine POM, [Focus Director 1] did not raise the fact that the Prochlorperazine POM jointly developed by Lexon and Medreich had not been provided by Lexon to date, nor did he seek clarity or assurance as to when the product would arrive.[980] This lack of information or engagement on the status of the Lexon/Medreich product cannot be reconciled with a genuine belief by Focus that the Lexon/Medreich product was about to arrive imminently.

5.328.2 As regards [AMCo Director 2]'s expectations, [AMCo Director 2] confirmed in interview that he could not remember anybody in AMCo *'putting their hand up and saying. "Stock is just about to arrive … from Lexon".'*[981] To the contrary, [AMCo Director 2] [✂][982] [AMCo Director 2]'s doubts about Medreich's ability to supply product undermine the suggestion that AMCo continued to pay Lexon on the basis that AMCo expected the Lexon/Medreich product to arrive imminently. The fact that these comments relate to Medreich's manufacturing ability in 2016, several years after conclusion of the Focus-Lexon Heads of Terms, do not

[977] Interview [Focus Director 1], 2 October 2018, page 204, lines 15 to page 205, line 2 (URN: PRO-C3294).

[978] In Lexon's response to the 16 February 2021 Letter of Facts, [Lexon Director 1] considered that [Focus Director 1]'s statement in this respect was not inconsistent with Focus believing that supply of the Lexon product was imminent on the basis that when the Focus-Lexon Heads of Terms was entered into *'Focus would presumably have assumed that no payment would be made … until Lexon delivered product'* (Lexon RLF, 21 April 2021, paragraph 63 (URN: PRO-C7104)). The CMA rejects [Lexon Director 1]'s representation on this point: Focus would indeed have known that under the Focus-Lexon Heads of Terms profit *would* indeed be payable before Lexon delivered product given that Focus was, in parallel, negotiating the Alliance-Focus Agreement.

[979] The CMA sets out in detail in paragraphs 5.582 to 5.620 below its finding that the correspondence in 2014 between Focus and Lexon (including [Lexon Director 1]'s email to [Focus Director 1] of 14 April 2014 (URN: PRO-E003794)) does not indicate Focus expecting to receive commercial volumes of product from Lexon or chasing Lexon for product.

[980] See Email [Focus Director 1] to [Lexon Director 1] entitled *'prochlorperazine 3mg Tabs'* 26 June 2015 (URN: PRO-E003877) and Email [Lexon Director 1] to [Focus Director 1] entitled *'FW: Prohlorperazine 3mg tabs'* 26 June 2015 (URN: PRO-E003878). Advanz submitted in this respect that after the sale of the business to AMCo, [Focus Director 1] disengaged and as a result the lack of product went unnoticed by the new management given the various mergers and acquisitions of its acquirer (Advanz RSO, 1 August 2019, paragraph 6.106.3 (URN: PRO-C5111), referring to paragraphs 3.180.6, 3.209 and 6.27). See also Advanz RLF, 22 April 2021, paragraph 4.156 (URN: PRO-C7112). The CMA addresses this submission specifically in paragraphs 5.542 to 5.544 below and finds that it is not credible that the lack of product went unnoticed by AMCo's management.

[981] Interview [AMCo Director 2], 7 January 2020, page 175, lines 9-18 (URN: PRO-C5994).

[982] Interview [AMCo Director 2], 7 January 2020, page 30, line 22 to page 31, line 4; page 32, lines 15 – 18; page 126, lines 9-20 (URN: PRO-C5994).

undermine this point, as Advanz suggests:[983] to the contrary, the payments made by Focus/AMCo to Lexon reached their highest point during 2016 and early 2017, meaning this should have acted as the greatest spur to AMCo questioning the rationale for the profit share payments if they were, as is claimed, being made on the expectation that the Lexon/Medreich product was imminent.

5.329 On the basis of the evidence above, the CMA finds that Focus' continued payments to Lexon cannot be explained by Focus/AMCo having considered that the Lexon/Medreich product was to be supplied to Focus imminently, such that it was rational for Focus/AMCo to continue making profit share payments to Lexon to secure that product.

Focus' motivations for agreeing to the profit share clause and making payments to Lexon: access to Lexon's pipeline of other products

5.330 [Focus Director 1] stated in an interview with the CMA that, alongside getting access to cheaper Prochlorperazine POM product from Lexon/Medreich, Focus agreed to make payments to Lexon – and to continue honouring that commitment under the Focus-Lexon Heads of Terms – because of a desire to maintain a relationship with Lexon in the hope of being appointed as supplier for other Lexon products in the future.[984] As Advanz submitted in its representations, [Focus Director 1] thought that *'by agreeing to this provision, Lexon would reward Focus by making Focus a distributor of those products'*.[985]

5.331 The notion that Focus agreed to, and then honoured, the profit share provision because of a desire to gain access to other products in Lexon's pipeline was alleged to have remained a factor in explaining the payments after Focus had been purchased by AMCo: [AMCo Director 2] also gave this explanation as part of the explanation for the continued payments in his interview, describing the *'relationship [with Lexon] is a key element to it'*.[986]

5.332 For the reasons set out below, the CMA concludes that [Focus Director 1] and [AMCo Director 2]'s explanations do not represent a credible explanation of Focus' decision to agree to make such substantial payments to Lexon pursuant to the Focus-Lexon Heads of Terms in the absence of any delivery of product by Lexon to Focus.

5.333 First, the Focus-Lexon Heads of Terms made no mention of any other products (see paragraph 3.106) and related solely to Prochlorperazine POM. [Focus

[983] Advanz RLF, 22 April 2021, paragraph 4.204.4 (URN: PRO-C7112). As to Advanz's submission in paragraph 4.204.4 that the lack of product from Lexon went unnoticed by AMCo's management, see paragraphs 5.542 to 5.544 below.

[984] Interview [Focus Director 1], 2 October 2018, page 65, line 22 to page 66, line 6; page 71, lines 13-19; page 167, line 25 to page 168, line 19; page 169, lines 14-19 and page 173, line 18 to page 174, line 7 (URN: PRO-C3294).

[985] Advanz RSO, 1 August 2019, paragraph 3.209 (URN: PRO-C5111).

[986] Interview [AMCo Director 2], 7 January 2020, page 191, lines 10 to 16 (URN: PRO-C5994).

Director 1] confirmed to the CMA that he made no attempt to link, contractually, the substantial payments being made with a commitment from Lexon to supply relevant future products to Focus.[987] Instead, the only commitment that Lexon made in the Focus-Lexon Heads of Terms was not to supply Prochlorperazine POM to other undertakings. Relatedly, [AMCo Director 2] stated in his interview that he was not aware of [Lexon Director 1] ever making any commitment or assurance to him that, in return for AMCo's continued profit share payments, AMCo would be given other (Lexon/Medreich) products.[988]

5.334 Second, when asked about the Lexon pipeline that was alleged to be so valuable, and which allegedly motivated Focus to pay Lexon profit share payments ultimately totalling some £7.86 million, relevant Focus and AMCo individuals were only able to identify fragmentary details relating to the pipeline that could not credibly explain such substantial payments being made:

5.334.1 [Focus Director 1] was unable in interview confidently to name any such product, and was able only uncertainly to name one other product.[989]

5.334.2 [Focus Director 2] was not able to identify any such products in Lexon's pipeline, with the exception of the one product (fluoxetine) that actually came to fruition.[990]

5.334.3 [AMCo Director 2] was able to name only two products in Lexon's pipeline that would have been of interest to AMCo, and was only able to point to one that actually materialised in terms of a relationship between Lexon and Concordia/AMCo/Focus (fluoxetine).[991] [AMCo Director 2] accepted

[987] Interview [Focus Director 1], 2 October 2018, page 173, line 18 to page 175, line 1 (URN: PRO-C3294).

[988] Interview [AMCo Director 2], 7 January 2020, page 192, line 3 (URN: PRO-C5994).

[989] Interview [Focus Director 1], 2 October 2018, page 172, lines 1-12 (URN: PRO-C3294). Advanz submitted in this respect that the fact that in the context of a section 26A CA98 interview, [Focus Director 1] was not able to recall immediately upon being asked, specific APIs of Lexon's pipeline around seven years after the relevant discussions with Lexon had taken place and around four years after his exit from Focus, is of no significance (Advanz RSO, 1 August 2019, paragraph 6.105 (URN: PRO-C5111)). The CMA accepts in this respect that [Focus Director 1] might not have been able to recall details of all, or even very many, of Lexon's pipeline products; however, it finds that his inability to name more than one product is telling given that this Lexon pipeline was alleged to be a key reason why Focus was continuing to pay profit share payments to Lexon and given, in relation to timing, that [Focus Director 1] informed the CMA that his consultancy lasted until [✂] (Interview with [Focus Director 1], 2 October 2018, page 12, lines 22-24 (URN: PRO-C3294)), that is only [✂] years prior to his interview with the CMA in October 2018.

[990] Interview [Focus Director 2], 8 January 2020, page 24 lines 10 to 15 (URN: PRO-C5887). Advanz submitted in respect of [Focus Director 2]'s evidence that the interview took place some eight years after a discussion between Focus and Lexon took place in 2012 around potential distribution of products (Advanz RLF, 22 April 2021 paragraph 4.192 (URN: PRO-C7112)). However, the CMA considers that analogous reasoning applies to the timing of [Focus Director 2]'s interview as to [Focus Director 1]'s (see note 989).

[991] Interview [AMCo Director 2], 7 January 2020, page 35, lines 5 to 12 (URN: PRO-C5994). Advanz submitted in this respect that [AMCo Director 2]'s understanding of the discussions between Focus and Lexon prior to March 2015 was limited to his recollection of what [Focus Director 1] and [Focus Director 2] had told him (Advanz RLF, 22 April 2021, paragraph 4.193 (URN: PRO-C7112)). However, AMCo (under [AMCo Director 2]) continued to make payments to Lexon during 2015 and 2016, up until 31 July 2018. On this basis, the CMA considers that [AMCo Director 2] could reasonably (at the time of his interview in 2020) have been expected to have understood *why* his company was making significant profit share payments to Lexon over this time.

that the other product he mentioned (erythromycin) '*never went anywhere*'.[992]

5.335 Third, in relation to the one drug that [Focus Director 1], [Focus Director 2] and [AMCo Director 2] did all name in connection with Focus/AMCo's interest in the Lexon/Medreich pipeline of products, that is, fluoxetine:

5.335.1 the profits AMCo envisaged earning in respect of fluoxetine were still modest in comparison to the profit share payments it was making to Lexon in respect of Prochlorperazine POM, such that an interest in supplying fluoxetine and earning those profits could not explain AMCo's willingness to continue to make the payments to Lexon;[993] and

5.335.2 the fact that AMCo reached agreement with Medreich in June 2015 in relation to fluoxetine[994] undermines the suggestion that AMCo made payments to Lexon *after* that point that were motivated by the aim of obtaining fluoxetine, given that this product had already been contractually secured for AMCo.

5.336 Fourth, the Lexon/Medreich nortriptyline pipeline product that came to fruition in 2015, and was available for distribution, was not offered by Lexon to Focus[995] despite the fact that Focus/AMCo were paying Lexon over £300,000 per quarter during 2015, and the profit share payments were increasing.[996] Whilst Lexon has submitted that there was a commercial explanation for its choice of a different distributor to Focus,[997] its failure to offer the product to AMCo is plainly at odds with

[992] Interview [AMCo Director 2], 7 January 2020, page 127, lines 21 to 23 (URN: PRO-C5994).

[993] In February 2016, AMCo projected annual profits from Fluoxetine that, in the period 2016-2020, were on average per year only slightly over half the amount AMCo was paying Lexon per year pursuant to the Prochlorperazine POM profit share (Section 26 response of Advanz, dated 4 December 2020 to CMA Notice of 25 November 2020, response to question 3 (URN: PRO-C6441)). Whilst Cinven submitted that AMCo's anticipated revenues for Fluoxetine did increase to [✂] per year profit in 2020 (Cinven RLF, 22 April 2021, paragraph 2.34 footnote 49 (URN: PRO-C7107)) even this future amount does not greatly exceed the annual profit share payments Focus was making to Lexon which reached over £700,000 per quarter in 2017 (see Annex I:) – and such profit share payments were certain, whereas any prospect of obtaining access to the Lexon/Medreich pipeline was not, in particular because Focus had no contractual right to any other product developed by Lexon/Medreich.

[994] Section 26 response of Advanz, dated 4 December 2020, to CMA Notice of 25 November 2020 (URN: PRO-C6441) and Annex 1 of Section 26 response of Advanz, dated 4 December 2020, to CMA Notice of 25 November 2020 (URN: PRO-C6445).

[995] [Lexon Director 1] confirmed that Lexon did not consider distributing this product via Focus and that the product was launched via [✂] in 2015 (Lexon Oral Hearing, 25 September 2019, page 63, lines 16 to 21 (URN: PRO-C5607)). Advanz also confirmed that, to the best of its knowledge, Lexon did not offer to Focus/AMCo its nortriptyline product (Advanz's 6 January 2020 response to the CMA's questions dated 26 November 2019, response to question 5 (URN: PRO-C5635)).

[996] See Annex I:.

[997] [Lexon Director 1] stated that he wanted to give the nortriptyline product to [✂] and that he thought AMCo had a nortriptyline product in their own development pipeline (Lexon Oral Hearing, 25 September 2019, page 63, line 16 to page 64, line 1 (URN: PRO-C5607)). In respect of the [✂] relationship, Advanz pointed out that [Lexon Director 1] had not stated whether Focus was aware of Lexon's partnership with [✂] in respect of nortriptyline and therefore the CMA should not assume that this partnership ought to have called into question AMCo's approach to its relationship with Lexon (Advanz RLF, 22 April 2021, paragraph 4.197 (URN: PRO-C7112)). However, the CMA notes that Lexon's relationship with [✂] would have become public once [✂] started supplying the Lexon/Medreich product and that, even if AMCo had its own development, it might still have benefited from being given access to Lexon's nortriptyline product: the Focus nortriptyline MA was not granted until 8 August 2016

any expectation or understanding on Focus or AMCo's part that it would be granted preferential access to Lexon's product pipeline.

5.337 Fifth, when asked by the CMA, Advanz was not able to provide any internal Focus/AMCo document that analysed or quantified the value of the Lexon/Medreich product pipeline to Focus/AMCo in terms of a prospective distribution opportunity. Advanz was also unable to provide any internal documentary evidence that the profit share payments were in any way linked to the expectation of Lexon appointing Focus as distributor of other Lexon/Medreich products.[998] The only documents Advanz pointed to in this respect[999] fail to establish any link between the profit share payments and access to the Lexon pipeline:

5.337.1 Advanz cited email communications from April 2012 between [Focus Director 1], [Focus Director 2], and [Lexon Director 1], relating to a number of Lexon '*potential development projects*',[1000] but these significantly predate the Market Exclusion Agreement and appear to discuss potential joint development products between Focus and Lexon, as opposed to products Lexon would produce in the context of the Lexon and Medreich joint venture and which would then be distributed by Focus: i.e. they do not relate to Lexon's own pipeline of products;[1001]

5.337.2 the minutes of a Lexon board meeting of 12 March 2013[1002] referring to Focus support for the development of products in Greece predate the Market Exclusion Agreement and do not explain what product is relevant; the minutes are not clear whether Focus would be obtaining access to a Lexon/Medreich product or whether Focus would be assisting to develop a

(https:\\assets.publishing.service.gov.uk\government\uploads\system\uploads\attachment_data\file\552454\Monthly_new_MA_listing_August_2016.pdf), whereas the Medreich nortriptyline MA was granted in March 2015 (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/424805/Granted_marketing_authorisations_March_2015.pdf)). Further, the contention that there was no advantage in Lexon offering nortriptyline to Focus/AMCo given Focus/AMCo had their own product in development squarely contradicts Focus and AMCo's commentary in relation to Prochlorperazine POM that they wanted access to Lexon/Medreich's Prochlorperazine POM despite having access to the Alliance product, and also, from June 2015, their own Primegen development.

[998] Advanz's 6 January 2020 response to the CMA's questions dated 26 November 2019, response to question 4 (URN: PRO-C5635). For this reason the CMA rejects Cinven's representation that the legitimacy of Focus' motivations should not be assessed with the benefit of hindsight given that '*Focus, in effect, made an investment in developing its future relationship with Lexon*' (Cinven RLF, 22 April 2021, paragraph 2.35 (URN: PRO-C7107)). Such an investment would have been expected to have been reflected in contemporaneous documentation given the scale of the sums being invested by Focus (and, from the time of its acquisition, effectively by AMCo).

[999] Advanz RSO, 1 August 2019, paragraph 3.215 (URN: PRO-C5111), as also referred to in Advanz RLF, 22 April 2021, paragraph 4.201 (URN: PRO-C7112).

[1000] Email from [Focus Director 1] to [Focus Director 2] entitled '*RE: [Lexon Director 1] prods /deal*' 12 April 2012 [RSO 001] (URN: PRO-C5108) and email from [Lexon Director 1] to [Focus Director 2] copying [Focus Director 1] entitled '*RE: Potential Development Products*' 23 April 2012 [RSO 002] (URN: PRO-C5109).

[1001] For example, the comment of [Lexon Director 1] on 23 April 2012, '*hold back on this for now – Medreich have 20mg licence and it may be simpler for me to get them to do it*' (email from [Lexon Director 1] to [Focus Director 2] copying [Focus Director 1] entitled '*RE: Potential Development Products*' 23 April 2012 [RSO 002] (URN: PRO-C5109)).

[1002] Lexon board meeting minutes 12 March 2013 (URN: PRO-C0051).

product; in addition, the CMA is mindful that no witnesses have mentioned or referred to this in the context of the Focus/Lexon relationship;

5.337.3 Advanz pointed to correspondence indicating that in 2016 and 2017, Concordia (i.e. AMCo and Focus' group) and Lexon had communications concerning the appointment of Concordia as exclusive distributor for Lexon's Prochlorperazine OTC;[1003] however the documents again fail to establish any link between the profit share payments and the discussion, and the notion that such an arrangement could in any case justify Focus' substantial payments to Lexon is further undermined by the fact that in January 2017 Advanz anticipated earning only £57,000 per annum from any such arrangement, describing the proposed arrangement as '*low-margin'*,[1004] such that it can have played no meaningful role in the justification of payments that had by that time already totalled over £5 million.[1005] Further, [AMCo Employee 3]'s internal email discussing the proposed distribution arrangement does not suggest that this was the result of a particular relationship with Lexon and, far from linking it to the profit share payments under the Focus-Lexon Heads of Terms, actually states that '*It complements the Prochlorperazine we currently have through Alliance Pharmaceuticals*';[1006] and

5.337.4 on 21 September 2017, [Lexon employee] wrote to [AMCo employee] and [AMCo employee], copying in [Lexon Director 1], to say that, '*[Lexon Director 1] and I are excited and positive about our abilities to enter into co-development in the future. In the meantime, please find attached an updated product list. A lot of the products on the third page "Under Development" are seeing light for the first time, so I'm basically giving you first dibs. I'll give you a bit of time to have a proper look through them to see if any are of interest before I start publicising them more heavily*'.[1007] Once more, there is no suggestion in the document that the discussions were in any way linked to the profit share payments that Focus/AMCo had made to Lexon in relation to Prochlorperazine POM, and was continuing to make at the time. Further, Advanz has not cited, and the CMA is not aware of, any respondent correspondence from AMCo/Concordia that

[1003] Email from [AMCo Employee 3] to [Lexon Director 1] entitled '*RE: Prochlorperazine'* 14 December 2016 (URN: PRO-E001959) and email from [AMCo employee] to [AMCo Employee 3] and others (all Concordia) entitled '*RE: New Product: Sign-off request'* 12 January 2017 (URN: PRO-E001973) and email from [AMCo employee] to [AMCo Employee 3] (all Concordia) entitled '*Re: New Product – Prochlorperazine*' 27 January 2017 (URN: PRO-E001987).

[1004] Email [AMCo Employee 3] to [AMCo employee] et al (Concordia) entitled '*New Product: Sign-off request*' 12 January 2017 (URN: PRO-E001973).

[1005] Source: Annex I:.

[1006] Email [AMCo Employee 3] to [AMCo employee] et al (Concordia) entitled '*New Product: Sign-off request*' 12 January 2017 (URN: PRO-E001973).

[1007] Email [Lexon employee] to [AMCo employee] and [AMCo employee], cc [Lexon Director 1] entitled '*Lexon Product List'* (URN: PRO-E000677), attaching a Lexon product list (URN: PRO-E000678). This document is highlighted by Cinven in its representations as evidence that Focus' pipeline strategy was '*borne out in practice*' (Cinven RSO, 15 August 2019, paragraph 4.44 (URN: PRO-C5132)).

actually seeks to take advantage of this offer of '*first dibs*' – as would have been expected had Focus/AMCo being paying Lexon profit share in the hope of obtaining access to the Lexon product pipeline.

5.338 Sixth, [AMCo Director 2]'s comments in interview describing Medreich as [✂],[1008] are hard to reconcile with his suggestion that he placed significant value on the prospect of a future relationship with Lexon (given it was Medreich's partner), such that he would make substantial profit share payments to Lexon in the hope of securing that relationship.[1009] This point becomes more significant as time progressed and Lexon/Medreich failed to supply the Prochlorperazine POM product that [AMCo Director 2] said he was expecting: it becomes increasingly less credible that AMCo would have paid profit share to Lexon in order to sustain its relationship with Lexon in the hope of receiving pipeline products when Lexon's product supplier (Medreich) had failed to produce Prochlorperazine POM after several years.

5.339 Seventh, the CMA is not aware of any contemporaneous documentation from Medreich that suggests that – notwithstanding its position as product manufacturer – it understood that the profit share payments it received were motivated by obtaining access to its supposedly valuable pipeline of products: [Medreich Director 2]'s email of 21 July 2017 describing the rationale for the payment of profit share to Medreich does not mention this point.[1010]

5.340 On the basis of the evidence above, the CMA finds that it is not credible that Focus agreed to the inclusion of the profit share clause in the Focus-Lexon Heads of Terms, and then continued to make profit share payments to Lexon, in the hope or expectation of being given priority access to other products that Lexon/Medreich were developing in terms of their product pipeline.

Focus' motivations for agreeing to the profit share clause: the agreement between Focus and Lexon was entered into long before the Alliance-Focus Agreement and without reference to the Alliance product

5.341 [Focus Director 1] has stated that an agreement was reached with [Lexon Director 1] that Focus would distribute Lexon/Medreich's Prochlorperazine POM tablets as early as July to December 2012,[1011] which would imply that its terms were not in

[1008] Interview [AMCo Director 2], 7 January 2020, page 22, lines 3 to 5; page 30, line 19 to page 31, line 4; page 31, lines 21 to 23 (URN: PRO-C5994).

[1009] Such doubt is compounded by the fact that elsewhere in the same interview [AMCo Director 2] stated his unwillingness to spend money on manufacturing product in circumstances where [✂] (Interview [AMCo Director 2], 7 January 2020, pages 110-111 (URN: PRO-C5994)). [AMCo Director 2]'s professed [✂].

[1010] Email [Medreich Director 2] to [Meiji employee] entitled *'Re: Prochlorperazine – profit sharing'* 21 July 2017 (URN: PRO-E003351). [Medreich Director 2]'s own commentary on the contents of his email of 21 July 2017 are set out in paragraph 5.578. The Parties' representations on the significance of [Medreich Director 2]'s email of 21 July 2017, and the CMA's consideration of them, are set out in paragraphs 5.579 to 5.581.

[1011] See interview [Focus Director 1], 2 October 2018, page 123, lines 23 to 25 (URN: PRO-C3294): '… *[Lexon Director 1] and I probably had our, our initial, initial discussions about the -- sort of, July the year before, around that time.*'. He

fact linked to the Alliance-Focus Agreement.[1012] In this respect, he stated that: *'I don't think it [the Profit Share Clause] was actually put in with the Alliance thing in, in mind because they were two completely separate agreements made at very different times.'*[1013]

5.342 The CMA has considered the explanation put forward by [Focus Director 1] together with the documentary evidence and other witness evidence before the CMA. The CMA rejects [Focus Director 1]'s explanation and finds that his comment that the profit share clause in the Focus-Lexon Heads of Terms was not put in with reference to the supply of product from Alliance cannot be sustained.

5.342.1 First, it is inconsistent with [Focus Director 1]'s own actions when, in 2014, he dated the Focus-Lexon Heads of Terms as commencing on 1 August 2013.[1014]

5.342.2 Second, there is no documentary evidence that suggests that Lexon and Focus had agreed relevant terms in relation to the distribution of Prochlorperazine POM before June 2013. The first documentary evidence of an agreement between Lexon and Focus is the internal Focus 22 June 2013 email described above (see paragraph 5.195), and the content of that email (an update from [Focus Director 1] to [Focus Director 2] in case [Focus Director 2] was called by [Alliance Employee 1]) implies that the relevant agreements have been recently discussed, with *'[Lexon Director 1] chasing to see what is happening'*.

5.342.3 Third, it is inconsistent with [Lexon Director 1]'s interview evidence that distribution discussions would not generally have taken place until some six months before the grant of the licence.[1015] Whilst Advanz noted in its representations that [Lexon Director 1] said he might have mentioned Prochlorperazine POM to [Focus Director 1] at an earlier stage,[1016] the

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confirmed that, although he could not remember exactly when the agreement with Lexon had been reached, he was confident that the terms of the agreement had been documented during 2012. See interview [Focus Director 1], 2 October 2018, page 158, line 12 to page 159, line 17 (URN: PRO-C3294). See also Email [Morgan Lewis Partner] to [CMA Official] entitled '*RE: Case 50511-2 – Interview with [Focus Director 1] – draft transcript'* 14 January 2019 (URN: PRO-C3289) attaching [Focus Director 1] statement entitled *'letter for Morgan Lewis 13-1-19'* (URN: PRO-C3290).

[1012] Based on [Focus Director 1]'s comments in interview, Advanz submitted in its representations on the Statement of Objections that, in late 2012 / early 2013, in the context of their broader commercial relationship, Lexon appointed Focus as the distributor for Prochlorperazine POM which Lexon had jointly developed with Medreich (Advanz RSO, 1 August 2019, paragraph 6.9 (URN: PRO-C5111)). In relation to the evidence on timing of [Lexon Director 1], Advanz also submitted that [Lexon Director 1]'s recollection in his interview was that he could *not* recall the precise sequence of events and that there was uncertainty about what [Lexon Director 1] was referring to when he stated '*there or thereabouts*'; on this basis, Advanz restated its view that Lexon appointed Focus as the distributor for Prochlorperazine POM in late 2012/early 2013, albeit that the agreement was formalised on 1 August 2013 (Advanz RLF, 22 April 2021, paragraph 4.79 (URN: PRO-C7112)).

[1013] Interview [Focus Director 1], 2 October 2018, page 76, lines 23 to 26 (URN: PRO-C3294) as cited by Advanz in its Advanz RSO, 1 August 2019, paragraph 6.16 (URN: PRO-C5111).

[1014] Email [Focus Director 1] to [Lexon Director 1] entitled '*FW: Emailing: 20140808172223*' 8 August 2014 (URN: PRO-E000426) attaching PDF document entitled '*20140808172223.pdf*' (URN: PRO-E000427).

[1015] Interview [Lexon Director 1], 10 September 2018, Part 1, CD 3, page 7, line 24 to page 8, line 9 (URN: PRO-C3188).

[1016] Advanz RLF, 22 April 2021 paragraph 4.81 (URN: PRO-C7112), citing Interview [Lexon Director 1], 10 September 2018, Part 1, CD 3, page 7, line 24 to 25 (URN: PRO-C3188).

CMA finds that simply mentioning the product to Focus is not tantamount to appointing Focus as Lexon's distributor or agreeing terms (let alone a term as unusual and specific as the profit share payable irrespective of source). Any ambiguity as regards [Lexon Director 1]'s interview comments is, in any event, removed by his subsequent evidence in this respect in his written comments, where he stated that '*it is not correct that Lexon agreed to supply Focus exclusively in 2012*' and that although informal discussions were held about the possibility of an arrangement from October 2012,[1017] the terms of the Focus-Lexon Heads of Terms were agreed in '*June/July 2013 on the basis that the agreement would take effect from 01 August 2013*'.[1018] The CMA considers it appropriate to place some weight on [Lexon Director 1]'s evidence in this respect given that it accords with the contemporaneous documentary evidence as to the timing of the negotiation of the Focus-Lexon Heads of Terms and the CMA sees no reason why [Lexon Director 1] might wish to provide misleading evidence to this effect as regards the timing of the agreement with Focus.

5.342.4 Fourth, it is not consistent with the submission of Alliance[1019] or the witness evidence of [Alliance Employee 1],[1020] who each stated that Lexon and Alliance were in discussions concerning the possibility of a supply agreement between the two undertakings during the first six months of 2013, which would have been futile had Lexon already agreed in 2012 exclusively to supply to Focus the Prochlorperazine POM it was jointly developed with Medreich. Whilst Advanz stated in its representations that there was nothing that precluded Lexon from exploring the possibility of a collaboration in place or in addition to its existing commitments vis-à-vis Focus,[1021] any such additional relationship would not have been possible if Lexon had agreed by that point to appoint Focus exclusively as its (only) distributor.

5.343 On the basis of the evidence set out above, the CMA rejects [Focus Director 1]'s statement that an agreement was reached with [Lexon Director 1] that Focus would distribute Lexon/Medreich's Prochlorperazine POM tablets as early as July to December 2012. Based on [Focus Director 1]'s email of 22 June 2013[1022] (see paragraph 5.195), the CMA concludes that Focus and Lexon reached at least a provisional agreement on the profit share arrangement – that is, the profit share percentage payable to Lexon irrespective of the source of product on which profits

[1017] [Lexon Director 1]'s written evidence is in line with that of [Focus Director 2] who stated that discussions about profit share and products in 2012 were of the nature of a general discussion (Interview [Focus Director 2], 8 January 2020, pages 24-25 (URN: PRO-C5887)).

[1018] Lexon RLF, 21 April 2021, paragraph 24 (URN: PRO-C7104).

[1019] Alliance Submission 9 May 2018, paragraph 2.2b (URN: PRO-C1834).

[1020] Interview [Alliance Employee 1], 4 October 2018, part 1, page 28, line 3 to 4 (URN: PRO-C2909).

[1021] Advanz RLF, 22 April 2021, paragraph 4.82 (URN: PRO-C7112).

[1022] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' dated 22 June 2013 (URN: PRO-E001476).

were derived – and the restriction on Lexon supplying its Prochlorperazine POM in June 2013. Although the precise date on which the agreement was entered into is not recorded within the documentary evidence, the Focus-Lexon Heads of Terms was entered into by no later than 1 August 2013.

5.344 The CMA therefore finds that [Focus Director 1]'s comment that the profit share clause was not included in the Focus-Lexon Heads of Terms with reference to the supply of product from Alliance cannot be sustained. In June 2013, Focus had no Prochlorperazine POM development in progress itself[1023] and it would have been public knowledge based on licence databases at the time that the only possible source of Prochlorperazine POM was Alliance. It is therefore difficult to understand how the profit share clause can have been included in the Focus-Lexon Heads of Terms other than with reference to the Alliance product.

Advanz's further representations on Focus' motivations for agreeing the clause: the computation was not important to Focus

5.345 In addition to the reasons cited by [Focus Director 1] in interview, Advanz also provided additional commentary[1024] on Focus' willingness to agree and honour the profit share clause, submitting that '*Focus intended that it would be a relatively short-term distributor of Alliance's product and so the computation in the [Focus-Lexon Heads of Terms] was not important to Focus in the context of it securing the long-term supply of cheaper product from Lexon that Focus intended to distribute instead*'.[1025] The CMA finds that this is not a credible explanation for Focus' agreement to pay the majority of its profits from Focus' sales of the Alliance product to Lexon.

5.345.1 First, as explained above (see paragraphs 5.325 to 5.329) the CMA does not accept [Focus Director 1]'s evidence that he expected the arrangement with Alliance to be short lived. This evidence is at odds with Focus' decision to accept a five year agreement exclusively to supply the Alliance product in circumstances where Focus would have had no certainty as to when the Lexon product would be made available (such as to calculate the level of the payments it would be making to Lexon in the meantime).

[1023] [Focus Director 1] stated in interview that Focus had looked at developing the product but decided against it (Interview [Focus Director 1], 2 October 2018, page 46, lines 4 to 7 and page 50, lines 20 to 23 (URN: PRO-C3294)).

[1024] Advanz further submitted that Focus agreed to the profit share clause because it would afford Focus the opportunity to be first in the market with generic Prochlorperazine POM and then to move the price up which would afford Focus an opportunity to maximise on the profits that it calculated it could make once it started distributing Lexon's cheaper Prochlorperazine POM instead (Advanz RSO, 1 August 2019 paragraph 3.218 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraph 4.179 (URN: PRO-C7112)). However, the CMA finds that this is not an explanation of the profit share clause *itself*: Focus' objective to enter the market selling a de-branded Prochlorperazine POM was achieved through Focus securing an agreement with Alliance, not through Focus agreeing to make payments of profits to Lexon. Advanz's submission about the Lexon product being cheaper has been considered and rejected in paragraphs 5.314 to 5.324 above.

[1025] Advanz RSO, 1 August 2019 paragraphs 3.208 and 6.16 (URN: PRO-C5111).

5.345.2 Second, given Advanz's submission that Focus was motivated by gaining access to a supply of cheaper product from Lexon,[1026] it would have been self-defeating for Focus to have effectively disregarded in its 'computation' any profit share that had to be sacrificed to Lexon in the meantime.

Focus entered into conflicting agreements, where it was the sole supplier of the Lexon product, yet was prohibited from supplying it

5.346 Focus' willingness to sign up to incompatible exclusivity provisions under the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms provides further support for the Market Exclusion Agreement between Alliance and Lexon.

5.347 The Alliance-Focus Agreement included a contractual prohibition on Focus supplying Prochlorperazine POM from any source other than Alliance (i.e. including the product jointly developed by Lexon and Medreich). Clauses 4(3) and 6(1) of the Alliance-Focus Agreement (as amended by the Addendum on 22 August 2013) required Focus to source *'Prochlorperazine maleate 3mg buccal tablets in packs of 50's' 'exclusively from [Alliance]'* and prevented Focus without the prior written consent of Alliance from *'sell[ing] or market[ing] in the United Kingdom any products having the same active ingredient'*.[1027] This meant that Focus was contractually prohibited from supplying the Prochlorperazine POM jointly developed by Lexon and Medreich.

5.348 However, at broadly the same time, Focus entered into the Focus-Lexon Heads of Terms, that gave it exclusive rights to the Lexon/Medreich product which, under the terms of the Alliance-Focus agreement, it had committed not to purchase and/or then sell or market. Specifically, the Focus-Lexon Heads of Terms provided that Focus would be granted *'exclusive distribution rights to the product'*.[1028]

5.349 Focus' willingness to enter into these conflicting agreements is supportive of the Market Exclusion Agreement, as this provided for the supply of commercial volumes of only the Alliance product, while compensating Lexon for its agreement

[1026] The CMA's finding as regards whether the Lexon product (if supplied) would have been cheaper than the Alliance product are set out in paragraphs 5.314 to 5.324 above.

[1027] Clause 6(1) of the Alliance-Focus Agreement required Focus to '*obtain its requirements for supplies of [Prochlorperazine POM] for the United Kingdom exclusively from [Alliance]*…'. That clause did not contemplate Focus being permitted to source Prochlorperazine POM from another source if it first obtained the written consent of Alliance (Section 26 response of Alliance, part two, dated 16 November 2017, to CMA Notice dated 2 October 2017, Appendix 2, Alliance-Focus Agreement (URN: PRO-C0369)).

[1028] See the Focus-Lexon Heads of Terms as sent by [Lexon Director 1] to [Focus Director 1] on 8 August 2014 (Document entitled *'Heads of Agreement'* signed 1 August 2013 (URN: PRO-E000429)). Although a further provision in the Focus-Lexon Heads of Terms stated that '*Exclusivity only applies if the target Forecast volumes are achieved per annum by product. – To be agreed between FP and Lexon*', the CMA has seen no evidence that any target forecast volumes were agreed but Lexon regarded the Focus-Lexon Heads of Terms as precluding Lexon from selling to other distributors (see [Lexon Director 1] Witness Statement of 31 July 2019 (URN: PRO-C5092) paragraphs 27-28). It has not been suggested by [Lexon Director 1] or other witnesses that Lexon had the contractual ability, and/or otherwise intended, to supply product other than through Focus.

not to enter the market with its product. This conduct cannot credibly be explained using the alternative reasoning advanced by those involved.

[Focus Director 1]'s claim that under the Alliance-Focus Agreement Focus was not in fact required to purchase only from Alliance

5.350 During an interview with the CMA, [Focus Director 1] claimed that there was, in practice, no requirement upon Focus to purchase exclusively from Alliance. [Focus Director 1] pointed to the fact that clause 4(3) of the Alliance-Focus Agreement provided that such sales of competing products could not be made '*without the prior written consent*', and that Focus would have been able to seek Alliance's consent for such sales.[1029]

5.351 The CMA rejects [Focus Director 1]'s view. This is because:

5.351.1 Clause 6(1) of the Alliance-Focus Agreement, which required Focus to *'obtain its requirements for supplies of the Products for the United Kingdom exclusively from [Alliance]*', although being subject to other provisions of the agreement, was not (unlike other clauses in the agreement) drafted as itself being subject to a consent provision – meaning that Focus could have had no reasonable expectation that Alliance would have been willing to permit Focus to purchase (and then distribute) a competing product alongside Alliance's own product;

5.351.2 in any event, the CMA does not consider that Alliance would have had any commercial incentive to consent to a request by Focus to be permitted to supply a rival product, given that this would necessarily have resulted in decreased sales on the part of Alliance (which had agreed exclusively to supply Focus pursuant to clause 2 of the Alliance-Focus Agreement). In fact, the CMA has seen no evidence suggesting that Focus sought Alliance's consent,[1030] nor was such consent given at any time during the Alliance-Focus Agreement; and

5.351.3 the notion that Focus understood that it would not have been able to supply Prochlorperazine POM sourced from Alliance alongside Prochlorperazine POM from other sources is consistent with AMCo's internal deliberations in 2015 at the time of its purchase of Primegen when it modelled that launching its own Primegen Prochlorperazine POM would

[1029] Interview [Focus Director 1], 2 October 2018, page 141, line 6 to page 142, line 2 and page 146, lines 10-14 (URN: PRO-C3294).

[1030] [Focus Director 1] stated that he did not ever recall discussing with Alliance the possibility of supplying another product (Interview [Focus Director 1], 2 October 2018, page 142, line 25 to page 143, line 2 (URN: PRO-C3294)).

lead to it competing against both Lexon and Alliance's Prochlorperazine POM (see paragraph 5.497 below).[1031]

5.352 Advanz also made representations on whether there was a binding non-compete obligation on Focus in the Alliance-Focus Agreement: the CMA considers these in Annex C:.

[Focus Director 1]'s evidence on Focus' rationale for entry into the two agreements

5.353 In his witness interview and subsequent statement to the CMA, [Focus Director 1] submitted that Focus' rationale for entering into the two agreements was as follows:

5.353.1 Having initially supplied the Alliance Prochlorperazine POM product and raised its price, within six months to a year Focus could switch to the cheaper Lexon product which would cost less than one pound.[1032] Having agreed supply arrangements with both Alliance and Lexon, [Focus Director 1] submitted that he would have decreased his forecast product orders from Alliance, and sought to 'play off' the two suppliers to secure improved terms.[1033]

5.353.2 Entry into a second agreement (that is, with Lexon) protected Focus in the event that Alliance decided no longer to use Focus.[1034]

5.354 The CMA finds that [Focus Director 1]'s explanation for Focus' entry into the two agreements in July and August 2013 cannot be sustained.[1035]

5.354.1 First, the CMA finds that Focus' non-compete obligation in the Alliance-Focus Agreement (see paragraph 5.347 above) undermines [Focus Director 1]'s stated explanation that the arrangement would allow him to increase prices to wholesalers and then switch to a lower cost product produced by Lexon.[1036] Sales by Focus of the Lexon/Medreich Prochlorperazine POM product would be a clear breach of the non-

[1031] See Email [AMCo Employee 4] to various colleagues at AMCo entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) attaching Project CAPITAL BD Workstream 30 June 2015, slides 15-17 (URN: PRO-E001636).

[1032] Interview [Focus Director 1], 2 October 2018, page 47, lines 10 to 17; page 73, line 10; page 208, lines 10 to 12 and page 274, lines 8 to 10 (URN: PRO-C3294).

[1033] Interview [Focus Director 1], 2 October 2018, page 48, lines 16 to 20 and page 72, lines 20 to 25 (URN: PRO-C3294). [Focus Director 1] statement to the CMA, dated 13 January 2019 (URN: PRO-C3290). Advanz described his approach as *'strictly commercial and opportunistic'* (Advanz RSO, paragraph 3.98 (URN: PRO-C5111)).

[1034] Interview [Focus Director 1], 2 October 2018, page 59, lines 4 to 7 (URN: PRO-C3294).

[1035] For these reasons, the CMA rejects Cinven's submission that the evidence on the case file shows that Focus '*decided to hedge its bets and enter into separate bilateral distribution agreements with each supplier*' (Cinven RSO, paragraph 4.36 (URN: PRO-C5132)).

[1036] For the same reason, the CMA rejects Advanz's submission that the arrangement would allow Focus to get a foothold on the market, to establish contacts, and to be recognised in the market as the trusted distributor of Prochlorperazine POM, whilst also getting an additional revenue stream at a time when it was looking for a buyer of its business (Advanz RSO, paragraph 3.189 (URN: PRO-C5111)): even if these factors could explain Focus' interest in distributing Prochlorperazine POM, they would not explain Focus' entry into conflicting agreements.

compete obligation on Focus,[1037] and would render Focus liable to the consequences of contractual breach from Alliance.[1038]

5.354.2 Second, as explained above (see paragraphs 5.325 to 5.329) the CMA does not accept [Focus Director 1]'s evidence that he expected the arrangement with Alliance to be short lived.

5.354.3 Third, for the reasons set out in paragraphs 5.314 to 5.324, because of Focus' intended price increase of the Prochlorperazine POM product, the CMA rejects [Focus Director 1]'s stated commercial assumption that, at the time of entry into the two agreements, Focus would have considered that the Lexon Prochlorperazine POM product would – in equivalent supply price terms, and even putting to one side any potential for price renegotiation with Alliance – be cheaper than that sourced from Alliance.

5.354.4 Fourth, the CMA rejects [Focus Director 1]'s purported concern about having access to a lower cost of goods because competing generics[1039] were coming.[1040] In early 2013, there was only one MA holder, the incumbent supplier, Alliance. The CMA has seen no evidence to substantiate [Focus Director 1]'s claim that '*NRIM and … Morningside who were … talking to the market about … launching that product within a year*'.[1041] The Primegen licence was not granted until February 2016 and Morningside did not obtain a licence until 2017. Further, Focus' expectations of future pricing increases in mid-2013[1042] and its forecasting in April 2014 (assuming that it would continue to supply 100% of market demand through into mid-2015)[1043] are not consistent with other generic entrants entering within a year of the conclusion of the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms in mid-2013.

[1037] [Focus Director 1] stated in interview that he considered Alliance would have been 'pragmatic' in the event that Focus wished to breach the non-compete obligation, a point raised by Cinven in its representations (Cinven RSO, paragraph 4.97 (URN: PRO-C5132) citing Interview [Focus Director 1], 2 October 2018, pages 139ff (URN: PRO-C3294)); however, [Focus Director 1] was not able satisfactorily to explain why he considered Alliance would accept such a position, not least given that Alliance and Focus had not varied the exclusivity obligation on Focus or the five year term when adding Prochlorperazine POM to the contract (see Interview [Focus Director 1], page 146 (URN: PRO-C3294)). For this reason, the CMA rejects Advanz's submission that it was entirely rational for Focus to obtain a revenue stream from the supply of an available product (from Alliance), and at the same time to protect its position by securing a distribution agreement with the prospective supplier of the same product (Lexon/Medreich), whose product it anticipated would be materially cheaper (Advanz RSO, paragraph 3.199 (URN: PRO-C5111)): this submission ignores any likely reaction of Alliance (and, in any event, does not take account of the fact that from Focus' own perspective the Lexon product would not be materially cheaper given Focus' intended price rises: see paragraphs 5.314 to 5.324 above).

[1038] The CMA rejects Cinven's submission that it is '*implausible to suggest that Focus would not be willing to accept an exclusivity clause that it may subsequently breach (thereby accepting the potential risk of litigation) but it would be willing to take part in a multilateral infringement of competition law*' (Cinven RSO, paragraph 4.61 and paragraph 4.96 (URN: PRO-C5132)): the breach of the exclusivity clause would become apparent to Alliance when Focus sold Lexon product.

[1039] Interview [Focus Director 1], 2 October 2018, page 274, lines 8 to 10 (URN: PRO-C3294).

[1040] Cinven RSO, 15 August 2019, paragraph 4.98 (URN: PRO-C5132).

[1041] Interview [Focus Director 1], 2 October 2018, page 48, lines 11 to 14 (URN: PRO-C3294).

[1042] Email [Focus Director 1] to [Focus Director 2] entitled *'Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

[1043] *Focus Prochlorperazine Forecast – 04 04 14* 4 April 2014 (URN: PRO-E001117).

5.355 The CMA considers that, contrary to Advanz's submission,[1044] the fact that Alliance and Focus had discussed the potential appointment of Focus as the distributor of de-branded Buccastem in 2011 is irrelevant in this respect (see paragraph 3.68). The documentary evidence is clear that further discussions between Alliance and Focus in respect of Buccastem/Prochlorperazine POM were initiated in 2013 only after Alliance and Lexon had been in discussion.

Conclusion regarding the Focus-Lexon value transfer

5.356 Having considered the evidence described above, including the Parties' representations, the CMA finds that:

5.356.1 the Focus-Lexon Heads of Terms provided for a significant payment (that is, value transfer) from Focus to Lexon; and

5.356.2 the purpose of that payment (that is, value transfer) was for Focus to compensate Lexon for its agreement not to enter the market.

Subsequent conduct of the Parties provides evidence of the Market Exclusion Agreement

5.357 Evidence from the period after the Market Exclusion Agreement was entered into, including documentary evidence and the conduct of the Parties, provides further evidence of the fact that there was a common understanding reached between Alliance and Lexon that, in return for the indirect value transfer (via Focus), Lexon agreed not to enter with the Prochlorperazine POM that it had jointly developed with Medreich. The CMA sets out the evidence below in respect of each of Alliance, Lexon, Focus and Medreich.

Subsequent conduct - Alliance

Introduction and section summary

5.358 The CMA sets out in this section documentary evidence and conduct of Alliance subsequent to the conclusion of the Implementing Agreements that provides further evidence of the existence of the Market Exclusion Agreement, including:

5.358.1 Alliance's decision to de-brand Buccastem despite also agreeing to supply Focus at a fixed price and therefore deny itself the potential to profit from the price increases that de-branding facilitated;

[1044] Advanz RSO paragraph 3.197 (URN: PRO-C5111).

5.358.2 Alliance Forecasts, which record Alliance's expectation that its forecasted sales would not be affected by entry on the part of Lexon; and

5.358.3 other aspects of Alliance's documentary evidence.

Alliance's decision to de-brand Buccastem is further evidence of the existence of the Market Exclusion Agreement

5.359 For the reasons set out in detail in this section, the CMA finds that Alliance's decision to de-brand Buccastem POM, while at the same time accept a fixed price of £5.65 on its sales of Prochlorperazine POM to Focus, is explained on the basis that it would enable Focus to compensate Lexon for not entering the market. The CMA finds that, absent the benefits of preventing Lexon's market entry, such conduct would not have made commercial sense, and the CMA rejects Alliance's submissions that it was done to allow Alliance to enable it to compete more effectively with Lexon.

5.360 The main benefit of de-branding a pharmaceutical product is that it will no longer be subject to the price and profit controls of the PPRS. Where products have been de-branded they can then be (and have been in this case) the subject of significant price increases. However, in this case, Alliance's decision to de-brand Buccastem POM coincided with its decision to supply Focus at a fixed price of £5.65, which was in line with the price that it charged for the branded product while it remained subject to the PPRS. Alliance, therefore, denied itself the potential to inflate the price above its prevailing level, or to benefit from Focus' inflation of the price, and in doing so denied itself this key benefit of de-branding its product.

5.361 De-branding Buccastem POM did, though, involve a number of significant disadvantages to Alliance:

5.361.1 As of May 2013, Alliance considered that around 40% of prescriptions specified that *'Buccastem'* should be prescribed, while the remaining 60% referred to generic prochlorperazine.[1045] The significance of this is that, when a pharmacy receives a 'closed' prescription for branded Buccastem, it can only dispense Buccastem against it. In contrast, a pharmacy that receives an 'open' prescription for generic prochlorperazine may choose to dispense any of the relevant suppliers' product against that prescription and will often seek the best value option available (whether branded or generic). The implication of this is that, on de-branding Buccastem, Alliance was denying itself the benefit of the 'closed' prescriptions, in relation to which it had guaranteed sales that could not be contested by a new entrant on to the market, including Lexon. This issue was indeed

[1045] Meeting minutes entitled *'UK Review & Planning Meeting – Alliance Pharmaceuticals'* 16 May 2013 09:00 – 12:00 (URN: PRO-E000999).

recognised by employees of Alliance at the time it was considering de-branding Buccastem.[1046] In one such document, the notes of an Alliance Review & Planning Meeting on 16 May 2013, it was observed that the branded prescription rate was so high that the withdrawal of the Buccastem brand could not be contemplated: *'Progress launch of own generic prochlorperazine and put into Category A. still [sic] 40% branded prescriptions so could not discontinue Buccastem'*.[1047]

5.361.2 De-branding was considered likely to result in a decline in prescriptions for Prochlorperazine POM overall, as clinicians used to prescribing Buccastem may switch to other treatments as a consequence of the confusion caused by withdrawing the brand and because its price could be increased. In an email dated 6 August 2013 from [Alliance Employee 3] to [Alliance Director 3] and [Alliance employee], Alliance forecasted that its monthly product volumes would see a reduction of 24% as a consequence of these factors: *'Forecast figures are based on current usage and also a moderate decline as you withdraw a brand and, as a consequence, there is confusion in the market. Also if the price increases then the volumes will decline as alternatives are sought by prescribers'*.[1048]

5.362 Accordingly, on de-branding, Alliance pursued conduct that was expected to result in a decline in the size of the Prochlorperazine POM market overall and a decline in the market share that could be protected through closed prescriptions. At the same time, Alliance denied itself the potential to realise the benefit of the price rises and revenue gains that would ordinarily justify such conduct. Alliance's decision to de-brand its product can be explained only on the basis that it enabled Focus to increase its price and compensate Lexon for its agreement not to enter the market, with the benefit of protecting Alliance from that competitive threat.

The claims of [Alliance Director 2] and [Alliance Employee 1] regarding Alliance's rationale for de-branding Buccastem

5.363 [Alliance Director 2] has observed that, after Alliance had de-branded Buccastem, Focus was expected to increase the price of generic Prochlorperazine POM prior to Lexon's anticipated market entry.[1049] Although [Alliance Director 2] did not

[1046] Email [Alliance Employee 2] to [Alliance employee] copying [Alliance Employee 1] entitled *'Generic Prochlorperazine'* 21 May 2013 (URN: PRO-E001002). [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 2.11(c) (URN: PRO-C5098): Email [Alliance Director 1] to [Alliance Employee 2] entitled *'RE: Buccastem/Prochlorperazine generic threat'* 25 March 2013 (URN: PRO-E000990). Meeting minutes entitled *'UK Review & Planning Meeting – Alliance Pharmaceuticals'* 16 May 2013 09:00 – 12:00 (URN: PRO-E000999).

[1047] Meeting minutes entitled *'UK Review & Planning Meeting – Alliance Pharmaceuticals'* 16 May 2013 09:00 – 12:00 (URN: PRO-E000999). Similarly, in its representations, Alliance observed that *'this particular product had particular brand value with an exceptionally high percentage of branded prescriptions (40%).*' See Alliance RSO, 1 August 2019, paragraph 3.14 (URN: PRO-C5096).

[1048] Email [Alliance Employee 3] to [Alliance Director 3] and [Alliance employee] entitled *'FW: sales units forecast review – UK'* 6 August 2013 (URN: PRO-E001030).

[1049] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 4.6(b) (URN: PRO-C5098).

suggest that this is what motivated the decision to de-brand,[1050] Alliance has submitted that, although Alliance did not benefit by increasing its price directly, it would benefit from de-branding insofar as competition to its product would start from a price level that could have been inflated by Focus, such that pressure on its own selling price to Focus could be delayed.[1051]

5.364 It is, however, evident from Alliance's own documents that this was not the basis upon which Alliance chose to de-brand Buccastem POM. Alliance's forecasts (see paragraphs 5.379 to 5.405) demonstrate that, having entered into the arrangements described above, it did not expect a window of no competition to be followed by Lexon's market entry, such that de-branding could be used to delay pressure on the Alliance selling price to Focus. In reality, Alliance's forecasts assumed that Lexon would not enter the market and that the entry threat that had concerned it previously was no longer a pressing issue.[1052]

5.365 Consistent with the CMA's analysis that this factor did not motivate Alliance's decision to de-brand, the CMA's investigation has not identified any documents in which Alliance sought to quantify this supposed benefit, or to compare it with the significant disadvantages of de-branding.

5.366 In his first witness statement, [Alliance Director 2] outlined some of the disadvantages and concerns of the decision to de-brand in the following terms:

5.366.1 Buccastem has strong brand recognition and this *'could be expected to lead a high proportion of physicians to continue to prescribe the branded product, even if there was generic competition'*.[1053] He explained that the brand recognition for Buccastem would *'suggest to a generic company that branded prescriptions might decline slowly (i.e., more than would be expected for other products susceptible to debranding) and thereby potentially discourage them from launching'*.[1054] [Alliance Director 2] stated

[1050] [Alliance Director 2] Witness Statement of 31 July 2019, paragraphs 3.1 to 3.14 (URN: PRO-C5098).

[1051] Alliance RSO, 1 August 2019, paragraph 3.21 (URN: PRO-C5096).

[1052] Further, even on the basis of Alliance's claim that its forecasts assumed that Lexon would enter at the start of 2014 (which are not accepted – see paragraphs 5.390 to 5.396 below; Alliance RLF, 29 April 2021, paragraphs 4.7 to 4.10 (URN: PRO-C7118)), the very limited window that Focus would have had to raise prices prior to Lexon's entry in such circumstances could not reasonably have been expected to offset the significant and known disadvantages of de-branding. On the basis of Alliance's claims regarding its forecasts, Lexon's entry would have occurred very quickly, such that the period in which Focus's price was unconstrained would have been either non-existent or at most limited to a month or two: in practice, the price of the product was not increased by Focus until February 2014, and after the date on which Alliance submits that it was forecasting entry to take *place* (Alliance observes that *'Focus raised the outsell price of Prochlorperazine POM twice, from £6.49 to £9.98 in February 2014 and £11.98 in May 2014.'* See Alliance RSO, 1 August 2019, paragraph 3.23C (URN: PRO-C5096)).

Moreover, absent any influence on Focus' price, Alliance would have had no insight into whether any such price would have been implemented prior to the date on which Alliance claims to have forecasted Lexon's entry. This opportunity for a possible but short-lived increased in price would have to be weighed against the significant expected costs of de-branding, including (i) a significant 24% decline in the size of the market, as prescribers switched away from the product (see paragraph 5.361 above); and (ii) the complete loss of Alliance's assured base of closed prescription sales which, at the relevant time, was extremely significant and in relation to which Alliance would not have faced generic competition (see paragraph 5.361).

[1053] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 2.11(c) (URN: PRO-C5098).

[1054] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 2.11(c) (URN: PRO-C5098).

that he would have been 'cautious' therefore about de-branding Buccastem.[1055]

5.366.2 De-branding was at odds with Alliance's strategic priorities,[1056] and he and [Alliance Director 1] would have needed to be convinced that it was the right option.[1057]

5.366.3 De-branding is a complex multi-stage process that is likely to involve stock write-offs, packaging changes, interfacing with the contract manufacturer and regulatory matters.[1058]

5.367 Although [Alliance Director 2] articulated a series of concerns with de-branding, and said that he would have been reluctant to de-brand any product, he stated that he had eventually concluded that *'debranding was the only feasible way to retain any value from this product'*, and that it was the *'lesser evil'* when compared to selling the brand in competition with generics or discontinuing the product.[1059] [Alliance Director 2] did not, however, provide any explanation as to the basis on which he submitted that de-branding was *'the only feasible way to retain any value'* or why it was the *'lesser evil'* notwithstanding his views of the many costs and downsides it involves. [Alliance Director 2]'s statement does not therefore provide any support for the notion that, absent the Market Exclusion Agreement, de-branding Prochlorperazine POM was a beneficial strategy for Alliance in terms of taking unilateral action to respond to a competitive threat from Lexon.

5.368 At Alliance's oral hearing, [Alliance Director 2] was asked for further insight into how de-branding was expected to benefit Alliance. He sought to justify the de-branding by suggesting that branded prescriptions were not, in fact, protected from generic competition, such that de-branding did not involve giving up an assured base of sales in the manner described at paragraph 5.361 above.[1060]

5.369 [Alliance Director 2]'s remarks regarding the potential of pharmacies to dispense generic product on receipt of branded prescriptions were not accurate. As explained above, and as had been previously accepted by [Alliance Director 2]

[1055] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 2.12 (URN: PRO-C5098).

[1056] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 3.11 (URN: PRO-C5098).

[1057] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 3.12 (URN: PRO-C5098).

[1058] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 3.13 (URN: PRO-C5098).

[1059] [Alliance Director 2] Witness Statement of 31 July 2019,paragraph 3.6 (URN: PRO-C5098).

[1060] Alliance Oral Hearing, 8 October 2019, page 58, lines 14 to 16 (URN: PRO-C5605). Contrary to what [Alliance Director 2] said at the time, Alliance subsequently submitted that [Alliance Director 2] was referring to circumstances in which a branded product was available, and its 'belief' that pharmacies 'may' consider it permissible to dispense an equivalent generic product where a branded product was specified but was not available to the clinician. See Alliance clarifications following the oral hearing dated 8 October 2019, response to question 2 (URN: PRO-C5594). The CMA considers it apparent from the transcript that [Alliance Director 2]'s submission was that pharmacies could generally dispense generic products on receipt of a closed prescription.

during an interview with the CMA,[1061] pharmacies would have been obliged to dispense available branded Buccastem on receipt of a prescription specifying Buccastem. Such sales could not therefore have been contested by a new entrant.

5.370 At the oral hearing [Alliance Director 2] also suggested that de-branding and supplying a generic product would have improved Alliance's ability to compete over time,[1062] and Alliance made the submission that this is because prescribers and dispensers are encouraged to prescribe/dispense generic products.[1063] [Alliance Director 1] made the related point that where a branded product faces generic competition, retail pharmacies prefer to dispense generics as patients prefer to always receive a generic pack rather than to receive branded pack with one prescription and a generic pack with another.[1064]

5.371 These points are unpersuasive. There is no reason to suppose that generic prochlorperazine would, other things being equal, be better able than the branded product to compete with new entrants. Branded or generic products can be dispensed on receipt of an 'open' prescription and pharmacies are motivated to purchase the best value product available (see 3.37). While it is the case that clinicians are encouraged to prescribe using the generic name so as to provide pharmacies with the option of dispensing available branded or generic packs,[1065] the CMA is aware of no guidance from DHSC that encourages pharmacies to dispense a generic product in circumstances where a branded product is available that they consider to represent a better value proposition. Contrary to Alliance's submissions, there is therefore no reason to assume that pharmacies will favour a generic product in such circumstances. Further, any reluctance on the part of pharmacies or patients to switch patients between branded and generic pack would, in these circumstances, plainly mitigate in favour of Alliance retaining its brand, as it would suggest that they would be reluctant to have to switch to the new generic pack following launch, having previously received only Buccastem. The reality is in fact that pharmacies often pay a premium for branded pack, because for some proportion of their demand they have no choice but to dispense branded product (see paragraph 5.361 above) and because some patients express a

[1061] Interview [Alliance Director 2], 5 October 2018, page 38, lines 6 to 8 (URN: PRO-C2941). [Alliance Director 2] observed that '*You are going to get GPs writing Buccastem'* and *'[w]hen I go to the pharmacy, that [prescription] has to be filled with Buccastem'*.

[1062] Alliance Oral Hearing, 8 October 2019, page 58, lines 3 to 6 (URN: PRO-C5605).

[1063] Section 26 response of Alliance dated 12 December 2019, to CMA notice of 26 November 2019, response to question 6 (URN: PRO-C5491).

[1064] Interview [Alliance Director 1], 8 October 2018, page 18, lines 11 to 20 (URN: PRO-C2944).

[1065] See paragraphs 2.6 to 2.8 of the consultation on Community pharmacy drug reimbursement reforms (see https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/819801/community-pharmacy-reimbursement-consultation-document.pdf).

preference for product that they have grown familiar with during the period in which it did not face generic entry.[1066]

5.372 Even where an originator supplier does consider that it may benefit from supplying a generic product, it can achieve this by offering both branded and generic products alongside one another and does not need to sacrifice the significant benefits of retaining its brand. This is a strategy that has been used by some firms to enable them to offer low priced generic product to compete with new entrants, while at the time maintaining a higher price for the brand.[1067] Alliance itself maintained branded Deltacortril and supplied an equivalent generic product for five years,[1068] before again withdrawing the generic product.[1069] It was, in May 2013, also an option that was contemplated within Alliance in relation to Prochlorperazine.[1070]

Alliance's representations regarding its rationale for de-branding Buccastem

5.373 Alliance submits that it *'is clear from the contemporaneous documents'* that *'Alliance recognised there would be both potential advantages and drawbacks to the decision to debrand and, having weighed up those considerations, formed the view that the lesser evil would be to debrand and distribute Prochlorperazine POM via Focus'.*[1071]

5.374 In making this submission, Alliance did not refer to any contemporaneous documents that refer to the advantages of its decision to de-brand Prochlorperazine POM, or that weighed up the perceived advantages and disadvantages. As set out above, the CMA has been able to identify within Alliance's contemporaneous evidence documents that refer only to the significant disadvantages of de-branding. The only advantage of de-branding that is referred to in Alliance documents more generally is the potential to increase its selling price (see, for example, paragraph 3.76), but for the reasons outlined above that advantage was not relevant given the adoption of the fixed supply price to Focus.

[1066] See, for example, figure 3.1 (page 172) of the CMA's decision in *Paroxetine* (CE-9531/11), which records that following the period of GSK's infringing agreements, and the onset of true generic entry, GSK retained Seroxat and was able to sustain a price that was significantly in excess of the prevailing generic price. In the Commission's Decision in *Lundbeck*, following generic entry branded prices were far in excess of the average generic selling prices following true generic entry (see Commission decision of 19 June 2013 in Case 39226 *Lundbeck,* paragraphs 212 and 213). Alliance has itself also acknowledged that generic products are typically cheaper than the relevant brand, see Section 26 response of Alliance dated 12 December 2019, to CMA notice of 26 November 2019, response to question 6 (URN: PRO-C5491).

[1067] This option was followed by Lundbeck following generic entry in the supply of citalopram: Commission decision of 19 June 2013 in Case 39226 *Lundbeck*, paragraph 213.

[1068] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 2.5 (URN: PRO-C5098).

[1069] Alliance submits that it is inappropriate to refer to Deltacortril as evidence that Alliance could have supplied branded Buccastem POM alongside the generic Prochlorperazine POM. Alliance submits that doing so would have conflicted with its appointment of Focus as the exclusive distributor of its product (Alliance RLF, 29 April 2021, paragraph 3.10 (URN: PRO-C7118)). This is incorrect, as all such product (including branded product) could have been supplied exclusively to Focus (Alliance has itself referred to a branded product that it supplies through a distributor – see paragraph 5.283).

[1070] Alliance RSO, 1 August 2019, paragraph 3.15 (URN: PRO-C5096).

[1071] Alliance RLF, 29 April 2021, paragraph 1.7 (URN: PRO-C7118).

5.375 Alliance submits that the CMA is wrong to refer to the high branded prescription rate that was relevant to Buccastem POM immediately prior to its withdrawal, such that the CMA has overstated the disadvantages to Alliance regarding the loss of closed prescriptions for Buccastem that could not be contested by generic entrants. In this regard, Alliance submits that:

5.375.1 the branded prescribing rates were not as high as the figure referred to in Alliance documents at the time, citing NHS data for England and Wales only that suggests that the actual rate was in fact 32%.[1072] Alliance also refers to an email from [Alliance Employee 2][1073] that it says is evidence of [Alliance Employee 2] 'querying' the 40% branded prescribing rate.

5.375.2 It is more relevant to consider the branded prescription rate that would have evolved over time and, in this regard, it is relevant that: (i) after the withdrawal of Buccastem POM in December 2013 the branded prescription rate dropped to 18% in January 2014;[1074] and (ii) Alliance would have been conscious of the impact of IT tools such as Scriptswitch, which could be used to encourage clinicians to prescribe using the generic rather than branded name.[1075]

5.375.3 A 'simplistic' connection cannot be drawn between the branded prescribing rate and the decision to de-brand, as Alliance had taken the decision to retain its Atarax brand despite it having a lower branded prescribing rate of 10%. This decision reflected the benefit to Alliance of price modulating: adopting a lower price for branded Atarax and thereby permitting (under the terms of the PPRS) a higher price for other branded products.[1076]

5.376 In relation to Alliance's criticisms of the CMA's reference to the 40% branded prescribing rate, it is observed that:

5.376.1 The 40% figure was used by Alliance, at the time, to inform its decision as to whether or not to de-brand Buccastem POM (as shown by Alliance's contemporaneous documentation: see paragraph 5.361), and it is therefore of most relevance to an assessment of the motivations of Alliance's decision to de-brand Buccastem POM in 2013. As regards the email that Alliance refers to in which [Alliance Employee 2] seeks confirmation as to the accuracy of the 40% figure, it is apparent from [Alliance Employee 2]'s email that the figure has been determined by

[1072] Alliance RLF, 29 April 2021, paragraph 3.5.1 (URN: PRO-C7118).

[1073] Email [Alliance Employee 2] to [Alliance employee] entitled *'Generic Prochlorperazine'* 21 May 2013 (URN: PRO-E001002).

[1074] Alliance RLF, 29 April 2021, paragraph 3.5.2 (URN: PRO-C7118).

[1075] Alliance RLF, 29 April 2021, paragraph 3.5.3 (URN: PRO-C7118).

[1076] Alliance RLF, 29 April 2021, paragraph 3.5.4 (URN: PRO-C7118).

reference to available data, and there is no evidence of a response to that request, or of Alliance adopting a revised figure in any consideration of the pros and cons of de-branding. In any case, it is observed that the figure of 32% that Alliance now refers to is nevertheless also very high, and losing the protection afforded by so many closed prescriptions would constitute a significant disadvantage to de-branding in the face of new entry.

5.376.2 It is accepted that, if the branded prescribing rate was expected to fall, the result would be that the significant disadvantages of losing the brand may have been lessened over time. However, while it may have been the case that some erosion of the 'exceptionally high'[1077] branded prescribing rate was possible, this was not considered to be a relevant consideration in the contemporaneous documents that considered the point. Although Alliance claims that the impact of Scriptswitch would have been in the minds of Alliance at the time, there is no evidence of any such consideration (and indeed no evidence of any detailed assessment of what would occur had Alliance in fact still anticipated that Lexon entry may occur). In any event, [Alliance Director 2] has outlined his expectation that any decline in the prescription rate would be '*slow*' given recognition of the brand among clinicians.[1078] Further, in an email to [Alliance Employee 2] dated 25 March 2013 in which [Alliance Director 1] was assessing the threat of a generic version of Buccastem and replying to an observation by [Alliance Employee 2] regarding the current branded prescribing rate, [Alliance Director 1] commented that *'Given the uniqueness of the product and the complex generic prescription, such products often have a good survival of branded'*.[1079]

5.376.3 Alliance's reference to the actual branded prescribing rate observed after the brand was withdrawn is irrelevant, as the branded prescribing rate would inevitably drop far more under such circumstances as compared to a situation in which it remained available.

5.376.4 The CMA has not suggested that there is a simple and automatic relationship between the branded prescribing rate and a company's de-branding decision. The CMA's finding is that, in the circumstances of this case (involving de-branding at the same time as the adoption of fixed price terms that preserve the prior Alliance price point), Alliance's decision to de-brand is explained on the basis of the Market Exclusion Agreement. The Atarax example cited by Alliance, in which Alliance concluded that there were advantages to retaining the brand in the face of generic

[1077] Alliance itself observed that *'this particular product had particular brand value with an exceptionally high percentage of branded prescriptions (40%).*' See Alliance RSO, 1 August 2019, paragraph 3.14 (URN: PRO-C5096).

[1078] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 2.11(c) (URN: PRO-C5098).

[1079] Email [Alliance Director 1] to [Alliance Employee 2] entitled *'Buccastem/Prochlorperazine generic threat'* 25 March 2013 (URN: PRO-E000990).

competition, even in circumstances where the branded prescribing rate was much lower, serves only to reinforce this analysis.

5.377 Alliance has submitted the sales volatility it experienced when supplying a branded product (for example, Xenazine) in the face of generic entry 'would have' informed its decision to avoid the instability that would be likely to ensure if Alliance distributed its own product.[1080]

5.378 The CMA observes that de-branding a product in the face of generic entry is liable significantly to increase, rather than decrease, volatility. Most obviously, by de-branding Buccastem, Alliance (i) gave up the stability afforded to it by the very high branded prescribing rate that had existed; (ii) exposed itself to competition across all sales; and (iii) facilitated substantial increases in market price that were expected to cause a fall in market volumes (see paragraphs 5.361 above).

Alliance Forecasts are further evidence of the existence of the Market Exclusion Agreement

The sales forecasts for 2014 and 2015

5.379 Consistent with the June-July 2013 correspondence involving Alliance, Lexon and Focus, Alliance's forecasts foresaw no entry by Lexon in either 2014 or 2015. Alliance's sales forecasts are therefore further evidence of the existence of the Market Exclusion Agreement.

5.380 As set out in detail below, and in contrast to the frequently documented concerns in earlier evidence in Spring 2013 regarding Lexon's potential entry,[1081] Alliance's Prochlorperazine POM sales forecasts for 2014 and 2015 anticipated no loss of volumes to the Lexon product and are consistent therefore with Alliance no longer having been concerned that Lexon would enter the market within that period. Rather, they reveal that Alliance expected de-branding and Focus's price increases to cause a decline in the size of the market at the end of 2013, and that sales during 2014 and 2015 would otherwise remain constant and unaffected by the entry that Alliance had previously feared.

5.381 Alliance's 2013 forecasts record that, in 2011 and 2012, Alliance had supplied 310,868 and 315,643 packs of Buccastem, respectively.[1082] In June 2013, Alliance forecasted that it would supply 308,982 in 2013 and 315,858 packs in each of 2014 and 2015. As of August 2013, Alliance updated its forecasts to assume that it would supply 280,000 units in 2014 and 240,000 units in each of 2015 and 2016.

[1080] Alliance RLF, 29 April 2021, 3.6.3 (URN: PRO-C7118).

[1081] See paragraphs 3.73 to 3.84.

[1082] See Annex 1 to the CMA's Letter of Facts of 16 February 2021, which shows data representing Alliance's forecasts for the volume of Prochlorperazine POM it would supply, made on a monthly basis from January 2013 to November 2016, as collated by the CMA from forecasts obtained from Alliance and referencing the underlying forecast evidence (URN: PRO-C6692, URN: PRO-C6697, URN: PRO-C6702, URN: PRO-C6707 and URN: PRO-C6712).

Following the grant of the Medreich Prochlorperazine POM MA in January 2014, and the failure to supply a batch of product to Focus at the end of 2013 that was instead supplied in 2014,[1083] Alliance's forecasts from February 2014 onwards were that it would supply to Focus around 321,120 packs of Prochlorperazine POM in 2014, and 240,000 packs in 2015.

5.382 Although, as of February 2014 there was a forecasted fall in sales between 2014 and 2015, the evidence confirms that that forecasted fall in sales volumes was the consequence of an arrangement whereby Alliance would supply 80,000 packs in excess of Focus' requirements for onward sale in 2014, so that Focus could develop a stockholding of that amount (the 'stock build') and that that decrease in sales volumes from 2014 to 2015 did not therefore relate to the expected impact of generic competition from Lexon and Medreich.[1084] The implication of the stock build is that Alliance's forecast was that Focus' requirements for onward sale would be around 241,120 packs in 2014 (that is, Alliance's forecasted sales to Focus, less the 80,000 pack 'stock build'), and around 240,000 packs in 2015.[1085]

5.383 This means that, when the impact of the Focus stock build is excluded such that the forecasts relate solely to the sales that Alliance expected to be made to customers, Alliance's forecasts instead foresaw a decline in sales to the market between 2013 and 2014 of approximately 24% fewer packs (that is the difference between the June 2013 forecast of 315,858 packs for 2014 and the early 2014 forecast of 241,120 packs for 2014 (excluding the 80,000 stock-build)). The evidence demonstrates though that this decline was not based on a belief that

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[1083] See Annex 1 to the CMA's Letter of Facts of 16 February 2021, which shows data representing Alliance's forecasts for the volume of Prochlorperazine POM it would supply, made on a monthly basis from January 2013 to November 2016, as collated by the CMA from forecasts obtained from Alliance and referencing the underlying forecast evidence (URN: PRO-C6692, URN: PRO-C6697, URN: PRO-C6702, URN: PRO-C6707 and URN: PRO-C6712), in particular Alliance's November 2013 expectation of supplying 80,000 packs in December 2013, whereas it ultimately sold just under 40,000 packs; this resulted in an increase in the forecasted sales in 2014 (from 280,000 to 321,125).

[1084] See, in particular:

(a) On 06 August 2013, [Alliance employee] asked [Alliance Employee 3] to explain the basis for a forecast for Prochlorperazine POM. [Alliance Employee 3] explained that: '*[...] The forecast is 40k units for the first four months to reflect a stock build which the vendor has agreed, this is currently being documented*'. [Alliance Employee 3]'s comments relate to the forecast for Prochlorperazine recorded in Alliance's master forecasting documents in July 2013 (URN: PRO-E004620), which forecast supply to Focus of 40,000 packs for the first four months, followed by consistent monthly supply of 19,667 packs. The additional 20,333 packs Alliance forecast it would supply in each of the first four months, compared to subsequent months, represented Alliance's understanding of Focus' requirements to build stock. Email [Alliance Employee 3] to [Alliance Director 3] and [Alliance employee] entitled *'FW: sales units forecast review – UK'* 6 August 2013 (URN: PRO-E001030).

(b) On 03 October 2014, [Alliance Employee 1] commented to [Alliance Director 2] on the variance between Alliance's performance in 2014, and its budget for 2015. He commented in relation to Prochlorperazine POM: '*2015 versus 2014 = [..,] Prochlorperazine (Stock build at -£[✂] Margin)*'. See email [Alliance Employee 1] to [Alliance Director 2] entitled *'Latest EP 2015 Budget'* 3 October 2014 (URN: PRO-E004832). At Alliance's forecast COGs (£[✂]) and selling price (£5.65) for Prochlorperazine POM in 2015, £[✂] margin corresponds closely to the supply of 80,000 packs to Focus in 2014 for its stock build.

[1085] The expectation of static sales volumes during 2014 is further evidenced by [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014 page 12 (URN: PRO-E001103). That document records that *'margin generation for this product should be stable'* during 2014. Although Alliance has submitted that this simply reflects the fixed supply price within its agreement with Focus, it is noted that stability in the margins generated by the product would also necessitate stable volumes, and the absence of new entry.

Focus would lose market share to Lexon, but was in fact the expected impact of de-branding and price increases implemented by Focus:

5.383.1 In an email dated 06 August 2013 email from [Alliance Employee 3] to [Alliance Director 3] and [Alliance employee], [Alliance Employee 3]'s explanation of this reduction does not refer to loss of market share to a competitor Prochlorperazine POM product. Instead, she stated that the *'Forecast figures are based on current usage and also a moderate decline as you withdraw a brand and, as a consequence, there is confusion in the market. Also if the price increases then the volumes will decline as alternatives are sought by prescribers'*.[1086]

5.383.2 On 14 November 2013 [Focus Director 1] emailed [Focus Director 2] to explain Focus' internal sales forecasting for Prochlorperazine POM. Focus' internal sales forecast was that it would *'pick up to full market by Qtr 1 ish [of 2014]'*, by which point, it would supply 20,000 packs per month. [Focus Director 1] explained that *'the current market is 25,000 packs per month but i [sic] have assumed some lost volume with the price increases'*.[1087] Focus therefore adopted forecasts that were aligned with those adopted by Alliance, and likewise anticipated a volume decrease as a result of price increases rather than because of expected market share losses to Lexon/Medreich.

[Alliance Director 2]'s claims that Alliance forecasted a decline in sales from January 2015 due to the market entry of Lexon

5.384 In his first witness statement, [Alliance Director 2] stated that Alliance was expecting Lexon to enter the market and that this is reflected in the decline in sales volumes that Alliance expected to achieve in 2015 compared to 2014. [Alliance Director 2]'s comments were made before the CMA obtained the detailed forecasting evidence that is referred to in the section described above. The key elements of his evidence can be summarised as follows:

5.384.1 An AIM listed company such as Alliance has *'an obligation to investors to deliver monthly forecasts which include revenue predictions for each product'*. He explained that forecasts are a *'highly important, detailed and time consuming part of our business, since forecasts form the backbone of how we message to investors and presenting accurate and reliable forecasts can make or break our reputation in the marketplace'*.[1088] Given

[1086] Email [Alliance Employee 3] to [Alliance Director 3] and [Alliance employee] entitled *'FW: sales units forecast review – UK'* 6 August 2013 (URN: PRO-E001030). The average monthly volume of Buccastem POM supplied by Alliance from 2011 to July 2013, was 25,800 packs. At the time of [Alliance Employee 3]'s email, Alliance forecasted supplying 19,667 packs of Prochlorperazine POM to Focus a month, a reduction of 24% (see paragraph 5.382 above).

[1087] Email [Focus Director 1] to [Focus Director 2] entitled *'FW: other OLS for budget'* 14 November 2013 (URN: PRO-E003759)

[1088] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 5.1 (URN: PRO-C5098).

their importance, [Alliance Director 2] signed the forecasts off as did the CFO and other management.[1089]

5.384.2 [Alliance Director 2] stated that he can *'remember clearly that [Alliance's] forecasts for prochlorperazine from 2014 onwards showed that we seriously expected competition and a subsequent decline in our new unbranded product's sales within a one-year+ perspective'*.[1090] He stated that, as at January 2014, *'APL was predicting that revenue for 2014 would be £1.9m while revenue for calendar year 2015 would be £1.3m'*. He goes on to explain that *'[i]t can be seen that throughout 2014 there was an expected decline of 25 to 30% in calendar year 2015 compared with the forecast outturn for calendar year 2014 (with revenue falling to £1.3 to £1.4m)'*.

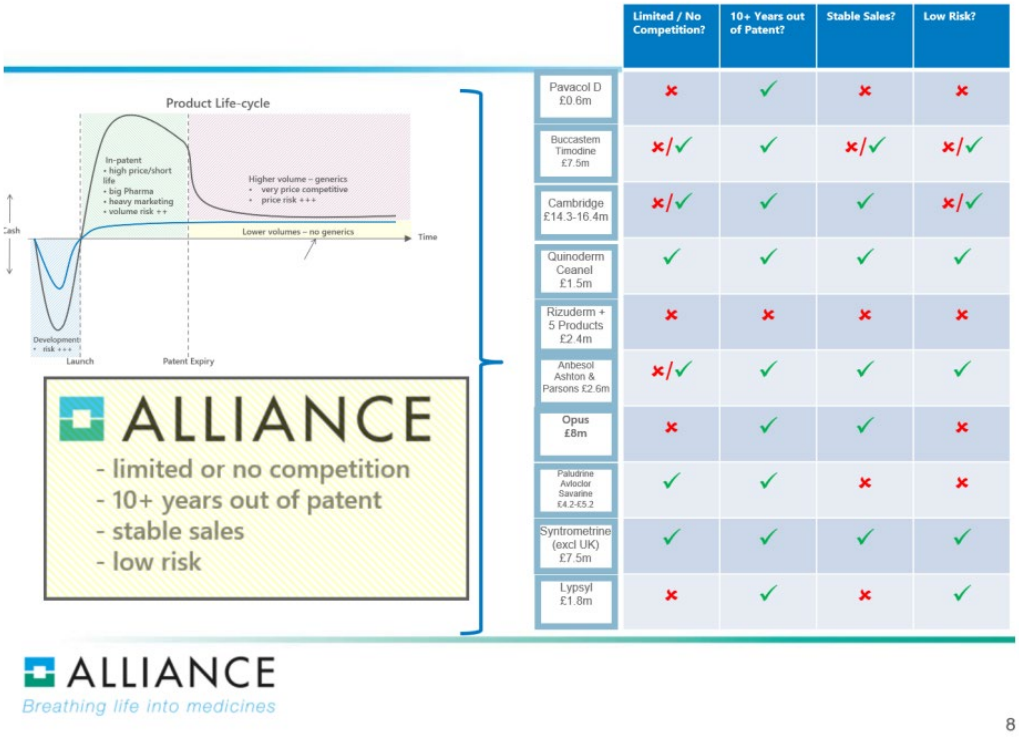
5.384.3 [Alliance Director 2] observed that he *'was involved in the production of forecasts'* and *'reported on revenue expectations both to the APP Board and to the AIM market'.*[1091] [Alliance Director 2] states that he can *'recall clearly that our forecasts were built on the firm expectation that there would be increased competition, initially from a Lexon product, and that there was a general pessimism about the future sales of this product.'* [Alliance Director 2] concludes: *'To put it simply, as far as I was concerned, those forecasts reflected a predicted declining revenue profile for prochlorperazine on the basis of a reasonable expectation of market entry. In my mind, at the time they were delivered, those forecasts were correct*'.

5.385 The contemporaneous documentary evidence described above demonstrates that [Alliance Director 2]'s recollection that the fall in sales revenue between 2014 and 2015 related to Lexon's anticipated market entry is incorrect. As explained above, the decline in sales between 2014 and 2015 did not relate to the onset of competition, but is in fact explained by the 'stock build' as described above.

5.386 In his second witness statement, which was submitted after the CMA had issued a Letter of Facts detailing the evidence outlined above, [Alliance Director 2] referred the CMA to further evidence which in his submission demonstrates that during May/June 2014, Alliance remained concerned about the competitive threat posed by Lexon.[1092] The evidence that [Alliance Director 2] referred to focussed on the following slide, which was included in a presentation that he gave in May and June 2014:[1093]

[1089] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 5.2 (URN: PRO-C5098).
[1090] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 5.5 (URN: PRO-C5098).
[1091] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 5.6 (URN: PRO-C5098).
[1092] [Alliance Director 2] Witness Statement of 29 April 2021, paragraphs 2.8 to 2.15 (URN: PRO-C7119).
[1093] [Alliance Director 2] Witness Statement of 29 April 2021, Exhibit 1, Slide 8, Build 2 (URN: PRO-C7119).

Exhibit 1, Slide 8, Build 2



5.387 [Alliance Director 2] submitted that, in the second line referring to 'Buccastem Timodine', the first cross or tick (where there are two) in each column refers to 'Buccastem' (which was in fact de-branded by this time), and the second to Timodine, which is considered in the same row.[1094] [Alliance Director 2] submitted that the implication of the crosses is therefore that Alliance considered that Prochlorperazine POM was expected to face competition, that its sales were not expected to be stable and that there was a high risk that it would face competition.[1095] [Alliance Director 2] submitted that he can be confident that the associated ticks are intended to apply to Timodine as that product did not face any such risks.[1096]

5.388 The CMA considers there to be a number of reasons to question the credibility of [Alliance Director 2]'s account of this document:

5.388.1 [Alliance Director 2] had previously informed the CMA that the fall in sales volumes that were forecasted between 2014 and 2015 reflected his clear recollection that Alliance had expected entry to occur within a '*one-year+ perspective*' (see paragraph 5.384).[1097] However, it is evident from paragraphs 5.379 to 5.383 above that that forecasted fall in sales did not relate to any such concern and that his recollection was incorrect. Given

[1094] [Alliance Director 2] Witness Statement of 29 April 2021, paragraph 2.10 (URN: PRO-C7119).
[1095] [Alliance Director 2] Witness Statement of 29 April 2021, paragraphs 2.11 to 2.12 (URN: PRO-C7119).
[1096] [Alliance Director 2] Witness Statement of 29 April 2021, paragraph 2.10 (URN: PRO-C7119).
[1097] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 5.5 (URN: PRO-C5098).

that the forecasted fall in sales was demonstrably not due to the impact of competition and was therefore contrary to [Alliance Director 2]'s recollection, his corresponding evidence that certain 'crosses' are evidence of the same recollection must, from the outset, be considered somewhat questionable.

5.388.2 It is unclear why, if Alliance and [Alliance Director 2] did consider that there was a high risk that the Alliance volumes would fall due to the onset of competition, that was not reflected in its forecasts. As outlined above, [Alliance Director 2] has submitted to the CMA that those forecasts *'form the backbone of how we message to investors and presenting accurate and reliable forecasts can make or break our reputation in the marketplace*', yet they repeatedly assumed that no entry would take place.[1098]

5.388.3 It is also unclear why, at the same time as [Alliance Director 2] was giving his presentation and in his submission warning that prochlorperazine revenues could soon be exposed to competition, [Alliance Employee 1] (who was [Alliance Director 2]'s direct report) was preparing a presentation in which he proposed to highlight that the opposite was in fact the case. In an internal email dated 28 May 2014, [Alliance Employee 1] refers to a slide that would be used to illustrate a *'steady state and how I am keeping it that way'*.[1099] [Alliance Employee 1] goes on to suggest that he *'may do a case study on Buccastem / Prochlorperazine on how a transition to a generic can (in the short term – 2 or 3 years) maintain value'*.

5.388.4 [Alliance Director 2]'s description of the content and meaning of the slide, and how the ticks and crosses in the second row relate to Buccastem and Timodine, do not account for the contents of the table more generally, calling into account his interpretation of the second row:

(a) The column titles appear on their face to ask: in column 1, whether each drug or portfolio of drugs is *currently* subject to limited or no generic competition; in column two, whether it is more than 10 years since the relevant patent protection expired; in column three whether the relevant portfolio *currently* experiences sales volatility; and, in column four, to ask whether or not the position should be regarded as low risk (which, in essence, means whether the product faces a risk going forward). However, on [Alliance Director 2]'s reading of the slide, all of the columns are given a forward looking meaning such that

[1098] [Alliance Director 2] Witness Statement of 31 July 2019, paragraph 5.1(URN: PRO-C5098).

[1099] Email [Alliance Employee 1] to [Alliance employee] entitled *'Strategy EP'* 28 May 2014 (URN: PRO-E001122) with reference to the attached *'EP UK Bedrock'* presentation (URN: PRO-E001123).

they are all said to state that Buccastem is likely to face generic competition in the near future.

(b) The products are grouped by acquisition event, and there is either a cross or a tick or a cross/tick in relation to each row (even where that includes two or more products). It is clear that for the other acquisition events, involving a portfolio of products, the cross/tick entry is used merely to highlight that the situation is mixed and not to refer to specific products within the relevant portfolio. For all entries, and irrespective of the number of products in some portfolios and the fact that some of those portfolios include many products, there is either a single cross, a single tick, or a cross/tick (always in that order[1100]) in each entry. By way of illustration, the 'Cambridge' row, which is said by [Alliance Director 2] to relate to a number of products,[1101] also includes a cross/tick, undermining the suggestion that the cross/tick entry is intended to relate to two different products in the way that is suggested for Buccastem and Timodine.

(c) Given the above, the CMA considers that the more natural explanation for the table is that there is a single entry for each acquisition / group of products (consistent with the fact that the slide deck from which the table is taken is a discussion of acquisition strategy), which is either a cross or a tick or a cross/tick. On this basis, the cross/tick entry is used to identify a half-way-house or intermediate or mixed position and in this regard it is relevant that the contemporaneous evidence from the time also implies that the competitive landscape Timodine faced was not in fact entirely stable and without risk, and refers to sales volatility resulting from the lack of availability of a competitor product.[1102] On this basis, and given the substantial surrounding evidence that Alliance did not expect Lexon to enter in the coming year, the cross/ticks would more likely signify that Alliance was indicating a mixed position for those products, which would be consistent with the fact that for 'Buccastem' a rival undertaking did hold a licence for the product, there was some volatility linked to de-branding and the appointment of Focus (including the stock build), and that a risk continued to exist in so far as Lexon/Medreich had a licence that could be utilised if the Market Exclusion Agreement collapsed.

[1100] There are no 'tick/cross' entries, which also suggests that 'cross/tick' is in fact used to indicate a mixed position across multiple products, rather than indicating a differentiated position across two products.

[1101] [Alliance Director 2] Witness Statement of 29 April 2021, paragraph 2.14(a) (URN: PRO-C7119).

[1102] See, for example (i) Spreadsheet entitled *'Risks, Opportunities & Sensitivities'*, October 2013 (URN: PRO-E004627); (ii) *'Alliance UK Performance Report'*, January 2014, page 18 (URN: PRO-E004756); and (iii) Email [Alliance Employee 1] to [Alliance Employee 3] entitled *'RE: sales unit review – EP'* 4 December 2013 (URN: PRO-E004800).

5.389 In these circumstances, the CMA therefore considers that the crosses and ticks recorded in the presentation are of limited evidential value. Given the relative detail, clarity and significance that is said to be attached by Alliance to its forecasts (see paragraph 5.384 above), which is consistent also with the contemporaneous record of [Alliance Employee 1]'s thinking at the time (see paragraph 5.388 above), the CMA considers that significantly greater evidential weight should be afforded to them.

Alliance's representations on its forecast evidence

5.390 In its response to the SO, Alliance submitted that Alliance's forecasts demonstrate that it expected its revenues to decline, and for Lexon entry to occur in 2015, as reflected in the forecasted fall in sales at the end of 2014.[1103] Alliance stated that at that time it expected demand for Alliance's product to diminish following the entry of a competitor and informed the CMA that *'Alliance consistently held the expectation of revenue decline in 2015 throughout 2014'*.[1104]

5.391 In its response to the Letter of Facts of February 2021, however, Alliance appears to accept that the decrease in sales between 2014 and 2015 was not due to the expected entry of a new competitor, and does not contest the finding that that fall relates to the Focus 'stock build': Alliance submits instead that it is the fall in sales to the market between 2013 and 2014 that demonstrates its concern that Lexon would imminently enter the market.[1105] Alliance does, however, maintain that throughout 2014 it remained concerned that Lexon would enter the market.[1106]

5.392 Alliance makes the following submissions regarding its claim that the expected fall in sales to the market between 2013 and 2014 was due to Lexon's anticipated market entry:[1107]

5.392.1 Alliance disputes the evidential weight that should be placed on the email from [Alliance Employee 3] (see paragraph 5.383 above) and the finding that the fall in volumes between 2013 and 2014 was due to confusion caused by de-branding and a price increase on the part of Focus. Alliance submits that:

(a) [Alliance Employee 3]'s role on the finance team would not have given her a detailed knowledge of the competitive conditions relevant to specific products; and

(b) [Alliance Employee 3]'s reference to *'alternatives being sought by prescribers'* is 'not inconsistent' with the prospect of entry being

[1103] Alliance RSO, 1 August 2019, paragraph 4.81 (URN: PRO-C5096).
[1104] Alliance RSO, 1 August 2019, paragraph 4.81(b)(ii) (URN: PRO-C5096).
[1105] Alliance RLF, 29 April 2021, paragraphs 4.3 to 4.10 (URN: PRO-C7118).
[1106] Alliance RLF, 29 April 2021, paragraph 4.16 (URN: PRO-C7118).
[1107] Alliance RLF, 29 April 2021, paragraph 4.13 (URN: PRO-C7118).

expected at the time, and that she is noting in 'non-expert terms' that volumes may decline due to substitutes in the market.

5.392.2 Alliance refers to its 'CCBTM minutes' dated 20 June 2013, which includes the comment that the *'price of Buccastem will increase to £5.89 which will help cover the loss of sales'*,[1108] and states that this shows that price increases were viewed as a countervailing measure to address the expected loss of sales.

5.392.3 In relation to the Focus correspondence dated 14 November 2013 and considered at paragraph 5.383, in which [Focus Director 1] referred to the *'lost volume with price increases'*, Alliance submits that (i) the expected loss of volume is consistent with an expectation of generic entry capturing such volumes; (ii) the evidence confirms the view that there was a general expectation of declining volumes; and (iii) the CMA has not presented any economic analysis that could allow it to formulate the view that volumes of Prochlorperazine POM would fall as a result of wholesale price increases.[1109]

5.393 Alliance's submissions regarding the reason for the expected fall in sales between 2013 and 2014 are unconvincing:

5.393.1 In response to the Alliance's submissions concerning the email from [Alliance Employee 3] dated 6 August 2013, it is noted that:

(a) [Alliance Employee 3]'s comments are sent in response to an email request from [Alliance Director 3] addressed to [Alliance Employee 3] and [Alliance employee] raising *'[s]ome further points for you'.*[1110] It is therefore clear that [Alliance Director 3] would have expected [Alliance Employee 3] to provide authoritative commentary on the sales unit forecasts.

(b) [Alliance Employee 3] confidently reports her understanding of the reasons for the fall in expected sales and her email does not suggest any uncertainty or doubt regarding the detailed and entirely credible explanation that she provides. Contrary to Alliance's claims that her role would not have given her detailed knowledge of such factors, Alliance had itself explained in a prior response to a section 26 Notice[1111] that its commercial and finance team (including [Alliance Employee 3]) discussed forecast spreadsheets on a monthly basis

[1108] Meeting minutes entitled *'Consumer Community Business Team Meeting'* 12 June 2013 (URN: PRO-E004780).

[1109] Alliance RLF, 29 April 2021, paragraph 4.15 (URN: PRO-C7118).

[1110] Email [Alliance Director 3] to [Alliance employee], [Alliance Employee 3], and [Alliance employee] entitled *'RE: sales units forecast review – UK'* 6 August 2013 (URN: PRO-E001030).

[1111] Section 26 response of Alliance dated 19 December 2019 to CMA notice of 26 November 2019, pages 5 and 6 (URN: PRO-C5591).

and the finance team would update the spreadsheets based on those discussions. Alliance has separately confirmed that [Alliance Employee 3]'s role *'was to facilitate the updating of forecasts documentation'*, which was a role that no doubt required obtaining accurate information regarding the changes being made.[1112] It is also evident that, although [Alliance Employee 3] is not herself part of the commercial teams responsible for selling the product, she was regularly provided with the relevant commentary on the performance of product for the purposes of her role.[1113]

(c) Alliance is wrong to suggest that the phrase *'alternatives being sought by prescribers'* is consistent with a loss of sales to a new generic entrant.[1114] The notion of *prescribers* seeking alternatives applies only to clinicians seeking alternative products to prescribe, rather than to the generic substitution by *dispensers* (i.e. pharmacies) that would have been prompted by generic entry on the part of Lexon. Moreover, it is observed that Alliance's interpretation is entirely at odds with its claim that the strategy was for Focus to implement price increases *before* generic entry, such that any expected switching cannot have been expected to relate to switching from Alliance to Lexon (see paragraph 5.363). Finally, it is noted that in this context there is no need to present an economic analysis regarding the impact of price increases on volumes. That is because the purpose of this analysis is to consider Alliance's expectations at the time, and their consistency with the existence and content of the Market Exclusion Agreement as described above.

(d) [Alliance Employee 3]'s forecasts in this regard were consistent with commentary within Alliance from the period after Buccastem was de-branded. In an email from [Alliance Employee 1] to [Alliance Director 1] dated 17 January 2014, [Alliance Employee 1] observed that the de-branding of Buccastem POM had in practice resulted in GPs

[1112] Section 26 response of Alliance dated 20 January 2020, to CMA follow-up questions of 16 January 2020, question 7 (URN: PRO-C5782).

[1113] Email [Alliance Employee 1] to [Alliance Employee 3] and [Alliance Director 2] copying [Alliance employee] entitled '*FW: Prochlorperazine for Alliance Pharmaceuticals'* 16 December 2013 (URN: PRO-E004803); Email [Alliance employee] to [Alliance Employee 3] entitled '*RE: Prochlorperazine for Alliance Pharmaceuticals'* 18 December 2013 (URN: PRO-E004804); Email [Alliance Employee 1] to [Alliance employee] and [Alliance employee] copying [Alliance employee], [Alliance Employee 3] and [Alliance employee] entitled '*FW: Focus Aspirin & Prochlorperazine Forecast – March 2014'* 19 March 2014 (URN: PRO-E004813); Email [Alliance employee] to [Alliance Employee 3], [Alliance employee], [Alliance employee] and [Alliance employee] copying [Alliance employee] entitled '*RE: Sales unit forecast review – July 2015'* 6 August 2015 (URN: PRO-E001190); Email [Alliance employee] to [Alliance Employee 3] copying [Alliance Employee 1] entitled *'7+5 updates for EP'* 13 August 2015 (URN: PRO-E001193).

[1114] Alliance RLF, 29 April 2021, paragraph 4.13.2 (URN: PRO-C7118).

switching away from Prochlorperazine POM and prescribing Stemetil instead.[1115]

5.393.2 As regards the CCBTM minutes and Alliance's claim that the Alliance price rise was regarded as helping to make up for the expected loss of sales volumes, it is evident that this has no bearing on the CMA's finding as to the *cause* of the expected sales losses and its finding that those expected sales losses have nothing to do with Lexon's entry.

5.393.3 It is also clear that Alliance is wrong to claim that [Focus Director 1] was envisaging lost volume due to the entry of Lexon in his email dated 14 November 2013. The forecast to which [Focus Director 1] refers in his email makes clear that he was envisaging that Focus would make purchases only from Alliance (see paragraph 5.383), and the assumed decline in market volumes can in no way be attributed to purchases from Lexon.

5.394 In support of its claim that, at the start of 2014, Alliance continued to be concerned about Lexon's entry, Alliance makes the following submissions:[1116]

5.394.1 its CCBTM minutes dated 8 July 2013, after the date of the [Alliance Director 1] notebook entry, continue to refer to a *'generic licence threat'*,[1117] with negotiations with Focus ongoing;[1118]

5.394.2 Alliance submits that *'there was a general expectation of declining sales volume over the next two years when compared to historical sales'* and *'[t]his decline in sales volumes is entirely consistent with an expectation of competitive entry'*;[1119]

5.394.3 it is evident from [Alliance Director 2]'s second witness statement, and the presentations from May and June 2014 that he discusses in that statement, that Alliance remained concerned about the generic entry threat;[1120]

5.394.4 an internal email dated 24 October 2014 refers to *'what the impact on our demand is going to be given our competitor has gone to POM';*[1121] and

[1115] Email [Alliance Employee 1] to various recipients at Alliance entitled *'RE: prochlorperazine'* 5 March 2014 (URN: PRO-E001111).

[1116] Alliance RLF, 29 April 2021, paragraph 4.16 (URN: PRO-C7118).

[1117] Meeting minutes entitled '*Consumer Community Business Team Meeting*' 8 July 2013 (URN: PRO-E004791).

[1118] Alliance RLF, 29 April 2021, paragraph 4.16.1 (URN: PRO-C7118).

[1119] Alliance RLF, 29 April 2021, paragraph 4.16.2 (URN: PRO-C7118).

[1120] Alliance RLF, 29 April 2021, paragraph 4.16.3 (URN: PRO-C7118).

[1121] Alliance RLF, 29 April 2021, paragraph 4.16.4 (URN: PRO-C7118), citing email [Alliance employee] to [Alliance employee] entitled '*Buccastem'* 24 October 2014 (URN: PRO-E001149).

5.394.5 from November 2014 Alliance's internal documents refer to anticipated competitive entry.

5.395 Alliance's submissions regarding its claimed expectation of Lexon's generic entry are unconvincing:

5.395.1 The *'generic licence threat'* wording that is quoted by Alliance in relation to its July 2013 meeting note was a heading that (or a *'Generic threat'* heading) had been included in its monthly CCBTM minutes since April 2013,[1122] and that heading precedes an observation that [Alliance Employee 1] was still finalising the agreement with Focus. It does not suggest that Alliance remained concerned that Lexon would enter having finalised and implemented the terms of the agreement documented in the [Alliance Director 1] notebook entry dated 11 June 2013, such that it is at odds with the existence of the Market Exclusion Agreement. Rather, the natural reading of that meeting note, when seen in the context of the prior meeting notes, is that it records that steps continued to be taken in response to the entry threat which, in this case, was the negotiation of the Alliance-Focus Agreement.

5.395.2 Alliance's statement that there was a general expectation of declining sales misrepresents the evidence. In reality, the forecasts show an expected decline in sales at the end of 2013, to be followed by stable sales to the market in 2014 and 2015 (with a stock-build by Focus in 2014). As outlined above, the evidence makes clear that the forecasted fall in sales at the end of 2013 was not due to the expected impact of Lexon's entry.

5.395.3 The evidence presented by [Alliance Director 2] is considered at paragraphs 5.384 to 5.389 above, and is unpersuasive for the reasons given.

5.395.4 The 24 October 2014 email referring to a competitor that *'has gone to POM'* does not relate to Lexon.[1123] Most obviously, the product had not *'gone to POM'* as it had not entered the market at that time, nor had there been any suggestion that it would do so following grant of the Medreich MA 10 months earlier such that Alliance would need to reconsider its stock position. Consistent with this, the email is in fact contemplating the need to find more supply of the Buccastem OTC *'8's'* product given that a competitor OTC product would apparently be available on prescription only, and refers to the option of taking production stock away from the

[1122] See Meeting minutes entitled *'Consumer Community Business Team Meeting'* 12 June 2013 (URN: PRO-E004780); Meeting minutes entitled *'Consumer Community Business Team Meeting'* 9 May 2013 (URN: PRO-E004775) and Meeting minutes entitled *'Consumer Community Business Team Meeting'* 11 April 2013 (URN: PRO-E004768).

[1123] Alliance RLF, 29 April 2021, paragraph 4.16.4 (URN: PRO-C7118), citing email [Alliance employee] to [Alliance employee] entitled '*Buccastem'* 24 October 2014 (URN: PRO-E001149).

Prochlorperazine POM 50 pack to achieve that. Plainly, there would be no reason for Alliance to seek to increase supply of its Buccastem OTC 8s pack in response to Lexon's entry with Prochlorperazine POM. A subsequent document confirms that sales of Buccastem OTC '8's' did in fact increase in 2015 due to the withdrawal from the market of OTC domperidone,[1124] which is a drug that was required to be supplied by prescription only as of September 2014 and had therefore '*gone to POM*' shortly before the 24 October 2014 email cited by Alliance.[1125]

5.395.5 While it is correct that from November 2014 Alliance's forecasts do begin to contemplate generic entry, for the reasons set out below it is evident that the potential entrant in question is Primegen and not Lexon.

5.396 Finally, in considering the plausibility of Alliance's representations, it must be emphasised that Alliance has not explained why, even on its own case that it forecasted a fall in sales at the end of 2013, any concern about Lexon's potential entry was considered sufficient to justify a forecast fall in sales at the end of 2013, but insufficient to merit a forecast fall in sales thereafter.

From November 2014 Alliance did forecast market entry in 2016, but the expected entrant was Primegen and not Lexon

5.397 As set out in detail below, from November 2014, it is evident from Alliance's internal documents that it was concerned that its sales volumes would be impacted by the entry of a competitor. However, for the reasons set out below it is apparent that it was the entry of another firm, Primegen, that Alliance was anticipating would enter the market. Alliance's forecasts continued therefore to assume that Lexon would not enter the market, and therefore constitute further evidence of the Market Exclusion Agreement.

5.398 The evidence below demonstrates that, from November 2014, Alliance anticipated losing market share to a single competitor (referred to below as the 'Expected Generic Entrant') and forecasted a significant reduction in the volumes supplied in 2016 versus those supplied in 2015. Unlike the documents from 2013 that contemplated Lexon's generic entry and that regularly referred to Lexon by name, the documents from this period make no reference to the identity of the Expected Generic Entrant:[1126]

[1124] Email [Alliance Employee 1] to [Alliance Director 2] and [Alliance employee] entitled *'RE: Buccastem 8's Question'* 18 November 2015 (URN: PRO-E001223). Commenting on the increase in sales of the Buccastem OTC 8 pack, [Alliance Employee 1] suggests that one of the factors has been the *'absence of P Domperidone'*.

[1125] See https://pharmaceutical-journal.com/article/opinion/otc-domperidone-will-be-missed, which observes that *'On 3 September 2014, community pharmacists were given 48 hours to remove over-the-counter (OTC) domperidone products from their shelves over concerns about cardiac safety'.*

[1126] See also email [Alliance employee] to [Alliance Employee 1] entitled *'Established Products sales unit forecast – Nov 14'* 1 December 2014 (URN: PRO-E004839); email [Alliance employee] to [Alliance Employee 1] entitled *'EP Queries*

5.398.1 The minutes of a Western Europe Quarterly Performance meeting on 21 April 2015 include the following: *'Prochlorperazine: [Alliance Employee 1] to look into maintaining the value as there is a competitor possibly coming out in October. [Alliance Employee 1] has forecast a drop next year'*.[1127]

5.398.2 A summary of the established products portfolio for the purpose of preparing the 2016 budget, dated 10 September 2015, noted: '*[Prochlorperazine:] Competitor entering market mid 2016, reducing sales volume by 50%*'.[1128]

5.398.3 A paper on the 2016 budget prepared for the 17th December 2015 board meeting noted that: '*Prochlorperazine volumes are expected to drop in 2016 due to a competitor entering the market (impact of -£0.7m sales and gross margin -£0.6m), with a corresponding reduction in orders from 8 (2015) to 5 (2016)*'.[1129]

5.399 Although the Expected Generic Entrant is not named, it can be inferred that it is in fact Primegen rather than Lexon:

5.399.1 An email from [Alliance Employee 1] to [Alliance employee] on 17 December 2014 refers to the Expected Generic Entrant as *'another generic entrant'*. The word *'another'* distinguishes the generic entrant referred to from a potential generic competitor about which Alliance was already aware, and had taken steps to address, namely, Lexon.[1130]

5.399.2 During this period, Primegen had emerged as a potential competitor to Alliance. Its licence was ultimately granted in February 2016, which is relatively close to the date that Alliance forecast the Expected Generic Entrant to launch.

5.399.3 In contrast, there is nothing to suggest that, having observed no entry on the part of Lexon during 2014, despite Medreich having received its licence in January 2014, Alliance received information that gave it reason to believe that Lexon would enter the market in mid-2016 (as opposed to during 2015, or even the first half of 2016).

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from [✂]' 17 December 2014 (URN: PRO-E001152); email [Alliance employee] to [Alliance Director 3] and [Alliance employee] entitled '*RE: Sales unit review'* 29 January 2015 (URN: PRO-E001157); and email [Alliance Employee 1] to [Alliance employee] and [Alliance Director 2] entitled *'RE: Sales Unit Forecasting Update Mar 15 – Established Products'* 27 March 2015 (URN: PRO-E001169).

[1127] Meeting minutes entitled '*Western Europe Quarterly Performance Meeting (Part 1)'* 21 April 2015 (URN: PRO-E004747).

[1128] Spreadsheet entitled *'Budget 2016 : Company Summary by Business Unit - Established Products'* 10 September 2015 (URN: PRO-E001205).

[1129] Paper entitled '*Budget 2016 – Commentary'* 17 December 2015, page 3 (URN: PRO-E001230).

[1130] Email [Alliance employee] to [Alliance Employee 1] entitled *'EP Queries from [✂]'* 17 December 2014 (URN: PRO-E001152).

[Alliance Employee 1]'s evidence concerning the identity of the Expected Generic Entrant

5.400 During his interview with the CMA, [Alliance Employee 1] was asked about a number of the documents cited above, and asked which supplier was being referred to. [Alliance Employee 1]'s recollections in this regard were mixed, and evolved as the interview progressed:

5.400.1 Although stating that he could not be sure as to which potential entrant was being referred to, [Alliance Employee 1]'s initial response to documents from the relevant period was that the Expected Generic Entrant was Primegen.[1131]

5.400.2 [Alliance Employee 1] subsequently stated that he may have confused the dates regarding Primegen's expected entry, and that the reference to a generic entrant might not therefore be to Primegen.[1132]

5.400.3 [Alliance Employee 1] suggested that the relevant entrant could in fact have been Lexon, although he suggested that it was assumed that if Lexon had not launched by then, there was an assumption that something had stopped them from doing so.[1133]

5.401 The CMA finds that [Alliance Employee 1]'s initial recollection, that the Expected Generic Entrant was Primegen, to be considerably more likely. As set out above, it is broadly consistent with the timing on which the relevant MA would be granted (which ultimately occurred in February 2016[1134]), and, to the contrary, there is no evidence at all to indicate that the Lexon product was expected to come to market in *'mid 2016'*.

5.402 In this regard, it is significant that, although [Alliance Employee 1] considered that the Expected Generic Entrant could have been a reference to Lexon, this is incompatible with other aspects of [Alliance Employee 1]'s evidence concerning his awareness of the status of Lexon's entry. When previously asked about the constant forecasts that he was receiving from Focus, that preceded the anticipated impact of the Expected Generic Entrant, [Alliance Employee 1] explained that he

[1131] See, for example: Interview [Alliance Employee 1], 9 October 2018, page 77, line 20 and page 89, line 26 to page 90, line 2 (URN: PRO-C2910).

[1132] Interview [Alliance Employee 1], 9 October 2018, page 95, lines 7-20 (URN: PRO-C2910).

[1133] Interview [Alliance Employee 1], 9 October 2018, page 90, lines 15-20 (URN: PRO-C2910).

[1134] See paragraph 3.156.

had no information on the status of the Lexon product and that he did not seek such information:

> *'this was where it started becoming uncomfortable because I didn't want to really ask the questions. [...] I'm not naive enough to think that there was some other arrangements going on.'*[1135]

> *'I didn't know what was happening. But the competitor hadn't launched. Was the competitor being supplied with my product? I don't know. Was there a problem with the manufacture of the competitor's product? I didn't know. Was there a … other scenario? I don't know.'*[1136]

> *'So, I -- I -- truthfully, I just didn't want to know what was going on and it was a -- and I did raise it with the business. I did raise it with our lawyer at the time. But we distributed the product to a third party. We were getting our 40,000 units every few months. What was going on out there was not our responsibility […] It was -- it was a distributor that was managing one of mine and 42 products. The forecasts coming in, I didn't ask any questions.'*[1137]

5.403 This claimed lack of knowledge of the status of the Lexon product, and the reluctance to seek information, is necessarily at odds with any suggestion by [Alliance Employee 1] that the Expected Generic Entrant could in fact have been Lexon. Given their incompatibility, both accounts should be given limited weight.

Alliance's representations concerning the identity of the Expected Generic Entrant

5.404 In its response to the Letter of Facts of February 2021, Alliance submits that it is incorrect that the Expected Generic Entrant referred to at that time was Primegen rather than Lexon:

5.404.1 insofar as Alliance's documents did only refer to a single competitor, this does not provide the basis for concluding that Alliance was not concerned with any threat of entry by Lexon and Medreich. Alliance refers to [Alliance Employee 1]'s comment in interview that Lexon was *'still in the frame'*[1138] from Alliance's perspective;[1139]

5.404.2 any consideration of the threat of entry would have necessarily factored in the threat posed by Lexon and Medreich given that they had been granted

[1135] Interview [Alliance Employee 1], 4 October 2018, page 154, lines 13 to 15 and page 155, lines 2 to 3 (URN: PRO-C2909).

[1136] Interview [Alliance Employee 1], 4 October 2018, page 155, lines 7 to 11 (URN: PRO-C2909).

[1137] Interview [Alliance Employee 1], 4 October 2018, page 157, lines 10 to 21 (URN: PRO-C2909).

[1138] Alliance RLF, 29 April 2021, paragraph 4.35.3 (URN: PRO-C7118), citing Interview [Alliance Employee 1], 9 October 2018 page 89, line 26 (URN: PRO-C2910).

[1139] Alliance RLF, 29 April 2021, paragraph 4.35.3 (URN: PRO-C7118).

an MA 10 months earlier, while the entry threat posed by the Primegen MA was not known to either Alliance or Focus until later in 2015;[1140] and

5.404.3 as regards the email dated 17 December 2014, Alliance submits that the reference to *'another generic entrant'* should more naturally be read as in addition to the generic product launched by Alliance.[1141]

5.405 Alliance's submissions are unpersuasive:

5.405.1 It is unclear why, if Alliance considered that Lexon represented a potential entrant, its forecasts would not take account of this entry threat in the same way that it did for the Expected Generic Entrant. The differing treatment between the two threats is consistent with Alliance having reached an agreement with Lexon that it would not enter the market.

5.405.2 It is accepted that the documentary evidence does not record the date on which Alliance first became aware of the potential Primegen product. Nevertheless, given the documentary evidence described above and the timeline associated with that product, it can be inferred that the relevant product (that is, the Expected Generic Entrant) was indeed Primegen's. This conclusion is reinforced by the implausibility of the relevant references having been to Lexon. As of November 2014, there was no reason at all to consider that Lexon had gone from not constituting a threat, to constituting a threat that would materialise only in mid-2016.[1142] Furthermore, any finding that Alliance had updated its forecasts in response to such intelligence would be inconsistent with other submissions advanced on behalf of Alliance, including its claim that it received no insight regarding the status of the Lexon product (see paragraph 5.402) and its prior claim that in 2014 it was expecting Lexon's entry to occur at the end of 2014.[1143]

5.405.3 The CMA does not accept that the plain reading of the *'another generic entrant'* reference in the 17 December 2014 email refers to a generic entrant further to Alliance itself, such that it could constitute a reference to Lexon. Although Alliance had launched its own generic product, it would realistically have regarded itself as the incumbent rather than an entrant, and the reference to 'another' entrant would most naturally be read as in addition to Lexon. Moreover, it is evident from Alliance's documents that it considered the Expected Generic Entrant to be a 'new' competitor that

[1140] Alliance RLF, 29 April 2021, paragraph 4.35.4 (URN: PRO-C7118).

[1141] Alliance RLF, 29 April 2021, paragraph 4.36.1(b) (URN: PRO-C7118), citing email [Alliance employee] to [Alliance Employee 1] entitled *'EP Queries from [✂]'* 17 December 2014 (URN: PRO-E001152).

[1142] See also Email [Alliance Employee 1] to [Alliance Director 2] and [Alliance employee] entitled *'Buccastem 8s Question'* 18 November 2015 (URN: PRO-E001223), in which [Alliance Employee 1] observes that the launch of the generic entrant was not expected in 2015, but in mid-2016.

[1143] Alliance RLF, 29 April 2021, paragraph 3.32 (URN: PRO-C7118).

might or might not to choose to obtain a licence to dispense the OTC product, which cannot be a reference to Lexon given that it had long since obtained the corresponding OTC licence.[1144]

Other Alliance documents that represent further evidence of the Market Exclusion Agreement

5.406 The Alliance internal documents described below represent further evidence of the Market Exclusion Agreement.

5.407 First, in [Alliance Employee 1]'s self-assessment (in the context of a performance appraisal) he recorded that, as a consequence of the arrangements he had put in place with different 'external companies', the sales value Alliance generated from Prochlorperazine POM would be maintained and, it is inferred, unaffected by the threat of entry that had previously been envisaged. He observed that, *'[t]he management of external companies and individuals has ensured the value will be maintained in Prochlorperazine (EP biggest product going into 2014)'* (emphasis added).[1145] He also stated in the same document that *'margin generation for this product should be stable'* during 2014.[1146] The CMA infers that the only credible basis for [Alliance Employee 1]'s claim that the *'value will be maintained'* is that he understood that the threat of generic competition had been 'managed'.

5.408 Second, it is clear from the documentary evidence obtained by the CMA from Alliance in the period from March to June 2013 that Alliance had been highly concerned about the specific competitive threat caused by the prospect of market entry by Lexon.[1147] However, following the decision by Alliance to appoint Focus, there are no further references expressing concern on the part of Alliance about the competitive threat posed by Lexon. On this basis, the CMA infers that Alliance understood that the appointment of Focus by each of Lexon and Alliance had addressed the competitive threat of entry by Lexon/Medreich.[1148]

[Alliance Employee 1]'s explanation of his *appraisal statement*

5.409 In his interview with the CMA, [Alliance Employee 1] confirmed that the reference to '*external companies*' was to Focus and Lexon.[1149] More generally, he stated that this comment referred to dealing with external people that were new to him, that

[1144] Email [Alliance Employee 1] to [Alliance Director 2] and [Alliance employee] entitled *'Buccastem 8s Question'* 18 November 2015 (URN: PRO-E001223). In response to a question from [Alliance Director 2] as to whether the new entrant might impact on the supply of OTC pack as well as the supply of Prochlorperazine POM, [Alliance Employee 1] observes that '*[i]f they are registering a POM 50 pack they may also register a P 8 pack'*.

[1145] [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014, page 18 (URN: PRO-E001103).

[1146] [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014, page 12 (URN: PRO-E001103). Although the relevant passage does not refer to Prochlorperazine POM directly, it is evident from the reference to the drug moving from brand to generic in the latter half of 2013 that the passage does refer to Prochlorperazine POM.

[1147] See paragraphs 3.73 to 3.84 above.

[1148] There were Alliance documents that were concerned about the competitive effect of entry (see paragraphs 5.397 to 5.405) but the CMA finds that such references were to the anticipated entry of Primegen.

[1149] Interview [Alliance Employee 1], 9 October 2018, page 116 lines 5 to 10 (URN: PRO-C2910).

his actions had led to an agreement being in place with Focus with forecasts for Prochlorperazine POM orders from Alliance, and that he was seeking to be optimistic and upbeat in his outlook.[1150]

5.410 This explanation is unpersuasive. Prior to the publication of the Medreich Prochlorperazine POM MA, [Alliance Employee 1] had been aware that it was likely to be granted imminently,[1151] and the licence was in fact granted in in the same month (January 2014) as his self-assessment took place. In circumstances where it is known that a competitor had just obtained, or was about to obtain, an MA, it is difficult to credibly suggest, even optimistically, that *'value will be maintained'* in a product or that '*margin generation for this product should be stable*'. The CMA infers therefore that [Alliance Employee 1] was confident that the value would be maintained for Prochlorperazine POM because of the agreement reached with Lexon. This is also consistent with [Alliance Employee 1]'s reference to the management of more than one firm (the *'management of external companies'*), which would make little sense had [Alliance Employee 1] only reached an agreement with a single company (Focus) and taken no steps to 'manage' Lexon.

The Parties' representations on Alliance's subsequent documentary evidence

5.411 Alliance disputes the evidential significance of [Alliance Employee 1]'s appraisal and submits that (i) such a document inevitably 'talks up' its subject activity; (ii) the facts do in any case explain and justify the comments, on the basis that Alliance had decided to de-brand, supply Focus exclusively at a fixed price and therefore preserved 'some' value; and (iii) given that de-branding enabled Focus to increase the price such that pressure on the Alliance selling price to Focus could be deferred, the arrangement could be said to maintain value and it is not surprising that [Alliance Employee 1] would want to seek credit for such work.[1152]

5.412 Alliance's submissions are unpersuasive:

5.412.1 While it is conceivable that an individual may seek to put a positive gloss on his or her work, it is far less likely that an individual would misleadingly claim (i) to have 'managed' a number of external companies and (ii) to have 'ensured' the maintenance of the value of the product, had the imminent threat of entry, and the significant loss of product volumes and margins that was liable to have followed, remained a concern.

[1150] Interview [Alliance Employee 1], 9 October 2018, pages 116-124 (URN: PRO-C2910).

[1151] On 13 February 2014, [Alliance Employee 1] was contacted by a colleague in Alliance to inform him that two further licences had been granted in January 2014 to Medreich for prochlorperazine (the 5mg licence and the 3mg POM licence). [Alliance Employee 1] responded, *'… yes saw this and was aware. I thought it was coming in December so mid Jan not a surprise'* (email [Alliance Employee 1], to [Alliance employee] entitled '*RE: Monthly list of granted marketing authorisations: Marketing authorisations granted in January 2014*' 13 February 2014 (URN: PRO-E001108)).

[1152] Alliance RSO, 1 August 2019, paragraph 4.74 (URN: PRO-C5096).

5.412.2 Contrary to Alliance's claims, [Alliance Employee 1]'s comments are not consistent with Alliance having unilaterally decided to de-brand its product and appoint Focus on fixed supply terms. Neither measure would have prevented significant sales losses had entry occurred, and the appointment of Focus does not explain [Alliance Employee 1]'s reference to having managed '*external companies*' (emphasis added).

5.412.3 The fact that the arrangement would enable Focus to increase its price would not have enabled Alliance to maintain its sales volumes in the face of generic entry. Accordingly, this point also fails to adequately explain [Alliance Employee 1]'s comments that value would be maintained.

5.413 Alliance disputes the inference made above regarding the absence of reference to Lexon's threatened entry in the period after the Market Exclusion Agreement was formed, and the Implementing Agreements, were entered into. Its submissions are as follows:

5.413.1 The absence of documents referring to Lexon's potential entry reflects the fact that, from Alliance's perspective, it had taken steps to respond to the Lexon threat and there was nothing left for it to do.[1153] The product was then in the hands of Focus. Alliance cites [Alliance Employee 1]'s evidence that, after implementing the agreement with Focus, he focussed on the many other products in his portfolio.[1154]

5.413.2 There are a number of documents that do record Alliance's ongoing concern, including its forecasts and the email dated 24 October 2014 in which [Alliance employee] observes that Alliance's *'competitor has gone to POM'* (see paragraph 5.394).[1155] Alliance submit that this must be a reference to Lexon as no other party had obtained a Prochlorperazine POM licence at this time.[1156]

5.413.3 The forecast decline in sales, from the January 2014 forecasts onwards, contradicts the finding that Alliance was no longer concerned about the competitive threat from Lexon.[1157]

5.413.4 In an email dated 18 June 2015 [Alliance Employee 1] asked a colleague why Alliance had stopped supplying Lexon with OTC product,[1158] while noting that he needed to explain to the colleague why supply should be

[1153] Alliance RSO, 1 August 2019, paragraph 4.68 (URN: PRO-C5096).

[1154] Interview [Alliance Employee 1], 4 October 2018 pages 70 to 71 (URN: PRO-C2909).

[1155] Alliance RSO, 1 August 2019, paragraph 4.69 (URN: PRO-C5096).

[1156] Alliance RSO, 1 August 2019, paragraph 4.70 (URN: PRO-C5096).

[1157] Alliance RSO, 1 August 2019, paragraph 4.71 (URN: PRO-C5096).

[1158] Email [Alliance Employee 1] to [Alliance employee] entitled *'RE: Buccastem 8'* 18 June 2015 (URN: PRO-E001185). [Alliance Employee 1] commented: '*Just not sure why we stopped supplying Lexon? I need to understand and explain why we perhaps should'.*

reinstated.[1159] Alliance refers to [Alliance Employee 1]'s evidence in interview that the purpose of this statement was to avoid provoking Lexon to launch its own OTC product. Alliance suggests that this shows *'competition working'* as Alliance was unsure of Lexon's intentions.[1160]

5.414 Alliance's submissions are unpersuasive:

5.414.1 While it is accepted that certain discussions regarding de-branding and the appointment of a distributor would no longer have been required in 2014 following Alliance's entry into the agreement with Focus, it would nevertheless still be expected that the impact on Alliance's product turnover would have remained a concern to Alliance. As outlined at paragraphs 5.379 to 5.405 above, such concerns were discussed by Alliance when Primegen emerged as a potential entrant, yet after the Market Exclusion Agreements and Implementing Agreements were entered into there was no reference at all to Lexon, and no document enquiring as to its status.

5.414.2 As outlined at paragraph 5.395, the CMA does not accept that the 24 October 2014 email can reasonably be regarded as a reference to the entry threat posed by Lexon.

5.414.3 As outlined above, the CMA rejects Alliance's claims that its forecasts evidence an ongoing concern with the anticipated entry of Lexon.

5.414.4 It is evident that the 18 June 2015 email cited by Alliance does not undermine that CMA's findings. Even on the assumption that [Alliance Employee 1]'s statement that the email concerned the risk of Lexon launching its own *OTC* product is correct,[1161] any such concern with Lexon supplying an *OTC* product is irrelevant to the CMA's finding that Alliance and Lexon had agreed that Lexon would not commercialise the *POM* product.

5.415 As part of Lexon's representations, [Lexon Director 1] stated in his witness statement that an entry in a notebook referring to *'Check RAMA for competitor 8 + 50s pack size'*[1162] was made by [Alliance Director 1] and therefore demonstrated that he and Alliance were still unsure after 12 September 2013 as to whether Lexon was seeking a licence for the Prochlorperazine POM product, and that this

[1159] Alliance RSO, 1 August 2019, paragraph 4.72 (URN: PRO-C5096).

[1160] Alliance RSO, 1 August 2019, paragraph 4.72 (URN: PRO-C5096).

[1161] The alternative reading is that the concern that [Alliance Employee 1] wished to express orally was that ceasing supply of the OTC pack may induce Lexon to supply its Prochlorperazine POM product. The notion that Lexon had chosen not to supply its product and that Alliance was concerned that it may *choose* to do so if not satisfied with its returns, is consistent with the existence of the Market Exclusion Agreement.

[1162] Notebook entry [Alliance employee] 9 October 2013, page 6 (URN: PRO-E003981).

is therefore inconsistent with the existence of an agreement between Alliance and Lexon.[1163]

5.416 Alliance has however since confirmed that the author of the Alliance notebook was [Alliance employee] of Alliance's Regulatory team.[1164] The fact that [Alliance employee], a member of the Alliance regulatory team, was contemplating in September 2013 checking RAMA to see whether competitor marketing authorisations had been granted for P and/or POM Prochlorperazine 3mg buccal tablets does not refute that Lexon and Alliance had by that time entered into the Market Exclusion Agreement.

Subsequent conduct - Lexon

Introduction and section summary

5.417 The CMA sets out in this section documentary evidence and conduct of Lexon subsequent to the conclusion of the Implementing Agreements that provides further evidence of the existence of the Market Exclusion Agreement, including:

5.417.1 Lexon's documentation following the Focus-Lexon Heads of Terms records that Lexon anticipated earning healthy returns without launching the Medreich product, and that it would not launch its own product;

5.417.2 Lexon did not order any Prochlorperazine POM product from Medreich until an order for a single batch was placed on 23 June 2015;

5.417.3 [Lexon Director 1]'s witness evidence about consistently seeking Prochlorperazine POM product from Medreich is not persuasive; and

5.417.4 Lexon evidence relating to the Primegen second profit share renegotiation is supportive of the existence of the Market Exclusion Agreement.

Lexon documentation following the Focus-Lexon Heads of Terms records that Lexon anticipated earning healthy returns without launching the Medreich product, and that it would not launch its own product

5.418 Focus and Lexon concluded the Focus-Lexon Heads of Terms by 1 August 2013 (see paragraph 5.275 above). The Focus-Lexon Heads of Terms provided for Focus to distribute the product Lexon had developed with Medreich, but also

[1163] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 40 (URN: PRO-C5092).

[1164] Section 26 response of Alliance dated 12 December 2019, to CMA notice of 26 November 2019, response to question 4 (URN: PRO-C5491).

provided that Focus would pay Lexon 75% of profits on sales of Prochlorperazine POM from any source. In practical terms, in August 2013, such sales could only have been of Alliance's product as Alliance remained the only licence holder of Prochlorperazine POM product in the UK: Medreich had obtained the licence for the P product on 3 July 2013 (see paragraph 3.62), but did not subsequently obtain its licence for Prochlorperazine POM until 9 January 2014 (see paragraph 3.203); no further licences for Prochlorperazine POM were obtained until Primegen obtained its licence in February 2016.

5.419 Contemporaneous evidence from Lexon shows that (i) in September 2013 [Lexon Director 1] expected to obtain revenues from Prochlorperazine POM even though Medreich was yet to obtain a licence; and (ii) [Lexon Director 1] regarded Prochlorperazine POM as having been launched when Alliance Prochlorperazine POM product was first sold though Focus:

5.419.1 On 12 September 2013, [Lexon Director 1] informed the Lexon Board that '*Prochlorperazine is due to be launched next month from which healthy returns are expected*'.[1165]

5.419.2 Lexon Board Minutes of 14 January 2014 record that (despite the fact that the Medreich licence had only recently been granted and no Medreich Prochlorperazine POM had been produced), ' *[Lexon Director 1] discussed the status of drug development. Prochlorperazine has now been launched ….*'.[1166]

5.420 [Lexon Director 1]'s statements in this respect are supportive of the existence of the Market Exclusion Agreement:[1167]

5.420.1 given the timing and context, these references in September 2013 and January 2014 are to Focus' launch of the Alliance product that was de-branded in December 2013, and Lexon's expectation that it would receive profits on the sale of the Alliance product by Focus;

5.420.2 the Lexon board minutes do not reference the delay to the obtaining of the Medreich Prochlorperazine POM product or the expected timing gap between receipt of the licence and manufacture and sale of any Medreich product; and

[1165] Meeting minutes entitled *'Lexon (UK) Limited Board meeting minutes'* 12 September 2013, page 2 (URN: PRO-C0054).

[1166] Meeting minutes entitled *'Lexon (UK) Limited Board meeting minutes'* 14 January 2014, page 3 (URN: PRO-E000374).

[1167] The CMA does not accept Advanz's representation that the documents in question '*contain ambiguous, even obscure, statements*' from [Lexon Director 1] (Advanz RLF, 22 April 2021, paragraph 4.91 (URN: PRO-C7112)). The meaning of the documents is clear in the wider context of the other documentary evidence that supports the existence of the Market Exclusion Agreement at this point in time.

5.420.3 [Lexon Director 1]'s expectation of '*healthy returns*' from Prochlorperazine POM related to the receipt of profits from Focus on sale of the Alliance product, and the absence of any commentary on the returns that may be generated from the Lexon/Medreich product or the timing of its launch is supportive of the existence of the Market Exclusion Agreement.

5.421 Further, in an email between [Lexon Director 1] and a third party business contact of 3 December 2013, [Lexon Director 1] referred to the Alliance product, to be sold by Focus, as '*It's mine*'.[1168] The fact that [Lexon Director 1] described the Alliance product to be sold by Focus as being his shows that, in late 2013, following the agreement between Alliance and Lexon, and the conclusion of the Focus-Lexon Heads of Terms, [Lexon Director 1] regarded Lexon's commercial position in relation to Prochlorperazine POM as relating to the Alliance/Focus product – rather than being dependent on Medreich obtaining a licence and manufacturing and selling a product. This is supportive of the existence of the Market Exclusion Agreement agreed between Alliance and Lexon, pursuant to which Lexon and Medreich would not need to manufacture the product that they had developed together.

5.422 Contemporaneous documentary evidence from Lexon is clear that, having made the agreement with Alliance and implemented this through the Focus-Lexon Heads of Terms, Lexon did not want Medreich to produce product once it had obtained its licence on 9 January 2014. Specifically, shortly after Focus started selling the debranded Alliance Prochlorperazine POM in December 2013, on 4 February 2014, [Lexon Director 1] responded to an email from [Medreich Employee 1] relating to commercialisation of prochlorperazine. [Medreich Employee 1] had queried: '*We have 3 licenses [sic]. According to me the Focus deal is on the 3mg POM licence only? So we should start the work now to introduce the 3 mg P and the 5 mg in Medreich livery. I think we should also get ready to do the 3 mg POM as well, even if only so that Alliance cannot try to increase the Purchase price going forward*'. [Lexon Director 1] responded:

> *'3mg POM is best left alone as we make far much [sic] more as it is. I have agree [sic] that we make a batch every 3 years and drift it into the Alliance stock…(can I have the batch size so I can plan)*
>
> *… The 5mg – its [sic] all down to COG's - … If we can make it work then happy to proceed."*[1169]

[1168] Email [Lexon Director 1] to [Alissa Healthcare employee] entitled '*Re: Prochlorperazine 3mg … Focus*' 3 December 2013 (URN: PRO-E000343). The CMA infers that this must be a reference to the Alliance product, to be sold by Focus, as, in December 2013, Medreich had not yet obtained an MA for the Prochlorperazine POM product. [Lexon Director 1] stated that this was a reference to the Focus-Lexon Heads of Terms under which sales of product '*were Lexon's even though product may have been sourced from elsewhere until I was in a position to supply*' (Lexon RLF, 21 April 2021, paragraph 27 (URN: PRO-C7104)).

[1169] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

5.423 This email provides clear evidence that Lexon had agreed not to supply commercial volumes of the Prochlorperazine POM product it had developed with Medreich on the basis that the agreement Lexon had reached with Alliance would result in Lexon and Medreich making '*far much [sic] more*' than competing with Alliance. The plain wording of [Lexon Director 1]'s email of 4 February 2014 is also clear that he had made an agreement that a batch of Medreich stock would be produced every three years. This would provide for the maintenance of the licence as regards the Sunset Clause.

5.424 Lexon's commercial position in relation to Prochlorperazine POM contrasts with the position that it took in relation to prochlorperazine 5mg tablets (which were made using the same API[1170]). As cited above, [Lexon Director 1] confirmed to Medreich on 4 February 2014 that he was '*happy to proceed*' regarding the supply of the 5mg product. As a result of those written instructions from Lexon in February 2014, Medreich plc subsequently placed an internal order for prochlorperazine 5mg tablets in March 2014, but – importantly – did not do so for Prochlorperazine POM.[1171]

[Lexon Director 1]'s claims that the documents do not suggest an intention for Medreich not to produce commercial volumes of the product

5.425 [Lexon Director 1] commented in relation to the documents cited at paragraph 5.419 above that '*I was reporting that I expected healthy returns from the PRO POM as I was constantly reassured by Medreich that the product was coming*'.[1172] However, he had previously stated that the reference in the 12 September 2013 Lexon board minutes to Prochlorperazine '*due to be launched*'[1173] referred to the '*activation of the Focus Agreement*'.[1174] The CMA finds that [Lexon Director 1]'s explanation in his witness statement – that the expectation of healthy returns referred to profit share under the Focus-Lexon Heads of Terms – more coherently explains this reference given the timing of the 12 September 2013 board meeting and the fact that no Medreich Prochlorperazine POM licence had been obtained by that point. This reading is confirmed by the content of [Lexon Director 1]'s 4 February 2014 email.

[1170] Medreich submission 21 March 2019 in response to the CMA questions of 15 March 2019, response to question 1.1 (URN: PRO-C3856).

[1171] Medreich submission 8 November 2021 in response to the CMA questions of 22 October 2021, paragraphs 2.2, 2.3 and 2.5 (URN: PRO-C7817).

[1172] Lexon RLF, 21 April 2021, paragraph 26 (URN: PRO-C7104).

[1173] Meeting minutes entitled *'Lexon (UK) Limited Board meeting minutes'* 12 September 2013, page 2 (URN: PRO-C0054).

[1174] Witness Statement of [Lexon Director 1] 31 July 2019, paragraph 71 (URN: PRO-C5092).

5.426 In his initial witness interview with the CMA, [Lexon Director 1] was not able to provide a coherent explanation for the content of his email of 4 February 2014.[1175]

5.427 In his subsequent witness statement provided to the CMA, provided in response to the Statement of Objections, [Lexon Director 1] commented on his email of 4 February 2014, stating that he did not recall the email, but that as a result of the Focus-Lexon Heads of Terms, Lexon and Medreich '*were in fact doing well and I thought that perhaps there was benefit in not pushing production of the 3 mg POM Product*'. [Lexon Director 1] denied Lexon was party to the Market Exclusion Agreement, but rather he was '*simply acknowledging the commercial advantage which had arisen entirely fortuitously*'. He added that the short time taken to prepare the response email indicated that his response was '*not fully considered*'. Importantly, he added that he was:

> *'wrong in suggesting that we were making more money taking a profit share on Focus sales of the Alliance Product than if we were able to sell the Medreich Product'* and he *'realised this fairly quickly and in early February 2014 instructed [Medreich Director 2] to order a batch of [✂] 3 mg POM Product'*.[1176]

5.428 In support of this claim that his statement in his email of 4 February 2014 was not fully considered, [Lexon Director 1] provided in his witness statement some outline calculations to support his claim that Lexon would have made more money through selling the Medreich product than taking a profit share of Focus' sales of the Alliance product.[1177]

5.429 Later in his witness statement, [Lexon Director 1] addressed the impact of the price rises implemented by Focus on Lexon's incentives and stated that, although Lexon was, fortuitously, benefiting from these price rises through the profit sharing provision, the increase in the price made him '*keener still to get supplies from Medreich because we would have made much more money since the cost price of*

[1175] [Lexon Director 1] stated: '*On that, that wasn't my intention. But we don't make more on it as it is we would have made far much more money far much more money if we manufactured ourselves so I can't understand why I wrote that. I've agreed to make batches every three years, well I hadn't … I don't recall the email and I don't recall my mind-set of why I've written what I've written*' (Interview [Lexon Director 1] Part 1 CD4, page 25, lines 10 to 14 and page 29, line 27 to page 30, line 1 (URN: PRO-C3189)).

[1176] Witness Statement of [Lexon Director 1], 31 July 2019, paragraphs 81-82 (URN: PRO-C5092).

[1177] See [Lexon Director 1] Witness Statement, 31 July 2019 paragraphs 60-64 (URN: PRO-C5092). In its representations on the Statement of Objections, Lexon submitted that, judged in May/June 2013, Lexon would have made more money by selling the Medreich product given that its cost of goods was circa [✂] compared to £5.65 a pack for the Alliance product (Lexon RSO, 31 July 2019, paragraph 32 (URN: PRO-C5091)). For the reasons set out below, this analysis is overly simplistic. Most notably, it ignores the impact of price rises in the absence of competition between the Alliance and Lexon/Medreich products.

the Product from Medreich was only around [✂], whereas the cost price to Focus of the Alliance product in September 2017 was £5.65 [sic]'.[1178]

5.430 The CMA rejects [Lexon Director 1]'s evidence as regards his email of 4 February 2014 for the following reasons.

5.430.1 The evidence does not support [Lexon Director 1]'s claim that his instruction to Medreich not to commercialise the product was based upon a temporary misjudgement regarding the profitability of commercialising his product versus receiving payments while not supplying.

(a) As outlined above, [Lexon Director 1] had commented since 12 September 2013 on the '*healthy returns*' that could be earned via the Alliance product.

(b) It is evident that when explaining the arrangement to Medreich in his email of 4 February 2014 [Lexon Director 1] had made clear that the payments were made on the basis that the Lexon/Medreich product would not be commercialised – as evident from his reference to producing a batch every three years.

(c) It is also apparent from [Medreich Employee 1]'s prior email to [Lexon Director 1] on 4 February 2014 that [Lexon Director 1] must already have previously informed [Medreich Employee 1] that the intention was not to commercialise the Prochlorperazine POM product. This is because, having outlined his understanding that the agreement with Focus related only to Prochlorperazine POM and that Medreich should take steps to enter the market in respect of the 3mg OTC product and prochlorperazine 5mg tablets, [Medreich Employee 1] suggested in his email of 4 February 2014 that Medreich also *'get ready to do the 3 mg POM as well, even if only so that Alliance cannot try to increase the Purchase price going forward'* and that while Medreich was '*extremely happy with the deal on the table!*', Medreich would *'however have to be able to sell batches <u>at some stage</u> either in our of [sic] Focus livery as OLS <u>as you suggest</u>…'* (emphasis added).[1179]

5.430.2 Similarly, in the period afterwards, it is evident that [Lexon Director 1] remained of the view that Prochlorperazine POM should not be commercialised given the fact that he did not place an order with Medreich until 23 June 2015 (see paragraphs 5.434 to 5.455 below) and the fact

[1178] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 75 (URN: PRO-C5092). In fact, the transfer price from Focus to Alliance in September 2017 was £6.10 (see paragraph 3.175).

[1179] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled '*Products*' 4 February 2014 (URN: PRO-E002744).

that he had by 28 March 2014 informed [Medreich Employee 1] that Medreich could budget its share of the profit share as being £300,000 '*per year*': that annual profits figure of £300,000 was based entirely on Medreich's anticipated share of profit share payments relating to Focus' sale of the Alliance product.[1180]

5.430.3 [Lexon Director 1]'s *ex post* profitability analysis set out in his witness statement contains a number of unrealistic assumptions and fails to take account of the increases in Focus' price that were possible in the absence of price competition between the Alliance and Lexon/Medreich products (see Annex D:).

5.430.4 [Lexon Director 1]'s claims that Lexon would have been incentivised to enter even as the price rose (see paragraph 5.429) is also not accepted. His analysis ignores: (i) the likely impact of price competition between the Alliance and Lexon/Medreich products and (ii) the fact that sales of the Lexon/Medreich product would only cover a portion of the market, not all of it (see Annex D:).

5.430.5 [Lexon Director 1]'s statement that he realised he had misjudged profitability in his email of 4 February 2014 and therefore, in early February 2014, instructed [Medreich Director 2] to order a batch of [✂] Prochlorperazine POM tablets is not supported by the evidence as regards the date of Lexon ordering product from Medreich or, relatedly, Medreich plc's placing of an order internally with its production arm (see paragraphs 5.434 to 5.455 below).

5.430.6 When [Medreich Employee 1] replied the following day to [Lexon Director 1]'s email of 4 February 2014, confirming that '*3 mg we leave to you for the time being*', [Lexon Director 1] did not respond to say that he had made a mistake or changed his mind: rather, he commented on another drug product and then said '*Other points are fine*', confirming his approval.[1181]

5.431 [Lexon Director 1] did not comment in his witness statement on the sentence contained in his 4 February 2014 email, '*I have agree [sic] that we make a batch every 3 years and drift it into the Alliance stock…*', and stated that he did not recall

[1180] Email [Medreich Employee 1] to [Medreich Director 1] cc [Medreich employee] and [Medreich Director 2] entitled '*RE: Prochlorperazine 3 mg x 50 Focus'* 28 March 2014 (URN: PRO-E002787): '*Talked to [Lexon Director 1] As [sic] per the attached we can budget our share of the profit share per year of £300k. There is an upside for our profit of £95k, if we can get a trade price increase*.' The attachment confirms that the sum of £300,000 is expected to relate solely to profits earned by Focus on the sale of the Alliance product (URN: PRO-E002788). No reference is made to profit share payments that were expected to be earned in relation to sale of the Medreich product.

[1181] Email [Lexon Director 1] to [Medreich Employee 1] entitled '*RE: Products*' (URN: PRO-E002751).

the email,[1182] but in response to a specific CMA question on this, Lexon submitted that:

> *'[Lexon Director 1] says that there was no specific agreement to which he was referring here. [Lexon Director 1] believes that he was responding to the first paragraph of [Medreich Employee 1]'s email regarding the need to initiate the commercialisation of Prochlorperazine and his concern that "to maintain our licences we have to have an API site inspection reports". The response from [Lexon Director 1] makes sense if we delete the word "have". Accordingly, [Lexon Director 1] was simply observing that to avoid the difficulty alluded to "I [ ] agree that we make a batch every 3 years". [Lexon Director 1] did not agree that he would "only" agree to make a batch every three years and that is not what his email says. He is only pointing out that the maintenance of the licences can be satisfied by making a batch every three years and drifting it into the Alliance stock. [Lexon Director 1] says that the reference to drifting product into the Alliance stock was a phrase used to describe introducing product into a market where there is an established supplier slowly in order not to destabilise the market and the market price.'*[1183]

5.432 The CMA does not consider Lexon's explanation that [Lexon Director 1] was in fact agreeing with [Medreich Employee 1]'s prior email to be persuasive.

5.432.1 [Lexon Director 1] did not provide this explanation of the phrase in his initial interview, stating that he did not know why he had written that sentence, but that he was probably just '*fobbing off*' [Medreich Employee 1].[1184]

5.432.2 [Lexon Director 1]'s inclusion of the word '*have*' clearly indicates that he is referring to a past agreement, as opposed to expressing his agreement in the present tense with [Medreich Employee 1]'s previous email.

5.432.3 [Lexon Director 1]'s clearly stated position in his reply email was that he was *not* agreeing with [Medreich Employee 1]'s suggestion that '*we should also get ready to do the 3mg POM as well*': to the contrary, [Lexon Director 1] stated in the preceding sentence that '*The 3mg POM is best left alone*'.

5.432.4 Further, in his prior email, [Medreich Employee 1] had not suggested anything about producing a single batch every three years, such that

[1182] Witness Statement of [Lexon Director 1], 31 July 2019, paragraph 81 (URN: PRO-C5092).

[1183] Lexon submission 10 December 2019 in response to CMA questions of 26 November 2019, response to question 6 (URN: PRO-C5477).

[1184] Interview [Lexon Director 1] Part 1 CD4, page 26, line 25 to page 27, line 2 (URN: PRO-C3189)).

[Lexon Director 1] cannot have been agreeing with any such suggestion on the part of [Medreich Employee 1].

5.432.5 The specificity of [Lexon Director 1]'s phrase about '*a batch every 3 years*' matches far more closely as a description of what had been agreed between Alliance and Lexon, consistent with the [Alliance Director 1] notebook entry[1185] (see paragraph 5.194 above), than to [Medreich Employee 1]'s commentary in the email to which [Lexon Director 1] was responding.

5.432.6 The wording of [Lexon Director 1]'s email refers to actions that would necessarily be taken by Focus, such that the meaning that [Lexon Director 1] seeks to attribute to it is not credible. [Lexon Director 1] could not agree with [Medreich Employee 1] that the single batch of product would be drifted into Alliance stock, as it was not Lexon that supplied the Alliance product.

5.433 On the basis of the above, the CMA finds that the documentary evidence described above demonstrates that, when Medreich was granted its licence in January 2014, Lexon did not intend to produce the Medreich product on the basis that it would instead receive profit share payments from Focus. The contemporary documentation represents further evidence that Lexon had already agreed with Alliance pursuant to the Market Exclusion Agreement that Lexon (and Medreich) would be paid a share of Focus' profits on the sale of the Alliance product in return for its commitment not to enter the market.

Lexon did not order any Prochlorperazine POM product from Medreich until an order for a single batch was placed on 23 June 2015

5.434 Despite the fact that Medreich's Prochlorperazine POM licence was granted on 9 January 2014, Lexon did not place a formal order or give a written instruction to Medreich for Prochlorperazine POM until 23 June 2015,[1186] and that order was for a single batch, equating to [✂] packs of 50 tablets.[1187] Further, contrary to [Lexon Director 1]'s (Lexon) claim in his witness statement[1188] that in early February 2014 (and implicitly on 5 or 6 February[1189]) he instructed Medreich to order a batch of [✂] Prochlorperazine POM tablets, no such order or instruction was placed.

[1185] [Alliance Director 1] Notebook entry CXH005 p36 (URN: PRO-E003980).

[1186] Medreich submission 21 March 2019 in response to the CMA questions of 15 March 2019, question 2.1 (URN: PRO-C3856).

[1187] Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: FW: batch size*' 23 June 2015 (URN: PRO-E002980) and attachment '*Lexon PO – 416174*' (URN: PRO-E002981).

[1188] [Lexon Director 1] Witness Statement 31 July 2019, paragraphs 81-82 (URN: PRO-C5092).

[1189] [Lexon Director 1] stated that he realised the statements he made in his email of 4 February 2014 were wrong '*fairly quickly*' and this was confirmed in an email of [Medreich Director 2] of 6 February 2014, discussed at paragraph 5.443 below ([Lexon Director 1] Witness Statement 31 July 2019, paragraph 82 (URN: PRO-C5092)). On this basis, [Lexon Director 1]'s claim appears to be that he placed the oral order on 5 or on 6 February 2014. The CMA notes, however,

5.435 Medreich has stated to the CMA in written evidence that in relation to Prochlorperazine POM:[1190]

5.435.1 it had not been able to locate any record of Lexon placing an oral order with Medreich to produce a batch of Prochlorperazine POM on 5 or 6 February 2014 (that is, immediately after [Lexon Director 1]'s email of 4 February 2014);[1191]

5.435.2 it does not consider it likely that Lexon placed an oral order with Medreich to produce a batch of Prochlorperazine POM on 5 or 6 February 2014, for the following reasons:[1192]

(a) Medreich's procedures required written orders – generally written purchase orders, or occasionally another form of written instruction from the customer such as an email.[1193] Lexon was therefore required to place orders with Medreich by submitting a written purchase order or providing another form of written instruction. Such a purchase order or written confirmation was (and is) required before Medreich plc can raise a corresponding purchase order with Medreich Ltd's manufacturing facility in India. In turn, Medreich Ltd required a purchase order from Medreich plc before itself raising relevant purchase orders for the required input materials, such as API, packaging foil etc. An oral order would not have been consistent with those procedures; and

(b) Medreich considers that an order by Lexon (whether oral or written) requiring Medreich to produce a batch of Prochlorperazine POM on 5 or 6 February would be inconsistent with the email communications sent between Medreich and Lexon around that time, including [Lexon Director 1]'s instruction on 4 February 2014 that '*The 3mg POM is best left alone as we make far much [sic] more as it is*',[1194] [Medreich Director 2]'s email of 5 February 2014 to [Medreich Employee 1] stating '*ok to go with his strategy, just need to make a batch as he*

that [Lexon Director 1]'s email to Medreich on 5 February 2014 does not suggest that had made a mistake the day before: see paragraph 5.430.6 citing Email [Lexon Director 1] to [Medreich Employee 1] entitled '*RE: Products*' (URN: PRO-E002751).

[1190] Medreich submission, dated 10 December 2019, in response to the CMA questions of 26 November 2019 (URN: PRO-C5472), Medreich submission, dated 12 December 2019, in response to the CMA questions of 26 November 2019 (URN: PRO-C5489) and Medreich submission, dated 8 November 2021, in response to the CMA questions of 22 October 2021 (URN: PRO-C7817).

[1191] Medreich submission, dated 10 December 2019, in response to the CMA questions of 26 November 2019, paragraph 1.1 (URN: PRO-C5472).

[1192] Medreich submission, dated 10 December 2019, in response to the CMA questions of 26 November 2019, paragraph 1.2 (URN: PRO-C5472).

[1193] Medreich submission, dated 8 November 2021, in response to the CMA questions of 22 October 2021, paragraphs 1.1 and 1.2 (URN: PRO-C7817).

[1194] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

agress [sic] also'[1195] and the exchange between [Medreich Director 2] and [Lexon Director 1] of 6 February 2014 asking about the feasibility of doing a 28 pack for Prochlorperazine POM or OTC;[1196]

5.435.3 Medreich's internal due diligence confirmed that the first order received for Prochlorperazine POM from Lexon was on 23 June 2015. Medreich's manufacturing facility was not able to locate any evidence of an order being made by Lexon prior to this time, and nor does it have any evidence of the relevant materials that would be required to fulfil an order of Prochlorperazine POM being purchased prior to this time;[1197]

5.435.4 Medreich plc first placed an order for Prochlorperazine POM with Medreich Ltd, its manufacturing arm, on 23 June 2015 for [✂] packs after receipt of Lexon's purchase order for the equivalent volume submitted on the same day;[1198]

5.435.5 Medreich's current policy is that it will not produce a validation batch unless it has a written purchase order from a customer. Medreich expects that this was also the policy at the time the Prochlorperazine POM validation batches were first produced;[1199]

5.435.6 the first validation batch of [✂] packs of 50 tablets each, amounting to [✂] tablets (i.e. the minimum batch size), was produced in November 2016 (batch number 361016), with an expiry date of October 2018, but was subsequently identified to have a technical problem and was destroyed;[1200] and

5.435.7 the second validation batch (batch number: 370729) was produced in August 2017 and shipped in September 2017 and [✂] of these packs were supplied to Lexon on 28 November 2017.[1201]

5.436 The direct Medreich evidence in relation to Prochlorperazine POM accords with the fact that the CMA is not aware of any contemporaneous documentary evidence confirming or supporting [Lexon Director 1]'s claim that he placed an oral order with

[1195] Email [Medreich Director 2] to [Medreich Employee 1] entitled '*FW: Products*' 5 February 2014 (URN: PRO-E002746).

[1196] Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: Prochlorperazine*' 6 February 2014 (URN: PRO-E002756).

[1197] Medreich submission, dated 10 December 2019, in response to the CMA questions of 26 November 2019, paragraphs 1.3 to 1.5 (URN: PRO-C5472).

[1198] Medreich submission, dated 8 November 2021, in response to the CMA questions of 22 October 2021, paragraphs 4.1 and 4.2 (URN: PRO-C7817).

[1199] Medreich submission, dated 12 December 2019, in response to the CMA questions of 26 November 2019, paragraph 2.3 (URN: PRO-C5489).

[1200] Medreich submission, dated 12 December 2019, in response to the CMA questions of 26 November 2019, paragraph 2.4, Table 1 (URN: PRO-C5489).

[1201] Medreich submission, dated 12 December 2019, in response to the CMA questions of 26 November 2019, paragraph 2.4, Table 1 (URN: PRO-C5489).

Medreich for Prochlorperazine POM on 5 or 6 February 2014.[1202] This position is also corroborated by the steps that Medreich took to commence supply of prochlorperazine 5mg tablets in contrast to the absence of such steps for Prochlorperazine POM:

5.436.1 As outlined in paragraphs 5.422 to 5.424 above, [Lexon Director 1] had stated to [Medreich Employee 1] in his email of 4 February 2014 that, unlike for Prochlorperazine POM, he was '*happy to proceed*' with regard to prochlorperazine 5mg.[1203]

5.436.2 As a result of receipt of this written instruction from Lexon, Medreich proceeded to place an order with Medreich Ltd for prochlorperazine 5mg tablets on 21 March 2014 and produced a validation batch for prochlorperazine 5mg tablets in September/October 2014.[1204]

5.437 If [Lexon Director 1] had, as he claimed, instructed Medreich orally to produce Prochlorperazine POM in early February 2014, it would have been expected that Medreich plc would have included Prochlorperazine POM in its internal order to Medreich Ltd on 21 March 2014 alongside prochlorperazine 5mg tablets which, Medreich has confirmed, it could have done.[1205] For the sake of completeness, even if [Lexon Director 1] had attempted in early February 2014 to give such an instruction orally, but Medreich had required written confirmation, Medreich could simply have asked him to submit a purchase order, as it did when he indicated that Medreich should proceed with Prochlorperazine POM on 22 June 2015,[1206] placing the order the day after.[1207]

5.438 Medreich's evidence that Lexon did not place an order for Prochlorperazine POM product with Medreich until 23 June 2015 is consistent with contemporaneous Medreich documentation from March 2014 (that is, *after* [Lexon Director 1] claimed he ordered product from Medreich on 5 or 6 February 2014) which demonstrates Medreich budgeting future Prochlorperazine POM profit based on receipt of profit share income on Focus' sale of the Alliance product.[1208] Such budgeting by

[1202] The email correspondence between [Focus Director 1] and [Lexon Director 1] of 4 November 2014 which refers to the placement of an order of Prochlorperazine POM is discussed in paragraph 5.439 below (email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832)).

[1203] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

[1204] Medreich submission, dated 8 November 2021, in response to the CMA questions of 22 October 2021 paragraphs 2.2, 2.3 and 3.1 (URN: PRO-C7817).

[1205] Medreich submission, dated 8 November 2021, in response to the CMA questions of 22 October 2021 paragraph 2.5 (URN: PRO-C7817).

[1206] Email [Medreich Director 2] to [Lexon Director 1] entitled '*RE: FW: batch size*' 22 June 2015 (URN: PRO-E000517): '*Can you please place an order at [✂] please for [✂] packs*'.

[1207] Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: FW: batch size*' 23 June 2015 (URN: PRO-E000521): '*Enclosed as requested*' and attached Lexon purchase order dated 23 June 2015 (URN: PRO-E000522).

[1208] On 28 March 2014, [Medreich Employee 1] emailed [Medreich Director 1] attaching an excel spreadsheet entitled '*Prochlorperazine 2014 budget*' that set out details of the profit share Medreich would receive based on Focus' sales of the Alliance product. In the cover email, [Medreich Employee 1] stated that Medreich could budget that it would generate

Medreich would be inconsistent with Lexon having urged Medreich to begin production of the Medreich Prochlorperazine POM product at that time, which would inevitably have disrupted or caused to cease the revenue stream that Lexon and Medreich were enjoying.

5.439 The only documentary evidence referring to an order prior to the date of the written Lexon purchase order on 23 June 2015 is an email exchange between [Focus Director 1] and [Lexon Director 1] of 4 November 2014, which is said to summarise the outcome of a meeting held on 3 November 2014, and that states that Lexon had placed an order at that time. In that email [Focus Director 1] stated:

> *'Following our meeting yesterday I am just confirming the agreement regarding prochlorperazine 3mg tabs .*
>
> ***You have placed an order for stock** and would expect the stock to arrive in early 2015, once you have a confirmed date I can place a purchase order on you for the stock. …'* (emphasis added).[1209]

5.440 However, in the absence of any record of the order referred to by [Focus Director 1] or any further correspondence about the progress or whereabouts of the order, and given the existence of the subsequent order, it appears highly unlikely that any such order had in fact been made by [Lexon Director 1] at the time. The CMA finds therefore that, whatever the rationale for [Focus Director 1]'s statement (see paragraphs 5.612 to 5.616 below for the CMA's detailed analysis of this email), this evidence does not undermine the Medreich evidence set out above demonstrating that Lexon did not place an order until 23 June 2015 (see paragraph 5.435 above) which itself is consistent with [Lexon Director 1]'s expressed view on 4 February 2014 that the '*3mg POM is best left alone as we make far much [sic] more as it is*'.[1210]

5.441 Lexon's order of a single batch of product in June 2015 provides support for the existence of the Market Exclusion Agreement. There was no urgency for Lexon to place an order with Medreich initially, but [Lexon Director 1] did later order a single batch, consistent with his agreement with Alliance that he would produce a batch periodically for the purpose of the Sunset Clause.

£300,000 annual profit through the Focus profit share (email [Medreich Employee 1] to [Medreich Director 1] cc [Medreich employee] and [Medreich Director 2] entitled '*RE: Prochlorperazine 3 mg x 50 Focus*' 28 March 2014 (URN: PRO-E002787) attaching Excel Spreadsheet entitled '*Prochlorperazine 2014 budget*' (URN: PRO-E002788)). There is nothing in the email exchange between [Medreich Employee 1] and [Medreich Director 1] referring to Medreich's own production of Prochlorperazine POM.

[1209] Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

[1210] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

[Lexon Director 1]'s claim about having placed an oral order before 23 June 2015 (including in February 2014)

5.442 [Lexon Director 1] accepted that Lexon had not submitted a formal, written order for Prochlorperazine POM until 23 June 2015.[1211] However, he claimed that:

> *'I did instruct Medreich's London office (through [Medreich Employee 1] and/or [Medreich Director 2]) to order the POM Product on many occasions from 30 July 2013 onwards'.*[1212]

5.443 [Lexon Director 1] claimed in his witness statement provided to the CMA that, following the realisation of the mistake about profitability he had made in his email of 4 February 2014 (see paragraph 5.427 above), '*in early February 2014 [I] instructed [Medreich Director 2] to order a batch of [✂] 3 mg POM Product*'.[1213] By way of corroboration of this, [Lexon Director 1] referred to:

5.443.1 an internal Medreich email written by [Medreich Director 2] of 6 February 2014 in which [Medreich Director 2] stated '*we intend to commercialize [sic] Prochlorperazine. The batch size as per dossier is below. Are the batch sizes reproducible in plant as I can then place orders accordingly*';[1214]

5.443.2 [Medreich Director 1]'s CMA interview,[1215] in which [Medreich Director 1] stated that:

(a) three validation batches were manufactured in the first quarter of 2014 but that these batches failed to meet the licensing conditions;[1216] and

(b) Medreich's systems would not allow the manufacture of any product unless a confirmed order was placed.[1217]

[1211] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 85 (URN: PRO-C5092).

[1212] [Lexon Director 1] Witness Statement, 31 July 2019 paragraph 85 (URN: PRO-C5092). [Lexon Director 1] repeated this assertion in Lexon RLF, 21 April 2021, paragraph 28 (URN: PRO-C7104).

[1213] [Lexon Director 1] Witness Statement, 31 July 2019 paragraph 82 (URN: PRO-C5092). The CMA notes that in later representations it was not clear whether Lexon maintained the view that [Lexon Director 1] had in fact placed an oral order for product in early February 2014. Lexon later submitted that '*the first order [by Medreich PLC with Medreich Limited] was, at the latest, 26 August 2014*' (Lexon RLF, 25 November 2021, paragraph 8 (URN: PRO-C7901)) and '*… the facts demonstrate that* ***even if Lexon had ordered*** *a validation batch of the 3mg Product in early 2014 production could not have taken place any earlier than was the case since the initial marketing authorisation had been granted in error and there were delays in auditing API'* (emphasis added) (paragraph 10).

[1214] Email [Medreich Director 2] to [Medreich employee] cc various others at Medreich entitled *FW: Prochloroperazine* [sic]' 6 February 2014 (URN: PRO-E002752). See also in this respect the Lexon RSO, 31 July 2019, paragraphs 26-27 (URN: PRO-C5091).

[1215] Lexon also referred to [Medreich Director 1]'s interview evidence as support for the proposition that the policy for the production of validation batches at Medreich was more informal prior to the acquisition of Meiji, citing [Medreich Director 1]'s claim that validation would start immediately upon the registration for the product being granted (Lexon RLF, 25 November 2021, paragraph 7 (URN: PRO-C7901), citing interview [Medreich Director 1], 22 November 2018, page 58 line 21 to page 60 line 10 (URN: PRO-C3464)).

[1216] Interview [Medreich Director 1], 22 November 2018, page 59, lines 6-17 (URN: PRO-C3464).

[1217] Interview [Medreich Director 1], 22 November 2018, page 184, lines 18-19 (URN: PRO-C3464).

5.444 In addition, Lexon referred in this respect to internal email Medreich correspondence between [Medreich Director 2] and [Medreich employee] of 27 August 2014 referring to '*three bathes [sic] of [✂] are registered*'.[1218]

5.445 The evidence relied on by [Lexon Director 1] and Lexon to support [Lexon Director 1]'s claim that he placed an oral order in early February 2014, or at the latest by 26 August 2014,[1219] is not persuasive for the reasons set out below.

5.446 The email of [Medreich Director 2] of 6 February 2014[1220] does not constitute evidence that [Lexon Director 1] had (on 5 February 2014 or earlier in day the day on 6 February 2014) revoked his recent, prior written instruction to Medreich of 4 February 2014 that Prochlorperazine POM was '*best left alone*'[1221] and placed an order for Prochlorperazine POM product, or otherwise instructed Medreich to produce it. [Lexon Director 1]'s characterisation of [Medreich Director 2]'s email of 6 February 2014 as constituting 'an order' (following an instruction to do the same from Lexon) cannot be sustained:[1222]

5.446.1 [Medreich Director 2]'s email does not constitute an order: to the contrary, he refers to '*plac[ing] orders accordingly*'.

5.446.2 Nor does [Medreich Director 2] make any reference to Lexon having placed an order for Prochlorperazine POM tablets.

5.446.3 The email chain refers to the batch size for both 3mg and 5mg tablets. When [Medreich Director 2] states '*We intend to commercialise Prochlorperazine*', it is not clear on the face of the email itself whether he is referring to prochlorperazine 5mg tablets or prochlorperazine 3mg tablets (whether OTC or POM). In fact, the CMA infers from the fact that [Lexon Director 1] had told Medreich two days previously that he was happy to proceed with prochlorperazine 5mg tablets[1223] and that Medreich proceeded to place an internal order for 5mg prochlorperazine tablets on 21 March 2014[1224] (but not for Prochlorperazine POM), it was more likely that [Medreich Director 2] was referring to prochlorperazine 5mg tablets in

[1218] Lexon RLF, 25 November 2021, paragraphs 7 and 8 (URN: PRO-C7901), citing email [Medreich employee] to [Medreich Director 2] entitled '*RE: Prochloroperazine 3mg*' 27 August 2014 (URN: PRO-E002867).

[1219] Lexon RLF, 25 November 2021, paragraph 8 (URN: PRO-C7901), which stated that the first order by Medreich PLC to Medreich Ltd was, at the latest, 26 August 2014, presumably suggesting therefore that any order or written instruction by Lexon to Medreich must also have been before that point.

[1220] Email [Medreich Director 2] to [Medreich employee] cc various others at Medreich entitled *FW: Prochlorperazine*' 6 February 2014 (URN: PRO-E002752).

[1221] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*RE*: *Products*' 4 February 2014 (URN: PRO-E002750).

[1222] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 85 (URN: PRO-C5092).

[1223] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*RE*: *Products*' 4 February 2014 (URN: PRO-E002750).

[1224] See Medreich submission 21 March 2019 in response to the CMA questions of 15 March 2019, response to question 1.2 (URN: PRO-C3856) and annex order for Prochlorperazine 5mg tablets of 21 March 2014 (URN: PRO-C3857) and Medreich submission 8 November 2021 in response to the CMA questions of 22 October 2021, paragraph 2.1 (URN: PRO-C7817).

his email of 6 February 2014. By way of further context, the prochlorperazine 5mg tablets were delivered to Lexon on 4 June 2015;[1225] in contrast, Medreich did not even internally order Prochlorperazine POM product until 23 June 2015,[1226] as recorded in the Medreich Exco meeting minutes of 24 June 2015 ('*Order for Prochlorperazine has been placed on India, this is the 1 batch required in order to keep the license [sic] active*')[1227] which was then belatedly formally submitted on 10 July 2015.[1228] These timings make it more likely that [Medreich Director 2] was referring to prochlorperazine 5mg tablets in his email of 6 February 2014.

5.446.4 [Medreich Director 2] was still referring in internal Medreich correspondence to his *intention to place* an order regarding Prochlorperazine POM (as opposed to having *placed* an order) in June 2015: on 18 June 2015, he emailed a colleague stating '*We intend to place commercial orders for the below 2 products [including Prochlorperazine 3mg Buccal Tablets]. Please advise lowest commercial batch possible in order to place orders.*'[1229]

5.446.5 Medreich's correspondence with [Lexon Director 1] between 19 and 23 June 2015 is not consistent with [Lexon Director 1] having previously instructed Medreich to produce a batch of Prochlorperazine POM. [Medreich Employee 1] advised [Lexon Director 1] of the minimum batch size on 19 June 2015, and then [Medreich Director 2] asked [Lexon Director 1] how many batches he wanted and in what pack size on 22 June 2015.[1230] Such questions would have been unnecessary had [Lexon Director 1] already instructed Medreich to proceed with an order of a Prochlorperazine POM batch. Following confirmation from [Lexon Director 1] on 22 June 2015 that he only wanted one batch of Prochlorperazine POM, [Medreich Director 2] replied to him expressly to request that [Lexon Director 1] '*place an order at [✂] please for [✂] packs*'.[1231]

5.447 The interview evidence given by [Medreich Director 1] about validation starting immediately after receipt of the licence and the production of three validation

[1225] Medreich submission 21 March 2019 in response to the CMA questions of 15 March 2019, response to question 1.4 (URN: PRO-C3856).

[1226] Medreich submission 8 November 2021 in response to the CMA questions of 22 October 2021, paragraph 4.1 (URN: PRO-C7817).

[1227] Email [Medreich employee] to various Medreich colleagues entitled '*Exco minutes*' 29 June 2015 (URN: PRO-E002984) attaching '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich PIC Offices'* 29 June 2015 (URN: PRO-E002985).

[1228] The order for Prochlorperazine POM was in fact not raised with Medreich India until 10 July 2015 (Email [Medreich Director 2] to [Medreich employee] entitled '*Re: Prochlorperazine 3mg order*' 10 July 2015 (URN: PRO-E002997) and email from [Medreich employee] to [Medreich employee] and [Medreich Director 2] cc various others entitled '*RE: Prochloroperazine 3mg order*' 10 July 2015 (URN: PRO-E002998)).

[1229] Email [Medreich Director 2] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled *'FW: batch size'* 18 June 2015 (URN: PRO-E002974).

[1230] Email [Medreich Director 2] to [Lexon Director 1] entitled *'RE: FW: batch size*' 22 June 2015 (URN: PRO-E000517).

[1231] Email [Medreich Director 2] to [Lexon Director 1] entitled *'RE: FW: batch size*' 22 June 2015 (URN: PRO-E000517).

batches in the first quarter of 2014 cannot be reconciled with the detailed evidence given by Medreich, which clearly and precisely contradicts [Medreich Director 1]'s account of the timing of such validation batches. That evidence confirms that the validation batches were in fact produced in November 2016 and then August 2017 (see paragraph 5.435 above), and that even the validation batch for prochlorperazine 5mg tablets, which had been ordered internally by Medreich in March 2014, was not produced until September/October 2014.[1232] The evidence provided by Medreich is also supported by other contemporaneous documentation on the file that does not suggest that Medreich had produced, or was seeking to produce, validation batches for Prochlorperazine POM during the first quarter of 2014, namely:[1233]

5.447.1 a Medreich meeting note of 7 March 2014 which refers to '*5mg batches to be taken in May 2014*' but does not mention validation batches for the (3mg) Prochlorperazine POM;[1234] and

5.447.2 a Medreich regulatory status chart of March 2014 where the '*Medreich PLC Comments*' column for Prochlorperazine refers to '*Validation Batches of 5mg to be taken in May 2014'* but is silent about the (3mg) Prochlorperazine POM.[1235]

5.448 With respect to the internal Medreich email of [Medreich employee] to [Medreich Director 2] of 27 August 2014,[1236] this does not provide convincing evidence of Lexon having placed an order for product prior to 23 June 2015 (or indeed of Medreich having produced validation batches in 2014). [Medreich employee] states that '*three bathes [sic] of [✂] are registered*' in response to a question from [Medreich Director 2] asking for the registered batch size of Prochlorperazine 3mg tablets. When provided with that information, [Medreich Director 2] then forwarded the information to another Medreich colleague stating:

> *'There maybe a possibility of doing a batch of Prochloroperazine [sic] 3mg.*
>
> *In the license [sic] [✂] tablets batch size is registered.*

[1232] Medreich submission of 8 November 2021 in response to the CMA questions of 22 October 2021, paragraphs 2.1 and 3.1 (URN: PRO-C7817).

[1233] Even if, contrary to Medreich's evidence and the CMA's findings, a validation batch of Prochlorperazine POM had been produced in 2014, this would not change the CMA's finding in relation to Lexon's intention to order only a single batch for the purpose of the Sunset Clause. There is no evidence of which the CMA is aware that, even if a validation batch had been produced in 2014, this was supplied or intended to be supplied to Lexon: Lexon itself confirmed that it received the first batch of Prochlorperazine POM from Medreich on 30 November 2017: Section 26 response of Lexon dated 27 November 2018 to CMA Notice of 7 November 2018, question 2 (URN: PRO-C2977).

[1234] Minutes of meeting 7 March 2014 Medreich Bangalore Office, subject '*Validation Batches Medreich PLC*' (URN: PRO-E002770).

[1235] Table entitled '*Current Regulatory Status of newly acquired Products – updated March 2014*' (URN: PRO-E002771).

[1236] Lexon RLF, 25 November 2021, paragraphs 7 and 8 (URN: PRO-C7901) citing email [Medreich employee] to [Medreich Director 2] entitled '*RE: Prochloroperazine 3mg*' 27 August 2014 (URN: PRO-E002867).

From the equipment point of view are we ok as this is not a big line and we do need small batch sizes.

So if can confirm that [✂] tablets is ok to manufacture will be great.'[1237]

5.449 [Medreich Director 2]'s email is clear he did not understand the reference to '*three bathes [sic] of [✂] are registered*' to be a reference to product having been ordered or produced: to the contrary, he states that, based on that information, there '*maybe [sic] a possibility of doing a batch of Prochloroperazine [sic] 3mg*' and asks '*So if can confirm that [✂] tablets is ok to manufacture will be great*'. The CMA therefore rejects Lexon's reliance on this email as evidence that, in combination with [Medreich Director 1]'s statements about the failed production of validation batches in 2014 (see paragraph 5.447 above), the first order by Medreich plc on Medreich Limited for Prochlorperazine POM was '*at the latest, 26 August 2014*'.[1238] As noted above (see paragraph 5.435) Medreich has stated clearly that Medreich plc first placed an order for Prochlorperazine POM with Medreich Ltd, its manufacturing arm, on 23 June 2015 for [✂] packs after receipt of Lexon's purchase order for the equivalent volume submitted on the same day.[1239]

5.450 By way of rebuttal to [Lexon Director 1]'s claims to have ordered a batch in early February 2014, the CMA relies additionally in this respect on evidence provided by [Medreich Director 2] in a meeting with the CMA, in which he stated that (i) the order process would have necessitated a written purchase order from Lexon to Medreich plc (UK) and then onto Medreich manufacturing in India and (ii) [Lexon Director 1] would either have placed the order formally or would have sent an email instructing Medreich plc (UK) to place the order.[1240] Consistent with [Medreich Director 2]'s account, and Medreich's written evidence as cited above, a written order was placed by [Lexon Director 1] – but only on 23 June 2015. Although the CMA considers that [Medreich Director 2]'s evidence to it in respect of certain points has not been complete and truthful,[1241] the CMA did not find [Medreich Director 2]'s evidence on this point to be incomplete and untruthful; the CMA considers it appropriate to rely on [Medreich Director 2]'s evidence in this respect given that it is line with the evidence obtained from Medreich on this point and

[1237] Email [Medreich Director 2] to [Medreich employee], cc [Medreich employee] entitled '*FW: Prochloroperazine 3mg*' 27 August 2014 (URN: PRO-E002867).

[1238] Lexon RLF, 25 November 2021, paragraph 8 (URN: PRO-C7901). It is not wholly clear whether Lexon considered that the Medreich internal order was actually placed (and acted on) by 26 August 2014: Lexon later submitted in the same submission that '*The Table [in the Medreich response of 8 November 2021 to CMA questions of 22 October 2021] shows that the timeline delay was caused due to a number of errors … which would have applied equally in relation to the three validation batches ordered in August 2014* ***had Medreich proceeded at that time***' (emphasis added, paragraph 9).

[1239] Medreich submission, dated 10 December 2019, in response to the CMA questions of 26 November 2019 (URN: PRO-C5472) and Medreich submission, dated 8 November 2021, in response to the CMA questions of 22 October 2021, paragraphs 4.1 and 4.2 (URN: PRO-C7817)).

[1240] Transcript of meeting with [Medreich Director 2],14 January 2020, page 27, lines 21-25 and page 31, lines 5-9 (URN: PRO-C6019).

[1241] See Final decision of CMA withdrawing immunity from [Medreich Director 2] from director disqualification proceedings 23 October 2020 (URN: PRO-C6362).

because the CMA is not aware of any reason why [Medreich Director 2] would have an incentive to make such an observation were it not in fact accurate.

5.451 In his subsequent evidence to the CMA, [Lexon Director 1] noted that [Medreich Director 2]'s evidence about a written purchase order referred to a physical order from Medreich plc (UK), as opposed to an order from the customer.[1242] Lexon also noted that the information provided by Medreich was that it '*expects'* that, prior to the acquisition by Meiji, Medreich required a written purchase order before producing a validation batch: Lexon stated that Medreich's use of the term '*expects*' in this context shows that Medreich did not *know* that this was the case,[1243] and that prior to the acquisition of Medreich by Meiji, the procedure was much more informal and it was [Lexon Director 1]'s understanding that his verbal orders were accepted by Medreich plc (UK) and passed on to Medreich Limited in India.[1244] [Lexon Director 1] again referenced [Medreich Director 1]'s comments in interview that three validation batches were manufactured in the first quarter of 2014 and that this must have been on the basis of a Lexon order.[1245] In addition, Lexon referred to evidence on the CMA's file (including as discussed in paragraphs 5.447 and 5.448 above) that it says showed that Medreich's policy in this respect prior to the acquisition of Meiji was more informal.[1246] The CMA does not consider [Lexon Director 1]'s and Lexon's representations compelling in this respect:

5.451.1 Whilst the passages of the evidence provided by [Medreich Director 2] in a meeting with the CMA as cited by [Lexon Director 1] and Lexon do at times refer to orders within Medreich, and refer to starting the process verbally, [Medreich Director 2] went on later to state relatively unambiguously that Medreich's internal order would follow back-to-back on Lexon having placed an order and that he would have expected written instructions from Lexon in this respect ('*the least that [Lexon Director 1] would have done is send an email saying [I'm going to place an order]*');[1247] no such written instructions were received until the 23 June 2015 order. This is in contrast to the position in relation to prochlorperazine 5mg tablets in which [Lexon Director 1] had stated on 4 February 2014 '*The 5mg – its [sic] all down to COG's - … If we can make it work then happy to proceed*'.[1248]

[1242] Lexon RLF, 21 April 2021, paragraph 28 (URN: PRO-C7104), citing transcript of meeting with [Medreich Director 2], 14 January 2020, page 27 lines 21-24 (URN: PRO-C6019), and Lexon RLF, 25 November 2021, paragraph 7 (URN: PRO-C7901)), citing transcript of meeting with [Medreich Director 2] 14 January 2020, page 27 line 20 and page 29 line 13 (URN: PRO-C6019).

[1243] Lexon RLF, 25 November 2021, paragraph 6 (URN: PRO-C7901)).

[1244] Lexon RLF, 21 April 2021, paragraph 28 (URN: PRO-C7104)

[1245] Lexon RLF, 21 April 2021, paragraph 28 (URN: PRO-C7104).

[1246] Lexon RLF, 25 November 2021, paragraph 7 (URN: PRO-C7901).

[1247] Transcript of meeting with [Medreich Director 2],14 January 2020, page 31, lines 5-9 (URN: PRO-C6019).

[1248] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

5.451.2 [Medreich Director 2]'s evidence in this respect supports the evidence received from Medreich that it *did* require a written purchase order or some other form of written instruction from a customer prior to raising a purchasing order with its manufacturing facility[1249] and that it would have expected that a written order from the customer would be required prior to manufacture of any validation batch[1250] (see paragraph 5.435 above).

5.451.3 In any event, the Medreich evidence is also very clear that – in contrast to the position regarding prochlorperazine 5mg tablets (see paragraph 5.436 above) – no validation batch for Prochlorperazine POM was produced until November 2016 (see paragraph 5.435 above).[1251]

5.452 [Lexon Director 1] also referred to correspondence between Medreich UK and Medreich India of 27 August 2014, following his own email of 22 August 2014 asking Medreich about batch size for Prochlorperazine POM,[1252] in which [Medreich Director 2] had discussed the potential for manufacture of a batch of Prochlorperazine 3mg.[1253] However, [Medreich Director 2] referred only in that email to the fact that there '***maybe a possibility*** *of doing a batch of Prochloroperazine [sic] 3mg*' (emphasis added) and added '*we do need small batch sizes*'.[1254] The fact that [Medreich Director 2] referred to '*maybe a possibility'* of production, and that he expressly emphasised the need for a small batch are both consistent with the fact that no order had as at August 2014 been placed by Lexon and that, when an order would be placed, that would be for the minimum amount necessary (in order to avoid the application of the Sunset Clause): as [Medreich employee] subsequently wrote on 12 March 2015, '*Sales in UK sheet will be minimal to ensure licence is kept active*'.[1255]

5.453 Further, the content of [Lexon Director 1]'s own email to Medreich of 22 August 2014[1256] itself undermines [Lexon Director 1]'s claim that he had placed an oral order with Medreich by this point. In the email, [Lexon Director 1] asks [Medreich Director 2]: '*Please can you advise batch size and landed and released COGs for prochlorperazine 3mg 50s*'. However, it would be expected that, had [Lexon

[1249] Medreich submission, dated 10 December 2019, in response to the CMA questions of 26 November 2019 (URN: PRO-C5472) and Medreich submission dated 8 November 2021 in response to the CMA questions of 22 October 2021, paragraph 1.2 (URN: PRO-C7817)).

[1250] Medreich submission, dated 12 December 2019, in response to the CMA questions of 26 November 2019 (URN: PRO-C5489).

[1251] Medreich submission, dated 12 December 2019, in response to the CMA questions of 26 November 2019 (URN: PRO-C5489).

[1252] Email [Lexon Director 1] to [Medreich Director 2] entitled '*[No subject]*' 22 August 2014 (URN: PRO-E000434).

[1253] [Lexon Director 1] Witness Statement, 31 July 2019, paragraphs 87 and 88 (URN: PRO-C5092).

[1254] Email [Medreich Director 2] to [Medreich employee], cc [Medreich employee] entitled '*FW: Prochloroperazine 3mg*' 27 August 2014 (URN: PRO-E002867).

[1255] Email [Medreich employee] to [Medreich employee] entitled '*Fluoxetine Licence sale*' 12 March 2015 (URN: PRO-E002945).

[1256] Email [Lexon Director 1] to [Medreich Director 2] entitled '*[No subject]*' 22 August 2014 (URN: PRO-E000434).

Director 1] already placed an order with Medreich, even orally, he would have known the batch size and the cost of goods.

5.454 Finally, [Lexon Director 1] referred to his exchange with Focus on 2 and 3 September 2014[1257] in which [Lexon Director 1] relayed information about the minimum batch size to Focus and provided information about the lead time for ordering of product.[1258] However, this exchange does not suggest that Lexon had already ordered a batch from Medreich: the provision of this information from Medreich to Lexon (and then on to Focus) suggests rather that this batch size information was being provided for the first time, which is inconsistent with [Lexon Director 1]'s claim to have already placed an order at an earlier point, but which is consistent with [Medreich Director 2] referring in internal Medreich correspondence the week prior to there being '***maybe a possibility*** *of doing a batch of Prochloroperazine [sic] 3mg*' (emphasis added) (see paragraph 5.452 above).[1259] Further, notwithstanding the exchange between Focus and Lexon on 3 September 2014, no order was placed by Focus with Lexon, or by Lexon with Medreich at that point (see additionally in this respect paragraphs 5.605 to 5.608 below setting out the CMA's analysis of this email exchange in detail).

CMA conclusion that the first order of Prochlorperazine POM from Lexon was on 23 June 2015

5.455 Based on the evidence set out above, the CMA finds that Lexon did not place an order on Medreich for Prochlorperazine POM until 23 June 2015, which provides evidence in support of the existence of the Market Exclusion Agreement agreed with Alliance. Specifically, the CMA finds that no oral order was placed by Lexon in early February 2014; rather, [Lexon Director 1] proceeded, as did Medreich, on the basis that Lexon and Medreich would continue to receive profit share income from Focus based on sales of the Alliance product, in exchange for Lexon's agreement not to enter the market with the Prochlorperazine POM it had developed with Medreich.

[Lexon Director 1]'s witness evidence about consistently seeking Prochlorperazine POM product from Medreich is not persuasive

5.456 [Lexon Director 1] provided extensive submissions in his witness statement to support the proposition that he had taken all possible steps to bring Prochlorperazine POM to market as soon as possible after grant of the licence[1260] on 9 January 2014. [Lexon Director 1] submitted that there were problems with the Medreich regulatory position, of which he was not made aware until 14 September

[1257] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003813).

[1258] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 89 (URN: PRO-C5092).

[1259] Email [Medreich Director 2] to [Medreich employee], cc [Medreich employee] entitled '*FW: Prochloroperazine 3mg*' 27 August 2014 (URN: PRO-E002867).

[1260] [Lexon Director 1] Witness Statement, 31 July 2019, paragraphs 67 to 106 (URN: PRO-C5092).

2015,[1261] as well as problems with the production of the product (including in particular sourcing of API),[1262] and that these issues explained the delay in production of the product, rather than any lack of incentive on the part of Lexon or Medreich to bring the product to market as a result of the Market Exclusion Agreement.[1263]

5.457 The CMA finds that [Lexon Director 1]'s submissions are not persuasive in this respect, and the evidence he refers to in this regard does not undermine the existence of the Market Exclusion Agreement. Whilst there were regulatory and manufacturing difficulties encountered by Medreich as regards Prochlorperazine POM, these do not explain Lexon and Medreich's conduct and actions. In particular, the CMA has evaluated the evidence cited by [Lexon Director 1] having regard to the CMA's findings, based on Medreich's evidence, that Lexon did not place a written order for Prochlorperazine POM until 23 June 2015 and did not place an oral order with Medreich prior to that (see paragraphs 5.434 to 5.455 above).

5.458 First, [Lexon Director 1] refers to a necessary correction required to the Medreich Prochlorperazine POM licence, which was originally granted on 9 January 2014 but was varied to include a '50s' blister pack on 14 March 2014 (see paragraph 3.215), and difficulties sourcing API, stating additionally that he was not informed about either of these at the time.[1264] However, these points are irrelevant given that – in contrast to prochlorperazine 5mg – [Lexon Director 1] had not placed an order or given written instructions to proceed for Prochlorperazine POM at this point in any event (see paragraphs 5.434 to 5.455 above) and given that this decision by Lexon not to order Prochlorperazine POM was driven by commercial reasons rather than based on an inability to supply product (see paragraph 5.422 and paragraph 5.460 below). The same API was used for both Prochlorperazine POM and prochlorperazine 5mg tablets[1265] and yet the issues Medreich encountered with its API supplier in 2014 did not prevent the production of the prochlorperazine 5mg tablets by 4 June 2015 (see paragraph 5.446.3 above) – that is before Lexon had even submitted an order for Prochlorperazine POM.

5.459 With respect to issues relating to API, the CMA additionally notes that [Lexon Director 1] did write to [Focus Director 1] on 14 April 2014 stating, *'My sincere apologies but [✂]'* and noting that he would have a further update in June but that

[1261] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 93 (URN: PRO-C5092).

[1262] [Lexon Director 1] Witness Statement, 31 July 2019, paragraphs 110 to 111 (URN: PRO-C5092).

[1263] Lexon submitted that '… *the facts demonstrate that even if Lexon had ordered a validation batch of the 3mg Product in early 2014 production could not have taken place any earlier than was the case since the initial marketing authorisation had been granted in error and there were delays in auditing API'* (Lexon RLF, 25 November 2021, paragraph 10 (URN: PRO-C7901)).

[1264] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 86 (URN: PRO-C5092). [Lexon Director 1] provided further detailed commentary about the difficulties in obtaining API for prochlorperazine experienced by multiple companies who sought a licence in paragraphs 111 to 120 of his witness statement (URN: PRO-C5092).

[1265] Medreich submission dated 21 March 2019 in response to the CMA questions of 15 March 2019, response to question 1.1 (URN: PRO-C3856).

'*Once again I do apologise for the confusion but as I am sure you can guess there is nothing short term I can do to address the problem*'.[1266] However, this email must be seen in the context of the fact that [Lexon Director 1] had already informed Medreich in February 2014 that Prochlorperazine POM was '*best left alone*';[1267] furthermore, notwithstanding this email, [Lexon Director 1] has stated in his witness statement that he was not made aware around this time of problems with the API supplier.[1268] The CMA's detailed assessment of this email of 14 April 2014 is set out in paragraphs 5.598 to 5.602 below: for the reasons set out in full there, the CMA does not consider that this email provides evidence of Lexon's intention to supply commercial volumes of Prochlorperazine POM to Focus.

5.460 Second, in the context of the fact that an order had been submitted for the 5mg prochlorperazine product by April 2014 (see paragraph 5.436.2), but not for the Prochlorperazine POM or 3mg OTC product, [Lexon Director 1] explained that '*Medreich did not have a licence for the POM Product to enable the launch and did not have such a licence until 15 September 2015*'.[1269] However:

5.460.1 given [Lexon Director 1]'s evidence in his witness statement that he was '*totally unaware of this [regulatory issue] at the time*',[1270] this could not explain why [Lexon Director 1] did not place a written order for stock for Prochlorperazine POM until 23 June 2015 despite Medreich's processes requiring this (see paragraphs 5.434 to 5.455) above; and

5.460.2 [Lexon Director 1]'s description of the regulatory position is a mischaracterisation; as far as Lexon and Medreich were aware, Medreich *did* have a Prochlorperazine POM licence at this point in April 2014 and, notwithstanding the complications that arose subsequently in relation to the regulatory position that required resolution, Lexon would nevertheless have been able to market the Medreich product if it had wished based on advice from the MHRA (see paragraph 3.239).

5.461 Third, [Lexon Director 1] cited correspondence from the MHRA on 17 December 2014 indicating regulatory issues with the grant of the initial licence,[1271] and

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[1266] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794).

[1267] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

[1268] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 86 (URN: PRO-C5092). [Lexon Director 1] stated in interview in respect of his email of 14 April 2014 that he was passing on information he had received from Medreich about API issues that he did not believe but nevertheless passed on to Focus (Interview [Lexon Director 1] 10 September 2018 CD 4/5 page 6 line 7 to page 7 line 16 (URN: PRO-C3189)).

[1269] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 87 (URN: PRO-C5092).

[1270] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 87 (URN: PRO-C5092).

[1271] Email [MHRA employee] to [Medreich employee] cc [MHRA employee] entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 17 December 2014 (URN: PRO-E002900). [Medreich Employee 1] replied arranging a conference call for 22 December see Email [Medreich Employee 1] to [MHRA employee] entitled '*PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 18 December 2014 (URN: PRO-E002908). [Medreich Employee 1] also raised the issue at the Medreich Executive Committee meeting see '*Medreich Executive Committee Meeting Minutes'* 18 December 2014 (URN: PRO-E002907).

pointed to the fact Medreich took prompt steps to try to resolve the issue, including appointment of a consultant. [Lexon Director 1] submitted that this demonstrated that Medreich was keen to pursue its grant of the licence as quickly as possible so that they could start production and supply the market.[1272] However, this reasoning is not persuasive in undermining the existence of the Market Exclusion Agreement. Lexon and Medreich's entitlement to profit share under the Market Exclusion Agreement was predicated on the notion that they *could* supply product, but were not doing so, and thereby should be compensated. In this scenario, both Lexon and Medreich would have had an interest in ensuring that any regulatory issues were resolved and that Medreich would be able to produce product if and/or when required, not least because of the need ultimately to produce a (single) batch to avoid the application of the Sunset Clause.

5.462 Fourth, [Lexon Director 1] referred to the correspondence between Lexon and Medreich on 22 June 2015 in relation to the placing of an order and submitted that because he had asked at that point for the order to be done '*all as the POM for now*',[1273] this showed he had no intention of delaying the launch of the POM product.[1274] [Lexon Director 1] explained that he would have asked for the smallest commercial batch given that this is what would have normally been done with the launch of a new product to ensure that if there were any regulatory issues on launch they could be dealt with without having too much stock and a second batch could be ordered once the initial stock had gone through.[1275] However:

5.462.1 given that Medreich had obtained its licence on 9 January 2014, [Lexon Director 1] had *already delayed* ordering Prochlorperazine POM as compared to what would have been expected had Lexon wished to proceed promptly with manufacture of commercial volumes of Prochlorperazine POM;

5.462.2 the correspondence between [Medreich Director 2] and [Lexon Director 1] on 22 June 2015, in which [Lexon Director 1] requested that the order be done '*all as the POM for now*' itself shows that, as of June 2015, Medreich did not know how many batches or what pack size [Lexon Director 1] wished to order – hence why [Medreich Director 2] ultimately requested [Lexon Director 1] to '*please place an order at [✂] please for [✂] packs*';[1276] as noted in paragraph 5.446.5 above, this exchange is not consistent with any suggestion that [Lexon Director 1] had already placed an order with Medreich for Prochlorperazine POM product by this point;

[1272] [Lexon Director 1] Witness Statement 31 July 2019, paragraph 90 (URN: PRO-C5092).

[1273] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*RE: FW: batch size*' 22 June 2015 (URN: PRO-E002975).

[1274] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 91 (URN: PRO-C5092).

[1275] [Lexon Director 1] Witness Statement, paragraph 91 (URN: PRO-C5092).

[1276] Email [Medreich Director 2] to [Lexon Director 1] entitled *'RE: FW: batch size*' 22 June 2015 (URN: PRO-E000517).

5.462.3 as regards [Lexon Director 1]'s explanation that the minimum batch size reflected caution associated with a new product, there is no discussion in the correspondence at that time between Lexon and Medreich of placing subsequent (larger) orders in the event that the first order was successful: when [Medreich Director 2] asked [Lexon Director 1] '*How many batches ? 2 batches ?*' [Lexon Director 1] replied '*Just one*',[1277] but did not make any reference to future batches if this one was successful; further, Medreich itself recorded in its Exco meeting minutes on 24 June 2015 that the internal Medreich order of one batch was the '*1 batch required in order to keep the license [sic] active*', and did not reference any future (larger) batches;[1278,1279] and

5.462.4 an order of [✂] tablets equates to (a theoretical maximum of) [✂] packs, which would have been significantly less than a month's supply at an annual market size of around 220,000 packs (see Table 1, paragraph 3.23); and

5.462.5 a later Medreich budget from February 2017[1280] records that in relation to Prochlorperazine POM Medreich anticipated continued receipt of significant profit share payments during its financial years 2018 and 2019, despite referring only to anticipated sales of a single batch in those financial years, which is not consistent with any suggestion that it believed that Lexon would in the future place orders for commercial volumes of Prochlorperazine POM following the delivery of the batch of [✂] packs.

5.463 Fifth, [Lexon Director 1] referred to the contemporaneous Medreich internal evidence which referred to the 23 June 2015 order as being '*the 1 batch required in order to keep the license [sic] active*'.[1281] [Lexon Director 1] commented that

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[1277] Email [Medreich Director 2] to [Lexon Director 1] entitled '*RE: FW: batch size'* 22 June 2015 (URN: PRO-E000517).

[1278] Email [Medreich employee] to various Medreich colleagues entitled '*Exco minutes*' 29 June 2015 (URN: PRO-E002984) attaching '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich PIC Offices'* 29 June 2015 (URN: PRO-E002985).

[1279] Medreich has confirmed that after the first Lexon purchase order on 23 June 2015, the next purchase order was placed for 40,000 Prochlorperazine POM tablets on 26 March 2018 (Medreich submission dated 8 November 2021 in response to the CMA questions of 22 October 2021, paragraph 5.2 (URN: PRO-C7817)), referencing email [Lexon Director 1] to [Medreich employee], cc [Medreich employee] entitled '*RE: India order'* 29 March 2018 (URN: PRO-E003648), attaching '*Lexon PO – 721039*' (URN: PRO-E003649). Based on information supplied by Lexon, this subsequent order was not supplied by Medreich during the Infringement Period (see Section 26 response of Lexon dated 27 November 2018 to CMA Notice of 7 November 2018, question 2 (URN: PRO-C2977)). In any event, the CMA does not consider this subsequent order by Lexon in March 2018 to be inconsistent with the existence of the Market Exclusion Agreement: this order was placed after the commencement of the CMA's investigation in October 2017, after the time at which Medreich had informed Lexon it would no longer receive profit share payments in respect of Prochlorperazine POM (see paragraph 3.272) and approaching the 31 July 2018 expiry date for the Focus-Lexon Heads of Terms.

[1280] Email [Medreich employee] to [Medreich Director 2] entitled '*FW: FY18 Budget files*' 16 February 2017 (URN: PRO-E003253) attaching Excel spreadsheet entitled '*Medreich plc FY18 Budget v3*' (URN: PRO-E003254); the spreadsheet shows in tab '*UK*' budgeted sales of [✂] packs of Medreich's Prochlorperazine POM in each of FY18 and FY19 at a price of £[✂], that is equivalent in revenue to £[✂] per year, but details in tab '*UK Profit Share*' budgeted receipts of £950,000 profit share for each of FY18 and FY19.

[1281] Email [Medreich employee] to various Medreich colleagues entitled '*Exco minutes*' 29 June 2015 (URN: PRO-E002984) attaching '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 14th June 2015 at 10:30am in the Board Room of Medreich PIC Offices*' 29 June 2015 (URN: PRO-E002985) (see also PRO-E002983)).

keeping the licence active might have been Medreich's priority, but his priority was to get the POM Product launched.[1282] However, Medreich's internal understanding of the rationale for production of a single (small) batch is likely to have derived from [Lexon Director 1] as the commercial partner in the joint venture. Indeed it is in line with [Lexon Director 1]'s statement in his email of 4 February 2014 that '*I have agree [sic] that we make a batch every 3 years and drift it into the Alliance stock*'.[1283] [Lexon Director 1]'s own actions do not indicate a 'priority' to getting the Prochlorperazine POM product launched given that he delayed ordering any product until 23 June 2015 (see paragraphs 5.434 to 5.455 above).

5.464 Sixth, [Lexon Director 1] referred to an email from Medreich to him of 14 September 2015 that informed him of regulatory issues with the licence.[1284] Based on this email, [Lexon Director 1] submitted that he realised that Medreich had not been realistic in terms of timescales and was [✂].[1285] Following the confirmation by the MHRA of approval of the licence on 15 September 2015,[1286] [Lexon Director 1] stated that he instructed Medreich to 'push' Prochlorperazine POM,[1287] including making subsequent demands for supplies[1288] including telephone calls to Medreich to complain.[1289] However, the fact there may have been some degree of urgency with respect to the production of a batch of product during the latter part of 2015 through to 2017 is not probative of Lexon having had, from 9 January 2014, when the licence was granted, a genuine commercial interest in production and sale of commercial volumes of Prochlorperazine POM inconsistent with the existence of the Market Exclusion Agreement;[1290] this is because:[1291]

5.464.1 in late September 2015, the three year Sunset Clause deadline was starting to approach as regards Prochlorperazine POM (it would have expired on 9 January 2017, had it not been extended) meaning that Lexon would have wished to ensure Medreich was able to produce product; the

[1282] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 92 (URN: PRO-C5092).

[1283] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

[1284] Email [Medreich Employee 1] to [Lexon Director 1] entitled ' *FW: Prochlorperazine status PL 21880/0122 & 0126_email response from [✂]*' 11 September 2015 (URN: PRO-E003009).

[1285] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 93 (URN: PRO-C5092).

[1286] Email [MHRA employee] to [Medreich employee] entitled '*RE: PL 21880/0126; Prochlorperazine Maleate 3mg Buccal Tablets*' 15 September 2015 (URN: PRO-E003010).

[1287] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 94 (URN: PRO-C5092).

[1288] [Lexon Director 1] Witness Statement, 31 July 2019, paragraphs 95 and 102 (URN: PRO-C5092).

[1289] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 102 (URN: PRO-C5092).

[1290] For this reason, the CMA does not consider that the evidence cited by [Lexon Director 1] in his witness statement relating to potential production of a batch of product by Medreich in 2016 and 2017 is inconsistent with the existence of the Market Exclusion Agreement (see [Lexon Director 1] Witness Statement, 31 July 2019, paragraphs 95 – 98, 100 – 103 and 105 – 106 (URN: PRO-C5092), as well as the evidence cited by Cinven in its representations on the Statement of Objections (Cinven RSO, 15 August 2019, paragraph 4.105(e)-(g) (URN: PRO-C5132)).

[1291] For this reason, the CMA rejects Cinven's submission that Lexon's placing of an order with Medreich in June 2015 is itself inconsistent with the CMA's contention that there was no intention to obtain a commercial supply of Prochlorperazine POM (Cinven RSO, 15 August 2019, paragraph 4.106 (URN: PRO-C5132)).

importance of this milestone was referenced in Medreich contemporaneous internal correspondence;[1292] and

5.464.2 although it was possible to obtain an extension to the Sunset Clause,[1293] as time went on, it was commercially important for Lexon to be able to demonstrate through production of a batch that it was able to enter the market with product; further, the expiry of the five year term of the Focus-Lexon Heads of Terms was also approaching; Medreich's ability to make the product was also relevant if the arrangement with Alliance and Focus was discontinued for any reason (i.e. so that Lexon could itself enter the market). By way of evidence of this:

(a) [Lexon Director 1] himself wrote to Medreich on 10 January 2017, stating that:

'our partners in the UK on Prochlorperazine 3mg have muted [sic] that they will probably want to serve notice on the agreement soon and without supply we will lose in excess of £180,000 per month between our companies if we are not in a position to supply…'.[1294]

(b) In his witness statement, [Lexon Director 1] himself commented that '*Focus could have cancelled the Focus Agreement at any time on six months' notice so I needed to know that I had stock available*'.[1295]

(c) [Medreich Director 2] commented to the new owners of Medreich (Meiji) in July 2017 that:

'3mg has never been manufactured or supplied .. Profit share comes from 3mg only.

There is a deal in place that for Medreich Not [sic] to bring 3mg in market we get royalty … But two things are crucial now :

1. *The company with whom Lexon has done the deal wants to see our product failing which deal is off.. [sic]*

2. *Secondly from regulatory perspective we need to produce 1 batch of 3mg to avoid sunset cluase [sic] else we shall lose the license [sic]. As per sunset clause regulation we have to produce and sell 1 batch once*

[1292] For example by [Medreich Director 2] in his email to [Medreich employee] of 13 May 2016: '*Both the above licenses [sic] are facing sunset clause which means we will lose the license [sic]*' (email [Medreich Director 2] to [Medreich employee] cc various others entitled '*Prochloroperazine 3mg*' 13 May 2016 (URN: PRO-E003088)).

[1293] [Lexon Director 1] commented that the pressure that he placed on Medreich to produce product should not be seen as reflecting the Sunset Clause risk because an extension could be, and was readily, granted before the licence expired ([Lexon Director 1] Witness Statement, 31 July 2019, paragraph 95 (URN: PRO-C5092)).

[1294] Email [Lexon Director 1] to [Medreich employee], cc [Medreich employee] and [Medreich Director 2] entitled '*Supply*' 10 January 2017 (URN: PRO-E000634).

[1295] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 83 (URN: PRO-C5092).

every 3 years to maintain the license [sic] or else MHra [sic] will kill the license [sic].'[1296]

5.465 Seventh, [Lexon Director 1] pointed to oral evidence given by [Medreich Director 2] to the CMA in which [Medreich Director 2] had commented that [Lexon Director 1] had made phone calls and was '*always chasing for the product*'.[1297] Lexon also pointed to interview evidence given by [Medreich Director 2], in his capacity as a former employee of Medreich, the leniency applicant, to the CMA in which [Medreich Director 2] had said that there had never been any verbal or written instructions from Lexon that the product should not be manufactured, and that Lexon had never delayed the product but had always been chasing Medreich for the product.[1298]

5.466 In relation to this evidence given by [Medreich Director 2], the CMA finds that it is not correct, as [Medreich Director 2] suggested, that Lexon was '*always chasing for the product*'. The CMA has decided, in the context of withdrawal of [Medreich Director 2]'s immunity from director disqualification proceedings, that the statements he made to the CMA about Lexon never delaying the product and always chasing for product were not complete and truthful, and therefore should not be relied on, in particular given that:[1299]

5.466.1 [Medreich Director 2] was copied into the email exchange between [Lexon Director 1] and [Medreich Employee 1] of 4 February 2014 in which [Lexon Director 1] stated '*The 3mg POM is best left alone as we make far much more as it is*';[1300]

5.466.2 [Medreich Director 2] responded to [Medreich Employee 1] in respect of [Lexon Director 1]'s communication: '*Prochlorperazine 3mg (pom / p) – ok to go with his strategy, just need to make a batch as he agress [sic] also*';[1301] and

5.466.3 Medreich has confirmed that there were no written records of an order from Lexon prior to the order being placed on behalf of Lexon on 23 July 2015 and that its manufacturing facility has not been able to locate any

[1296] Email [Medreich Director 2] to [Meiji employee] entitled '*Re: Prochlorperazine – profit sharing*' 21 July 2017 (URN: PRO-E003351). [Lexon Director 1] submitted comments on the significance of [Medreich Director 2]'s email of 21 July 2017 which are addressed in paragraph 5.579 ([Lexon Director 1] Witness Statement, 31 July 2019, paragraph 104 (URN: PRO-C5092)).

[1297] Lexon RLF, 21 April 2021, paragraph 28 (URN: PRO-C7104), citing transcript of meeting with [Medreich Director 2] 14 January 2020, page 16 lines 2-7 and page 18 lines 2-3 (URN: PRO-C6019).

[1298] Lexon RSO, 31 July 2019, paragraphs 24 and 25 (URN: PRO-C5091) citing Interview [Medreich Director 2] pages 64, 66-67 and 124 (URN: PRO-C3684).

[1299] See Final decision of CMA withdrawing immunity from [Medreich Director 2] from director disqualification proceedings 23 October 2020 paragraphs 39-47 (URN: PRO-C6362). See further in this respect paragraph 5.578 below.

[1300] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750). The CMA's analysis of [Lexon Director 1]'s and Lexon's representations on this email is set out in paragraphs 5.426 to 5.432 above.

[1301] Email [Medreich Director 2] to [Medreich Employee 1] entitled '*FW: Products*' 5 February 2014 (URN: PRO-E002746).

evidence of an order being made by Lexon prior to this time, and nor does it have any evidence of the relevant materials that would be required to fulfil an order of Prochlorperazine POM being purchased prior to this time.[1302]

5.467 It is possible that [Lexon Director 1] may have chased Medreich for the single batch of product following the order that he placed with Medreich on 23 June 2015 as the initial Sunset Clause deadline approached on 9 January 2017: see paragraph 5.464 above; this would be consistent with [Medreich Director 2]'s own written comments in his email of 21 July 2017 that '*There is a deal in place that for Medreich Not [sic] to bring 3mg in market we get royalty … But two things are crucial now …*', where he outlined the importance of Medreich's being able to produce product;[1303] however, this does not undermine the CMA's finding that Lexon did not seek commercial volumes of product from Medreich in the period following the grant of Medreich's licence on 9 January 2014.

Conclusion on [Lexon Director 1]'s witness statement evidence

5.468 The CMA finds that, for the reasons set out above, none of the evidence cited by [Lexon Director 1] in his witness statement establishes that he sought to obtain product from Medreich in order to be able to launch commercial volumes of Prochlorperazine POM on the market in competition with Alliance. No product was ordered by Lexon from Medreich at all until 23 June 2015 (see paragraphs 5.434 to 5.455 above) and, from then on, [Lexon Director 1]'s concern was ensuring the production of a single batch of product. This would be entirely consistent with the terms of the Market Exclusion Agreement and the need to ensure, for both regulatory and commercial reasons, that Lexon/Medreich were able to produce the product if they wished to do so. That conclusion is in line with the plain reading of the contemporaneous document evidence.

Lexon evidence relating to the Primegen second profit share renegotiation is supportive of the existence of the Market Exclusion Agreement

5.469 Lexon evidence relating to the second profit share renegotiation with Focus/AMCo concerning the Primegen licence is further evidence of the existence of the Market Exclusion Agreement.

5.470 After AMCo had acquired Primegen on 2 June 2015, with its own Prochlorperazine POM licence in development, it is clear from the contemporary correspondence that [Focus Director 1] and [Lexon Director 1] had been in contact in relation to a

[1302] Medreich submission, dated 10 December 2019, in response to the CMA questions of 26 November 2019 (URN: PRO-C5472).

[1303] Email [Medreich Director 2] to [Meiji employee] entitled '*Prochlorperazine – profit sharing*' 21 July 2017 (URN: PRO-E003351). [Lexon Director 1] submitted comments on the significance of [Medreich Director 2]'s email of 21 July 2017 which are addressed in paragraph 5.579 ([Lexon Director 1] Witness Statement, 31 July 2019, paragraph 104 (URN: PRO-C5092)).

revision to the Focus/Lexon profit share split under the Focus-Lexon Heads of Terms. At this point, in June 2015, Lexon/Medreich had not supplied any product to Focus over the year and a half since the grant of the Medreich licence on 9 January 2014 notwithstanding their receipt of significant profit share payments (totalling some £1.07 million) from Focus earned from its sale of the Alliance product. Despite this, in an email of 26 June 2015, [Focus Director 1] informed [Focus Director 2] in relation to the timing of the revision to the profit share split that:

> *'[Lexon Director 1] has been back on the phone the 50/50 wont [sic] start until licence grant – Medrich [sic] wont [sic] go for 1st Oct ! and [sic] looking at [AMCo employee 4] e mail [sic] it looks like the launch date is July 16 so I presume the licence was further away than [Primegen employee] suggested. So we won't see any upside this year.'*[1304]

5.471 Lexon's representation to Focus that Medreich would not accept a revision to the terms of the Focus-Lexon Heads of Terms profit share (to 50%/50% on all profits) as taking effect until after AMCo's Primegen MA licence had formally been granted is further evidence of the existence of the Market Exclusion Agreement given that:

5.471.1 it shows that when AMCo/Focus had sought to use its Primegen Prochlorperazine POM development project as leverage to renegotiate the profit share split with Lexon, [Lexon Director 1] considered that – despite having not supplied any product under a nominal supply agreement – Lexon/Medreich nevertheless had commercial leverage in that negotiation, such that Lexon/Medreich could push back on the start date for the profit share amendment;

5.471.2 Lexon's commercial position is explicable only if [Lexon Director 1] considered that Lexon/Medreich were entitled to the majority of the profit share as compensation for their agreement not to enter the market for as long as they remained the only companies with a licence to compete with Alliance; and

5.471.3 [Focus Director 1]'s email shows that Lexon/Medreich considered it could legitimately continue to insist upon retaining the majority of the profit share during the period in which only Lexon/Medreich retained a licence to compete with Alliance; only when a further MA holder emerged (i.e. AMCo/Primegen) would it be appropriate to adjust the profit share to provide for an even allocation between AMCo/Focus/Primegen and Lexon/Medreich.

[1304] Email [Focus Director 1] to [Focus Director 2] entitled '*FW: Prochlorperazine 3mg*' 26 June 2015 (URN: PRO-E001634).

5.472 The CMA's findings relating to the significance of the Focus email of 26 June 2015 are corroborated by subsequent correspondence from [Lexon Director 1] himself. He expressly recognised the rationale for the amended profit share when explaining the need for the amendment to 50/50 on all profits to colleagues at Lexon and Medreich. Specifically, [Lexon Director 1] explained the basis for an amendment to the profit share, including Medreich's taking of a third of the Lexon profits going forward, by reference to the existence of a new player (Primegen):

> *'This is wrong There is a new player and we need to accommodate that as per conversation with [Medreich Director 2] and [Medreich Director 1]'.*[1305]

5.473 The need to accommodate a 'new player' (AMCo/Focus/Primegen) supports the existence of the Market Exclusion Agreement: namely that Lexon and Medreich's compensation under the Focus-Lexon Heads of Terms was based on their having a licence, but not supplying product. The CMA infers that, in referring to the need to accommodate Primegen as a '*new player*', [Lexon Director 1] recognised that the level of payments that each undertaking received pursuant to the profit share was linked to that undertaking's ability to supply Prochlorperazine POM, and represented compensation for its not supplying it. This is why, when AMCo acquired its own MA (Primegen), against which Prochlorperazine POM would not be supplied, AMCo was entitled to a greater share of the profit share payments: the justification for Lexon continuing to receive 75% of the profit share below £10.50 no longer applied given that AMCo would have its own licence against which it too could have supplied product.

[Lexon Director 1]'s evidence regarding the second profit share renegotiation relating to Primegen

5.474 In his witness statement provided to the CMA, [Lexon Director 1] accepted that one factor for the amendment to the profit share in the Focus-Lexon Heads of Terms to 50/50 on all profits in 2016 was because of the Primegen licence.[1306] However, [Lexon Director 1] also suggested that his agreement to adjust the profit share split in Focus' favour was influenced by the unforeseen delay in obtaining Medreich product and by his embarrassment in this respect vis-à-vis Focus: '*I was also embarrassed by our failure to deliver product and we agreed to make an adjustment to a 50/50 share as a fair compromise with effect from Quarter 2 2016*'.[1307] [Lexon Director 1] added in subsequent evidence that [Focus Director 1] was '*unhappy that due to problems with the licensing of the Medreich product, I had not been able to get supplies of the Medreich POM*'.[1308]

[1305] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130).

[1306] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 99 (URN: PRO-C5092). See also Lexon RLF, 21 April 2021, paragraph 31 (URN: PRO-C7104).

[1307] [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 99 (URN: PRO-C5092).

[1308] Lexon RLF, 21 April 2021, paragraph 31 (URN: PRO-C7104).

5.475 [Lexon Director 1] added that no connection could be drawn between the second profit share renegotiation and the existence of a Market Exclusion Agreement given that Lexon had commissioned three validation batches in the first quarter of 2014.[1309] He stated that the reference to a need to accommodate a 'new player' in his email of 8 July 2016 was to Primegen, and the grant of the licence which was '*a factor taken into account to reduce the Lexon profit share from Focus*' but, [Lexon Director 1] insisted this did not change Medreich's understanding that Lexon expected Medreich to supply product.[1310]

5.476 As regards his push-back in June 2015 on the timing for the change to a 50/50 share split (as discussed in paragraph 5.470 above), [Lexon Director 1] commented that:

> *'I was not prepared to agree to change the terms of the [Focus-Lexon Heads of Terms] at that time because it was a contractually binding commitment on Focus and I continued to believe that Medreich would begin supplying the product very soon, having placed a written order with Medreich only three days before on 23 June 2015'.*[1311] *…*
>
> *'Focus was contractually bound to Lexon to make the payments under the terms of the [Focus-Lexon Heads of Terms and so had no option but to accept the position.'*[1312]

5.477 The CMA rejects [Lexon Director 1]'s submission that the second profit share renegotiation was informed by delay in the delivery of the Medreich product and consequent 'embarrassment' on the part of Lexon. The explanation for the profit share amendment was based on a change in the Parties' relative commercial positions given that Focus/AMCo (through Primegen) had obtained their own development of Prochlorperazine POM. The CMA rejects [Lexon Director 1]'s witness evidence as summarised above on the basis that:

5.477.1 the contemporaneous documentary evidence relating to the second profit share renegotiation does not refer at any point to Lexon's failure to deliver product; rather, it explains the justification for the amendment in terms of the forthcoming Primegen licence (see paragraphs 5.470 and 5.472 above). In particular, [Lexon Director 1]'s summary email to Medreich explaining the amended profit share referred to the need to accommodate '*a new player*' but did not refer to any other reasons,[1313] a point not explained by [Lexon Director 1] in his representations;[1314] to the extent

[1309] Lexon RLF, 21 April 2021, paragraph 31 (URN: PRO-C7104).

[1310] Lexon RLF, 21 April 2021, paragraph 54 (URN: PRO-C7104).

[1311] Lexon RLF, 21 April 2021, paragraph 30 (URN: PRO-C7104).

[1312] Lexon RLF, 21 April 2021, paragraph 53 (URN: PRO-C7104).

[1313] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130).

[1314] Lexon RLF, 21 April 2021, paragraph 31 (URN: PRO-C7104).

that the profit share amendment was driven by Medreich's own failure to supply product, it would have been expected that [Lexon Director 1] would, at the very least, have referenced this when explaining the amendment to Medreich;

5.477.2 the contemporaneous documentary evidence relating to the second profit share renegotiation does not provide any support for [Lexon Director 1]'s claim that [Focus Director 1] was unhappy that Lexon had not supplied any Medreich product;

5.477.3 as set out in paragraph 5.470 above, far from displaying any 'embarrassment' about the lack of product, Lexon/Medreich actually pushed back on the start date for the implementation of the profit share split;

5.477.4 Lexon/Medreich insisted, and Focus/AMCo accepted, that the revision should be made only upon the actual grant of the Primegen licence, thereby demonstrating that the amendment was based upon the fact that AMCo was itself also now not launching a new product, i.e. it was the 'new player' that had to be 'accommodated' (see paragraph 5.472 above); and

5.477.5 [Lexon Director 1]'s claim that he had by 2015 commissioned three validation batches has been demonstrated to be incorrect (see paragraphs 5.434 to 5.455 above).

5.478 As regards [Lexon Director 1]'s evidence on Lexon's push-back in June 2015 on the start date for the profit share amendment (as set out in paragraph 5.476 above), as recorded in [Focus Director 1]'s email of 26 June 2015, the CMA finds that this is not persuasive.

5.478.1 First, whilst Focus was nominally under a contractually binding commitment to pay the existing profit share payments to Lexon, this commitment should be seen in the context of Lexon's failure to supply product to Focus between August 2013 and June 2015 (that is, nearly two years, and some one a half years since grant of the Medreich licence on 9 January 2014); absent the Market Exclusion Agreement, it is not credible that Lexon would have regarded itself as in a solid position to insist on contractual performance by Focus given Lexon's fundamental failure to fulfil its obligation to provide product to Focus.

5.478.2 Second, alternatively, to the extent that [Lexon Director 1] genuinely considered that he could insist as a contractual matter upon the payment of the profit share pursuant to the Focus-Lexon Heads of Terms, it is not clear why he would have been willing to accept any revision to the profit share terms.

5.478.3 Third, it is not correct, as [Lexon Director 1] claimed, that Focus had '*no option*' but to accept Lexon's position: it could have given notice to Lexon to terminate the Focus-Lexon Heads of Terms, as [Lexon Director 1] himself recognised.[1315]

5.478.4 Fourth, it is clear that [Lexon Director 1] had already been willing to amend the profit share in November 2014 (see paragraph 3.168) and *was* subsequently prepared to change the profit share terms by February 2016: the only difference between June 2015 (when [Lexon Director 1] was resistant to the amendment) and February 2016 (when he accepted it) was that the Primegen licence had been granted – a factor which has nothing to do with Medreich's failure to supply product.

5.478.5 Fifth, [Lexon Director 1]'s statement that he believed in late June 2015 that Medreich would start supplying product '*very soon*' on the basis that Lexon had recently placed a written order with Medreich on 23 June 2015 is not credible. [Lexon Director 1]'s evidence to the CMA has been that Lexon had consistently been seeking product from Medreich from 30 July 2013 (see paragraphs 5.442 to 5.468 above).[1316] If that were the case, it is not clear why the submission of a written order on 23 June 2015 would have led [Lexon Director 1] to believe that product would be supplied '*very soon*'.

The Parties' representations on the Lexon evidence regarding the Primegen second profit share renegotiation

5.479 Advanz submitted that [Focus Director 1]'s email of 26 June 2015[1317] simply recorded an attempt by Medreich/Lexon to push back on the start date of the revised profit share by exploiting the fact that AMCo had no alternative source of supply at the time save for Alliance's product, which was significantly more expensive than the product AMCo expected to receive from Lexon/Medreich.[1318] Similarly, Cinven submitted that Lexon's resistance was consistent with the explanation that AMCo/Focus sought to use the fact that it had a potential alternative route to market at a lower cost of goods to '*secure better supply terms*' from Lexon.[1319]

5.480 However, Advanz and Cinven's attempted positioning of Lexon's push-back fails to take proper account of the fact that Lexon/Medreich had failed to supply any product to Focus by this point: the profit share with Lexon did not equate to '*supply*

[1315] Lexon RLF, 21 April 2021, paragraph 61 (URN: PRO-C7104).

[1316] See [Lexon Director 1] Witness Statement, 31 July 2019, paragraph 85 (URN: PRO-C5092).

[1317] Email [Focus Director 1] to [Focus Director 2] entitled 'FW: *Prochlorperazine 3mg*' 26 June 2015 (URN: PRO-E001634).

[1318] Advanz RLF, 22 April 2021, paragraph 4.135.1 (URN: PRO-C7112) and Advanz RLF, 30 November 2021, paragraph 2.17.5 (URN: PRO-C7917).

[1319] Cinven RLF, 22 April 2021, paragraph 2.62 (URN: PRO-C7107).

terms' as there was no supply. Against that backdrop, it is not apparent how Lexon could reasonably have sought to exploit AMCo's dependence on the *Alliance* product given that supply by Alliance to AMCo/Focus would have been unaffected by Lexon's position. Rather, Lexon's position makes sense only if it considered that it and Medreich had commercial leverage: they had this because they were entitled to the majority of the profit share (below £10.50) as compensation for their agreement not to enter the market for as long as they remained the only companies with a licence to compete with Alliance. This is further demonstrated by Lexon's own analysis of the rationale for the profit share amendment resulting from the Primegen licence, which is very clear: '*There is a new player and we need to accommodate that as per conversation with [Medreich Director 2] and [Medreich Director 1]'*.[1320]

5.481 Cinven submitted that [Lexon Director 1]'s email to Medreich of 8 July 2016 referencing the '*new player*'[1321] did not make any reference to non-supply by Lexon/Medreich or AMCo/Focus/Primegen. Rather than being evidence of the fact that Primegen would not supply its product, the language in the email could have been motivated by Lexon's own reasons to sell the revised profit share to Medreich. Cinven submitted that the reference in [Lexon Director 1]'s email to a need to accommodate a '*new player*' is, in any event, consistent with Focus using the commercial leverage afforded by the Primegen MA to secure better supply terms while pursuing both options,[1322] which would not imply that AMCo had agreed not to enter the market with its Primegen product. The CMA rejects Cinven's submissions in this respect.

5.481.1 The CMA finds that Cinven's commentary fails to explain what [Lexon Director 1] can otherwise have actually meant in his email by the need to '*accommodate'* a '*new player*' and why this would warrant an amendment to the profit share split between Focus and Lexon. Whilst [Lexon Director 1] accepted that his reference to a '*new player*' was to Primegen,[1323] Cinven's critique does not explain why the fact that Focus' parent company had acquired its own licence should inevitably mean a change to the profit share split between Focus and Lexon.

5.481.2 The CMA finds that this wording is explained by reference to AMCo not supplying product against the Primegen licence, in a comparable way to Lexon not supplying product against the Medreich licence: hence the need – when considering the profits being shared on sales of the Alliance

[1320] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130).

[1321] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130).

[1322] Cinven RLF, 22 April 2021, paragraphs 2.59 and 2.60 (URN: PRO-C7107).

[1323] Lexon RLF, 21 April 2021, paragraph 54 (URN: PRO-C7104).

product – for Lexon/Medreich to reduce the amount of profit share they received.

5.481.3 Further, to the extent that, as Cinven suggests, Lexon may have had other reasons to sell the revised profit share to Medreich, it is unclear why Lexon would not have simply stated those reasons to Medreich – particularly if the explanation for the revised profit share were based in whole or in part on Medreich's own failure to supply product.

Conclusion re Lexon evidence regarding the Primegen second profit share renegotiation

5.482 The CMA finds that evidence regarding Lexon relating to the second profit share renegotiation with Focus/AMCo provides further evidence of the existence of the Market Exclusion Agreement.

Subsequent conduct - Focus

Introduction and section summary

5.483 The CMA sets out in this section documentary evidence and conduct of Focus subsequent to the conclusion of the Implementing Agreements that provides further evidence of the existence of the Market Exclusion Agreement, including:

5.483.1 Focus' forecast evidence shows that it did not expect to receive commercial volumes of product from Lexon;

5.483.2 Focus evidence relating to the Primegen licence grant / second profit share renegotiation demonstrates that Focus regarded the profit share payments it made to Lexon as compensation for not entering the market;

5.483.3 Focus continued to make payments to Lexon, despite the lack of receipt of any product, as compensation for Lexon's non-entry into the market; and

5.483.4 later documentary evidence from AMCo confirms that it was aware that Lexon had been involved in the negotiation of the Alliance-Focus Agreement.

Focus' forecast evidence shows that it did not expect to receive commercial volumes of product from Lexon

5.484 Although by 1 August 2013 Focus had agreed the Focus-Lexon Head of Terms under which Focus was – nominally – appointed as Lexon's exclusive distributor of Prochlorperazine POM, the CMA finds that it is clear from Focus' subsequent

conduct and documentary evidence that Focus did not expect to receive commercial volumes of Prochlorperazine POM from Lexon.

5.485 Having entered into the Focus-Lexon Heads of Terms, Focus internally forecasted in November 2013 that its purchases of Prochlorperazine POM in the period January to December 2014 would be made exclusively from Alliance;[1324] this is consistent with an expectation and intention not to purchase commercial volumes of Prochlorperazine POM from Lexon.[1325] Focus' internal forecast was made despite (i) the anticipated grant of the Medreich MA and (ii) the absence of any known issues with Medreich's ability to supply the product. Further, according to the documents obtained by the CMA and as confirmed by [Focus Director 1] in an interview with the CMA,[1326] Focus never provided any forecast to Lexon regarding the volume of Prochlorperazine POM that Focus would require from Lexon, even after Focus' receipt of the single batch of product from Lexon in March 2018.

5.486 Focus' forecasts in terms of its purchases of Prochlorperazine POM proved to be accurate, and Focus did not make any purchases of Prochlorperazine POM under the Focus-Lexon Heads of Terms from Lexon with the exception of a single batch of Prochlorperazine POM received from Lexon on 29 March 2018[1327] consisting of [✂] packs. This compared to Focus' total sales of Alliance's Prochlorperazine POM of 1,043,925 packs between December 2013 and July 2018.[1328]

[Focus Director 1]'s evidence regarding the absence of forecasts for Lexon product

5.487 [Focus Director 1] stated that he did discuss with Lexon the forecasted market share that Focus could achieve with Lexon's product. His explanations for not providing Lexon with forecasts were that Lexon could not make the product meaning forecasting was a '*moot point*', Focus wanted to commit to firm orders as

[1324] See email [Focus Director 1] to [Focus Director 2] entitled '*FW: other OLS for budget*' 14 November 2013 (URN: PRO-E003759). This assumes that all purchases would be made at the supply price specified in the Alliance-Focus Agreement, as shown by the fact that the cost of goods (CoG) in the email chain was £5.65 (the price at which Focus purchased product from Alliance) for each month in 2014. This internal evidence is consistent with Focus' forecasts as provided to Alliance. After the Medreich MA for Prochlorperazine POM tablets had been granted on 9 January 2014, on 10 January 2014, Focus placed two further orders for Prochlorperazine with Alliance for 40,000 packs (at £5.65 / pack) for delivery by 1 May and 40,000 for delivery by 2 June (See email [Focus employee] to [Alliance employee] and [Alliance Employee 1], cc [Focus employee] entitled '*New PO's 9165131 and 9165132*' 10 January 2014 (URN: PRO-E001099) attaching Focus Purchase Orders 10 January 2014 (URN: PRO-E001100)).

[1325] Cinven submitted that it was not at all surprising that Focus planned based on the product that was currently being supplied to it, as opposed to a product that had not yet received an MA or been shown to be ready for production; in addition, Cinven submitted that Focus may not have been content with this position and/or may have '*hoped in due course to be supplied by Lexon*' (Cinven RLF, 22 April 2021, paragraph 2.23 (a) and (b) (URN: PRO-C7107)). However, [Focus Director 1] does not mention in his email to [Focus Director 2] the potential for this situation to change when the Lexon product became available and [Focus Director 1] makes no such comment about hoping for Lexon product in his email to [Focus Director 2] of 14 November 2013 (email [Focus Director 1] to [Focus Director 2] entitled '*FW: other OLS for budget*' 14 November 2013 (URN: PRO-E003759)).

[1326] See interview [Focus Director 1], 2 October 2018, page 197, lines 13-15 (URN: PRO-C3294).

[1327] Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 2 (URN: PRO-C3149).

[1328] Source: Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 1 (URN: PRO-C3149 and PRO-C3150).

late as possible, and [Lexon Director 1] had not requested a forecast but had said that he *'had his initial stock order and then we'd […] go from that point'*.[1329]

5.488 The Parties further submitted in the context of Focus forecasting evidence that given that Lexon/Medreich did not obtain their MA until 9 January 2014, Focus would not have expected to receive product for a year from then; the Alliance-Focus Agreement required Focus to provide Alliance with rolling 15 month forecasts and it would not have made sense for Focus to spend time creating forecasts to share with Lexon when Lexon had not yet shown itself able to fulfil any such forecasts; on this basis, they submitted that the Focus forecasting evidence was not probative of the existence of the Market Exclusion Agreement.[1330]

5.489 The CMA rejects the Parties' representation in this respect and considers that the Focus forecast evidence cited above is further evidence of the Market Exclusion Agreement given that:

5.489.1 [Focus Director 1] did not refer to the possibility of any Lexon product when discussing the Prochlorperazine POM forecast internally with [Focus Director 2] in November 2013;[1331]

5.489.2 despite the stipulation in the Focus-Lexon Heads of Terms[1332] that Focus would be responsible for forecasting of sales volumes by providing Lexon with a rolling 12 month forecast, [Focus Director 1] did not provide any such forecast to [Lexon Director 1] after grant of the Medreich licence on 9 January 2014 before any difficulties with the Medreich production or licensing were known of; and

5.489.3 even with the elapse of time following the grant of the Medreich licence on 9 January 2014, Focus never provided any forecast to Lexon in terms of ordering Prochlorperazine POM from it (see paragraph 5.485 above); the fact that Focus did not provide any forecasts to Lexon is supportive of the existence of the Market Exclusion Agreement and indicative of the lack of any pressure from Focus on Lexon for commercial volumes of product.

[1329] Interview [Focus Director 1], 2 October 2018, page 197, lines 13-18 and 24-28, page 198, lines 4-6 and page 198, lines 18-19 (URN: PRO-C3294), as referenced by Advanz RLF, 22 April 2021, paragraph 4.100 (URN: PRO-C7112).

[1330] Advanz RSO, 1 August 2019, paragraphs 3.219 to 3.226 (URN: PRO-C5111) and Cinven RSO, 15 August 2019, paragraph 7.31 (URN: PRO-C5132) and Cinven RLF, 22 April 2021, paragraph 2.23(c) (URN: PRO-C7107).

[1331] Email [Focus Director 1] to [Focus Director 2] entitled '*FW: other OLS for budget*' 14 November 2013 (URN: PRO-E003759).

[1332] Focus-Lexon Heads of Terms (URN: PRO-E000429) as sent by [Lexon Director 1] to [Focus Director 1] on 8 August 2014 (URN: PRO-E000428).

Focus evidence relating to the Primegen licence grant / second profit share renegotiation demonstrates that Focus regarded the profits share payments it made to Lexon as compensation for not entering the market

5.490 Based on the evidence set out in this section below, the CMA finds that the conduct and documentary evidence relating to AMCo's use of the Primegen licence to renegotiate its profit share with Lexon is supportive of the existence of the Market Exclusion Agreement. As set out in detail in the section below:

5.490.1 At the time of AMCo's acquisition of Primegen in June 2015, [Focus Director 1] and [Focus Director 2] (that is, two of the vendor shareholders who had sold Focus to AMCo in October 2014) were concerned that AMCo's use of the Primegen licence in negotiations could result in the collapse of the arrangement with Alliance and Lexon/Medreich, and this concern is credibly explained with reference to Lexon/Medreich only by the existence of the Market Exclusion Agreement.

5.490.2 Following briefings from [Focus Director 1] and [Focus Director 2], AMCo's internal documents demonstrate that its management analysed the relative financial impact of launching AMCo's own Primegen product as against continuing to purchase Alliance product and paying profit share to Lexon (that is, to continue conduct which would be consistent with the Market Exclusion Agreement). AMCo's modelling shows that it considered the lack of supply of product by Lexon to be a consequence of the Market Exclusion Agreement, rather than reflecting an inability to supply product: AMCo's analysis shows that it understood that, if it launched its own Primegen product, it would be competing against both Alliance and Lexon, but that its continued supply of Alliance product (with profit share payments to Lexon) would not result in Lexon's market entry.

5.490.3 Further, AMCo's modelling is consistent with the premise and purpose of the Market Exclusion Agreement, on the basis that AMCo considered that its acquisition of a licence (through the Primegen acquisition) entitled it to a greater share of the profits it earned from the supply of the Alliance product.

5.490.4 AMCo used the Primegen licence as leverage with Lexon to secure a higher share of the profits earned from the supply of the Alliance product, and did not launch its own Primegen product.

5.490.5 AMCo's decision to continue making profit share payments to Lexon cannot be credibly explained by a commercial desire on AMCo/Focus' part to obtain access to a product with a lower cost of goods than the Alliance product: AMCo decided against launching its own Primegen product

despite the fact that this would have been cheaper than purchasing the Lexon product but continuing to pay profit share to Lexon.

5.491 In June 2015, around the time of AMCo's acquisition of Primegen, AMCo started to carry out modelling of what would happen if it launched its Primegen product. [AMCo Employee 2] referred to this on 15 June 2015 as '*the business case for the product'* noting that it would compare two different scenarios.[1333]

5.492 It is clear that, at the time AMCo was starting to carry out its modelling analysis, [Focus Director 1] and [Focus Director 2] (two of the previous owners of Focus, who were then employed by AMCo) were privately concerned that AMCo's use of the Primegen licence as leverage in commercial negotiations could affect their remuneration under the earn-out provisions in the sale and purchase agreement between AMCo and the Focus vendors[1334] by disturbing the commercial position Focus had reached with Alliance and Lexon/Medreich pursuant to the Market Exclusion Agreement. In relation to a question on 11 June 2015 from [AMCo employee] about potentially launching the Primegen product, [Focus Director 2] responded on 15 June 2015 to say that:

> *'The discussions we had on the product during the acquisition [of Primegen] was to leverage the license [sic] to improve margin and secure the business long term. [Focus Director 1] has the relationship with the current supplier from our side.'*[1335]

5.493 In relation to that email chain between [AMCo employee] and [Focus Director 2] about Prochlorperazine POM, [Focus Director 1] replied privately to [Focus Director 2], commenting that:

> *'They will f this up !!! I will reiterate the market position to [AMCo Director 1][1336] when I speak to him on weds [sic] and if you can once again take [AMCo Employee 2][1337] through it when you speak to him . If they push alliance [sic] or lexon/medriech [sic] too much it will end up being a car crash for all'.*[1338]

[1333] Email [AMCo Employee 2] to [AMCo employee] and [Focus Director 2] cc [Focus Director 1], [Focus Employee 1], [AMCo Employee 4], [AMCo Director 2] and [AMCo Director 1] entitled '*Re: Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E003874).

[1334] Agreement for the sale and purchase of Focus Pharmaceuticals executed 29 September 2014 Schedule 7 and Schedule 8 (URN: PRO-E003826).

[1335] Email [Focus Director 2] to [AMCo employee] cc [Focus Director 1], [Focus Employee 1], [AMCo Employee 2] and [AMCo Employee 4] entitled '*RE: Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001623).

[1336] Interview [Focus Director 1], 2 October 2018, page 258 lines 3-6 (URN: PRO-C3294).

[1337] Interview [Focus Director 1], 2 October 2018, page 258 lines 9-11 (URN: PRO-C3294).

[1338] Email [Focus Director 1] to [Focus Director 2] entitled '*Re: Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616). [Focus Director 2] responded to say '*I know which is why I asked [Focus Employee 1] to send it on. Hopefully [AMCo Employee 2] or [AMCo Director 1] will just say leave it to FOCUS, but I do not want a big meeting on it*' (Email [Focus Director 2] to [Focus Director 1] entitled '*RE: Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616)).

5.494 The CMA infers from [Focus Director 1]'s wording that he was concerned that if AMCo pushed either Alliance or Lexon/Medreich too hard in terms of commercial negotiations based on AMCo's obtaining of its own Prochlorperazine POM licence through Primegen, there was a risk that this would cause the existing commercial arrangements relating to Prochlorperazine POM as they stood in June 2015 (that is, the Market Exclusion Agreement) to collapse. This would be to the detriment of all of the undertakings involved: Alliance, Lexon/Medreich and Focus itself (including the Focus vendors).

5.495 The concern of [Focus Director 1] and [Focus Director 2] must be seen in context: at this point, nearly two years after conclusion of the Focus-Lexon Heads of Terms on 1 August 2013, although Alliance had been supplying Focus with commercial volumes of product at the fixed supply price, Lexon/Medreich had still not supplied any product to Focus, despite receiving very significant sums from Focus pursuant to the profit share clause in the Focus-Lexon Heads of Terms. For this reason, the CMA finds that [Focus Director 1]'s concern that Lexon/Medreich might nevertheless decide to abandon the prevailing arrangement relating to Prochlorperazine POM – resulting in a '*car crash for all*' – is explicable only if Focus considered that Lexon/Medreich's possession of an MA entitled it to a significant proportion of the profits earned by Focus on selling the Alliance product, as compensation for not commercialising its product.[1339]

5.496 Put differently, absent the Market Exclusion Agreement, the Focus vendors would not have been concerned about the prospect of Lexon having an incentive to terminate its agreement with Focus in the event that AMCo sought a greater share of the profits Focus earned on the supply of the Alliance product; this is because, if there were no Market Exclusion Agreement, the reason why Lexon would not have supplied product since the grant of the Medreich licence in January 2014 would have been because it was unable to do so.[1340] Given that lack of commercial leverage, Lexon could not – absent the Market Exclusion Agreement – reasonably have been expected to terminate the Focus-Lexon Heads of Terms had it received a lower share of Focus' profits, or to have resisted any attempt by AMCo to renegotiate the profit share in Focus' favour. [Focus Director 1]'s and [Focus Director 2]'s concern about Lexon/Medreich's potential reaction to being pushed by

[1339] Cinven submitted that this explanation would mean that it would make no sense for Focus to be concerned about the potential implications of AMCo renegotiating the profit share with Lexon because of the Primegen MA, as this would be the very thesis of the Market Exclusion Agreement and would be understood as such by Lexon (and Medreich) (Cinven RLF, 22 April 2021, paragraph 2.63(c) (URN: PRO-C7107). However, this ignores [Focus Director 1]'s concern that AMCo might try to push '*too much*' (as opposed to pushing them at all).

[1340] Cinven submitted in its representations that, from Focus' perspective, had Lexon been in a position to start supplying in the near future, it would have been credible that an attempt to renegotiate the terms by AMCo of the Focus-Lexon Heads of Terms could have led Lexon to switching to an alternative distributor (Cinven RLF, 22 April 2021, paragraph 2.63(b) (URN: PRO-C7107)). However, as Cinven recognises, this was not actually the case and, more importantly, there is no evidence to suggest that the Focus vendors considered it might be the case: in September 2015, Focus was still forecasting purchasing 100% of market demand from Alliance (see email [Focus Director 1] to [Alliance Employee 1] entitled '*RE: Update forecasts and PO's*' 1 September 2015 (URN: PRO-E001196)).

AMCo[1341] is therefore reasonably explicable only if Focus considered that Lexon was being compensated through the profit share for not supplying the product it had developed with Medreich – and was therefore entitled to a significant proportion of the profit share receipts. Similarly, the concern that the re-negotiation could be a 'car crash' for Alliance is explicable only if [Focus Director 1] considered that it could prompt Lexon's entry, which itself also supports the existence of the Market Exclusion Agreement.

5.497 The internal analysis carried out within AMCo in June 2015 was circulated by [AMCo Employee 4] on 29 June 2015 in the form of a PowerPoint presentation. These Project Capital slides assumed that:

5.497.1 AMCo's launch of the Primegen product (Scenario 1) would result in the entry of the Lexon/Medreich product (with Lexon shown – alongside Alliance – as a competitor along with potentially[1342] other future registrations); and

5.497.2 the Lexon/Medreich product would not be launched if AMCo/Focus continued with its existing arrangements supplying the Alliance product and paying profit share to Lexon (Scenario 2).[1343]

[1341] Cinven described [Focus Director 1] and [Focus Director 2] as being concerned that if AMCo launched its own product, the existing distribution agreements would be terminated as being unnecessary to AMCo/Focus (Cinven RSO, 15 August 2019, paragraph 4.48 (URN: PRO-C5132)); however, the concern expressed in [Focus Director 1]'s email of 15 June 2015 is expressed as being about AMCo pushing Alliance and Lexon/Medreich in negotiations, rather than AMCo launching its own product.

[1342] Cinven submitted that the '*potentially*' in Scenario 1 indicated that AMCo considered that there was only the potential for Lexon to launch (given its failure to supply to date) (Cinven RLF, 22 April 2021, paragraph 2.75(b) (URN: PRO-C7107)). However, Scenario 1 lists '2' competitors, '*Alliance & Lexon*' and the model proceeds on the basis that AMCo would compete with 2 competitors (as shown by the anticipated AMCo share of 33%, representing one third of the market). Given that the modelling does not consider the impact of further entrants, it is more likely that the 'potentially' wording applies to the prospect of other entrants rather than to Lexon. In any case, it is evident that under Scenario 2 (under which AMCo would continue to supply the Alliance product and share the profits with Lexon), AMCo did not consider there to be any need to refer to Lexon's entry (whether potential or otherwise).

[1343] Email [AMCo Employee 4] to various (AMCo) entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) attaching presentation entitled '*Project CAPITAL BD Workstream'* 30 June 2015 (URN: PRO-E001636).

Figure 4: Project CAPITAL BD Workstream 30 June 2015, Slide 16

Prochlorperazine Buccal Tabs 30mg x 50 - UK

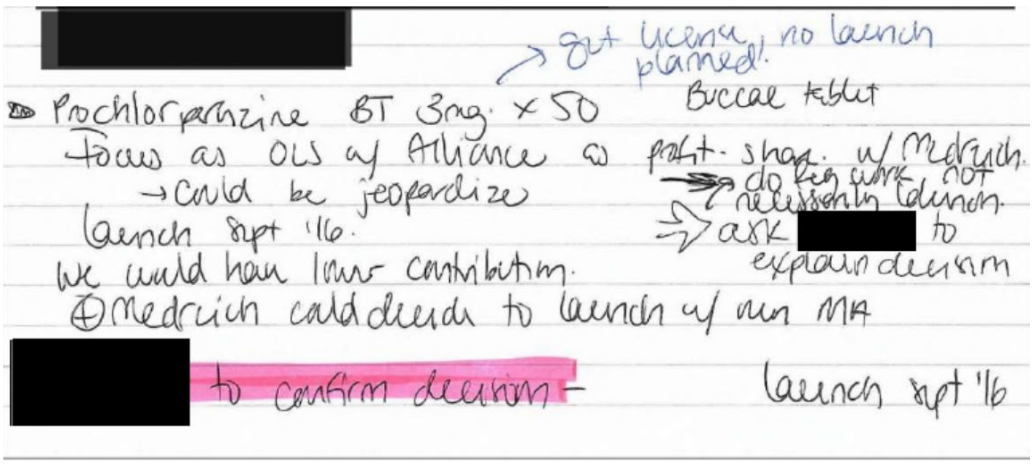
	Scenario 1 – AMCo to launch Primegen's MA	**Scenario 2** – continue the OLS supply Alliance – Focus
	AMCo Model	**FOCUS model**
# competitors	Potentially: 2 - Alliance & Lexon and other future registrations	other future registrations
Pricing (% discount)	£ 14.00 (Aprox. 42% discount vs June'15 - DT)	COG £ 5.60 + Profit Share If AVS > £ 10.50 = 50:50
Average Selling Price £	£ 14.00 - flat during 5 years	40% discount vs DT
DT Price assumption	Does not increase more than £ 23.98	To increase up to ≈ £ 36.00 and keep if flat
MS%	MS% - POM	MS% - POM
Y1	15%	100%
Y2	33%	100%
Y3	33%	100%
Y4	33%	100%
Y5	33%	100%

5.498 The Project Capital analysis demonstrates that AMCo expected Lexon to launch the Lexon/Medreich product if AMCo launched the Primegen product, and that AMCo would therefore compete with both the Lexon/Medreich and Alliance products (as well as potentially *'other future registrations'*) – hence explaining why AMCo modelled having a 33% share. Conversely, when modelling the existing scenario, AMCo assumed that it would retain a 100% market share and that Lexon would not launch the Lexon/Medreich product – albeit that it recognised that it might have to compete with *'other future registrations'*. The different treatment of Lexon's entry within this analysis across the two scenarios is explicable only on the basis that AMCo/Focus understood Lexon was not launching its product because of the compensation that it received pursuant to the profit share clause in the Focus-Lexon Heads of Terms.

5.499 The CMA's interpretation of the Project Capital presentation is supported by other documentary evidence obtained from AMCo that noted that if AMCo launched its own Prochlorperazine POM using the Primegen MA and the profit share payments ceased, Lexon and Medreich could decide to supply against their MA. In an AMCo notebook, an AMCo employee wrote in respect of Prochlorperazine POM that *'Focus as OLS … Alliance … profit share w/Medreich', 'could be jeopardize [sic]','do Reg work not necessarily launch -> ask [AMCo Employee 4] to explain decision'* and that *'Medreich could decide to launch w/ own MA'*,[1344] thereby

[1344] Advanz Hard Copy Document TXT021 page 1 (URN: PRO-E004055). Advanz criticised the fact that the CMA relied on a document of unknown date and authorship, which did not mention Lexon, and submitted that the note did not state

showing that Focus was aware that Medreich had not launched a product to date pursuant to the Market Exclusion Agreement:



5.500 Against the backdrop of that modelling analysis, the contemporaneous documentary evidence is clear that the prompt for the second profit share renegotiation between Focus and Lexon was the impending grant of the Primegen licence. This rationale for the second profit share renegotiation is consistent with the premise and purpose of the Market Exclusion Agreement – namely that Lexon was receiving profit share in return for not entering the market with product that could be developed pursuant to the Medreich licence, and AMCo considered that its acquisition of a licence (through the Primegen acquisition) entitled it to a greater share of the profits it earned from the supply of the Alliance product. Specifically, in an email exchange between [Focus Director 1] and [Lexon Director 1] on 26 June 2015,[1345] [Focus Director 1] stated:

> *'as you know we will have our own prochlorperazine licence available later this year and* ***therefore*** *we agreed an increase in our profit share agreement with yourselves [sic] from Oct [sic] 15'* (emphasis added).

5.501 The contemporaneous documentary evidence is also clear that AMCo decided to use the Primegen licence as a means of negotiating a revised profit share with

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that if AMCo were to cease paying its profit share, Lexon and Medreich could decide to supply their own product. Advanz submitted that all that could be concluded from the note is that: (i) AMCo was considering launching its own Prochlorperazine POM product in September 2016, using the Primegen MA; (ii) AMCo was mindful that if it brought its own product to market, Alliance "could" (but wouldn't necessarily) bring an end to the Alliance-Focus Distribution Agreement; and (iii) given that Focus was waiting for Lexon to launch its own product, if AMCo launched its own development, this would also result in Focus competing against Lexon/Medreich, once they were able to launch (Advanz RSO, 1 August 2019, paragraphs 3.240-3.242 (URN: PRO-C5111)) and Advanz RLF, 30 November 2021, paragraph 2.17.7 (URN: PRO-C7917)). The CMA considers that Advanz's submissions in this respect do not undermine the CMA's assessment of the reference in the note. It is noted that, based on the surrounding context, the note is most likely to date from the second half of 2015. Further, although it has not been possible to identify the author of the note, it is evident from the document that it is the note of an AMCo employee with insight across the Project Capital products, and it is significant that, like [AMCo Employee 4] in relation to the Project Capital slide (see paragraph 5.497 above), the employee has gained an understanding that '*Medreich could decide to launch w/ own MA*' (referencing the fact that Medreich was the holder of the Prochlorperazine POM licence). This wording is not consistent with AMCo's view about Focus competing with Lexon/Medreich once they were able to launch.

[1345] Email [Focus Director 1] to [Lexon Director 1] entitled '*prochlorperazine 3mg Tabs*' 26 June 2015 (URN: PRO-E003877).

Lexon, whilst nevertheless continuing to make significant profit share payments to Lexon, rather than launching its own product (which would have been considerably cheaper than either the Alliance or Lexon product: see paragraphs 5.314 to 5.324 above). This decision is evidenced in a number of internal AMCo documents between August 2015 and February 2016, specifically:

5.501.1 an August 2015 internal report, which stated in respect of Prochlorperazine POM, '*[AMCo employee] to confirm if we will launch given the situation with Focus / Medreich. In any case, the MA needs to be obtained ASAP to have leverage when negotiating terms with Lexon'*;[1346]

5.501.2 a further AMCo internal report from August 2015, which stated, '*MA needs to be obtained ASAP to have leverage when negotiating supply terms with the current partner*';[1347]

5.501.3 a September 2015 spreadsheet, which stated in respect of the launch plans for the Primegen Prochlorperazine POM product, *'No plans to launch for now. Launch plans pending outcome of discussions with Medreich'*;[1348] and

5.501.4 an internal December 2015 AMCo email which stated, *'AMCo is not planning to launch this product from Primegen. Just to keep a dormant MA. Thanks to this imminent MA, Focus has negotiated with Lexon and improved the profit share agreement we had with them'*.[1349]

5.502 The decision as expressed in these documents was informed by AMCo's internal analysis[1350] (see paragraph 5.497 above) that it would be more profitable to continue to share in the profits from the monopoly supply of Alliance product (on improved terms for AMCo) than it would be to market the Primegen product in competition with both the Alliance and Lexon product.

5.503 AMCo's position was most clearly set out by [AMCo Director 2] in an email exchange with [Focus Employee 1] on 8 February 2016 shortly after [AMCo

[1346] Report entitled '*Pharma Pipeline Review Meeting August 2015*' (URN: PRO-E004024).

[1347] Report entitled '*SDG – Strategic Projects Monthly Report*' August 2015 (URN: PRO-E001681), attached to email [AMCo employee] to [AMCo Director 1], [AMCo Employee 2] and [AMCo employee] (all AMCo) entitled '*SDG Strategic Projects Monthly Report ([✂]) – August 15*' 21 September 2015 (URN: PRO-E001680).

[1348] Excel spreadsheet entitled '*PPRM Report September 2015*' 20 October 2015 (URN: PRO-E001705).

[1349] Email [AMCo Employee 4] to [AMCo employee] and [AMCo employee] cc [AMCo Director 2] entitled '*Pipeline tracker updated – Prochlorperazine buccal tablets 3mg*' 9 December 2015 (URN: PRO-E001728).

[1350] Email [AMCo Employee 4] to various colleagues (AMCo) entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) attaching presentation entitled '*Project CAPITAL BD Workstream*' 30 June 2015 (URN: PRO-E001636).

Director 2] had met [Lexon Director 1] on 3 February 2016 to conclude the second profit share renegotiation. In that exchange:[1351]

5.503.1 [Focus Employee 1] explained that she had understood that AMCo was '*obtaining the licence but not proceeding with launch due to the Focus agreement on the Alliance product*' and sought to clarify whether AMCo's objective was to '*pursue an amended profit share with Lexon upon receipt of the licence*' given [AMCo Director 2] had told a colleague that he would provide order volumes for the Primegen product; and

5.503.2 [AMCo Director 2] confirmed: *'Nope that is the exact strategy and I met [Lexon Director 1] on Weds [sic] and agreed an instant 50;50 [sic] share. It will be effective April 1st'*. In relation to explaining to [Focus Employee 1] why he would still place order volumes for the Primegen product, [AMCo Director 2] explained:

> *'Ah. Don't worry about that stuff. We always need to be careful and mindful of the other team members. The new products team spend a huge amount of time and effort getting the product to market and can sometimes be deflated when we say we have done a deal and actually do not want product. My job is to ensure what we may do commercially does not demotivate others. That said I will be providing figures so we have stock just in case.'*[1352]

5.504 [AMCo Director 2]'s email is clear that AMCo's decision not to market its product was a consequence of the deal he had struck with [Lexon Director 1] regarding the amended profit share.[1353]

5.505 Having concluded a revised profit share with Lexon in February 2016, subsequent documentary evidence from later in 2016 confirms that AMCo did not take steps to produce and market its own Primegen product, in line with its decision not to launch the Primegen product. Evidence from AMCo stated clearly that the Primegen product was *'not considered as a launch'*[1354] and commented internally

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[1351] Email [AMCo Director 2] to [Focus Employee 1], entitled '*Re: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757).

[1352] Email [AMCo Director 2] to [Focus Employee 1], entitled '*Re: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757).

[1353] For these reasons, the CMA rejects Advanz and Cinven's submissions that it was the fact that AMCo/Focus had still not received product from Lexon by June 2015 that prompted a further renegotiation of the profit share clause in the Focus-Lexon Heads of Terms (Advanz RLF, 22 April 2021, paragraph 4.113 (URN: PRO-C7112) and Cinven RSO, 15 August 2019, paragraphs 4.58 and 4.59 (URN: PRO-C5132)) and rejects Advanz's submission that none of the contemporaneous documents link the second profit share renegotiation with the Market Exclusion Agreement (Advanz RLF, 22 April 2021, paragraph 4.113.3(b) (URN: PRO-C7112)).

[1354] Email [AMCo Employee 4] to [AMCo employee] and various others (all AMCo), cc [AMCo employee] entitled '*RE: Pipeline Tracker – Oct – [✂] comments*' 31 October 2016 (URN: PRO-E001925); see also email [AMCo employee] to [AMCo employee] cc [AMCo employee] entitled '*Re: Prochlorperazine Tablets 24M Payment milestone*' 10 January 2017 (URN: PRO-E001967) in which he commented on the fact AMCo were '*not going to launch*' the Primegen product.

that the Primegen Prochlorperazine POM product should not be made a priority for the contract manufacturer, [✂].[1355]

5.506 Based on the above, the CMA finds that AMCo's decision to use the Primegen development as leverage in commercial negotiations with Lexon, and to continue paying Lexon profit share payments on Focus' supply of the Alliance product, is evidence of the Market Exclusion Agreement. This is because:

5.506.1 AMCo's decision to continue making profit share payments to Lexon cannot be credibly explained as the Parties have suggested (see paragraphs 5.314 to 5.324 above) by a commercial desire on AMCo/Focus' part to obtain access to a product with a lower cost of goods than the Alliance product, given that AMCo had decided against launching its own lower cost alternative product (Primegen) in circumstances where it did not need to make significant quarterly payments in the hope that it might one day be supplied with product, and where it could have retained 100% of the profits made on selling the product.

5.506.2 AMCo's analysis shows that it understood that, if it launched its own Primegen product, it would be competing against both Alliance and Lexon.

5.507 The evidence surrounding the second profit share renegotiation therefore supports the CMA's finding that, in return for the indirect value transfer through Focus, Lexon agreed not to enter with the Prochlorperazine POM that it had jointly developed with Medreich.

[Focus Director 1]'s witness evidence on his 15 June 2015 email

5.508 [Focus Director 1] stated in interview that, when he referred to '*a car crash for all'* in his 15 June 2015 email to [Focus Director 2] (paragraph 5.493 above), he was referring to the Focus board members and the risk of AMCo jeopardising their compensation under the earn-out arrangements in place as part of the Focus sale contract.[1356] The CMA considers that this reading of the document is strained and not persuasive. The plain reading would be that the *'car crash for all'* reference includes, as well as Focus, the entities just mentioned by [Focus Director 1] in the same sentence (that is, Alliance and Lexon/Medreich), meaning that the Market Exclusion Agreement as a whole could collapse to the disbenefit of all undertakings involved.

5.509 However, even if [Focus Director 1]'s interpretation were correct, such that the '*all*' referred only to the Focus vendors (as opposed to the '*all*' referring to Focus, Alliance, Lexon/Medreich), this does not negate the analysis set out by the CMA in paragraphs 5.494 to 5.496 that [Focus Director 1] and [Focus Director 2]'s concern

[1355] Excel spreadsheet entitled '*PPRM Report – December 2016*' (URN: PRO-E002007).

[1356] Interview [Focus Director 1], 2 October 2018, page 255, line 25 to page 256, line 10 (URN: PRO-C3294).

about the collapse of the Prochlorperazine POM arrangements as they stood in June 2015 – and the notion that Lexon/Medreich might have commercial leverage in that negotiation – is reasonably explicable only if the Lexon/Medreich were being compensated for not producing product (i.e. if the Market Exclusion Agreement exists).[1357]

[AMCo Director 2]'s witness evidence on the Project Capital modelling and slide

5.510 [AMCo Director 2] disputed the CMA's interpretation of the Project Capital presentation as set out in paragraphs 5.497 and 5.498 above. In interview, he described the modelling as '*not necessarily the most sophisticated*' and stated that the slide set out a comparison between launching the Primegen product (Scenario 1) and the situation as it existed in June 2015 *'flatlined […] over a five-year period'* (Scenario 2).[1358] He stated that the modelling did not seek to capture as part of Scenario 2 the timing of Lexon coming to market.[1359] On the basis of [AMCo Director 2]'s explanation about the wholly static treatment of Scenario 2 as the status quo, Advanz submitted that no inference could be drawn from the slide that Lexon would launch its product only if AMCo launched the Primegen product.[1360]

5.511 The CMA does not find [AMCo Director 2]'s explanation persuasive:[1361]

5.511.1 The model takes account of increases in price that were expected to be achieved under the Focus model (Scenario 2) (by assuming the drug tariff

[1357] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616). Advanz and Cinven submitted in respect of [Focus Director 1]'s email of 15 June 2015 that this reflected the personal (legitimate) interest of the Focus vendors in preserving Focus' legacy distribution contracts, which could be adversely affected by an attempt to renegotiate those in favour of AMCo (Advanz RLF, 22 April 2021, paragraph 4.136 (URN: PRO-C7112) and Advanz RLF, 30 November 2021, paragraph 2.17.3 (URN: PRO-C7917), Cinven RSO, 15 August 2019, paragraph 4.45 (URN: PRO-C5132) and Cinven RLF, 22 April 2021, paragraph 2.63 (URN: PRO-C7107)). However, this does not negate the CMA's finding in paragraph 5.494 above: the concern expressed in [Focus Director 1]'s email in preserving those legacy distribution contracts is explained if Lexon understood it was being compensated through the profit share for not supplying the product it had developed with Medreich – and might therefore resist an attempt to reduce this compensation in Focus' favour. Alliance submitted in respect of [Focus Director 1]'s email of 15 June 2015 that the fact that it showed a concern about pushing Alliance too much on cost was evidence of a concern that Alliance might terminate the distribution agreement which would be inconsistent with Alliance being involved in the Market Exclusion Agreement (Alliance RLF, 30 November 2021, paragraph 3.13(a) (URN: PRO-C7914)). However, this reasoning does not follow: the fact that the Focus vendors were concerned that Alliance might, at some point, have been unwilling to accede to a reduced supply price in the context of a leverage threat from Focus/AMCo does not mean that Alliance was not party to the Market Exclusion Agreement: Alliance's argument is tantamount to saying that Alliance would have had to accept any degree of price reduction if it were party to the Market Exclusion Agreement, which cannot be correct.

[1358] Interview [AMCo Director 2], 7 January 2020, page 73 lines 23-25 and page 74, lines 6-13 (URN: PRO-C5994).

[1359] Interview [AMCo Director 2], 7 January 2020, page 78, lines 7-19 (URN: PRO-C5994).

[1360] Interview [AMCo Director 2], 7 January 2020, page 73, line 3 to page 76, line 13 (URN: PRO-C5994). See also Advanz RLF, 22 April 2021, paragraph 4.131.8 (URN: PRO-C7112).

[1361] Relatedly, Advanz submitted that the slide simply showed Focus weighing up its commercial alternatives: namely, using the Primegen MA in order to bring own product to market; or continuing to distribute Alliance's product, while it continued to wait for saleable product from Lexon. Advanz submitted that the slide also shows that in June 2015, Focus continued to expect Lexon to launch its own product, since it counted two competitors to its own product: Alliance and Lexon (Advanz RSO, 1 August 2019, paragraph 3.239 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraph 4.131.7 (URN: PRO-C7112)). Advanz also submitted that Scenario 1 (the launch of the Primegen product) was 'theoretical' given AMCo had no MA at the time and had doubts about whether it would obtain commercial volumes of the product given [✂] (Advanz RLF, 22 April 2021, paragraph 4.131.4 (URN: PRO-C7112)). For the reasons set out in this paragraph 5.511, the CMA rejects Advanz's interpretation of the slide: Scenario 2 does not make any reference to the

price would '*increase up to ≈ £36.00*'), and changes in the size of the market,[1362] such that the Focus model (Scenario 2) was in fact adjusted to take account of expected future events, rather than merely 'flatline' the current figures and assume that the status quo will persist.

5.511.2 [AMCo Director 2] submitted that the purpose of the modelling was to quantify the value of the Primegen MA to supply product and, within AMCo's own sales process, to demonstrate to a buyer that further leverage could be obtained using the Primegen MA as '*one of the commercial chips*'.[1363] However, this rationale is not apparent from the face of the Project Capital slide deck analysis itself; instead, slide 15 appears to present this as analysing the '*Opportunity: Launch as INN Generic*' and an assessment therefore as to whether that option should be pursued.[1364] That description is consistent with the content of the document, which compares the returns that could be earned from supplying its own product with those that could be earned by continuing to supply the Alliance product. In any case, however, the analysis described by [AMCo Director 2] would be of little use on the basis of either objective:

(a) If AMCo had a genuine belief that irrespective of its decision as to whether to launch its own product Lexon would imminently enter the market, it would have been necessary to reflect this in its forecast returns for maintaining supply of the Alliance product. Otherwise, although the forecasts that considered the implications of its own launch would accurately reflect Lexon's expected entry, the analysis used for the continued sale of the Alliance product would ignore that entry and, therefore, significantly over-value the forecasted returns for that option.

(b) In practice, and on the basis of the purpose referred to in the slides themselves or on the basis of the purpose suggested by [AMCo Director 2], the analysis performed by AMCo would be accurate and of value only if Lexon's assumed entry under Scenario 1 (the AMCo model), but not Scenario 2 (the Focus model), reflected a genuinely held belief that Lexon's entry would take place only if AMCo launched its own product.

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appearance of '*saleable product from Lexon*' over the following five years but instead is based on consistent purchasing by Focus of product from Alliance. Whilst Scenario 1 was conditional on obtaining the Primegen licence, the CMA has found that there is no basis for Advanz's claim that [✂] in June 2015 (see paragraph 5.514 below).

[1362] Shown on slide 15 of presentation entitled '*Project CAPITAL BD Workstream*' 30 June 2015 (URN: PRO-E001636) and in the calculations in the underlying financial modelling: see email [AMCo Employee 4] to [AMCo employee] and [AMCo employee] cc [AMCo Director 2] entitled '*Pipeline tracker updated – Prochlorperazine buccal tablets 3mg*' 9 December 2015 (URN: PRO-E001728) attaching excel spreadsheet entitled '*V2 Dossier_Prochlorperazine buccal tablets – UK updated Dec.2015*' 9 December 2015 (URN: PRO-E001729) (see sheet '*Appraisal Focus £10.50*').

[1363] Interview [AMCo Director 2], 7 January 2020, page 76, line 20 to page 77, line 3 (URN: PRO-C5994).

[1364] Presentation entitled '*Project CAPITAL BD Workstream*' 30 June 2015, slide 15 (URN: PRO-E001636).

5.512 The CMA therefore finds that the Project Capital analysis provides evidence in support of the existence of the Market Exclusion Agreement – namely that Lexon would continue not to launch whilst Focus/AMCo continued to purchase product from Alliance and pay profit share to Lexon, but would launch if AMCo were to launch its own Primegen product.

[AMCo Director 2]'s witness evidence on his email of 8 February 2016

5.513 In his interview with the CMA, [AMCo Director 2] commented on his email to [Focus Employee 1] of 8 February 2016 (see paragraph 5.503 above), explaining that his reference to *'do not want product'* is explained by the fact that AMCo did not *[✂]*. [AMCo Director 2] stated that although he thought he would probably be able to obtain one or two batches of stock from the Primegen contract manufacturer for Prochlorperazine POM, [✂], [✂].[1365]

5.514 The CMA rejects [AMCo Director 2]'s explanation for his email of 8 February 2016 and Advanz's related representations[1366] on this point for the reasons below:

5.514.1 first, and most obviously, [AMCo Director 2]'s email exchange with [Focus Employee 1] does not refer at all to [✂], and presents the explanation for not seeking product entirely in commercial terms in terms of the renegotiated '*deal*' with Lexon: *'we have done a deal and actually do not want product. My job is to ensure what we may do commercially does not demotivate others'*;[1367]

5.514.2 second, the CMA has not identified any contemporaneous AMCo documents from February 2016 (or earlier) that would substantiate [AMCo Director 2] having had [✂], or that provide support for the proposition that AMCo's decision not to proceed with purchasing stock from Primegen was [✂]; in those documents between August 2015 and February 2016 which evidence AMCo's use of the Primegen licence as leverage with Lexon, [✂] is referred to in three of those documents but [✂];[1368]

5.514.3 third, the identity of [✂] as the contract manufacturer for Primegen's Prochlorperazine POM was set out on the face of the Primegen sale and

[1365] Interview [AMCo Director 2], 7 January 2020, page 136, line 16 to page 140, line 12 (URN: PRO-C5994).

[1366] Advanz submitted in its representations that [✂] (Advanz RLF, 22 April 2021, paragraph 4.109 (URN: PRO-C7112)) and stated that [✂] (Advanz RLF, 22 April 2021, paragraph 4.134.2 (URN: PRO-C7112), citing Interview [AMCo Director 2], 7 January 2020, page 21, lines 23-26 and page 22, lines 1-2 (URN: PRO-C5994)).

[1367] Email [AMCo Director 2] to [Focus Employee 1], entitled *'RE: Prochlorperazine Buccal Tabs'*, dated 8 February 2016 (URN: PRO-E001757).

[1368] See paragraph 5.501 above including the Report entitled '*Pharma Pipeline Review Meeting August 2015*' (URN: PRO-E004024), Report entitled '*SDG – Strategic Projects Monthly Report*' August 2015 (URN: PRO-E001681) and excel spreadsheet entitled '*PPRM Report September 2015*' 20 October 2015 (URN: PRO-E001705).

purchase agreement, and was therefore clearly known to AMCo at the time it purchased Primegen;[1369] and

5.514.4 fourth, [AMCo Director 2]'s email is clear that he is contemplating ordering stock of the Primegen product *'just in case'* and does not [✂].[1370]

The Parties' representations on the rationale for the second profit share renegotiation and AMCo's use of the Primegen licence as leverage[1371]

5.515 In its representations on the rationale for the second profit share renegotiation, Advanz submitted that none of the relevant contemporaneous documents record or suggest a '*commitment*' by AMCo that, in return for a higher profit share, it would not bring the Primegen product to market.[1372] It noted that, in terms of renegotiating the profit share split with Lexon, Focus would *'play the Primegen card'* and would raise the point that it had an alternative commercial route and therefore it was no longer dependent on supply from Lexon – even though this was *'all tactical gameplay: AMCo had no MA and it had no product at the time'*.[1373] However:

5.515.1 AMCo's internal modelling at the time (discussed in paragraphs 5.497 and 5.498 above) shows that AMCo did consider that it would either launch its own Primegen product, or would continue paying profit share to Lexon: its internal analysis and documentation does not support Advanz's representations that this was *'all tactical gameplay'*; and

5.515.2 the implication of the argument put forward by Advanz is that Lexon should have believed that AMCo was seeking to increase its profit share split in order that Lexon's product would become competitively priced as against AMCo's own product; however:

(a) Lexon could not realistically have considered that to be the case and that the 50/50 profit share amendment would have meant that its product would become a competitively priced source of supply that was likely to generate sales, in a scenario where AMCo would soon

[1369] See Agreement for the sale and purchase of Primegen Limited, where [✂] is named in Schedule 13 as the manufacturer of Prochlorperazine 3mg buccal tablets (page 105 of the agreement) (URN: PRO-E003973).

[1370] Email [AMCo Director 2] to [Focus Employee 1] entitled '*Re: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757).

[1371] The CMA sets out its further consideration of certain representations of the Parties in relation to Focus' subsequent conduct in Annex E:: namely that Alliance's lack of involvement in the profit share re-negotiations between Focus and Lexon does not undermine the existence of the Market Exclusion Agreement and that Morningside's lack of involvement does not undermine the existence of the Market Exclusion Agreement.

[1372] Advanz RLF, 22 April 2021, paragraphs 4.113.3(b) and 4.131.9 (URN: PRO-C7112).

[1373] Advanz RLF, 22 April 2021, paragraph 4.128 (URN: PRO-C7112).

have access to its own product, with its own licence, manufactured by a contract manufacturer, and where it could retain 100% of profits;[1374]

(b) rather, in requiring an amendment to the profit share based on the use of its licence as leverage, AMCo's position must have been (and must have been understood by Lexon to be) that, otherwise, AMCo would launch its product in competition with Lexon (and Alliance); and

(c) Lexon's understanding of how AMCo was using the Primegen licence in the context of the profit share renegotiation is shown by its own commentary to Medreich in July 2016 in respect of the revised profit share: '*There is a new player and we need to accommodate that as per conversation with [Medreich Director 2] and [Medreich Director 1]'*.[1375]

5.516 Advanz made representations in relation to AMCo's intentions as regards the Primegen development project, submitting that *'Focus intended that, if that [Primegen] development succeeded, it would distribute its own Prochlorperazine POM'*.[1376] However, the evidence cited above in paragraphs 5.501 to 5.503 is clear that – irrespective of whether the Primegen development could or would succeed – AMCo had by early February 2016 (when [AMCo Director 2] met with [Lexon Director 1]) decided in favour of continuing its participation in the Market Exclusion Agreement rather than launching its own product.

5.517 Advanz further submitted that, [✂], *'AMCo had no choice but to continue to adhere to Focus's legacy distribution agreements with each of Alliance and Lexon pending the development of the Primegen Product'*.[1377]

5.518 However, Advanz's submission that AMCo's attempts to commercialise the Primegen MA were undermined by [✂][1378] and that [✂] was [✂][1379] do not undermine the CMA's findings in this respect. Whilst [✂], ultimately leading, as Advanz maintains,[1380] to AMCo stating in 2017 that [✂] did not want to continue the project, these materialised *after* AMCo had already decided to use the

[1374] As set out in detail in paragraphs 5.314 to 5.324, the cost of the [✂] product was adjusted in 2016 to €[✂] / £[✂], as compared to (given a Focus sales price to wholesalers of £21.20 in December 2015 and February 2016) an effective Lexon price of £[10-15] (prior to the profit share renegotiation in February 2016) or £[10-15] (following the profit share renegotiation in February 2016).

[1375] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130). [Lexon Director 1]'s comments on this document are addressed in paragraph 5.475 above.

[1376] Advanz RSO, 1 August 2019, paragraph 3.238 (URN: PRO-C5111).

[1377] Advanz RLF, 22 April 2021, paragraph 4.133 (URN: PRO-C7112).

[1378] Advanz RSO, 1 August 2019, paragraph 3.244 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraph 4.117 (URN: PRO-C7112).

[1379] Advanz RLF, 22 April 2021, paragraph 4.115 (URN: PRO-C7112).

[1380] Advanz RLF, 22 April 2021, paragraph 4.117 (URN: PRO-C7112), indirectly citing email [AMCo employee] to [AMCo employee] and [AMCo employee] cc [AMCo employee], [AMCo employee] and [AMCo employee] (all AMCo) entitled '*RE: Details on 2017 launches*' 7 March 2017 (URN: PRO-E002022).

Primegen licence as leverage with Lexon, rather than to manufacture its own product: this is demonstrated by the fact that the evidence relied on by Advanz in its submission in this respect dates from April 2016[1381] onwards, whereas the evidence relied on by the CMA in respect of AMCo's decision making with regard to use of the Primegen licence dates from between August 2015 and February 2016 (see paragraphs 5.501 to 5.503 above).[1382] Ultimately, when AMCo did contemplate purchasing Primegen stock from [✂], it was only as a 'safety net' rather than being commercial volumes for sale, as evident from:

5.518.1 [Focus Director 1]'s advice to [AMCo Director 2] on 8 February 2016: '*I wouldn't manufacture too much […] We sell approx 22,000 packs a month so maybe a month or two of stock of our own (This product will most likely get destroyed as it is only a safety net so I guess you won't want to write off too much value)*';[1383] and

5.518.2 [AMCo Director 2]'s email to [Focus Employee 1] on 8 February 2016: '*That said I will be providing figures* ***so we have stock just in case***' (emphasis added).[1384]

5.519 Further, it is not correct to say that AMCo had no choice but to continue with each of Alliance and Lexon: even putting to one side the lack of product delivered by Lexon, given Focus' ability to give six months' notice (see paragraphs 5.533 and 5.536 below) under the Focus-Lexon Heads of Terms, AMCo could have terminated the Focus-Lexon Heads of Terms and simply purchased product from Alliance, which would have been cheaper than sourcing product from Lexon (see paragraphs 5.314 to 5.324 above).

5.520 Advanz submitted there is evidence from May 2015 that shows that AMCo employees considered the merits of acquiring the rights to the Primegen product with a view to AMCo launching it into the market and that these internal deliberations evidence that neither the AMCo management nor the Focus principals understood a market sharing agreement between Alliance and Lexon to

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[1381] Advanz RLF, 22 April 2021, paragraph 4.117 (URN: PRO-C7112), including citing email [AMCo employee] to [AMCo Director 2], cc [AMCo employee] entitled '*FW: [✂]/AMCO meeting minutes*' 25 April 2016 (URN: PRO-E001802) and presentation entitled *'Pharma Pipeline Review Meeting – January 2017'* (URN: PRO-E001975).

[1382] Advanz's representations do not take account of the fact that the AMCo evidence prior to April 2016 is based on analysis of relative profitability of the different commercial options, rather than [✂], for example Advanz states '*While the CMA refers to a handful of AMCo documents that the CMA says indicate that AMCo had decided not to launch the Primegen Product these are variously dated from late December 2015 to 2017 i.e. when it was becoming clear to AMCo that the [✂] development was unlikely to materialise*' (Advanz RLF, 22 April 2021, paragraph 4.126 (URN: PRO-C7112)). Cinven submitted that [✂] (Cinven RLF, 22 April 2021 paragraph 2.67 (URN: PRO-C7107) – however, Cinven did not cite any contemporaneous documents in respect of this proposition and referred only to [AMCo Director 2]'s interview transcript (in relation to which, see paragraphs 5.513 and 5.514 above).

[1383] Email [Focus Director 1] to [AMCo Director 2] entitled '*RE: Recipharm meeting on Thursday*' 8 February 2016 (URN: PRO-E001759). The same day, [AMCo Director 2] asked colleagues in AMCo to '*manufacture 25k of Prochlorperazine Buccal tabs please*' (Email [AMCo Director 2] to [AMCo employee] and [AMCo employee], cc [Focus Employee 1] entitled '*RE: Quick questions*' 8 February 2016 (URN: PRO-E001762)).

[1384] Email [AMCo Director 2] to [Focus Employee 1] entitled '*Re: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757).

exist.[1385] However, Advanz's reference to this email from May 2015 is not persuasive:

5.520.1 the email referenced by Advanz was authored by [AMCo Employee 2] and was written and circulated to AMCo management prior to the Primegen acquisition taking place and prior to [Focus Director 1]'s email to [Focus Director 2] of 15 June 2015 that stated that: '*They will f this up !!! [sic] I will* ***reiterate the market position to [AMCo Director 1]***[1386] *when I speak to him on weds [sic] and* ***if you can once again take [AMCo Employee 2]***[1387] ***through it when you speak to him*** *. [sic] If they push alliance [sic] or lexon/Medreich [sic] too much it will end up being a car crash for all*' (emphasis added);[1388]

5.520.2 [Focus Director 1]'s email of 15 June 2015 as cited above is evidence that the Focus vendors were aware of the Market Exclusion Agreement (see paragraph 5.494 above) but that, at that point, the Focus vendors still needed to take AMCo management ([AMCo Director 1] and [AMCo Employee 2], the author of the May 2015 email cited by Advanz) through what [Focus Director 1] described as '*the market position*' a further time in mid-June 2015;[1389] and

5.520.3 ultimately, AMCo's decision-making in respect of the Primegen product development culminated not in AMCo seeking to launch its own product, but in adjusting the profit share with Lexon in February 2016.

5.521 Finally, Advanz submitted that the fact that Focus actively considered commercialising the Primegen MA and ending its distribution agreement with Alliance, is clear from the CMA's evidence on the case file, as shown for example in an internal email from [AMCo Employee 3] email of 19 July 2016.[1390] However, the CMA finds that the [AMCo Employee 3] email of 19 July 2016 cited by Advanz must be set alongside the other clearer and unambiguous correspondence as cited in paragraphs 5.501 to 5.503 (in documents prior to July 2016) and paragraph

[1385] Advanz RLF, 22 April 2021, paragraphs 4.104 and 4.105 (URN: PRO-C7112), citing email [AMCo Employee 2] to [AMCo Director 1] and [AMCo Director 2] (amongst others) entitled '*URGENT feedback required*' 14 May 2015 (URN: PRO-E001578).

[1386] Interview [Focus Director 1], 2 October 2018, page 258 lines 3-6 (URN: PRO-C3294).

[1387] Interview [Focus Director 1], 2 October 2018, page 258 lines 9-11 (URN: PRO-C3294.

[1388] Email [Focus Director 1] to [Focus Director 2] entitled '*Re: Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616).

[1389] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616).

[1390] Advanz RSO, 1 August 2019, paragraph 3.243 (URN: PRO-C5111), citing email [AMCo Employee 3] to [AMCo Director 2], [AMCo employee], [Focus Employee 1], and [AMCo employee] (all AMCo) entitled '*Alliance Pharmaceuticals Meeting Notes*' 19 July 2016 (URN: PRO-E001867) in which [AMCo Employee 3] had written *'[w]e have a distribution agreement through legacy Focus (3 month notice period?) […] Concordia [formerly AMCo] launch [is] ongoing but timeline slipping to 12.16 […] [f]lag reduced volume to Alliance and formalise in B.17 submission […] Launch Concordia development in 2017*'.

5.505 (in documents subsequent to July 2016) above showing that AMCo management had decided that it was not going to launch the Primegen product.[1391]

5.522 Cinven submitted that AMCo's decision to use the Primegen MA as commercial leverage against Lexon was not mutually exclusive with either: (i) obtaining access to the lower cost Lexon-Medreich product (which AMCo/Focus have submitted was the very purpose of continuing to pay the profit share); or (ii) launching the lower cost Primegen product, which Cinven claims AMCo continued to pursue after the second renegotiation.[1392] However, the evidence cited in paragraphs 5.314 to 5.324 shows that the Lexon-Medreich product would not have been cheaper than the Alliance product and the evidence cited above (see paragraphs 5.501 to 5.503 above) shows that AMCo did not seek to launch the lower cost Primegen product. Instead, AMCo simply chose to renegotiate the profit share with Lexon and continue to purchase the product from Alliance.

5.523 Based on the evidence set out above, the CMA concludes that Focus's conduct relating to the Primegen licence grant and the second profit share renegotiation is further evidence of the existence of the Market Exclusion Agreement. Focus/AMCo's approach to the second profit share renegotiation, its internally reasoned analysis, and its decision to proceed with the renegotiation rather than attempting to launch its own product, provide evidence that Lexon was being compensated through the Focus-Lexon Heads of Terms for not launching the competing product it had developed with Medreich.

Focus continued to make payments to Lexon, despite the lack of receipt of any product, as compensation for Lexon's non-entry into the market

5.524 Pursuant to the profit share clause in the Focus-Lexon Heads of Terms, Focus paid Lexon a total of £7,861,912.90 from January 2014 until the end of July 2018. Whilst the profit share payments were relatively modest when they started, as the sales price charged by Focus to wholesalers increased as Focus had anticipated (see paragraph 5.196.3 above), the payments became much more substantial, ultimately reaching over £600,000 per quarter during 2016 and early 2017.[1393] Focus made these payments to Lexon despite failing to receive any product from Lexon under the Focus-Lexon Heads of Terms with the exception of a single batch of [✂] packs in March 2018 (see paragraph 3.273)) and despite, therefore, the

[1391] Cinven also pointed to the fact that in April, May and June 2016 AMCo and [✂] discussed supply terms and engaged in the correspondence about manufacture between September and December 2016 (Cinven RLF, 22 April 2021, paragraph 2.65 (URN: PRO-C7107)). However, none of this evidence constitutes clear evidence that AMCo did wish to launch commercial volumes of the Primegen product, as opposed to continuing to discuss terms for a small batch of product which AMCo considered purchasing, in [AMCo Director 2]'s words, '*just in case*' (Email [AMCo Director 2] to [Focus Employee 1] entitled '*Re: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757)).

[1392] Cinven RLF, 22 April 2021, paragraph 2.70 (URN: PRO-C7107).

[1393] See Annex I:.

nominal product supplier under a supply agreement failing to honour the fundamental term of the agreement (namely to supply product).

5.525 The CMA finds that the sole credible explanation for Focus' decision, under its independent ownership until 30 September 2014 and then under AMCo's ownership from 1 October 2014, to continue making those profit share payments to Lexon is that the profit share payments represented compensation, pursuant to the Market Exclusion Agreement, for Lexon not launching the product it had developed with Medreich as a competitor into the market.

5.526 The CMA also finds that, despite the lack of product from Lexon, there is no evidence that Focus ever revisited or questioned the proposition that it should continue making profit share payments to Lexon, which is supportive of the fact that these payments were made pursuant to the Market Exclusion Agreement.

5.527 A number of alternative explanations for the continued payments made by Focus/AMCo to Lexon have been put forward by Focus and AMCo witnesses. These factors, it was said, explained why Focus/AMCo decided to continue making the payments despite not receiving any product from Lexon under the Focus-Lexon Heads of Terms with the exception of a single batch of [✂] packs in March 2018. The CMA has already considered the evidence relating to those explanations that have been put forward as explaining why Focus originally agreed to the inclusion of the profit share clause in the Focus-Lexon Heads of Terms (and then continued to make payments to Lexon pursuant to that clause despite the lack of product),[1394] including that Focus made the payments:

5.527.1 to access a cheaper Lexon/Medreich Prochlorperazine POM product (see paragraphs 5.314 to 5.324);

5.527.2 the expected short-term nature of the arrangement and Focus' expectation that the Lexon/Medreich product was 'imminent' (see paragraphs 5.325 to 5.329); and

5.527.3 to get access to Lexon's pipeline of other products (see paragraphs 5.330 to 5.340).

5.528 For the reasons set out previously, the CMA has found that none of those explanations, individually or collectively, credibly explains why Focus agreed to the inclusion of the profit share clause and/or Focus' willingness to make payments to Lexon under the clause despite the lack of product.

5.529 In this section below, the CMA considers other explanations put forward by Focus and AMCo witnesses, as well as the Parties, to explain why, as time progressed,

[1394] See paragraphs 5.304 to 5.345.

Focus and AMCo persisted in paying profit share payments to Lexon that increased in scale until Q2 2017, namely because:

5.529.1 Focus/AMCo was contractually obliged to do so;

5.529.2 AMCo management accepted advice from the vendors of Focus, [Focus Director 1] and [Focus Director 2], who were motivated by their own earn-out considerations; and

5.529.3 the Focus vendors disengaged, and the lack of product from Lexon went unnoticed by AMCo management.

5.530 For the reasons set out below, the CMA considers that, whether taken individually or collectively, these factors cannot credibly explain the continued payments (i.e. the transfer of value) from Focus to Lexon: these payments are credibly explained only by reference to compensation of Lexon pursuant to the Market Exclusion Agreement.

5.531 The CMA then sets out the Parties' further representations that the profit share renegotiations do provide evidence of Focus revisiting and questioning the profit share payments, and the CMA explains why it rejects these submissions.

Whether Focus continued to make the payments because it was contractually obliged to do so

5.532 [Lexon Director 1] initially suggested in interview that Focus was contractually bound to pay Lexon under the Focus-Lexon Heads of Terms, and this was why the payments were made despite the fact Lexon did not supply any Prochlorperazine POM to Focus with the exception of a single batch in March 2018.[1395] However, it is clear from the plain words of the Focus-Lexon Heads of Terms that either Focus or Lexon could terminate the agreement on the provision of six months' notice,[1396] and [Lexon Director 1] appears to have revised his position on this in his

[1395] The CMA understands from the interview with [Lexon Director 1] that he based this view on the fact that he thought that, under the terms of the Focus-Lexon Heads of Terms, termination was possible only on or after the initial five-year period of the agreement (Interview [Lexon Director 1], 10 September 2018, Part 1, CD 3, page 32 line 2 to page 33, line 6 (URN: PRO-C3188)).

[1396] '*Period of agreement and Termination Notice period:- The agreement will run for 5 Years [sic] from signing of Heads of agreement. Termination Notice period will be 6 months for either party.*' Focus-Lexon Heads of Terms (URN: PRO-E000429). See paragraph 3.106. In addition, the CMA notes that in reply to a Section 26 Notice from the CMA, Advanz stated that the Focus-Lexon Heads of Terms expired at the end of its stated five year term and that there was no need for a notice of termination to effect this. The information supplied by Advanz in response to the Notice does not indicate that Lexon contested this interpretation of the Focus-Lexon Heads of Terms by insisting upon a Termination Notice being served at the time the agreement was said to expire (Section 26 response of Advanz dated 20 February 2019, to the CMA Notice of 6 February 2019, questions 2(a) and 2(b) (URN: PRO-C3820)). That position is inconsistent with [Lexon Director 1]'s original understanding of the Focus-Lexon Heads of Terms as stated in his interview. If the agreement would automatically terminate upon the expiry of the five year term, then the Termination Notice contemplated by the agreement could only have been required within the initial five year term. Finally, the CMA notes that the Focus-Lexon Heads of Terms were amended twice in Focus' favour without any corresponding benefit for Lexon (see paragraphs 3.168 and 3.190). The CMA considers that this undermines the suggestion that there was no termination right prior to the expiry of the initial five year period. Were there no ability for Focus to terminate the Focus-Lexon Heads of Terms, Lexon would have had no incentive to agree to amendments that were not in its interests; that is, if Lexon had not agreed to the profit share amendments in Focus' favour, Focus could have terminated the Focus-Lexon Heads of Terms.

subsequent evidence to the CMA, in which he stated that Focus could have cancelled the Focus-Lexon Heads of Terms at any time on six months' notice.[1397]

5.533 More importantly, given that it was Focus making the payments to Lexon, [Focus Director 1]'s view was that Focus had the right to terminate the agreement during the five year term,[1398] such that he did not consider that the contract required him to continue to make payments to Lexon, despite Lexon not supplying product in return.[1399]

5.534 For the reasons above, the CMA does not consider that Focus' continued payments to Lexon can be explained by reference to the fact that Focus was under a contractual obligation to make those payments under the Focus-Lexon Heads of Terms. It is clear that, even putting to one side Lexon's fundamental failure under the contract to provide any product, Focus could have terminated the agreement on six months' notice to Lexon.

5.535 Cinven argued that the existence of a six month notice provision in the Focus-Lexon Heads of Terms would have substantially reduced Focus' incentives to exit from the agreement since it would have been required to continue making payments to Lexon for six months in any event.[1400] However, the CMA does not consider this argument persuasive in the context of a five year agreement, particularly in circumstances in which Focus, and then AMCo, were continuing to increase the market price of Prochlorperazine POM until June 2017 (see Figure 2) such that Focus/AMCo would have been aware that the profit share sacrificed to Lexon would increase as the agreement progressed.

5.536 In fact, to the extent that the notice provision in the Focus-Lexon Heads of Terms is relevant in understanding Focus' motivations for continuing to pay Lexon pursuant to the profit share term, the more significant point is that Focus was aware that Lexon could have terminated the agreement at any point by giving six months' notice (see paragraph 5.533 above). This raised the risk for Focus that Lexon – having received profit share payments from Focus over a prolonged period of time – could subsequently give notice and be free of any contractual obligation towards Focus under the Focus-Lexon Heads of Terms. The fact that Focus continued to pay profit share to Lexon despite not having any guarantee that Lexon would not terminate the Focus-Lexon Heads of Terms provides further evidence that the

[1397] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 83 (URN: PRO-C5092). [Lexon Director 1] confirmed this position in his response to the Letter of Facts, stating that '*Focus was contractually obliged to make the payments but could, of course, have terminated the Focus Agreement [the Focus-Lexon Heads of Terms] on six months' notice had it wished to do so*' (Lexon RLF, 21 April 2021, paragraph 61(URN: PRO-C7104)).

[1398] Interview [Focus Director 1], 2 October 2018, page 204, line 15 to page 205, line 2 (URN: PRO-C3294).

[1399] Similarly, Advanz submitted that it did not dispute that Focus could have terminated its contractual relationship with Lexon but it did not do so because it considered the launch of the Prochlorperazine POM to be imminent and because it was keen to keep up the commercial relationship with Lexon because of its (perceived valuable) pipeline (Advanz RLF, 22 April 2021, paragraph 4.189 (URN: PRO-C7112)). The CMA's analysis in respect of these stated motivations is set out in paragraphs 5.325 to 5.340 above.

[1400] Cinven RLF, 22 April 2021, paragraph 2.30(b) (URN: PRO-C7107).

profit share payments were compensation for Lexon not entering the market with the product it had developed with Medreich.

5.537 Finally, the CMA observes that if Focus had made such significant payments to Lexon on the basis of a contractual obligation in the Focus-Lexon Heads of Terms, it would be surprising if Focus did not expect comparable contractual performance by Lexon. In particular, it would be expected that Focus would have queried with Lexon whether the supply of a single batch of product of [✂] packs in March 2018 (accounting for less than a month's market demand for the product) actually constituted satisfactory contractual performance on the part of Lexon. This would have been expected from any purchaser, but in particular one that had by March 2018 paid over £7 million to Lexon in profit share payments.[1401] However, there is no evidence that Focus did raise concerns with Lexon in this respect.

Whether AMCo continued to make the payments because AMCo management accepted advice from [Focus Director 1] and [Focus Director 2], who were motivated by their own earn-out considerations

5.538 As two of the vendors of Focus, [Focus Director 1] and [Focus Director 2] had personal vested interests in preserving the existence of the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms in order to preserve the value of their earn-out consideration on the sale of Focus under the sale and purchase agreement.[1402] The CMA has considered whether AMCo may have continued to make profit share payments to Lexon under the Focus-Lexon Heads of Terms on the basis that AMCo management was acting on the advice of [Focus Director 1] and [Focus Director 2], who were both employed by AMCo after the sale of Focus to AMCo, without AMCo having regard to their conflict of interest in this respect.

5.539 The CMA finds that AMCo management's decision making in respect of the continued payment of profit share to Lexon cannot be explained on the basis that it was simply blindly following advice from [Focus Director 1] and [Focus Director 2].

5.540 First, it is clear that the AMCo management was in fact well aware of the potential for a conflict of interest arising in this respect, and aware therefore of the need to consider any advice from [Focus Director 1] and [Focus Director 2] accordingly, as evidenced by:

5.540.1 on 24 June 2015, [AMCo employee] emailed [AMCo Employee 2] and [AMCo Director 2] asking, in respect of '*Prochlorperazine*', '*[i]s there a conflict of interest with the Focus guys?*';[1403] this email demonstrates an

[1401] See Annex I:, assuming the profit share payment in respect of the Q4 2017 was paid from Lexon to Focus in January 2018 in line with the timing for past payments (or, in any event, by March 2018).

[1402] As noted by Advanz, Advanz RLF, 22 April 2021, paragraph 4.136 (URN: PRO-C7112).

[1403] Email [AMCo employee] to [AMCo Employee 2] and [AMCo Director 2] (all AMCo) entitled '*Prochlorperazine*' 24 June 2015 (URN: PRO-E001629). The CMA rejects Advanz's submission that the email simply reflected a question,

awareness within AMCo of the Focus vendors' potential conflict of interest in relation to their advice to AMCo on Prochlorperazine POM; and

5.540.2 in his interview with the CMA, [AMCo Director 2] commented that AMCo management was aware by 24 June 2015 of the Focus vendors' potential conflict of interest, and that he would have considered the Focus vendors' advice to AMCo management in that context.[1404]

5.541 Second, and as set out below (see paragraph 5.543), there is clear evidence that AMCo management did engage directly on Prochlorperazine POM, including with the fact that its subsidiary, Focus, was making significant profit share payments to Lexon in the absence of any product being supplied.

Whether AMCo continued to make the payments because the Focus vendors disengaged and the lack of product from Lexon went unnoticed by AMCo management

5.542 [Focus Director 1] stated in his interview with the CMA that after the sale of the Focus business to AMCo he disengaged.[1405] Advanz submitted that, as result of [Focus Director 1]'s disengagement, '*the lack of product went unnoticed by the new management given the various mergers and acquisitions of its acquirer*.'[1406]

5.543 The CMA has found (see paragraphs 5.538 to 5.541 above) that, although [Focus Director 1]'s personal motivations may have changed following the sale of the Focus business to AMCo, AMCo management was aware that [Focus Director 1]'s interest in preserving the status quo presented a potential conflict of interest. In addition, it is not credible to explain AMCo's continued payments to Lexon based on AMCo's new management not 'noticing' that they were paying for product that had not materialised. This is evident from the fact that:

5.543.1 [AMCo Director 2] commented in an interview with the CMA that he became involved in the Prochlorperazine POM situation from March 2015

rather than awareness (Advanz RLF, 22 April 2021, paragraphs 4.208-4.209 (URN: PRO-C7112)) – [AMCo employee]'s email shows an awareness of the potential for a conflict in raising the question, and in any event [AMCo Employee 2] responds '*Will uodate [sic] you later*' indicating an understanding of [AMCo employee]'s question (URN: PRO-E001629); [AMCo Director 2] did not question the premise that [AMCo employee]'s email showed an awareness of the potential for a conflict of interest (see interview [AMCo Director 2], 7 January 2020, page 57, line 26 to page 58, line 16 (URN: PRO-C5994)).

[1404] Interview [AMCo Director 2], 7 January 2020, page 50, line 18 to page 51, line 3; page 57, line 26 to page 58, lines 16; page 59 lines 18-26 (URN: PRO-C5994). The CMA rejects Advanz's suggestion that [AMCo Director 2] said that his awareness of the potential conflict of interest was not something that coloured his decision-making relative to Prochlorperazine POM (Advanz RLF, 22 April 2021, paragraphs 4.210-4.211 (URN: PRO-C7112)): whilst [AMCo Director 2] stated that he did not get into the details of what the implications would have been for the Focus vendors of cancelling contracts, he expressly confirmed that AMCo management was aware of the need to take the advice of the Focus vendors into account against the potential concern of the conflict of interest (Interview [AMCo Director 2], 7 January 2020, page 59, lines 18-26 (URN: PRO-C5994)).

[1405] Interview [Focus Director 1], 2 October 2018, page 189, lines 7-13; page 224, lines 4-11; and page 225, lines 13-15 (URN: PRO-C3294).

[1406] Advanz RSO, 1 August 2019, paragraphs 3.180.6 and 3.209 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraph 4.156 (URN: PRO-C7112).

and would have been briefed by [Focus Director 1], [Focus Director 2] and/or [Focus Employee 1].[1407] It is not credible that such a briefing would have omitted the key fact that, under the Focus-Lexon Heads of Terms, Lexon had not yet supplied any product to Focus. [AMCo Director 2]'s interview is, in any event, clear that he understood the details of the contractual arrangements in the summer of 2015.[1408]

5.543.2 AMCo management had commissioned an analysis of their commercial options with respect to Prochlorperazine POM in June 2015 in the context of their own Primegen product development – which clearly flushed out (even if it had not been clear before) that AMCo was paying Lexon profit share payments pursuant to an agreement under which Lexon had not delivered any product (see paragraph 5.497 above).[1409]

5.543.3 [AMCo Director 2] confirmed in interview that he had spoken with [Focus Director 1] about the fact that Lexon had not supplied any product.[1410]

5.543.4 [AMCo Director 2] subsequently met with [Lexon Director 1] in February 2016 to conclude an amendment to the profit share split under the Focus-Lexon Heads of Terms (see paragraph 5.503 above). It is not credible that he would have gone into this meeting without an understanding of the fact that Lexon had failed to supply product pursuant to a supply agreement dated 1 August 2013.

5.544 The CMA therefore finds that AMCo management did become aware of the fact that Lexon was not supplying product and that, under AMCo's ownership, Focus' continued payments of profit share to Lexon cannot be explained, as Advanz submitted, on the basis that this fact went unnoticed by new management.

The Parties' representations that the profit share renegotiations show that Focus questioned making profit share payments to Lexon

5.545 Advanz submitted that Focus questioned the profit share payments it was making in the absence of product from Lexon. Advanz pointed in this respect to the fact that the profit share payments were varied twice in Focus' favour, as well as arguing that the following evidence demonstrated that '*Focus sought to question*

[1407] Interview [AMCo Director 2], 7 January 2020, page 15, lines 21-22 and page 16, lines 14-20 (URN: PRO-C5994).

[1408] Interview [AMCo Director 2], 7 January 2020, page 20, lines 14-16 (URN: PRO-C5994).

[1409] See email [AMCo Employee 4] to various colleagues (AMCo) entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) attaching presentation entitled '*Project CAPITAL BD Workstream*' 30 June 2015 slide 15-17 (URN: PRO-E001636) (see paragraph 5.497).

[1410] Interview [AMCo Director 2], 7 January 2020, page 122, line 10-15 (URN: PRO-C5994).

and revisit the profit share the moment it began receiving supply from Alliance in January 2014':[1411]

5.545.1 the minutes of Focus sales meetings of 28 January 2014 and 24 March 2014 which referred to '*ACTION – discuss profit share agreement with Lexon – [Focus Director 1]'*;[1412]

5.545.2 the correspondence between [Focus Director 1] and [Lexon Director 1] of 14 April 2014 referring to their '*discussion regarding the agreement on profit share*';[1413] and

5.545.3 the fact that the profit share was altered in November 2014 following a meeting between [Focus Director 1] and [Lexon Director 1].[1414]

5.546 In addition, Advanz referred in this context to the correspondence between Focus and Lexon on 14 April 2014 and on 4 November 2014 as evidence of the consideration by Focus and Lexon of the profit share '*in the context of Lexon's ability to supply Focus with product*'[1415] and referred to comments made by [Focus Director 1] in his interview with the CMA that Advanz submitted showed that the profit share renegotiation in November 2014 '*was a direct consequence of Lexon's failure to deliver product*'.[1416]

5.547 Cinven further submitted that the '*[t]he timing of [the November 2014] renegotiation and the fact that it was agreed during a meeting concerning Lexon's failure to supply Focus confirms that this renegotiation was arrived at as a consequence of Lexon's failure to supply Focus in a timely manner*'.[1417] In addition, Cinven submitted that it is not reasonable to conclude that the November 2014 renegotiation showed Lexon rewarding Focus for price rises Focus had achieved given that such price rises were, on the CMA's case, precisely what was contemplated in the Market Exclusion Agreement, meaning that there was no basis

[1411] Advanz RSO, 1 August 2019, paragraph 3.210 (URN: PRO-C5111). See similarly Cinven RSO, 15 August 2019, paragraphs 4.51 and 4.54 (URN: PRO-C5132) and Cinven RLF, 22 April 2021, paragraph 2.41 (URN: PRO-C7107).

[1412] Advanz RSO, 1 August 2019, paragraph 3.210.1-3.210.2 (URN: PRO-C5111), citing *Focus Sales Meeting Minutes*, dated 28 January 2014, p.5 (URN: PRO-E003779) and Focus Sales Meeting Minutes, 24 March 2014, p.4 (URN: PRO-E003785).

[1413] Advanz RSO, 1 August 2019, paragraph 3.210.3 (URN: PRO-C5111), citing email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

[1414] Advanz RSO, 1 August 2019, paragraph 3.210.4 (URN: PRO-C5111), citing email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

[1415] Advanz RSO, 1 August 2019, paragraph 3.211.3 (URN: PRO-C5111) referring to email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795), email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796) and email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

[1416] Advanz RSO, 1 August 2019, paragraph 6.44 (URN: PRO-C5111), citing interview [Focus Director 1], 2 October 2018, page 155, lines 18-22 and page 209, lines 7-11 (URN: PRO-C3294).

[1417] Cinven RSO, 15 August 2019, paragraphs 4.55 and 4.172 (URN: PRO-C5132).

for Lexon to 'reward' Focus or to amend the profit share at this point in time (other than to reflect Lexon's failure to deliver product).[1418]

5.548 Finally, Advanz submitted that there was an inconsistency in the CMA relying on evidence and analysis around the second (Primegen) profit share renegotiation as evidence of the Market Exclusion Agreement whilst at the same time finding that there was no evidence of Focus revisiting or questioning the payment of profit share to Lexon.[1419]

5.549 The CMA does not accept Advanz's and Cinven's submissions in this respect.

5.550 First, the evidence referred to by Advanz does not demonstrate that Focus did question and revisit the profit share payments as soon as it received product from Alliance.

5.550.1 The Focus sales meetings minutes of 28 January and 24 March 2014 referred to discussing the profit share agreement with Lexon, but do not contain any suggestion that the profit share should be withheld or not paid to Lexon. Nor do the minutes refer to Lexon's failure to provide any product, which is unsurprising given that the Medreich MA had only recently been granted on 9 January 2014.[1420] It is relevant that those minutes do not, despite the stipulation in the Focus-Lexon Heads of Terms[1421] that Focus would be responsible for forecasting of sales volumes by providing Lexon with a rolling 12 month forecast, contain any reference to Focus providing any such forecast to Lexon despite the fact that the Medreich licence had been granted on 9 January 2014 and this was before any difficulties with the Medreich production or licensing were known of.

5.550.2 The correspondence in April 2014 between Focus and Lexon is considered in detail in paragraphs 5.598 to 5.602 below, but does not suggest that Focus was resistant to continuing to pay profit share to Lexon: to the contrary, [Focus Director 1] expressly states in his second email of 14 April 2014 that '*With regard to our discussion regarding the agreement on profit share I agree with your comments and we shall*

[1418] Cinven submission dated 10 December 2019 in response to the CMA's questions of 26 November 2019, paragraph 1.16(c) (URN: PRO-C5479).

[1419] Advanz RSO, 1 August 2019, paragraph 3.236 (URN: PRO-C5111); this submission is made in the context of Focus' awareness of the Market Exclusion Agreement.

[1420] The CMA does not accept Cinven's submission that '*the discussions with Lexon contemplated in Focus' sales meetings were foreshadowing the discussions that actually took place – i.e. discussions regarding Lexon's failure to supply Focus with the Lexon-Medreich product*' (Cinven submission dated 10 December 2019 in response to the CMA's questions of 26 November 2019, paragraph 1.8 (URN: PRO-C5479)) – the actual content of the correspondence between Focus and Lexon in April 2014 does not support this view given [Focus Director 1]'s willingness to continue paying profit share to Lexon.

[1421] Focus-Lexon Heads of Terms as sent by [Lexon Director 1] to [Focus Director 1] on 8 August 2014 (URN: PRO-E000429).

continue with the current agreement as signed in the heads of agreement [Focus-Lexon Heads of Terms]'.[1422]

5.551 Second, as regards the first profit share renegotiation, whilst it is correct that the profit share was amended in November 2014 to provide Focus with 50% of profits above £10.50, the CMA finds that the rationale for this profit share related to [Focus Director 1]'s efforts to achieve price increases rather than being a 'punishment' on Lexon for not having supplied product by this point.

5.551.1 The very particular structure of this revision (a change above a certain price level) was consistent with Focus having achieved significant price rises by this point, rather than reflecting Lexon's failure to deliver product (which would more naturally have been reflected in a reduced percentage across the board or, more simply, in Focus declining to make further profit share payments to Lexon unless and until Lexon actually supplied product under the Focus-Lexon Heads of Terms).

5.551.2 The amount of money paid by Focus to Lexon increased in absolute terms after the first profit share renegotiation in November 2014 which took effect from February 2015: the payment made by Focus to Lexon as against Focus' sales for Q4 2014 (under the original terms) was significantly exceeded by that for Q1 2015 when the revised terms took effect (see Annex I:); this itself suggests that the revision was not designed to punish Lexon for its failure to supply product.

5.551.3 There was no follow-up by Focus subsequent to the 4 November 2014 profit share renegotiation (see paragraph 5.614.3 below), which would have been expected had this adjustment actually been designed to 'punish' Lexon for its failure to deliver product.

5.551.4 Whilst the CMA accepts that price increases by Focus were anticipated as part of the Market Exclusion Agreement, it does not follow that the Parties would not contemplate revisions to the profit share as the price evolved.

5.551.5 [Lexon Director 1]'s interview evidence does not suggest that the profit share revision in November 2014 was because of Lexon's failure to deliver product.

(a) Although he stated he could not remember the precise conversation, [Lexon Director 1] initially stated that '*I'm -- I think it was to do with the fact that, they were putting the prices up and that, I would -- I would get -- I was getting money -- a share a -- for want of a better word for doing nothing. […] But I -- we're still trying to get stock out of*

[1422] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

Medreich. So, I think – I think... that was it really. I -- I don't remember the specifics of it but I can confirm I do remember this […] They -- I think they, they, they were putting the price up. The category had changed or something like that. […] And they were going to increase the -- the list price.'[1423]

(b) In terms of Focus' perspective, [Lexon Director 1] later added '*He [Focus Director 1] was -- he was basically saying I want a greater incentive if I can get a higher price for it, you -- you stand to gain*'[1424] and he responded positively when it was put to him that '*this was basically […] reward for Focus's effort in increasing the price*'.[1425]

(c) The CMA sees no reason why [Lexon Director 1] would have wished to mislead the CMA in terms of stating that the increased prices explained the revision to the profit share clause if the actual explanation had related simply to Lexon's failure to deliver product.

5.551.6 The email exchange on 4 November 2014 between [Focus Director 1] and [Lexon Director 1] does not refer to any reason for the change to the profit share.[1426] Although [Focus Director 1] and [Lexon Director 1] also discuss an order of stock and the potential '*availability of released product*' in their correspondence of 4 November 2014,[1427] there is no suggestion in [Focus Director 1]'s email setting out the amendment to the profit share or in [Lexon Director 1]'s response that these points are in any way linked.[1428] The CMA finds that [Focus Director 1]'s comments in interview, as cited by Advanz in its representations,[1429] do not call into question this finding: not only are [Focus Director 1]'s comments about the lack of product not reflected in any of the contemporaneous documentation, [Focus Director 1]'s interview comments also lead by referencing the extent of the price increase that Focus had achieved as the explanation for the amendment – which is in keeping with the structure of the amended clause.[1430]

5.551.7 When [Focus Director 1] reported to AMCo on the revised profit share, he did not refer to Lexon's failure to supply product in the context of the

[1423] Interview [Lexon Director 1], 19 September 2018, Part 2, page 11 lines 5-13 and page 13 lines 21-26 (URN: PRO-C3191).

[1424] Interview [Lexon Director 1], 19 September 2018, Part 2, page 17 lines 21-22 (URN: PRO-C3191).

[1425] Interview [Lexon Director 1], 19 September 2018, Part 2, page 18 lines 14-17 (URN: PRO-C3191).

[1426] Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

[1427] For the CMA's analysis of the potential explanations for this reference in the correspondence of 4 November 2014 to Lexon having placed an order for stock, see paragraphs 5.612 to 5.616 below.

[1428] The CMA therefore rejects Cinven's submission that the 4 November 2014 correspondence '*provides cogent evidence that Lexon's continued failure to supply Focus with the Lexon-Medreich product was the reason for the 2014 Renegotiation*' (Cinven RLF, 22 April 2021, paragraph 2.42(b) (URN: PRO-C7107)).

[1429] See note 1416 above.

[1430] See Interview [Focus Director 1], 2 October 2018, page 155, lines 18-22 and page 209, lines 6-11 (URN: PRO-C3294).

amended terms: on 7 November 2014, he wrote to [AMCo Director 1] and [AMCo Employee 1] that: '*For your information please see belowI [sic] have agreed an increase in the profit share for Focuswith [sic] Lexon over an ASP of £10.50, We [sic] are implementing a price increase for start of next year that will take us over this number . As this was one of the products raised in the last meeting i [sic] thought I would keep you in the loop and it may make [AMCo employee] a little happier .*'[1431]

5.552 Third, as regards the second profit share renegotiation in June 2015 to February 2016, this cannot be seen as Focus questioning whether it should pay profit share to Lexon. Despite Lexon's failure to deliver any product, the commercial question between Focus and Lexon was the level of the profit share split between them and how this was affected by AMCo's anticipated acquisition of its own MA through the acquisition of Primegen. At no time did AMCo question whether Focus should continue paying profit share payments to Lexon as a result of its failure to deliver product, or challenge Lexon in this respect. Nor does the contemporaneous documentary evidence relating to the second profit share renegotiation reference the delay in Lexon delivering product to Focus as a basis for the renegotiated terms.

5.553 Fourth, it is not credible that, as the Parties suggest, Focus

5.553.1 would have expressed concern about paying profit share payments to Lexon in January and February 2014, when the Medreich Prochlorperazine POM licence had only recently been granted and the level of the quarterly profit share payments to Lexon were around £100,000; but

5.553.2 would *not* have expressed such concern during later periods when Lexon/Medreich had failed to supply product after several years and the quarterly profit share payments to Lexon reached over £700,000 (see Annex I: – but there is no evidence of any such concerns being expressed in later periods.

5.554 Fifth, [Lexon Director 1] stated in interview that he did not remember Focus ever querying with him whether it should continue to pay profit share despite the absence of product. When asked whether the 14 April 2014 correspondence resulted in any protestation from Focus about continued payments, [Lexon Director 1] replied: '*I can't remember. No I can't remember. No well they continued to pay me. I never had a conversation with Focus that said that they came back and said we don't think we should pay you because you're not able to supply product.*'[1432] The CMA sees no reason why [Lexon Director 1] would have wished to provide

[1431] Email, [Focus Director 1] to [AMCo Director 1] and [AMCo Employee 1] entitled '*FW: Prochlorperazine 3mg Tabs Heads of Agreement*' 7 November 2014 (URN: PRO-E003836).

[1432] Interview [Lexon Director 1], 10 September 2018, Part 1 CD4, page 8, lines 3-6 (URN: PRO-C3189).

misleading evidence on this point: had such a conversation taken place, [Lexon Director 1] would presumably have wished to draw this to the CMA's attention in order to demonstrate that Focus' profit share payments were being made pursuant to the provisions of the Focus-Lexon Heads of Terms rather than based on another, unspecified consideration.

Conclusion on Focus' continued payments to Lexon as compensation for Lexon's non-entry into the market

5.555 The CMA has considered above the alternative explanations for the continued payments made by Focus/AMCo to Lexon as put forward by witnesses or by the Parties. For the reasons set out above, the CMA considers that, whether taken individually or collectively, these factors cannot credibly explain the continued payments (i.e. transfer of value) from Focus to Lexon. The absence of any other credible explanation for the value transfers supports the CMA's finding as to the existence of a common understanding (as agreed between Alliance and Lexon) that, in exchange for compensation, Lexon would not enter the market. Further, the CMA finds that, whilst the level of the profit share payments was varied, there is no evidence of Focus revisiting or questioning whether payments would continue to be made to Lexon under the profit share clause despite the lack of product supplied by Lexon/Medreich.

Later documentary evidence from AMCo confirms that it was aware that Lexon had been involved in the negotiation of the Alliance-Focus Agreement

5.556 The CMA finds that later AMCo documentary evidence provides strong evidence that an agreement had been reached between Alliance and Lexon in the form of the Market Exclusion Agreement. In an email dated 23 March 2017, [Focus Employee 1] provided internal commentary on Focus' sales of a number of products to wholesalers. In her email, she observed to [AMCo employee] that the relevant products (which included Prochlorperazine POM) were generally only available from Focus to mainline wholesalers (i.e. which would not include Lexon), but she added:

> *'The only reason that Lexon gets Prochlorperazine Buccal Tablets is because they helped set up the supply agreement with Alliance Pharma (who also make our Aspirin EC 300mg).'*[1433]

5.557 In other words, [Focus Employee 1]'s email confirms that it was Focus' understanding that the '*only reason*' that Focus (in its capacity as a supplier) supplied Lexon (in its capacity as a wholesaler, but not a mainline wholesaler) with Prochlorperazine POM was because Lexon, '*helped set up the supply agreement with Alliance*'. This email therefore shows that Lexon had been involved in setting

[1433] Email [Focus Employee 1] to [AMCo employee] entitled '*RE: Well Pharmacy price amendments – Focus lines*' 23 March 2017 (URN: PRO-E002030).

up the Alliance-Focus Agreement, pursuant to the Market Exclusion Agreement (see paragraph 5.195).

[Focus Employee 1]'s commentary on her email of 23 March 2017 and the associated representations of the Parties

5.558 In an interview with the CMA, [Focus Employee 1] stated in respect of her email of 23 March 2017 that, although this reflected her understanding at the time, she subsequently came to a different understanding, which she described as being that '*the profit share was because Lexon had a licence*'.[1434] However, the CMA rejects [Focus Employee 1]'s evidence in this respect and the suggestion that the CMA should not place evidentiary weight on the plain words of her email.

5.558.1 First, despite the fact that her email from March 2017 was relatively recent at the time of her interview in February 2019, she stated she could not recall why she had had that original understanding nor why her understanding had subsequently changed.[1435]

5.558.2 Second, [Focus Employee 1] was the [✂] at Focus and was present at Focus sales meetings in 2014 in which the Focus profit share with Lexon was discussed.[1436] Given [Focus Employee 1]'s role, her employment at Focus over a number of years,[1437] her presence at such meetings and the length of time that the Focus-Lexon Heads of Terms had been in place by the time she wrote her email in March 2017, it can be inferred that [Focus Employee 1] had at least a basic understanding of the Focus-Lexon Heads of Terms.

5.558.3 Third, [Focus Employee 1]'s email of 23 May 2017 does not express any equivocation or uncertainty on this point: her reasoning is crisp, concise and confident.

5.558.4 Fourth, the CMA's conclusion about the weight to be attributed to [Focus Employee 1]'s contemporaneous, documentary evidence in this respect is strengthened by comments made by [AMCo Director 2] in his second interview, where he was clear that [Focus Employee 1] would have been in a position to brief him on the commercial aspects of Focus' arrangements relating to Prochlorperazine POM and had been involved in

[1434] Interview [Focus Employee 1], 7 February 2019, page 44, lines 18-19 (URN: PRO-C3826).

[1435] Interview [Focus Employee 1], 7 February 2019, page 42, line 21 to page 48, line 1 (URN: PRO-C3826).

[1436] Interview [Focus Employee 1], 7 February 2019, page 8, line 26 to page 11, line 12 (URN: PRO-C3826). See for example Focus Sales Meeting Minutes, dated 28 January 2014 (URN: PRO-E003779).

[1437] From [✂] until [✂]. Interview [Focus Employee 1], 7 February 2019, page 8, line 26 to page 9, line 24.

AMCo's assessment as to whether or not it should keep paying Lexon under the profit share.[1438]

5.559 Advanz quoted [Focus Employee 1]'s interview transcript as evidence that her job at Focus was [✂], she was a long way removed from the senior individuals and she had no involvement in negotiating arrangements for the business, thereby explaining her misunderstanding of the situation.[1439] Advanz further submitted that the fact that [Focus Employee 1] participated in Focus discussions about product strategy related to Prochlorperazine POM does not contradict these explanations that her email of 23 March 2017 reflected a simple misunderstanding on her part.[1440] The CMA does not accept Advanz's submissions:

5.559.1 The CMA's finding is not that [Focus Employee 1] participated in negotiating arrangements relating to Prochlorperazine POM: it was that she had sufficient understanding of the basis of Focus' product strategy for Prochlorperazine POM to be able to comment on what had been previously negotiated by [Focus Director 1], as reflected in the plain wording of her email of 23 March 2017.

5.559.2 [Focus Employee 1] was one of only four individuals present in the Focus Sales Meetings in early 2014,[1441] the others being [Focus Director 1], [Focus Director 2] and [Focus employee]: this does not suggest that she was, as Advanz submits, a long way removed from the senior individuals.

5.560 Advanz submitted that, even if it were the case that Lexon recommended Focus to Alliance as its distributor, '*that in itself would not be untoward*'.[1442] Cinven similarly stated that '*[a]t most, the CMA's interpretation would allow for an inference that Focus was aware that Lexon had communications with Alliance regarding the potential for Focus to act as Alliance's distributor*'.[1443] The CMA rejects these submissions.

5.560.1 First, they gloss over the words actually used by [Focus Employee 1], which were that Lexon helped to *'set up the supply agreement',* rather than merely putting Alliance and Focus in touch or making a recommendation to Alliance.

5.560.2 Second, the plain reading of [Focus Employee 1]'s email is also consistent with the plain reading of [Focus Director 1]'s 22 June 2013 email: *'[…] the*

[1438] Interview [AMCo Director 2], 7 January 2020, page 16, lines 18-20, page 18, line 26 to page 19, line 2; page 195, lines 13-14 (URN: PRO-C5994).

[1439] Advanz RSO, 1 August 2019, paragraph 3.107 (URN: PRO-C5111).

[1440] Advanz RLF, 22 April 2021, paragraph 4.145 (URN: PRO-C7112).

[1441] See for example: *Focus Sales Meeting Minutes*, 28 January 2014 (URN: PRO-E003779), *Focus Sales Meeting Minutes*, 24 March 2014 (URN: PRO-E003785), and *Focus Sales Meeting Minutes*, 28 April 2014 (URN: PRO-E003799).

[1442] Advanz RSO, 1 August 2019, paragraphs 3.107 and 3.166.2(b) (URN: PRO-C5111).

[1443] Cinven RLF, 22 April 2021, paragraph 2.101 (URN: PRO-C7107).

agreement [Lexon Director 1] made was we [i.e. Focus] initially buy at 25% off thier [i.e. Alliance] [sic] current trade price for the initial stock to allow us to open generic bins […]'[1444] (as discussed at paragraph 5.195 above).

5.560.3 Third, Advanz and Cinven's positioning of [Focus Employee 1]'s explanation is also not consistent with the characterisation of Lexon's role in setting up the Alliance-Focus Agreement as originally described by [Alliance Director 1] – which supports the significance the CMA places on [Focus Employee 1]'s email. In his initial interview, [Alliance Director 1] was asked whether '*Lexon used […] the Medreich forthcoming product as leverage to get you [Alliance] to consider a deal with Focus*'; his response was: '[*t]hat's how it ended up*', and he subsequently added by way of further explanation: '*Yes I'm not sure of, you know whether Focus were the, a distribution partner for Lexon I don't know […] I just know that that conversation started with Lexon, and ended with Focus that's all I know*'.[1445] [Alliance Director 1]'s characterisation of Lexon's active role in relation to the Alliance-Focus Agreement is indeed '*untoward'* (contrary to Advanz's suggestion) and is supportive of the CMA's reading of [Focus Employee 1]'s email commentary, namely that Focus knew that Lexon had gone far beyond passively or innocuously discussing with Alliance the potential for Focus to act as Alliance's distributor.

5.560.4 Fourth, notwithstanding the points above, it is in any event entirely inexplicable why, absent the Market Exclusion Agreement, Lexon would be offering advice on how its rival should compete with it, nor why Alliance would seek or accept such advice.

5.561 The CMA also rejects Cinven's submission that the CMA should not place weight on [Focus Employee 1]'s email of 23 March 2017 as evidence of what had been agreed four years previously.[1446] [Focus Employee 1]'s explanation in her 23 March 2017 email summarised her understanding of the position at that time, in relation to arrangements that remained current at the time of her email. There is no reason to suppose that [Focus Employee 1]'s understanding would have become less reliable over time: if anything, the passage of time, and the continued implementation of an arrangement that involved making payments to a supplier that supplied nothing in return, would have been expected to have deepened and clarified her understanding of what had been agreed previously.

[1444] Email [Focus Director 1] to [Focus Director 2] entitled 'Fwd: *Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[1445] Interview [Alliance Director 1], 3 November 2017, CD 2, page 33, line 9 to line 23 (URN: PRO-C1148).

[1446] Cinven RSO, 15 August 2019, paragraph 4.162 (URN: PRO-C5132).

Subsequent conduct - Medreich

Introduction and section summary

5.562 The CMA sets out in this section documentary evidence and conduct of Medreich subsequent to the conclusion of the Implementing Agreements that provides further evidence of the existence of the Market Exclusion Agreement, including:

5.562.1 Medreich did not seek to produce Prochlorperazine POM in 2014;

5.562.2 Medreich based its budget forecasts on profit share receipts from Focus' sale of the Alliance product;

5.562.3 Medreich's understanding that Lexon's Prochlorperazine POM arrangement involved the incumbent supplier, Alliance;

5.562.4 Medreich's evidence on the reason for Lexon ordering one batch of product; and

5.562.5 Later Medreich documentary evidence describing the Market Exclusion Agreement.

Medreich did not seek to produce Prochlorperazine POM in 2014

5.563 As set out in detail in paragraph 5.658 to 5.663 below, Medreich was provided in early 2014 by [Lexon Director 1] with details of the commercial arrangement that he had put in place with regard to Prochlorperazine POM in the second half of 2013. For the reasons set out in paragraph 5.671, the CMA concludes that Medreich was aware (or could reasonably have foreseen it and was prepared to take the risk) of the Market Exclusion Agreement by 5 February 2014.

5.564 Medreich had written to Lexon on 4 February 2014 to enquire about producing both Prochlorperazine POM and prochlorperazine 5mg.[1447] In response to that email, [Lexon Director 1] had informed [Medreich Employee 1] that:

> *'The 3mg POM is best left alone as we make far much [sic] more as it is. I have agree [sic] that we make a batch every 3 years and drift it into the Alliance stock (can I have the batch size so I can plan)'*
>
> *[...]*

[1447] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled *'Products'* 4 February 2014 (URN: PRO-E002744).

The 5mg – its [sic] all down to COG's – […] If we can make it work then happy to proceed.'[1448]

5.565 The CMA finds that Medreich's conduct subsequent to [Lexon Director 1]'s communication provides evidence of the existence of the Market Exclusion Agreement, and in particular the fact that Lexon had agreed with Alliance that it would not enter with the Prochlorperazine POM that it had jointly developed with Medreich. Specifically:

5.565.1 Medreich proceeded to launch prochlorperazine 5mg, as evidenced by Medreich plc (the commercial arm) placing an order with Medreich Ltd (the manufacturing arm) for prochlorperazine 5mg tablets on 21 March 2014 and then producing a validation batch for prochlorperazine 5mg tablets in September and October 2014.[1449]

5.565.2 By contrast, although Medreich plc could have placed an internal order for production of Prochlorperazine POM on 21 March 2014,[1450] it did not do so. This is consistent with [Medreich Employee 1]'s statements in his response to [Lexon Director 1]'s email of 4 February 2014 (see paragraph 5.564), in which [Medreich Employee 1] stated: '*Prochlorperazine we will introduce 5 mg only for now […] 3 mg we leave to you for the time being*.'[1451]

5.565.3 In fact, Medreich plc did not place an internal order for Prochlorperazine POM with Medreich Ltd, its manufacturing arm, until 23 June 2015 after receipt of Lexon's purchase order of the same date.[1452]

5.566 Alliance submitted that the evidence set out above regarding Medreich's internal ordering did not refer to Alliance or have any connection to Alliance and could not be regarded as evidence of the Market Exclusion Agreement between Alliance and

[1448] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750). [Lexon Director 1]'s evidence in respect of this email has been set out in paragraphs 5.426 to 5.432 above. The CMA has found no reason to doubt the plain wording of [Lexon Director 1]'s email of 4 February 2014 that his instruction to Medreich was that the 3mg product was '*best left alone*'; in respect of [Lexon Director 1]'s respective counter-claims, the CMA has found that: (a) [Lexon Director 1]'s subsequent claims about relative profitability are not borne out: it was more profitable for Lexon to be party to the Market Exclusion Agreement (in line with the wording of his email) (see paragraph 5.430; (ii) [Lexon Director 1]'s subsequent claims that he had not (notwithstanding the wording of his email) reached an agreement are not credible (see paragraph 5.432); and (iii) Lexon did not order any Prochlorperazine POM product from Medreich until an order for a single batch was placed on 23 June 2015 (see paragraphs 5.434 to 5.455).

[1449] Medreich submission dated 8 November 2021, in response to CMA questions of 22 October 2021, paragraphs 2.2, 2.3 and 3.1 (URN: PRO-C7817) and Annex 1 of Medreich submission dated 8 November 2021, in response to CMA questions of 22 October 2021 (URN: PRO-C7818).

[1450] Medreich submission dated 8 November 2021, in response to CMA questions of 22 October 2021 paragraph 2.5 (URN: PRO-C7817).

[1451] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*RE: Products*' (URN: PRO-E002750).

[1452] Medreich submission dated 8 November 2021 in response to CMA questions of 22 October 2021 paragraphs 4.1 and 4.2 (URN: PRO-C7817) and Annex 2 of Medreich submission dated 8 November 2021, in response to CMA questions of 22 October 2021 (URN: PRO-C7819).

Lexon.[1453] However, the CMA finds that Medreich's conduct, further to Lexon's instructions, is corroborative evidence of the fact that Lexon and Medreich would receive compensation for not entering the market, consistent with the agreement reached between Alliance and Lexon to this effect (see paragraphs 5.190 to 5.202).

Medreich based its budget forecasts on profit share receipts from Focus' sale of the Alliance product

5.567 Evidence from March 2014 in the form of an email from [Medreich Employee 1] to [Medreich Director 1] dated 28 March 2014 demonstrates that Medreich considered that its future annual budgets could be based on its receipt of its share of the profits earned from Focus supplying the Alliance product, rather than on the basis of it and Lexon launching their own Prochlorperazine POM product.[1454] This provides further evidence that Lexon had agreed with Alliance that it would not supply commercial volumes of its product, and had communicated this to Medreich.[1455]

5.568 [Lexon Director 1] submitted in respect of [Medreich Employee 1]'s email of 28 March 2014 that he knew nothing of this exchange, there was nothing in it to indicate that Lexon was seeking to delay the launch of the Medreich product and there was no reference to an agreement between Lexon and Alliance.[1456] However, the document records that [Medreich Employee 1] was providing the relevant information having discussed what he should budget with [Lexon Director 1]: ('*Talked to [Lexon Director 1] As per the attached we can budget our share of the profit share per year of £300k'*).[1457] Further, [Lexon Director 1] does not explain why Medreich would be basing its future budgets on profit share receipts rather than sales of its own product: this is explained on the basis that Medreich intended not to produce its own product, pursuant to the agreement Lexon had made with Alliance.

[1453] Alliance RLF, 30 November 2021 paragraph 3.2 (URN: PRO-C7914).

[1454] Email from [Medreich Employee 1] to [Medreich Director 1] entitled '*RE: Prochlorperazine 3 mg x 50 Focus*' 28 March 2014 (URN: PRO-E002787) attaching Excel Spreadsheet entitled '*Prochlorperazine 2014 budget*' (URN: PRO-E002788).

[1455] Advanz submitted that the fact that Medreich knew the 25% / 75% profit share split between Focus and Lexon simply evidenced its knowledge of the Focus-Lexon Heads of Terms (Advanz RSO, 1 August 2019, paragraph 3.125.4 (URN: PRO-C5111)); however, this does not address the fact that Medreich's budget was based on receipt of profit share, rather than launch of its own product. Advanz also submitted that [Medreich Employee 1]'s email did not suggest a '*commitment*' not to enter into the market (Advanz RLF, 22 April 2021, paragraph 4.138 (URN: PRO-C7112)). However, the CMA does not consider that a 'commitment' on the part of Medreich is necessary for Medreich's email to be of evidential relevance: it demonstrates that Medreich, despite having obtained its product licence on 9 January 2014, was still budgeting on the basis of receipt of profit share based on Focus' sales of the Alliance product (rather than future manufacturing and sale of the Lexon/Medreich product).

[1456] Lexon RLF, 21 April 2021, paragraph 41 (URN: PRO-C7104).

[1457] Email from [Medreich Employee 1] to [Medreich Director 1] entitled '*RE: Prochlorperazine 3 mg x 50 Focus*' 28 March 2014 (URN: PRO-E002787).

Medreich's understanding that Lexon's Prochlorperazine POM arrangement involved the incumbent supplier, Alliance

5.569 An email from [Medreich Employee 1] to [Lexon Director 1] on 7 April 2014 provides further evidence from Medreich that supports the existence of the Market Exclusion Agreement. Following Lexon's provision to Medreich of the Q1 2014 Prochlorperazine POM profit share reconciliation statement, [Medreich Employee 1] contacted [Lexon Director 1] in respect of the statement – and in particular the fact that the Alliance cost of goods had been increased:

> *'I have been asked for a detailed analysis of how the COGS has increased now to £5.47 against a cost last quarter of £4.85. This is a product that should cost some [✂], so we feel that Alliance are making still the lion's share at £1m a year profit, and we are getting about £220k each. Is there anything that can be used to help me corroborate the increase in the COGS from Focus perhaps. Could we see please the supplier invoices? I do not want to be difficult as it is a clever arrangement, but I am cutting a bit of a sorry figure with the management here, as I cannot explain how suddenly the supplier is going for this 13% cost increase'.*[1458]

5.570 The CMA finds that Medreich was aware of Alliance's involvement in relation to the Prochlorperazine POM arrangement that had been negotiated by Lexon and which involved Focus. Medreich's questioning of the Alliance price rise makes sense only on the basis that Medreich understood Alliance to be party to the Market Exclusion Agreement, which [Medreich Employee 1] described as the '*clever arrangement*'.[1459] This evidence cannot be reconciled with Medreich having regarded Alliance as being an independent supplier to Focus that was free to change its supply price without scrutiny from Lexon and/or Medreich, and it therefore supports the existence of the Market Exclusion Agreement.

5.571 Alliance submitted that [Medreich Employee 1]'s email of 7 April 2014 could not be regarded as evidence of Alliance's involvement in the Market Exclusion Agreement. Alliance submitted that the fact that Focus showed Lexon and Medreich its cost of goods and that [Medreich Employee 1] referred to a '*clever arrangement*' did not mean Alliance was involved given that:

5.571.1 the profit share between Focus and Lexon did not involve Alliance;

5.571.2 Alliance had no knowledge of the Focus-Lexon Heads of Terms; and

[1458] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002803).

[1459] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002803).

5.571.3 the CMA adduced no evidence of Alliance being aware of Medreich's complaints about the Alliance to Focus transfer price.[1460]

5.572 However, Alliance's submission does not account for Medreich's questioning of the Alliance price increase (which would make no sense if Medreich simply regarded Alliance as a monopoly supplier of the product that was not party to the Market Exclusion Agreement and that was free to price as it wished) and the wording used in [Medreich Employee 1]'s email. In particular, his comment that '*we feel that Alliance are making still the lion's share at £1m a year profit, and we are getting about £220k each*', clearly implies that Medreich understood Alliance to be party to the Market Exclusion Agreement, rather than it being limited to Focus, Lexon and Medreich.

Medreich's evidence on the reason for Lexon ordering one batch of product

5.573 Medreich's internal documents show that Medreich understood that the order placed by Lexon on 23 June 2015 was for the purpose of avoiding the application of the Sunset Clause. The Medreich Exco meeting minutes of 24 June 2015 record that: '*Order for Prochlorperazine has been placed on India, this is for the 1 batch required in order to keep the license [sic] active*'.[1461] This demonstrates that, even after Lexon had delayed submitting the order until nearly a year and a half after the grant of the licence (on 9 January 2014), the order that was then placed was for the purpose of regulatory compliance with the Sunset Clause provision, rather than to allow Lexon/Medreich to produce and sell commercial volumes of the product in the market.[1462]

Later Medreich documentary evidence describing the Market Exclusion Agreement

5.574 Later documentary evidence within Medreich provides clear and compelling evidence that the Market Exclusion Agreement had been reached between Alliance and Lexon – and that Medreich understood the key points relating to the arrangement – including the fact that the commercial arrangements for Prochlorperazine POM extended beyond the terms of the written agreements and that there was a requirement to produce a single batch of the licence for both commercial and regulatory reasons.

5.575 Specifically, on 28 February 2017, [Medreich Director 2] was contacted by [Meiji employee] asking for information in respect of Medreich products. Specifically,

[1460] Alliance RLF 30 November 2021, paragraphs 3.3 to 3.6 (URN: PRO-C7914).

[1461] Minutes entitled '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich PLC Offices*' 29 June 2015, p.3 (URN: PRO-E002983 / PRO-E002985).

[1462] The CMA addresses [Lexon Director 1]'s comments in respect of this evidence ([Lexon Director 1] Witness Statement of 31 July 2019, paragraph 92 (URN: PRO-C5092)) in paragraph 5.463. Advanz submitted that the minutes make no reference to Focus (Advanz RSO, 1 August 2019, paragraph 3.125.4 (URN: PRO-C5111)); however, the CMA does not consider that this undermines the significance of Medreich's understanding of the purpose of the single order of product as it relates to the existence of the Market Exclusion Agreement.

[Meiji employee] requested information about which products were: (1) '*available for BD activities*', (2) delayed in terms of supply and (3) '*Products which has [sic] not been ordered after the approval [sic]*'. By way of response, [Medreich Director 2] commented in respect of the third category of products that:

> *'…On top of my head [sic], I only see Prochlorperazine 3mg as there is (was) only one other supplier. But that situation is changing as 2 more suppliers have come in… and we have placed order onto [sic] India which I believe has failed at India level. When we do profit share deals, there is no written agreement, it is gentleman [sic] word and invoices are raised based on off the record workings.'*[1463]

5.576 [Medreich Director 2]'s response shows that Medreich: (i) viewed Prochlorperazine POM as a product which had not been ordered despite being approved (as opposed to a product '*available for BD activities*' or a product where there was a delay in supply); and (ii) saw the Prochlorperazine POM profit sharing deal as being based partly on an unwritten agreement.

5.577 Several months later, on 21 July 2017, in response to queries from [Meiji employee] about how Medreich was obtaining an income stream in respect of Prochlorperazine POM, [Medreich Director 2] explained Medreich's understanding that:

> *'3mg has never been manufactured or supplied .. Profit share comes from 3mg only.*
>
> *There is a deal in place that for Medreich Not [sic] to bring 3mg in market we get royalty . . But two things are crucial now :*
>
> *1. The company with whom Lexon has done the deal wants to see our product failing which deal is off.. [sic]*
>
> *2. Secondly from regulatory perspective we need to produce 1 batch of 3mg to avoid sunset cluase [sic] else we shall lose the license [sic]. As per sunset clause regulation we have to produce and sell 1 batch once every 3*

[1463] Email [Medreich Director 2] to [Meiji employee] and [Medreich employee], cc various others at Medreich entitled '*RE: Follow up on the meeting in January*' 28 February 2017 (URN: PRO-E003257). Alliance submitted that this email was referring to a profit sharing arrangement between Focus, Lexon and Medreich, to which Alliance was not a party and of which it was not aware. Alliance argued that the email does not support a finding of an agreement with Alliance (Alliance RLF 30 November 2021 paragraph 3.7 (URN: PRO-C7914)). However, the CMA finds that [Medreich Director 2]'s email of 28 February 2017 needs to be read in conjunction with the wider evidence base, including the other Medreich documentary evidence discussed previously in this section, which clearly shows that Medreich was aware of Alliance's involvement in the Market Exclusion Agreement. Advanz submitted that the evidential value of [Medreich Director 2]'s email of 28 February 2017 was undermined by the fact that it was factually incorrect (in so far as Lexon and Medreich did have a (written) Product Development and Profit Sharing Agreement) and the profit share clause between Focus and Lexon was clearly recorded in the Focus-Lexon Heads of Terms (Advanz RLF 30 November 2021 paragraph 2.16 (URN: PRO-C7917)); however, the CMA considers it relevant that [Medreich Director 2] clearly viewed the arrangement relating to Prochlorperazine POM as being based in part on unwritten elements, consistent with the fact that it was not written in the Focus-Lexon Heads of Terms that Lexon (and Medreich) were being compensated for not supplying commercial volumes of their product in the market (see paragraphs 5.301 and 5.302).

years to maintain the license [sic] or else MHra [sic] will kill the license [sic].'[1464]

5.578 When asked about this email in an interview with the CMA, [Medreich Director 2] stated that he did not know that a '*deal*' with Lexon had been '*done*' - but rather he had *assumed* that there was a deal that generated money for Lexon which was shared with Medreich.[1465] The CMA does not, however, consider that [Medreich Director 2]'s evidence on this is credible on the basis that:[1466]

5.578.1 his explanation is inconsistent with the plain reading of his email;

5.578.2 the CMA does not consider it plausible that [Medreich Director 2] would have been unaware of the reasons for which Medreich had been in receipt of substantial payments since the start of 2014;[1467]

5.578.3 consistent with the email described above, [Medreich Employee 1][1468] told the CMA during interview that he considered that [Medreich Director 2] would have known about the details of the arrangements;

5.578.4 there are documents, to which [Medreich Director 2] was copied, in which the nature of the arrangement was explained and in response to which [Medreich Director 2] had communicated his agreement with the proposed course of action (see paragraph 3.212 above); and

5.578.5 Medreich informed the CMA that it had '*concerns in relation to the completeness and/or accuracy of certain statements*' made by [Medreich Director 2] during his interview with the CMA on 2 July 2018 and that it did not consider [Medreich Director 2]'s explanation of his email of 21 July 2017 to be '*complete and accurate*'.[1469]

[1464] Email [Medreich Director 2] to [Meiji employee] entitled 'Re: Prochlorperazine --- profit sharing' 21 July 2017 (URN: PRO-E003351).

[1465] Interview [Medreich Director 2] 2 July 2018, page 108, line 13 to page 110, line 5 (URN: PRO-C3684).

[1466] On 23 October 2020, the CMA wrote to [Medreich Director 2] informing him that the CMA was withdrawing his immunity from a competition disqualification order with effect from the date of that letter; the CMA's reasoning for that decision was set out in full in that letter, including that the CMA found that [Medreich Director 2] had not been complete and truthful in his interview in relation to the evidence he had provided at interview in respect of his email of 21 July 2017 (CMA Letter to [Medreich Director 2] 23 October 2020, paragraphs 61 to 72 (URN: PRO-C6362)).

[1467] [Medreich Director 2] was [✂] (Section 26 response of Medreich dated 12 October 2017, to CMA Notice of 10 October 2017, Section B (URN: PRO-C1303)). For these reasons, the CMA rejects Cinven's submission that [Medreich Director 2]'s evidence should not be relied upon his given his self-professed ignorance of the deal and his junior status (Cinven RSO, 15 August 2019 paragraphs 4.139-4.140 (URN: PRO-C5132)). Cinven also pointed out that [Medreich Director 2] had in 2014 emailed [Medreich Employee 1] to say that he did not understand the deal [Lexon Director 1] had arranged (email [Medreich Director 2] to [Medreich Employee 1] entitled '*FW: Prochlorperazine 3mg share profit*' 8 January 2014 (URN: PRO-E002687)): however, [Medreich Director 2]'s email of 8 January 2014, prior to Medreich's full briefing by Lexon, is not probative of [Medreich Director 2]'s level of understanding in July 2017.

[1468] See interview [Medreich Employee 1], 12 July 2018, page 68 lines 1 to 2, page 128, line 2 and page 175, lines 20 to page 176 line 2 (URN: PRO-C3666).

[1469] Medreich statement made in accordance with paragraph 5.38 of the CMA's Guidance on Leniency and no-action applications in cartel cases (OFT1495), page 3 lines 10-15 and page 6 line 19 to page 8 line 8 (URN: PRO-C3836).

5.579 [Lexon Director 1] commented on [Medreich Director 2]'s email of 21 July 2017 in his witness statement, describing it as '*a misinterpretation/over-simplification of the position'* given that [Medreich Director 2] '*simply did not understand the arrangement with Focus or chose to misdescribe it so as to avoid the need to justify Medreich's failure to deliver either the licence or stock since 2013*'.[1470] The CMA does not find these explanations persuasive:

5.579.1 for the reasons set out in paragraph 5.578 above, the CMA does not consider it credible that [Medreich Director 2] did not understand the situation;

5.579.2 it is clear from [Medreich Director 2]'s previous correspondence with [Meiji employee] on 28 February 2017 that [Medreich Director 2] had already been clear with Meiji that Prochlorperazine POM had not been produced given it fell into the category of '*Products which has [sic] not been ordered after the approval [sic]*'[1471] (see paragraph 5.575 above), meaning [Medreich Director 2] had no need in his email of 21 July 2017 as [Lexon Director 1] suggests to '*justify Medreich's failure to deliver either the licence or stock since 2013*'; and

5.579.3 the two reasons [Medreich Director 2] gave in in his email of 21 July 2017 for the need to produce product (namely the commercial need to sustain the '*deal*' and the regulatory need to produce a batch to avoid the application of the Sunset Clause) indicate that [Medreich Director 2] did have a sufficiently sophisticated understanding of what the '*deal*' was in order to comment meaningfully on what factors threatened its ongoing viability; these factors explain why [Lexon Director 1] – having delayed submitting an order for Prochlorperazine POM until 23 June 2015 – would during 2016 nevertheless consider it important to produce a batch of product (see paragraph 5.464).

5.580 Advanz submitted in respect of [Medreich Director 2]'s email of 21 July 2017 that it was unclear, did not relate to Focus and that, at its highest, the email referred to a bilateral arrangement between Medreich and Lexon but it did not indicate any knowledge of or an intention by Focus to contribute to the common objective.[1472] However, [Medreich Director 2]'s email does not make sense as referring simply to a bilateral arrangement between Lexon and Medreich: a deal between Lexon and Medreich alone not to enter the market would be meaningless; the 'deal' had to involve another party, consistent with [Medreich Director 2]'s words '*The company*

[1470] [Lexon Director 1] Witness Statement of 31 July 2019 (URN: PRO-C5092), paragraph 104.

[1471] Email [Medreich Director 2] to [Meiji employee] and [Medreich employee], cc various others at Medreich including [Meiji employee] entitled '*RE: Follow up on the meeting in January*' 28 February 2017 (URN: PRO-E003257).

[1472] Advanz RSO, 1 August 2019, paragraph 3.125.4 (URN: PRO-C5111).

with whom Lexon has done the deal' – and on this basis, the CMA finds that [Medreich Director 2]'s email is evidence of the Market Exclusion Agreement.

5.581 The CMA also rejects Cinven's submission that it should not place weight on [Medreich Director 2]'s email of 21 July 2017 as evidence of what had been agreed given that, Cinven says, this amounts to hearsay of something that happened three years previously.[1473] In this respect, the CMA notes that [Medreich Director 2]'s explanation in his 21 July 2017 email summarised his understanding of the position at that time. Medreich had been continuing to operate based on its understanding of the position since 5 February 2014 (see paragraph 5.563 above) and there is no reason to suppose that Medreich's understanding as to the basis for the Market Exclusion Agreement would have become less reliable over time: if anything, the passage of time and continued implementation of the arrangement (including discussion with [Lexon Director 1]: see paragraph 5.472) would have been expected to have deepened Medreich's understanding of what had been agreed previously – given that the Market Exclusion Agreement continued to be implemented over the course of that period.

Analysis of the correspondence in 2014 between Focus and Lexon

Introduction and section summary

5.582 The CMA sets out in this section, as part of its assessment of the existence of the Market Exclusion Agreement, its consideration of three sets of correspondence on 14 April 2014,[1474] 2 and 3 September 2014[1475] and 4 November 2014[1476] between [Focus Director 1] and [Lexon Director 1] (together the '2014 Correspondence') that refer to the supply of Prochlorperazine POM, but do not specify whether any such supply would be limited to the single batch of product needed to avoid the application of the Sunset Clause or reflected a plan to supply commercial batches of the product. This section:

5.582.1 provides an outline of the 2014 Correspondence;

5.582.2 considers the Parties' representations on each of:

[1473] Cinven RSO, 15 August 2019, paragraph 7.25(c)(iii) (URN: PRO-C5132).

[1474] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794); email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795) and email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

[1475] Email [Lexon Director 1] to [Focus Director 1] entitled '*Fwd: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811); email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812) and email [Lexon Director 1] to [Focus Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003813).

[1476] Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832) and email [Lexon Director 1] to [Focus Director 1] entitled '*RE: Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

(a) the 4 April 2014 exchange;

(b) the 2 and 3 September 2014 exchange; and

(c) the 4 November 2014 exchange; and

5.582.3 concludes on the evidential significance of the 2014 Correspondence.

5.583 In carrying out this assessment, the CMA has taken into consideration the extensive representations by Advanz[1477] and Cinven,[1478] including their submissions that the 2014 Correspondence demonstrates that:

5.583.1 Focus and Lexon did expect Lexon to supply commercial volumes of the Lexon product to Focus, and that such evidence is inconsistent with the existence of the Market Exclusion Agreement; or

5.583.2 insofar as Lexon was not in fact seeking to supply commercial volumes of its product to Focus, that Focus was being misled by Lexon in this regard and was unaware of the Market Exclusion Agreement, and that such evidence is inconsistent with Focus being aware of and participating in the Market Exclusion Agreement.

5.584 For the reasons outlined in full in this section, including in Annex F:, the CMA finds that:

5.584.1 if read in isolation (i.e. without regard to the wider evidence base), the 2014 Correspondence is unclear;

5.584.2 the explanations of the 2014 Correspondence urged by Advanz and Cinven are inconsistent with the wider evidence base;

5.584.3 there are several other plausible explanations of the 2014 Correspondence that are not inconsistent with the wider evidence base; and

5.584.4 in conclusion, assessing the 2014 Correspondence in the round, and in the context of the surrounding documentary evidence and the Parties' conduct, Focus and Lexon did not expect Lexon to supply commercial volumes of the Lexon Prochlorperazine POM product to Focus, and nor was Focus being misled by Lexon in this regard.

[1477] In particular, Advanz RSO, 1 August 2019, paragraphs 3.125.2(c), 3.180, 3.181 and 3.210-3.213, 3.223 and 6.20-6.30 (URN: PRO-C5111). Advanz RLF, 30 November 2021, paragraphs 1.3 and 1.6.1(f) (URN: PRO-C7917).

[1478] In particular, Cinven RSO, 15 August 2019, paragraphs 4.52-4.55, 4.103 and 4.174 (URN: PRO-C5132). Cinven RLF, 30 November 2021, paragraphs 3.12-3.15 (URN: PRO-C7919).

5.585 The CMA sets out in summary form below (paragraphs 5.586 to 5.593) the email exchanges comprising the 2014 Correspondence in context. It then analyses the witness evidence and Parties' representations as to the interpretation of the three email exchanges as regards the existence of the Market Exclusion Agreement (and Focus' participation in the Market Exclusion Agreement) (paragraphs 5.594 to 5.616) and sets out its conclusion (paragraphs 5.617 to 5.620). The detailed presentation and analysis of the alternative plausible explanations identified by the CMA for the 2014 Correspondence is set out in Annex F:.

Outline of the 2014 Correspondence between [Focus Director 1] and [Lexon Director 1]

5.586 The first exchange took place on 14 April 2014, on the same day that [Lexon Director 1] and [Focus Director 1] were scheduled to hold an in-person meeting.[1479] [Lexon Director 1] wrote to [Focus Director 1] informing him that *'My sincere apologies but [✂]'* and noting that he would have a further update in June but that '*Once again I do apologise for the confusion but as I am sure you can guess there is nothing short term I can do to address the problem*'.[1480] In his initial response of the same day, [Focus Director 1] responded, *'Thanks for the update [sic] I totally understand the issues involved and we can revisit in June when you have more information.'*[1481] A few minutes later, [Focus Director 1] sent a further response to [Lexon Director 1], which read, *'With regard to our discussion regarding the agreement on profit share I agree with your comments and we shall continue with the current agreement as signed in the heads of agreement'*.[1482]

5.587 As set out above (see paragraph 5.422), in the months prior to this exchange, Medreich had raised with Lexon whether they should start production of Prochlorperazine POM: [Medreich Employee 1] emailed [Lexon Director 1] on 4 February 2014 saying, '*I think we should also get ready to do the 3 mg POM as well, even if only so that Alliance cannot try to increase the Purchase price going forward*';[1483] however, [Lexon Director 1] had informed Medreich that (unlike for prochlorperazine 5mg, where he was '*happy to proceed*') Medreich should not commercialise Prochlorperazine POM, stating in response to [Medreich Employee 1]'s email that it was *'best left alone as we make far much [sic] more as it is'*[1484]

[1479] Email [Focus Director 1] to [Focus Director 2] entitled '*Lexon meeting*' 9 April 2014 (URN: PRO-E003793): that email referred to a forthcoming meeting between [Focus Director 1] and [Lexon Director 1] '*on Monday*'; the Monday after the email was sent would have been Monday 14 April 2014. The Parties have not stated in any of their representations that that meeting scheduled for Monday 14 April 2014 did not in fact take place.

[1480] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794).

[1481] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795).

[1482] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

[1483] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled '*Products*' 4 February 2014 (URN: PRO-E002744).

[1484] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

and that he had agreed to supply only the single batch needed to satisfy the Sunset Clause. In this regard, [Lexon Director 1] had in his email to Medreich of 4 February 2014 requested the relevant batch size from Medreich *'so I can plan'*. Consistent with [Lexon Director 1]'s instruction to Medreich not to commercialise Prochlorperazine POM:

5.587.1 on 21 March 2014 Medreich placed an internal order for prochlorperazine 5mg tablets but not for Prochlorperazine POM tablets (see paragraphs 5.436 and 5.437);

5.587.2 on 28 March 2014 an internal Medreich email[1485] recorded that [Lexon Director 1] had advised that Medreich should set its budget according to profit share payments that would be pursuant to Focus' sales of the Alliance product, rather than according to sales of its own product (see paragraph 5.567); on this basis, Medreich forecasted that it would earn £300k 'per year';

5.587.3 on 3 June 2014, an internal Medreich email, sent in the context of arranging for the audit of the API supplier, referred to the commercialization of prochlorperazine 5mg tablets, but did not refer to the Prochlorperazine POM (see paragraph 3.223);

5.587.4 on 22 August 2014, [Lexon Director 1] emailed [Medreich Director 2] to ask, '*Please can you advise batch size and landed and released COGs for prochlorperazine 3mg 50s*';[1486]

5.587.5 on 27 August 2014, an internal Medreich document recorded that there was '***maybe a possibility** of doing a batch of Prochloroperazine [sic] 3mg*' (emphasis added) but noting '*we do need small batch sizes*';[1487]

5.587.6 in March 2015, an internal Medreich email recorded that its understanding remained that UK sales of Prochlorperazine POM *'will be minimal to ensure licence is kept active'* and not therefore that it had been instructed to supply commercial volumes of Prochlorperazine POM;[1488]

5.587.7 in contrast to the commercial position taken as regards prochlorperazine 5mg tablets (see paragraphs 5.436 and 5.437), no order or other written instruction had been placed by Lexon on Medreich or by Medreich

[1485] Email [Medreich Employee 1] to [Medreich Director 1] cc [Medreich employee] and [Medreich Director 2] 28 March 2014 entitled '*RE: Prochlorperazine 3 mg x 50 Focus*' (URN: PRO-E002787).

[1486] Email [Lexon Director 1] to [Medreich Director 2] entitled '*[No subject]*' 22 August 2014 (URN: PRO-E000434).

[1487] Email [Medreich Director 2] to [Medreich employee], cc [Medreich employee] entitled '*FW: Prochloroperazine [sic] 3mg*' 27 August 2014 (URN: PRO-E002867).

[1488] Email [Medreich employee] to [Medreich employee] entitled '*Fluoxetine License sale*' 12 March 2015 (URN: PRO-E002945).

internally for Prochlorperazine POM product – indeed such an order was not placed until 23 June 2015 (see paragraph 5.434); and

5.587.8 the minutes of the Medreich Exco meeting held on 24 June 2015 record that [Medreich Employee 1] stated that the*, '[o]rder for Prochlorperazine has been placed on India, this is for the 1 batch required in order to keep the license [sic] active'*.[1489]

5.588 The second exchange took place on 2 and 3 September 2014. In response to a query on 22 August 2014 from [Lexon Director 1] for batch size and landed and released cost of goods for Prochlorperazine POM,[1490] Medreich informed [Lexon Director 1] that the minimum batch size for manufacturing was [✂] tablets[1491] and [Lexon Director 1] forwarded this information to [Focus Director 1].[1492] [Focus Director 1] responded to this email: *'Thanks mate I will update you on requirements soon , [sic] What would be the lead time'*.[1493] [Lexon Director 1] then replied to say: *'Initially I would say 20 weeks for the first then 12weeks [sic] thereafter'*.[1494]

5.589 Notwithstanding the contents of [Focus Director 1]'s email of 3 September 2014, there is no evidence that Focus did update Lexon on its requirements (see paragraph 5.607 below). Further, and as set out at paragraphs 5.434 to 5.455 above, it is evident that Lexon had not placed an order with Medreich at this point, despite having previously requested batch size information pursuant to [Lexon Director 1]'s intention to 'plan' as regards the single batch of product needed to satisfy the Sunset Clause.

5.590 The third email exchange is a summary of a meeting between [Focus Director 1] and [Lexon Director 1] held on 3 November 2014, as sent on 4 November 2014. By 3 November 2014, Focus had recently been sold to AMCo on 1 October 2014, with the result that a new management team would, at some point, assume responsibility for Focus' commercial arrangements for Prochlorperazine POM. As of November 2014, no product had been supplied by Lexon/Medreich to Focus,

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[1489] Email [Medreich employee] to various Medreich colleagues entitled '*Exco minutes*' 29 June 2015 (URN: PRO-E002984) attaching '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 24th June 2015 at 10:30am in the Board Room of Medreich PIC Offices*' 29 June 2015 (URN: PRO-E002985). [Lexon Director 1]'s comments on the significance of this document are addressed in paragraph 5.463.

[1490] Email [Lexon Director 1] to [Medreich Director 2] entitled '*[No subject]*' 22 August 2014 (URN: PRO-E000434).

[1491] Email [Medreich Director 2] to [Lexon Director 1] entitled '*Prochloroperazine [sic] 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E002874). In fact, contrary to this initial statement, the minimum batch size was later confirmed to be [✂] tablets (see paragraph 3.233).

[1492] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine [sic] 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811).

[1493] Email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine [sic] 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812).

[1494] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003813).

despite the fact that four sets of quarterly profit share payments had been paid by Focus to Lexon, totalling over £500,000 (see Annex I:).

5.591 In his email of 4 November 2014 summarising his meeting with [Lexon Director 1] of the day before, [Focus Director 1] stated:

> *'Following our meeting yesterday I am just confirming the agreement regarding prochlorperazine 3mg tabs .*
>
> *You have placed an order for stock and would expect the stock to arrive in early 2015 , once you have a confirmed date I can place a purchase order on you for the stock .*
>
> *We agreed an amendment to the profit share agreement in that up to an Asp [sic] of £10.50 the profit share will remain at 25%(Focus)/ 75% (Lexon), over an ASP of £10.50 the profit share will become 50%(Focus)/ 50%(Lexon) . I will amend the heads of agreement to mirror this and send on to you .'*[1495]

5.592 [Lexon Director 1] replied the same day, noting that he would *'advise as soon as I have a firm date for availability of released product along with the exact volumes … Regards the change to the profit share. Yes I am happy to proceed with your proposal'*.[1496]

5.593 However, despite these references to an order for Prochlorperazine POM having been placed, as of November 2014 [Lexon Director 1] had still not placed an order or otherwise given a written instruction for stock to Medreich (see paragraph 5.587 above). As set out in paragraph 5.434, [Lexon Director 1] did not place an order with Medreich until 23 June 2015 and Medreich itself did not seek to produce Prochlorperazine POM until 23 June 2015.

The 14 April 2014 exchange

Witness evidence and Parties' representations

5.594 [Lexon Director 1] and [Focus Director 1] maintain that this exchange is evidence that they each intended for Lexon to supply Focus with commercial volumes of Prochlorperazine POM product:

5.594.1 [Lexon Director 1] stated in interview in respect of his email of 14 April 2014 that he was passing on information he had received from Medreich about API issues that he did not believe but nevertheless passed on to Focus. [Lexon Director 1] stated that he did not remember [Focus Director

[1495] Email [Focus Director 1] to [Lexon Director 1] entitled '*RE*: *Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

[1496] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

1]'s reaction to the email but he did not think it would have been a surprise to [Focus Director 1] given that [Focus Director 1] [✂].[1497]

5.594.2 [Focus Director 1] stated in interview in respect of [Lexon Director 1]'s email of 14 April 2014 that he would have reacted negatively to [Lexon Director 1]'s email as it was a '*pain*' that Focus did not have the product sooner and that he imagined this would entail a delay of four to eight months before receiving the product – but he did not consider terminating the Focus-Lexon Heads of Terms agreement as he assumed Lexon would still be getting the product.[1498]

5.595 Advanz submitted that the 14 April 2014 exchange showed that Focus chased for status updates on the product and, relatedly, the fact that [Lexon Director 1] provided his '*sincere apologies*' to Focus for the delays in the Lexon/Medreich development shows that there was no common understanding between Focus and Lexon/Medreich that Lexon/Medreich would not be bringing commercial volumes of product to market.[1499]

5.596 Advanz referred also to the fact that, if there were a Market Exclusion Agreement, there would be no need for apologies from Lexon just three months after the grant of the MA or a meeting within a year – not least given that it would not have mattered to Focus if Lexon had failed to produce a batch and would therefore have lost its MA.[1500] Advanz submitted that, had the Market Exclusion Agreement existed, *'a chaser from Focus would have been met with an incredulous response from Lexon, along the lines of "why are you chasing – you know what the deal is". It would not have been met with "sincere apologies" for the delay, and lies'*.[1501] Advanz cited the exchange as one of a number of occasions where Lexon misled Focus as to the status of the production of the Lexon/Medreich Prochlorperazine POM and Lexon's intention to supply the product to Focus.[1502]

5.597 Cinven also stated that the fact that [Lexon Director 1] provided his '*sincere apologies*' showed evidence of Lexon's efforts to obtain product and Focus chasing for product.[1503] Cinven submitted that the 14 April 2014 exchange should be read in the context of Focus having already previously sought to chase Lexon for the Lexon/Medreich product within two weeks of the MA being granted; it based this on the notes in Focus sales meeting minutes in January and March 2014 that [Focus

[1497] Interview [Lexon Director 1], 10 September 2018, CD 4/5, page 6, line 7 to page 7, line 16 (URN: PRO-C3189).
[1498] Interview [Focus Director 1], 2 October 2018, page 205, line 17 to page 206, line 22 (URN: PRO-C3294).
[1499] Advanz RSO, 1 August 2019, paragraphs 3.148 and 6.26 (URN: PRO-C5111).
[1500] Advanz RLF, 22 April 2021, paragraphs 4.99 and 4.152 (URN: PRO-C7112).
[1501] Advanz RSO, 1 August 2019, paragraph 3.181 (URN: PRO-C5111).
[1502] Advanz RSO,1 August 2019, paragraphs 6.28 to 6.30 (URN: PRO-C5111).
[1503] Cinven RSO, 15 August 2019, paragraphs 4.103, 4.105(b) and 4.174 (URN: PRO-C5132).

Director 1] would discuss the profit share agreement with Lexon.[1504] Cinven submitted that the most plausible explanation of the 14 April 2014 discussion is that Focus and Lexon each recognised that Lexon's failure to supply might call for the terms of the profit-share to be amended in Focus' favour, but the Parties decided not to amend at this time and instead committed to revisit the issue in June 2014.[1505]

CMA Analysis

5.598 The CMA has considered the witness evidence on this exchange and the Parties' submission that this exchange provides evidence of Lexon intending to supply, and Focus intending to purchase, commercial volumes of Prochlorperazine POM, or of Lexon misleading Focus in this respect.

5.599 The CMA observes, first, that the 14 April 2014 emails do not state expressly that the Parties expected Lexon to supply commercial volumes of Prochlorperazine POM product to Focus. Rather, that is an inference which the Parties seek to draw from the correspondence.

5.600 The Parties' interpretation is, however, inconsistent with the surrounding contemporaneous evidence showing that Lexon and Medreich had no plans to commercialise the Prochlorperazine POM product. As outlined at paragraph 5.587 above, in the months prior to the 14 April 2014 exchange, [Lexon Director 1] had informed Medreich that '*The 3mg POM is best left alone'* and had said that Lexon would only *'make a batch every 3 years and drift it into the Alliance stock …'*,[1506] and Lexon did not place an order or otherwise instruct Medreich to produce Prochlorperazine POM product until 23 June 2015, when [Lexon Director 1] placed an order for a single batch of product.

5.601 As to the alternative explanation suggested by Focus, namely that Lexon was misleading Focus regarding the nature of its agreement with Alliance, such that Focus was not aware of any plan on Lexon's part to delay its market entry and had expected to source commercial volumes of the Lexon product:

5.601.1 The emails also do not state expressly that Focus expected Lexon to supply commercial volumes. Rather, as with the first potential interpretation addressed above, that is an inference which Focus seeks to draw from the correspondence.

[1504] Cinven RSO, 15 August 2019, paragraphs 4.103, 4.105(b) and 4.174 (URN: PRO-C5132) citing *Minutes of a Focus Sales Meeting*, 28 January 2014, page 5 (URN: PRO-E003779) and *Minutes of a Focus Sales Meeting*, 24 March 2014, page 4 (URN: PRO-E003785).

[1505] Cinven RLF, 30 November 2021, paragraph 3.14(b) (URN: PRO-C7919).

[1506] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750). [Lexon Director 1]'s comments on the significance of this document are addressed in paragraphs 5.426 to 5.429.

5.601.2 Such an explanation would also be inconsistent with the prior and subsequent evidence that Focus had been made aware of the Market Exclusion Agreement reached by Alliance and Lexon: see in this respect the evidence at paragraphs 5.195 to 5.200, as well as the fact that:

(a) [Focus Director 1]'s email of 22 June 2013 to [Focus Director 2],[1507] which records [Focus Director 1]'s understanding that Lexon and Alliance had agreed the terms on which Alliance will supply Focus, that refers to the fact that Focus would pay most of its profits to [Lexon Director 1] on the basis that it is *'his licence'*, and that does not refer to Focus purchasing product from Lexon;[1508]

(b) Focus' entry into a five-year supply agreement with Alliance with a non-compete clause that prohibited its supply of the Lexon product (see paragraph 3.104);

(c) Focus' forecasting expectations that show its expectation of obtaining product from Alliance rather than Lexon (see paragraphs 5.484 to 5.486 above);[1509]

(d) Focus' payments to Lexon, totalling £7.86 million over a period of four and a half years, that are explicable only on the basis of the Market Exclusion Agreement (see paragraphs 5.524 to 5.526);

(e) the evidence after AMCo acquired Focus relating to the Primegen development project, including the Project Capital presentation showing that AMCo viewed the lack of product from Lexon by June 2015 as being a function of the Market Exclusion Agreement, rather than because of an inability to supply[1510] (see paragraph 5.497); and

(f) [Focus Employee 1]'s email of 23 March 2017 to [AMCo employee], showing that Lexon helped set up the supply agreement between Alliance and Focus[1511] (see paragraph 5.556).

5.601.3 Furthermore, and contrary to the submissions of Advanz and Cinven, the exchange is not evidence of Focus 'chasing' Lexon for product, or for an

[1507] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[1508] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[1509] It is relevant in this respect that [Lexon Director 1] stated in interview that he did not remember Focus ever querying with him whether it should continue to pay profit share despite the absence of product. When asked whether the 14 April 2014 correspondence resulted in any protestation from Focus about continued payments, [Lexon Director 1] replied: *'I can't remember. No I can't remember. No well they continued to pay me. I never had a conversation with Focus that said that they came back and said we don't think we should pay you because you're not able to supply product*' (Interview [Lexon Director 1], 10 September 2018, Part 1 CD4/5, page 8, lines 3-6 (URN: PRO-C3189)).

[1510] Email [AMCo Employee 4] to various colleagues at AMCo entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) attaching '*Project CAPITAL BD Workstream'* 30 June 2015 (URN: PRO-E001636).

[1511] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030).

update on product, with Focus having expected commercial volumes of the Lexon product:[1512] the exchange was in fact initiated by Lexon, and the delay in provision of product was accepted without question by [Focus Director 1].[1513] In fact, in neither of his two replies did [Focus Director 1] ask for information about when the product was likely to become available, despite the fact that Focus had already made significant payments to Lexon in accordance with the profit share clause in the Focus-Lexon Heads of Terms at this point.[1514]

5.602 The CMA considers that there are other potential explanations of the 14 April 2014 email exchange that do not involve an expectation on the part of either Lexon or Focus of the supply of commercial volumes of Lexon's Prochlorperazine POM product by Lexon to Focus. As the CMA sets out in detail in Annex F:

5.602.1 The 14 April 2014 exchange can plausibly be explained on the basis that Focus and Lexon were contemplating and discussing the provision of the single batch of Prochlorperazine POM necessary to avoid the application of the Sunset Clause, and [Lexon Director 1] was apologising concerning the need to change the timing on which such a batch might ultimately be supplied.

5.602.2 As an extension of the first point set out above, it may be that Lexon was particularly keen to give the impression (to Focus, and potentially indirectly to Alliance) that Lexon was pressing ahead as fast as possible with the single batch, and could produce more product should the Market Exclusion Agreement be terminated.

5.602.3 The contents of the 14 April 2014 exchange may have been influenced by the authors' caution regarding what they put into writing (including possibly

[1512] Based on the email [Focus Director 1] to [Focus Director 2] entitled '*Lexon meeting*' 9 April 2014 (URN: PRO-E003793), Advanz has stated that the 14 April 2014 email from [Lexon Director 1] was preceded by a meeting between Focus and Lexon on 9 April 2014 (Advanz response of 6 January 2020 to the CMA's questions of 26 November 2019, page 8 (URN: PRO-C5635)). Advanz stated that it was clear from the contemporaneous evidence in its totality that the email of 14 April 2014 was a follow-up to that meeting between [Focus Director 1] and [Lexon Director 1], at which Focus appears to have set the agenda, such that the 14 April 2014 email should indeed be seen as an example of Focus chasing Lexon for an update. This reasoning is unfounded: the fact that [Focus Director 1] asked [Focus Director 2] on 9 April 2014 whether there were any points he should raise with [Focus Director 1] does not mean that '*Focus set the agenda*', or, more importantly, that a subsequent email by [Lexon Director 1] of 14 April 2014 can be construed as Focus chasing for product. Indeed, in the correspondence between [Focus Director 1] and [Focus Director 2] of 9 April 2014 to which Advanz refers, Prochlorperazine POM is not mentioned by either [Focus Director 1] or [Focus Director 2]: suggesting that obtaining stock from Lexon was not seen as a top priority for Focus.

[1513] On this basis the CMA rejects Cinven's submission that in April 2014 Focus was dissatisfied with the delay to the Lexon product (Cinven RLF, 22 April 2021, paragraph 2.41(c) (URN: PRO-C7107), citing Email [Lexon Director 1] to [Focus Director 1] entitled *'Prochlorperazine 3mg'* (URN: PRO-E003796)).

[1514] Focus had paid £196,412 by the time of the 14 April 2014 email and then paid a further £118,975 in July 2014 (see Annex I:). Cinven submitted that Prochlorperazine POM was not a '*top priority*' for Focus, or, subsequently, AMCo – and hence no inference should be drawn from the fact that Focus may be seen as having been generous in affording Lexon time to address supply issues (Cinven RSO, 15 August 2019, paragraph 4.50 (URN: PRO-C5132)). However, the evidence relating to Focus (and later AMCo – see paragraph 5.543) is clear that Focus and AMCo did engage on the status of the product: there is no reason why the fact that Focus was generating profits from other products means that, in and of itself, Focus (and then AMCo) would not have wished to protect their own commercial interests vis-à-vis Lexon.

deliberately creating a written record meant to give the impression that they were intending to supply and receive commercial volumes of product).

The 2 and 3 September 2014 exchange

Witness evidence and Parties' representations

5.603 [Lexon Director 1] and [Focus Director 1] have each stated that the 2 and 3 September 2014 exchange is consistent with their claims that they each had a genuine intention for Lexon to supply Focus with commercial volumes of Lexon/Medreich Prochlorperazine POM:

5.603.1 [Lexon Director 1] stated in interview in respect of his email of 2 September 2014 that he guessed from the email's contents that Medreich had informed him that they were ready to start manufacturing and he would therefore have asked about batch size and validation batches. [Lexon Director 1] said he would then have passed that information to Focus to say that Lexon needed an order from Focus or Lexon needed to order it.[1515] [Lexon Director 1] explained in respect of the contents of his email of 3 September 2014 that the reference to 12 weeks was because *'on a line like that if there's profit we'd airfreight it … [which was] more reliable than by boat'*.[1516] When asked, [Lexon Director 1] said he was sure [Focus Director 1] did come back to Lexon with his requirements and that Lexon would have raised a purchase order with Medreich. [Lexon Director 1] added that purchase orders are deleted after a year so he would have raised fresh purchase orders – and that explains why [Lexon Director 1] would have asked [Focus Director 1] for his requirements.[1517]

5.603.2 [Focus Director 1] stated in interview in respect of this correspondence that he could not remember going back to [Lexon Director 1] in terms of Focus' requirements '*because, at that time, I would've been tied up in the due diligence process [in relation to the sale of Focus], so it was probably on a list*'. He confirmed that he did not consider terminating the agreement at that point as *'the product was coming'* and he was expecting competition.[1518]

5.604 Cinven[1519] submitted to the CMA that the correspondence of 2 and 3 September 2014 provided evidence that Focus and Lexon intended that Focus would place multiple orders for product, and that this demonstrated that Focus was intending to

[1515] Interview [Lexon Director 1], 10 September 2018, CD 4/5, page 9, line 17 to page 10, line 26 (URN: PRO-C3189).
[1516] Interview [Lexon Director 1], 10 September 2018, CD 4/5, page 10, line 6-8 (URN: PRO-C3189).
[1517] Interview [Lexon Director 1], 10 September 2018, CD 4/5, page 9, line 17 to page 10, line 26 (URN: PRO-C3189).
[1518] Interview [Focus Director 1], 2 October 2018, page 207, line 10 to page 208, line 12 (URN: PRO-C3294).
[1519] Cinven RSO, 15 August 2019, paragraph 4.107 (URN: PRO-C5132).

order commercial quantities of Prochlorperazine POM from Lexon and not simply the single batch necessary to avoid the application of the Sunset Clause. This was because [Focus Director 1] had responded to the information about the minimum batch size provided by Lexon to say: *'Thanks mate I will update you on **requirements** soon , [sic] What would be the lead time'* (emphasis added),[1520] and [Lexon Director 1] had then replied to say: *'Initially I would say 20 weeks for the first **then 12weeks [sic] thereafter**'* (emphasis added).[1521] Advanz[1522] included the correspondence of 2 and 3 September 2014 as examples of evidence of Focus intending to place multiple orders for product, but was being misled by Lexon that product would be supplied.

CMA Analysis

5.605 As with the 14 April 2014 emails, the 2 and 3 September 2014 emails do not state expressly that Focus and Lexon expected Lexon to supply commercial volumes of product. Again, that is an inference which the Parties seek to draw from the correspondence.

5.606 Furthermore, the Parties' explanation is inconsistent with the surrounding contemporaneous evidence that Lexon had no intention of ordering commercial volumes of product from Medreich, and that its intention was to order only the single batch necessary to avoid the Sunset Clause (see paragraph 5.587 above). The evidence base shows that Lexon and Medreich's position on not ordering commercial volumes of Prochlorperazine POM had not changed during the course of 2014, as evident, *inter alia*, from the fact that [Medreich Director 2] had stated internally within Medreich on 27 August 2014 that there was *'maybe a possibility of doing a batch of Prochloroperazine [sic] 3mg'* of [✂] tablets but noted *'we do need small batch sizes'* – [Medreich Director 2]'s reference to the '*possibility*' of doing '*a batch*' is not consistent with [Lexon Director 1] seeking a commercial volume of product in the form of multiple batches from Medreich.[1523]

5.607 The CMA has also considered whether it may have been the case that Lexon was misleading Focus regarding Lexon's intention not to supply commercial volumes of

[1520] Email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine [sic] 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812).

[1521] Email [Lexon Director 1] to [Focus Director 1] entitled '*RE: Prochloroperazine [sic] 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003813).

[1522] Advanz RSO, 1 August 2019, paragraphs 3.180.8, 3.181, footnote 324 and 6.20-6.23 (URN: PRO-C5111). Advanz pointed to the fact that in his response email of 3 September 2014, [Focus Director 1] had referred to updating Lexon on his '*requirements*' (email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine [sic] 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812)) and that [Lexon Director 1] had stated in his email of 4 November 2014 that he would inform Focus of the '*volumes*' he had available (email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832)). However, the CMA does not consider that the use of the terms '*requirements*' and '*volumes*' necessarily indicate multiple orders: these could have been referring to a single batch.

[1523] Email [Medreich Director 2] to [Medreich employee], cc [Medreich employee] entitled '*FW: Prochloroperazine [sic] 3mg*' 27 August 2014 (URN: PRO-E002867).

the product and the existence of its Market Exclusion Agreement with Alliance. However:

5.607.1 As noted above, the emails also do not state expressly that Focus expected Lexon to supply commercial volumes. Rather, as with the first potential interpretation addressed above, that is an inference which Focus seeks to draw from the correspondence.

5.607.2 Such an explanation would be inconsistent with the evidence that Focus was aware of the Market Exclusion Agreement reached by Alliance and Lexon (see paragraph 5.601.2 above).

5.607.3 Despite [Focus Director 1]'s reference in his email of 3 September 2014 to updating Lexon on his '*requirements*', there is no contemporaneous evidence in which Focus followed-up with Lexon to confirm to Lexon what Focus' '*requirements*' would actually be.[1524]

5.607.4 Contrary to Advanz's submission, there is not evidence that Focus was *'chasing Lexon for updates and information'*.[1525] It is not clear whether or not there was a prior conversation between [Lexon Director 1] and [Focus Director 1] regarding the batch information which [Lexon Director 1] forwarded. Nor is there any evidence that [Focus Director 1] followed up on the correspondence.

5.608 The CMA finds that there are other potential explanations for the 2 and 3 September 2014 emails that do not involve an expectation on the part of either Lexon or Focus of the supply of commercial volumes of Lexon's Prochlorperazine POM product by Lexon to Focus whilst the Market Exclusion Agreement continued. As the CMA sets out in detail in Annex F:

5.608.1 The CMA considers that the [Lexon Director 1] email of 2 September 2014 and [Focus Director 1]'s response of 3 September 2014 can plausibly be explained on the basis that Focus and Lexon were contemplating and discussing the provision of the single batch of Prochlorperazine POM necessary to avoid the application of the Sunset Clause.

5.608.2 As an extension of the first point set out above, it may be that Lexon was particularly keen to give the impression (to Focus, and potentially indirectly to Alliance) that Lexon was pressing ahead as fast as possible with the single batch, and could produce more product should the Market Exclusion Agreement be terminated.

[1524] At interview, [Focus Director 1] said he could not remember whether he had gone back to Lexon with details of Focus' requirements for Prochlorperazine POM (interview [Focus Director 1], 2 October 2018, page 207, lines 10-11 (URN: PRO-C3294)).

[1525] Advanz response dated 6 January 2020 to the CMA's questions of 26 November 2019, page 9 (URN: PRO-C5635).

5.608.3 [Lexon Director 1]'s email response of 3 September 2014 commenting on lead times can plausibly be explained by [Lexon Director 1]:

(a) writing a stock response;

(b) contemplating future productions of the single batch needed periodically to avoid the Sunset Clause (that is, the batch to be produced in the following three years); or

(c) contemplating a possible situation in which the forthcoming new owners of the Focus business chose to end Focus' participation in the Market Exclusion Agreement (such that multiple batches of product were in fact ordered).

The 4 November 2014 exchange

Witness evidence and Parties' representations

5.609 During an interview with the CMA, [Lexon Director 1] commented that the reference to an order in the November 2014 exchange was pursuant to his ongoing attempts to obtain Prochlorperazine POM from Medreich.[1526] Both [Focus Director 1] and [Lexon Director 1] stated that the renegotiation of the profit share clause, as reflected in the November 2014 exchange, was a consequence of the price increases that had been achieved by Focus.

5.609.1 [Focus Director 1] stated in interview in respect of his email to [Lexon Director 1] on 4 November 2014 that the motivation for the profit share amendment was because the market price was over £10.50 and Lexon had not supplied any product. [Focus Director 1] said that he had had a meeting with [Lexon Director 1] but that [Lexon Director 1] had not been resistant to the amendment to the profit share.[1527]

5.609.2 [Lexon Director 1] stated in his interview that he did not remember anything about the meeting held with [Focus Director 1] but that he remembered the email and that it was prompted by the fact that Focus were putting the prices up and Lexon was getting money *'for want of a better word for doing nothing'*.[1528] As regards the order of product, [Lexon Director 1] commented that at that stage Lexon were *'still trying to get stock out of Medreich'*.[1529]

5.610 Advanz submitted, in the context of the 4 November 2014 correspondence between Focus and Lexon, that Focus was *'chasing Lexon for its Prochlorperazine*

[1526] Interview [Lexon Director 1], 19 September 2018, page 27, lines 11 to 13 (URN: PRO-C3191).

[1527] Interview [Focus Director 1], 2 October 2018, page 209, line 9 to page 210, line 16 (URN: PRO-C3294).

[1528] Interview [Lexon Director 1], 19 September 2018, page 10, line 27 to page 11, line 18 (URN: PRO-C3191).

[1529] Interview [Lexon Director 1], 19 September 2018, page 11, line 11 (URN: PRO-C3191).

POM because Focus faithfully believed that it was party to a distinct and legitimate distribution agreement with Lexon for its Prochlorperazine POM';[1530] relatedly, Cinven described the 3 November 2014 meeting as being *'about obtaining Prochlorperazine POM'* and *'regarding Lexon's failure to supply'*.[1531]

5.611 Cinven submitted that *'[w]hether or not Lexon accurately represented the status of its order with Medreich says nothing as to Focus' intention – Focus chased for the product and renegotiated the profit share in its favour on the back of Lexon's failure to supply … While Focus had no way of verifying whether Lexon had placed such an order, the CMA has not provided any reason why it should have doubted the veracity of [Lexon Director 1]'s statement in that regard'*.[1532] Cinven added that [Lexon Director 1]'s misleading of [Focus Director 1] was inconsistent with the notion that both Focus and Lexon were aware of the Market Exclusion Agreement, but was consistent with Focus pressurising Lexon for product.[1533]

CMA Analysis

5.612 [Focus Director 1]'s email of 4 November 2014 refers to the placing by Lexon of '*an order for stock*' and Focus placing '*a purchase order on [Lexon] for the stock'*;[1534] [Lexon Director 1]'s reply refers to advising Focus when Lexon has *'a firm date for availability of released product along with the exact volumes*'.[1535] However, the exchange between [Focus Director 1] and [Lexon Director 1] is ambiguous on its face as to whether they are referring to an order for a single batch of Prochlorperazine POM or commercial volumes of product.

5.613 The CMA considers that the suggestion that the Parties intended Lexon to supply commercial volumes of Prochlorperazine POM is inconsistent with the contemporaneous evidence showing that no such order had been placed by Lexon, no steps were being taken to obtain commercial volumes of Prochlorperazine POM product from Medreich and that [Lexon Director 1]'s intention was to order only the single batch of product necessary to avoid the application of the Sunset Clause (see paragraph 5.587 above). The contents of the exchange of 4 November 2014 as regards the placing of an order are therefore inaccurate (see further paragraphs 5.434 to 5.455).

5.614 The CMA also rejects Advanz and Cinven's submission that, insofar as [Lexon Director 1] was not in fact seeking commercial volumes of product from Medreich, the 4 November 2014 exchange represents evidence that [Lexon Director 1] was

[1530] Advanz RSO, 1 August 2019, paragraph 3.127 (URN: PRO-C5111).

[1531] Cinven RSO, 15 August 2019, paragraphs 4.106 and 4.110 (URN: PRO-C5132).

[1532] Cinven RSO, 15 August 2019, paragraph 4.106 and paragraph 7.35 (URN: PRO-C5132).

[1533] Cinven RLF, 22 April 2021, paragraphs 2.44-2.45 (URN: PRO-C7107).

[1534] Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

[1535] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

seeking to conceal his intended strategy of refraining from commercialising the product from Focus (such that Focus was not aware of the Market Exclusion Agreement and did itself intend to purchase commercial volumes of Prochlorperazine POM from Lexon).

5.614.1 First, the submission is inconsistent with other contemporaneous evidence that Focus was aware of the existence and objectives of the Market Exclusion Agreement and the fact that it would not be supplied with commercial volumes of Prochlorperazine POM by Lexon (see paragraph 5.601.2 above).

5.614.2 Second, although the 4 November 2014 email exchange was initiated by Focus, it does not show Focus actively '*chasing*' Lexon for commercial volumes: whilst [Focus Director 1]'s email did refer (incorrectly) to Lexon having placed an order for stock, the first and third paragraphs of his email relate to the continuation of the Focus-Lexon Heads of Terms and in particular the profit share term.

5.614.3 Third, following the 4 November 2014 email exchange, Focus did not – despite [Focus Director 1] recording Lexon's claimed expectation that *'the stock [would] … arrive in early 2015',*[1536] and despite the fact that Focus' payments to Lexon had totalled over £4.37 million by the end of 2016 (see Annex I:) – engage with Lexon to expedite Lexon's supply of Prochlorperazine POM, which would have been expected had Focus actually been anxious to obtain commercial volumes of product from Lexon.[1537] Despite the fact that profit share payments to Lexon from Focus continued to grow until early 2017, there is no evidence after the 4 November 2014 email exchange of Focus having approached Lexon regarding product availability, or having made enquiries regarding Lexon/Medreich's inability to supply, as evidenced by the fact that:[1538]

(a) In response to a request from the CMA to identify any instances recorded in documents where Focus chased Lexon for supply of Prochlorperazine POM, Advanz was not able to identify any documents where it is clear that Focus was seeking commercial

[1536] Email [Focus Director 1] to [Lexon Director 1] entitled *'Prochlorperazine 3mg tabs' dated 4 November 2014'* (URN: PRO-E003832).

[1537] Cinven represented that there were other reasons why after early 2015 Focus' efforts to obtain stock may have diminished, namely the Focus' vendors personal interest in satisfaction of their earn-out conditions and the fact that Prochlorperazine POM was not have been a top priority for Focus or, subsequently, AMCo (Cinven RLF, 22 April 2021, paragraph 2.46(c) (URN: PRO-C7107)). However, the evidence relating to Focus (and later AMCo – see paragraph 5.543) is clear that Focus and AMCo did engage on the status of the product.

[1538] In the context of considering the 2014 Correspondence, Cinven submitted to the CMA that *'Focus continued to submit orders for the supply of Prochlorperazine POM from Lexon, which is indicative of a customer trying to source product from its supplier and inconsistent with the CMA's narrative'* (Cinven RSO, 15 August 2019, paragraph 4.103 (URN: PRO-C5132)). However, Cinven did not provide any substantiation for this statement and the CMA is not aware of Focus having placed a purchase order for Prochlorperazine POM from Lexon.

volumes of product from Lexon.[1539] In fact, Advanz's response identified only one entry in a notebook by [AMCo Employee 3] dated April 2016 noting *'Make sure [Lexon Director 1] keeps on top of Medreich'*[1540] which Advanz considered to be evidence that Focus continued to chase Lexon for product even after Focus' acquisition by AMCo.[1541] However: (i) in the same notebook entry, [AMCo Employee 3] referred to the Lexon profit share and commented *'everyone works with us'*.[1542] In the absence of any other evidence from that period that Focus/AMCo was chasing Lexon/Medreich for product, the CMA finds that it is more plausible that the reference to *'Make sure [Lexon Director 1] keeps on top of Medreich'* was a reference to ensuring that Medreich remained in compliance with the Market Exclusion Agreement.

(b) [AMCo Director 2] commented in his interview with the CMA that he could not ever remember getting any clarity in terms of when the Lexon product would be delivered, whether that meant that there would be a delay of a year or two, or that the product was coming next week.[1543] [AMCo Director 2]'s comments are plainly inconsistent with any suggestion that Focus expected to receive product from Lexon and was actively 'chasing' Lexon for product.[1544] Given the value of the payments being made by Focus to Lexon at this point (which reached over £600,000 per quarter in respect of sales made during 2015) the CMA finds that [AMCo Director 2]'s inability to recollect specifics in terms of Focus/AMCo obtaining assurances from [Lexon Director 1] is consistent with Focus/AMCo not actually expecting to receive product from Lexon.

5.615 The CMA has also considered the related possibility, as Advanz and Cinven suggest, that the fact that Focus and Lexon agreed an amended profit share at their meeting on 3 November 2014 reflects Lexon's inability to supply commercial volumes of product to Focus by this point, which in turn shows that Focus was

[1539] Advanz response dated 6 January 2020 to CMA questions 26 November 2019, question 11 (URN: PRO-C5635). In this respect, the CMA was not necessarily seeking '*a routine and uninterrupted pattern of communications with Lexon in which Focus sought to "expedite" the process'* (Cinven RLF, 22 April 2021, paragraph 2.46(d) (URN: PRO-C7107)) – but the complete absence of any such documentation is – given the continuing profit share payments – instructive.

[1540] [AMCo Employee 3] Notebook EMN010, page 29 (URN: PRO-E004038). [AMCo Employee 3] was asked about what he meant by this phrase in his interview, but he stated that he did not recall what that meant (interview [AMCo Employee 3], 12 June 2018, page 34, line 17 (URN: PRO-C2419)).

[1541] Advanz RSO, 1 August 2019, paragraph 6.27 (URN: PRO-C5111). See also Advanz RLF, 22 April 2021, paragraph 4.151 (URN: PRO-C7112) and Advanz RLF, 30 November 2021, paragraph 2.17.9 (URN: PRO-C7917).

[1542] [AMCo Employee 3] Notebook EMN010, page 29 (URN: PRO-E004038).

[1543] Interview [AMCo Director 2], 7 January 2020, page 129, lines 2-7 (URN: PRO-C5994).

[1544] [AMCo Director 2] stated in his interview that he would not have been the person chasing Lexon for product (Interview [AMCo Director 2], 7 January 2020, page 128, line 8 (URN: PRO-C5994)). However, [AMCo Director 2] did not provide any meaningful explanation as regards the outcome of any such conversations held by others (such as [Focus Director 1]): he simply stated that there would have been conversations with Lexon (Interview [AMCo Director 2], 7 January 2020, page 129, line 19-20 (URN: PRO-C5994)).

expecting to obtain commercial volumes of Prochlorperazine POM from Lexon. However, the CMA rejects this explanation: there is no basis to regard the amendment to the profit share in November 2014 as relating to a failure by Lexon to deliver commercial quantities of product to Focus by this point. As explained in detail in paragraph 5.551, the lack of any connection drawn in the 4 November 2014 correspondence between the Lexon placement of an order and the profit share amendment, the particular structure of the profit share amendment, the lack of follow-up by Focus, the witness evidence on the rationale for the profit share amendment and [Focus Director 1]'s contemporary presentation of the profit share amendment to AMCo management do not support the Parties' submission in this respect.

5.616 The CMA finds that there are at least two alternative plausible explanations for the 4 November 2014 email exchange that do not involve an expectation on the part of either Lexon or Focus of the supply of commercial volumes of Lexon's Prochlorperazine POM product by Lexon to Focus. As the CMA sets out in detail in Annex F:

5.616.1 The CMA considers that the 4 November 2014 exchange can plausibly be explained on the basis that Focus and Lexon were contemplating and discussing the provision of the single batch of Prochlorperazine POM necessary to avoid the application of the Sunset Clause and that, Lexon additionally wished to demonstrate to Focus (and thereby, potentially, indirectly to Alliance, with whom Focus were in contact) its imminent ability to make the single batch (and more product, should the Market Exclusion Agreement be terminated).

5.616.2 Second, the contents of the 4 November 2014 exchange may have been influenced by the authors' caution regarding what they put into writing (including possibly deliberately creating a written record meant to give the impression that they were intending to supply and receive commercial volumes).

Conclusion on the evidential significance of the 2014 Correspondence

5.617 The CMA concludes that the Parties' explanations of the 2014 Correspondence are inconsistent with the wider evidence base and that there are other plausible explanations which are consistent with that evidence base. The CMA has considered the evidence in the round. The CMA finds that the 2014 Correspondence between [Lexon Director 1] and [Focus Director 1] is not explained by a genuine expectation on the part of Lexon and/or Focus of the supply by Lexon to Focus of commercial volumes of Prochlorperazine POM – including a scenario in which Focus expected to order commercial volumes of Prochlorperazine POM but was being misled by Lexon as to its progress and order status.

5.618 In particular, for the reasons explained in detail in Annex F: the CMA finds that the 2014 Correspondence can be explained on the basis that the references to the order of product were consistent with:

5.618.1 Lexon's plans, whilst the Market Exclusion Agreement continued, to place an order every three years for a single batch of product to prevent the expiry of the Sunset Clause – including Lexon potentially additionally wishing to give the impression during 2014 that it was pressing ahead as fast as possible with the single batch and could provide more product should the Market Exclusion Agreement be terminated; and/or

5.618.2 an understandable caution on the part of [Lexon Director 1] and [Focus Director 1] regarding what they put into the written record – including potentially deliberately creating during 2014 a written record meant to give the impression that they were intending to supply and receive commercial volumes.

5.619 The 2014 Correspondence is therefore not inconsistent with the existence of the Market Exclusion Agreement, or with Focus' participation in it.

5.620 The CMA's conclusion that the 2014 Correspondence are not inconsistent with the existence of the Market Exclusion Agreement is corroborated by the conduct of both Lexon and Focus after these email exchanges, for example:

5.620.1 on Lexon's part, it did not place an order or written instruction for product with Medreich until 23 June 2015, and when it did so it was for a single batch with no suggestion that this would be followed-up with subsequent larger batches (see paragraphs 5.434 to 5.455 and paragraph 5.462); and

5.620.2 on Focus/AMCo's part, despite the fact that profit share payments to Lexon from Focus continued to grow until they reached over £2.7 million per annum in early 2017, the evidence shows that Focus (under AMCo's ownership) did not engage with Lexon to expedite Lexon's supply of Prochlorperazine POM.

(a) Such follow-up would clearly have been expected if the 2014 Correspondence reflected, as the Parties suggest, Focus expecting to obtain commercial volumes of product from Lexon.

(b) But there is no evidence of Focus having approached Lexon regarding product availability during 2015, 2016 or 2017, or expressing frustration regarding Lexon/Medreich's inability to supply.

(c) To the contrary, the evidence from these years of AMCo's ownership of Focus provide strong positive evidence of the existence of the

Market Exclusion Agreement and Focus' knowing participation in it, as set out in paragraphs 5.490 to 5.523).

The CMA's assessment of the credibility of the Parties' submissions taken collectively and in the round

5.621 In addition to considering the Parties' submissions on specific points, the CMA has also considered the overall credibility of the Parties' submissions when assessed collectively and cumulatively. The CMA finds that the Parties' submissions would together require a series of highly improbable coincidences in their conduct.

5.622 The implication of the Parties' submissions is that Alliance's and Lexon's respective decisions to appoint Focus as distributor, and to do so at around the same time, was purely coincidental and the outcome of their own unilateral motivations: Lexon in seeking to appoint a distributor to launch its product in the market and Alliance in seeking to appoint a distributor to help it best respond to the competitive threat of the Lexon entry:

5.622.1 Focus and Lexon say that they had been in some form of discussions around Focus distributing the Lexon product for some time by summer 2013;

5.622.2 despite not having referred to Focus as a potential distributor of its product in the prior months, and despite Alliance having never previously used Focus to supply a product in the face of generic competition, Alliance says it unilaterally determined in summer 2013 that Focus was the best placed distributor to supply Alliance's de-branded Prochlorperazine POM product so as to enable Alliance to compete against the competitive threat from the forthcoming Lexon product; and

5.622.3 despite the relevance of its negotiations with one supplier to the other, the Parties submit that Focus did not inform either supplier that it was negotiating with its rival at the same time.

5.623 The implication of the Parties' submissions is also that it was an unintended coincidence that the pair of contracts put into place at approximately the same time in summer 2013 between Alliance and Focus and Focus and Lexon resulted in Lexon/Medreich receiving over £7.86 million from the profits earned on the supply of the Alliance product. The pair of contracts involved:

5.623.1 Alliance agreeing to exceptional supply terms that resulted in Focus earning significant profits on the sale of Alliance's Prochlorperazine POM (some £14.4 million to the end of July 2018), which Alliance has stated was the consequence of its willingness to allow Focus to increase the price of its de-branded product, together with Alliance's own reluctance to itself benefit from any such price increases;

5.623.2 Focus agreeing to pass the majority of those profits on to Lexon (some £7.86 million to the end of July 2018), and to persist in making such payments in the absence of supply from Lexon in return, which Focus has stated was motivated by a range of different factors, including its desire to obtain and supply the Lexon product when it became available, but which ultimately tangibly and directly yielded for Focus only a single batch of Lexon/Medreich Prochlorperazine POM product in March 2018; and

5.623.3 Lexon receiving payments totalling some £7.86 million (to the end of July 2018) as a result of the inclusion in the contract of a clause that Lexon had stated was designed to discourage Focus from sourcing product from other suppliers, but where those payments were actually a direct result of Focus selling the product of Lexon's competitor, Alliance; Lexon then paid a proportion of that revenue (some £2.90 million) to its manufacturing partner, Medreich, which Lexon has said had failed to manufacture and supply any product until November 2017.

5.624 When considered together, the Parties' submissions also imply that a series of documents that, on their plain reading, document the existence of the Market Exclusion Agreement, are, in fact, the outcome of a variety of errors, omissions and misunderstandings that, by coincidence, provide consistent evidence of the existence of the Market Exclusion Agreement. In particular, the Parties submit that:

5.624.1 the [Alliance Director 1] notebook of 11 June 2013[1545] should be read contrary to its plain meaning, such that the entry referred exclusively to Alliance's (regulatorily incorrect) proposed plans to retain its branded product, despite [Alliance Director 1] writing '*Lexon*' twice and referring to '*make batch – sell Focus ->*' (see paragraph 5.208);

5.624.2 [Focus Director 1] typed '*[Lexon Director 1]*' instead of '*[Alliance Employee 1]*' in his email of 22 June 2013[1546] when he referred to the '*the agreement [Lexon Director 1] made*' with Alliance regarding the terms of the Alliance-Focus Agreement (see paragraph 5.229);

5.624.3 [Lexon Director 1] made a temporary mistake when he instructed Medreich that Prochlorperazine POM was '*best left alone*' in his email of 4 February 2014 (see paragraph 5.427)[1547] but only corrected this mistake orally and did not reflect it in subsequent correspondence with Medreich in the months that followed;

[1545] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

[1546] Email [Focus Director 1] to [Focus Director 2] entitled 'Fwd: *Prochlorperazine IMS*' dated 22 June 2013 (URN: PRO-E001476).

[1547] Email [Lexon Director 1] to [Medreich Employee 1] entitled '*RE: Products*' 4 February 2014 (URN: PRO-E002750).

5.624.4 in that same email of 4 February 2014, [Lexon Director 1] mistakenly included the word '*have*' when signalling that he had agreed to supply only a batch of product every three years to avoid the Sunset Clause (see paragraph 5.431);[1548]

5.624.5 [Medreich Employee 1] was simply referring to the profit-sharing term in the Focus-Lexon Heads of Terms when he referred to Prochlorperazine POM as involving a '*clever arrangement*' in his email of 7 April 2014,[1549] despite the fact that he also referred in the same email to Alliance '*making still the lion's share*' (see paragraph 5.571);

5.624.6 [Focus Employee 1] made a mistake when she stated that '*[t]he only reason that Lexon gets Prochlorperazine Buccal Tablets is because they helped set up the supply agreement with Alliance*' in her email of 23 March 2017[1550] (see paragraph 5.558); and

5.624.7 [Medreich Director 2] made an assumption or misunderstood the commercial situation when he stated that '*There is a deal in place that for Medreich Not to bring 3mg in market we get royalty*' in his email of 21 July 2017[1551] (see paragraph 5.579).

5.625 The CMA has explained in the relevant parts of the Decision as cited above why it considers that the Parties' various explanations for the above documents should be rejected. The CMA finds that this assessment is further supported by the highly improbable coincidences that the Parties' submissions rest upon, including that:

5.625.1 both suppliers reached the view, independently, that Focus should be appointed as their distributor;

5.625.2 by coincidence, they separately negotiated supply terms that were themselves of an exceptional nature and that enabled Lexon/Medreich to receive over £7.86 million of the profits earned from the supply of the Alliance product; and

5.625.3 a series of documents were produced that, in error, recorded consistently the terms of the Market Exclusion.

[1548] Email [Lexon Director 1] to [Medreich Employee 1] entitled '*RE: Products*' 4 February 2014 (URN: PRO-E002750).

[1549] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002803).

[1550] Email [Focus Employee 1] to [AMCo employee] entitled '*RE: Well Pharmacy price amendments – Focus lines*' 23 March 2017 (URN: PRO-E002030).

[1551] Email [Medreich Director 2] to [Meiji employee] entitled '*Prochlorperazine – profit sharing*' 21 July 2017 (URN: PRO-E003351).

Conclusion on the existence of the Market Exclusion Agreement

5.626 As set out in the sections above in full, and by way of summary, the CMA has considered:

5.626.1 the evidence that Lexon had informed Alliance in early 2013 that it was preparing to enter the market with Prochlorperazine POM and the events leading up to the two meetings between Alliance and Lexon in 2013;

5.626.2 the contemporaneous documentary evidence from June and July 2013, including in particular [Alliance Director 1]'s 11 June 2013 notebook entry[1552] and [Focus Director 1]'s (Focus) email dated 22 June 2013;[1553]

5.626.3 the terms of the Implementing Agreements entered into between Alliance and Focus and between Focus and Lexon; and

5.626.4 the subsequent conduct and documentary evidence of each of Alliance, Lexon, Focus and Medreich after the conclusion of the Implementing Agreements; and

5.626.5 the three email exchanges between [Focus Director 1] and [Lexon Director 1] in 2014 that refer to the supply of product, but that do not specify whether any such supply would be limited to the single batch of product needed to avoid the application of the Sunset Clause or to a plan to supply commercial batches of the product.

5.627 The CMA has set out extensively the witness evidence in respect of this evidence and the Parties' representations on it.

5.628 Having considered that evidence, the witness evidence, and the Parties' representations in their totality, and in the round, the CMA concludes that:

5.628.1 most likely by 7 June 2013, and in any event by 22 June 2013, Alliance and Lexon had reached an agreement in principle that:

(a) Alliance would indirectly (through a third-party company, Focus) transfer value to Lexon by: (i) Alliance exclusively supply Focus with a de-branded version of Alliance's Buccastem POM product at a fixed selling price, and enabling Focus to implement a series of price increases; and (ii) Lexon entering into an agreement with Focus under which Lexon would (nominally) appoint Focus as the distributor of the Prochlorperazine POM product Lexon had jointly developed with Medreich and, under that agreement, Focus sharing with Lexon the

[1552] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980).

[1553] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon; and

(b) in return for that value transfer from Alliance, through Focus, Lexon would not enter the market with the Prochlorperazine POM product that it had jointly developed with Medreich; and

5.628.2 the terms of that Market Exclusion Agreement between Alliance and Lexon were not recorded in a formal written contract; however, its existence and terms can be established and inferred from the evidence, including the terms of the Implementing Agreements, and the Parties' conduct and documentary evidence subsequent to the conclusion of the Implementing Agreements.

Focus and Medreich's participation in the Market Exclusion Agreement

5.629 In this section, the CMA first sets out the reasons for its conclusion as to the existence of an overall plan pursuing a common objective. The CMA then addresses:

5.629.1 in relation to Focus' participation:

(a) its level of awareness;[1554] and

(b) its intentional contribution to the common objective; and

5.629.2 in relation to Medreich's participation:

(a) its level of awareness;[1555] and

(b) its intentional contribution to the common objective.

5.630 For the reasons set out below, the CMA concludes that both Focus and Medreich participated in the Market Exclusion Agreement, because:[1556]

5.630.1 there was an overall plan pursuing a common objective, which in this case was the implementation of the Market Exclusion Agreement;

5.630.2 they were each aware of the conduct which was put into effect by Alliance and Lexon in pursuit of the common objective, or could reasonably have foreseen it and were prepared to take the risk, and they were as a matter

[1554] I.e. the undertaking's awareness of the conduct planned or put into effect by other undertakings in pursuit of the common objective, or that it could reasonably have foreseen it and was prepared to take the risk (see paragraphs 5.143 to 5.146).

[1555] See note 1554 above.

[1556] See paragraphs 5.127 to 5.146 above. See also T-204/08 *Team Relocations v Commission*, EU:T:2011:286, paragraph 37 and T-180/15 *Icap and Others v Commission*, EU:T:2017:795, paragraph 100; C-194/14 *AC-Treuhand v Commission*, EU:C:2015:717, paragraph 30 and the case-law cited.

of fact in this case also each aware of the conduct which was put into effect by each other in pursuit of the common objective; and

5.630.3 they each made an intentional contribution to the common objective.

The existence of an overall plan pursuing a common objective

5.631 As set out in paragraph 5.628 above, the CMA has found that an agreement existed between Alliance and Lexon (that is, the Market Exclusion Agreement) which contained the following terms:

5.631.1 Alliance would indirectly (through Focus) transfer value to Lexon by exclusively supplying Focus with its Prochlorperazine POM, and Focus sharing the profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon; and

5.631.2 in return for that value transfer, Lexon would not enter the market with the Prochlorperazine POM that it had jointly developed with Medreich.

5.632 In other words, Alliance and Lexon agreed that Lexon would not compete with Alliance in return for being paid in the form of an indirect transfer of value, which ultimately totalled £7.86 million (£4.96 million for Lexon and £2.9 million for Medreich). That agreement was most likely entered into, in principle, by 7 June 2013 and lasted until 31 July 2018.

5.633 The CMA finds that there was an *'overall plan pursuing a common objective'*[1557] given, as set out at paragraphs 5.718 to 5.727 below, the object of the Market Exclusion Agreement was that Lexon and Alliance agreed not to compete with one another in the supply of Prochlorperazine POM in the UK through a market exclusion arrangement. The CMA concludes that this amounts to more than a plan simply to distort competition in the market.

5.634 Accordingly, in this section, the CMA refers to the term 'common objective' as referencing the implementation of the Market Exclusion Agreement.

Focus' awareness

Summary of CMA's conclusion

5.635 The CMA concludes that by at least 22 June 2013 Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) that Alliance and Lexon had entered into an arrangement (the Market Exclusion Agreement) in which they agreed that:

[1557] See paragraph 5.132 above.

5.635.1 Alliance would indirectly (through Focus) transfer value to Lexon by exclusively supplying Focus with its Prochlorperazine POM, and Focus sharing the profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon; and

5.635.2 in return for that value transfer, Lexon would not enter with the Prochlorperazine POM that it had jointly developed with Medreich.

5.636 In this respect, the CMA also concludes that Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) of the following conduct engaged in by Alliance and Lexon in pursuit of the common objective:

5.636.1 the supply of Prochlorperazine POM from Alliance to Focus at a fixed price in circumstances which enabled Focus to significantly increase the price at which it supplied Prochlorperazine POM; and

5.636.2 the profit share mechanism in place for the profits that Focus made on the sale of Alliance's Prochlorperazine POM to be shared with Lexon, without Lexon being required to supply any Prochlorperazine POM.

5.637 The CMA also concludes that, although not required to be demonstrated, Focus was in fact in this case aware (or could reasonably have foreseen it and was prepared to take the risk) that Medreich held the MA for the Prochlorperazine POM in which Lexon had a commercial interest and engaged in the following conduct in pursuit of the common objective:

5.637.1 receiving from Lexon part of the profits being paid to Lexon by Focus under the Focus-Lexon Heads of Terms; and

5.637.2 refraining from producing the jointly developed product (other than the single batch required to avoid the application of the Sunset Clause).

Evidence relied on by the CMA as regards Focus' awareness

5.638 First, the email of 22 June 2013 from [Focus Director 1] to [Focus Director 2][1558] demonstrates that Focus understood an agreement to have been reached between Alliance and Lexon (see paragraph 5.195 above). In particular:

5.638.1 [Focus Director 1] understood that [Lexon Director 1] had reached an agreement with Alliance as to the price at which Focus would purchase Prochlorperazine POM from Alliance: '*[Focus Director 2] In case [Alliance*

[1558] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

Employee 1] rings you , the agreement [Lexon Director 1] made was we [Focus] initially buy at 25% off their [sic] [Alliance's] trade price'.[1559]

5.638.2 [Focus Director 1] also understood that that there would be a profit share arrangement in place between Focus and Lexon (in favour of Lexon given '*it is his licence*'). Despite the reference to a profit share, the email does not make any reference to Focus purchasing Prochlorperazine POM from Lexon.[1560]

5.639 Second, as explained in paragraphs 5.556 and 5.557, subsequent evidence obtained from Focus also confirms Focus' understanding as to the Market Exclusion Agreement, and Lexon's role in helping to '*set up*' that agreement. Specifically, in an email dated 23 March 2017, [Focus Employee 1] observed to [AMCo employee] that:

> *'The only reason that Lexon gets Prochlorperazine Buccal Tablets is because they helped set up the supply agreement with Alliance Pharma (who also make our Aspirin EC 300mg).'*[1561]

5.640 Third, Focus was aware, or could reasonably have foreseen it and was prepared to take the risk, that it would be supplied at a fixed price by Alliance in circumstances which enabled Focus to significantly increase the price at which it supplied Prochlorperazine POM to wholesalers in the UK (see paragraphs 5.277 to 5.295). In particular:

5.640.1 As set out in the 22 June 2013 email, [Focus Director 1] was aware that Focus would be purchasing Prochlorperazine POM at the price that

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[1559] The fixed price at which Alliance would supply Focus is also clearly set out in the Alliance-Focus Agreement (see paragraph 3.104 above).

[1560] The witness evidence of [Focus Director 1], [Focus Director 2] and [Lexon Director 1] in relation to the 22 June 2013 email, and the Parties' related submissions on it, are set out in detail in paragraphs 5.227 to 5.247. For the reasons set out there, including the fact that the plain reading of the 22 June 2013 email is supported by other contemporaneous evidence, the CMA has rejected the witness claims in relation to the interpretation of the 22 June 2013 email and the alternative readings of the email as claimed by the witnesses and the Parties. Cinven has submitted that [Focus Director 1]'s email of 22 June 2013 does not '*prove*' Focus' awareness of the Market Exclusion Agreement between Alliance and Lexon, but '*[a]t most' 'would allow for an inference that Focus was aware that Lexon had communications with Alliance regarding the potential for Focus to act as Alliance's distributor*' (Cinven RLF, 22 April 2021, paragraph 2.86 (URN: PRO-C7107)). The CMA rejects this. First, there is no credible explanation as to why, absent the Market Exclusion Agreement, Alliance should discuss with Lexon who Alliance should appoint as a distributor to help counter the competitive threat posed by Lexon itself. Second, in any event, Cinven's reading of the email ignores the fact that [Focus Director 1] refers to Alliance and Lexon having agreed in principle the terms on which Alliance would supply Prochlorperazine POM to Focus, and also disregards the subsequent documentary evidence that supports the CMA's interpretation of [Focus Director 1]'s 22 June 2013, including in particular [Focus Employee 1]'s email of 23 March 2017 (Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030)): see paragraph 5.639.

[1561] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030). The CMA has considered the witness evidence of [Focus Employee 1] in relation to this email, and the Parties' related representations on the significance to be placed on it, in paragraphs 5.558 to 5.561. For the reasons explained there, the CMA rejects [Focus Employee 1]'s evidence in this respect, and does not accept the Parties' representations that the email is not evidence of the Market Exclusion Agreement or Focus' understanding and awareness of it. This includes the CMA's rejection, given the content and context of the email, of the Parties' representation that the email only shows, at most, that Focus was aware that Lexon had communications with Alliance regarding the potential for Focus to act as Alliance's distributor (see paragraph 5.560).

Alliance had previously been selling to wholesalers (*'ie they keep the current [Average Selling Price] and Focus sell the generic pack'*[1562]) and that *'Focus will set'* the onward price.

5.640.2 In an email to [Focus Director 2] on 18 July 2013, [Focus Director 1] forecast a series of price increases on the sale of Prochlorperazine POM. Despite the fact Focus was forecasting significant increases to the price of Prochlorperazine POM, it did not forecast any purchase of product from Lexon or loss of volume (which is evidence of an awareness of the common objective on Focus' part, namely that its sales of the Alliance product would not be impacted by any competition from the Lexon/Medreich product).[1563]

5.641 Fourth, Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) of the fact that:

5.641.1 there was a relationship between Lexon and Medreich, where Medreich held the MA for the Prochlorperazine POM product in which Lexon would have commercial involvement; this is evidenced by [Focus Director 1]'s email to [Lexon Director 1] of 10 July 2013,[1564] as corroborated by comments of [Focus Director 1] in interview;[1565] and

5.641.2 pursuant to the Market Exclusion Agreement, Focus would share the profits it made from the sale of Alliance's Prochlorperazine POM with Lexon, without Lexon being required to supply any of the Prochlorperazine POM product that it had jointly developed with Medreich (see paragraph 5.197). The CMA considers this to be clear from [Focus Director 1]'s email of 22 June 2013[1566] (see paragraph 5.197 above). The subsequent internal Focus email of 18 July 2013 email[1567] (see paragraph 5.199.3 above) which models Focus being able to increase prices whilst retaining

[1562] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[1563] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478). In relation to this email, Advanz submitted that it did not evidence Focus' awareness of the Market Exclusion Agreement given that the fact that Focus did not forecast any loss of volume is explained by the fact that Lexon/Medreich were six months away from receiving their Prochlorperazine POM MA, Focus would wish to maximise margins prior to a switch to Lexon and Focus was preparing the business for sale so would therefore not want to be forecasting a loss of volume (Advanz RSO, 1 August 2019, paragraphs 3.171 and 3.179 (URN: PRO-C5111)); see similarly Cinven RSO, 15 August 2019, paragraph 4.102 (URN: PRO-C5132). However, these points overlook the fact that this is an internal Focus email (not an analysis prepared for potential purchasers) but [Focus Director 1] does not mention at all, or provide for, the possibility of obtaining stock from Lexon: his calculations are based on continuing purchase of the Alliance product as prices are raised in the market – which is consistent with an awareness of the common objective, but not consistent with an expectation of receiving product from Lexon imminently. See further paragraphs 5.2645.254 to 5.268.

[1564] Email [Focus Director 1] to [Lexon Director 1] entitled '*Fwd: Rama as requested*' 10 July 2013 (URN: PRO-E000326). The CMA's analysis of the Parties' various representations on the significance of this document are set out in paragraphs 5.254 to 5.263.

[1565] Interview [Focus Director 1], 2 October 2018, page 46, line 8 (URN: PRO-C3294).

[1566] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[1567] Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

25% of profits) and the Focus-Lexon Heads of Terms[1568] (see paragraph 3.106 above) are also relevant evidence that support this conclusion.

5.642 Fifth, Focus entered into conflicting agreements.[1569]

5.642.1 Under the terms of the Alliance-Focus Agreement, Focus agreed to act as the exclusive supplier of Alliance's Prochlorperazine POM. Under that agreement, Focus agreed not to sell or market in the UK any competing Prochlorperazine POM (see paragraph 3.104). This clause therefore contractually prevented Focus from supplying the product jointly developed by Lexon and Medreich.[1570]

5.642.2 Focus reached this agreement at a point in time when it was also in the process of securing the exclusive rights to supply the product jointly developed by Lexon and Medreich (under the terms of the Focus-Lexon Heads of Terms).[1571]

5.642.3 As a party to both contracts, Focus would, or at least should, have been fully aware of the terms of both the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms and the conflict between their terms.[1572]

5.642.4 Focus entered into and maintained two apparently conflicting agreements, which required Focus to only supply the Alliance product and to share a significant proportion of its profits on those sales with Lexon in circumstances when Lexon was not providing Focus with any goods or services.[1573] The CMA infers from this that Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) of its role in effecting the transfer of value from Alliance to Lexon, and hence of the

[1568] Document entitled *'Heads of Agreement'* signed 1 August 2013 (URN: PRO-E000429).

[1569] The CMA has considered [Focus Director 1]'s evidence as to Focus' rationale for entering into conflicting agreements in paragraphs 5.353 to 5.355. For the reasons set out in that section, the CMA finds that [Focus Director 1]'s explanation for Focus' entry into the two agreements in July and August 2013 cannot be sustained.

[1570] The CMA has considered [Focus Director 1]'s evidence that Focus was not in fact required to purchase exclusively from Alliance in paragraphs 5.350 and 5.351). For the reasons set out in that section, the CMA rejects [Focus Director 1]'s claim. The CMA has also considered Advanz's representation that the evidence does not show that Alliance and Focus agreed and intended to be bound by the exclusivity obligation on Focus in Clauses 4(3) and 6(1) in the Alliance-Focus Agreement in Annex C:. For the reasons set out in that section, this representation is not accepted.

[1571] The CMA has considered [Focus Director 1]'s evidence, and the Parties' related representations, that the Focus-Lexon Heads of Terms were agreed significantly prior to this (during 2012) in paragraphs 5.341 to 5.344. For the reasons set out in that section, the CMA finds that [Focus Director 1]'s explanation is not credible and that [Focus Director 1]'s comments that Focus and Lexon had not discussed the prospect of Focus obtaining product from Alliance at the time of agreement of the profit share clause in the Focus-Lexon Heads of Terms cannot be sustained.

[1572] Indeed, it is clear from an email from [Focus Director 2] to [Alliance employee] that the original contract upon which the Alliance-Focus Agreement is based (i.e. relating to Aspirin 300mg E/C tablets) was drafted by Focus, see Email [Focus Director 2] to [Alliance employee] entitled '*Meeting Follow-up*' 20 June 2011 (URN: PRO-E001466).

[1573] The CMA considers the witness evidence of [Focus Director 1] as to the rationale for Focus entering into the two agreements in paragraphs 5.353 to 5.355. For the reasons set out there, the CMA finds that [Focus Director 1]'s explanation for Focus' entry into the two agreements in July and August 2013 cannot be sustained.

essential characteristics of the Market Exclusion Agreement and of the common objective.[1574]

5.643 Sixth, Focus made payments to Lexon for no benefit other than to compensate Lexon for its agreement not to supply commercial volumes of its product. Pursuant to the terms of the profit share mechanism in the Focus-Lexon Heads of Terms, Focus agreed to pay a substantial share of its profits on the sale of Prochlorperazine POM to Lexon (initially 75% of the profits it made on sales of Prochlorperazine POM from any source, i.e. irrespective of whether the product was sourced from Lexon or not). Therefore, Focus agreed to make these payments to Lexon without a requirement on Lexon to supply it with any product. In other words, Focus committed to sacrifice the majority of its Prochlorperazine POM profits for no offsetting income or benefit.[1575]

5.643.1 The CMA considers it is not credible that, absent an awareness of (and an intention to contribute to – see paragraphs 5.649 to 5.654 below) the common objective, Focus would: (i) agree to such a profit share; or (ii) continue to make payments by reference to it for a period of some four and a half years (in particular when it had entered into a contractual commitment under the Alliance-Focus Agreement to supply only the Alliance Prochlorperazine POM – see paragraph 3.104 above).

5.643.2 The arrangement resulted in Focus paying Lexon some £7.86 million (before VAT) over a four and a half year period. Further, although the profit share split between Focus and Lexon was amended twice, the CMA has not seen any evidence that Focus ever revisited or questioned whether to make profit share payments to Lexon despite the absence of product from Lexon/Medreich.[1576]

[1574] Advanz submitted that the fact that Focus entered into distribution agreements with each of Alliance and Lexon is not sufficient to demonstrate that Focus participated in the Market Exclusion Agreement and that nothing could be inferred in this respect given the commercial context of the two agreements (Advanz RSO, 1 August 2019, paragraphs 3.109 and 3.196 (URN: PRO-C5111)). However, the CMA's finding is based not only on Focus' entry into the agreements, but on the wider contemporaneous evidence base set out in this section, including evidence from Focus itself, as well as the conflicting nature of the agreements entered into by Focus. For similar reasons, the CMA rejects Advanz's submission that the fact that Alliance and Lexon may have foreseen a role for Focus does not constitute evidence that Focus was aware of this (Advanz RSO, 1 August 2019, paragraph 3.164 (URN: PRO-C5111)): the CMA's finding of Focus' awareness is not based on showing that the other Parties foresaw a role for Focus, and this representation overlooks the evidence relating to Focus' awareness set out in this section and the active role played by Focus in entering into the agreements and making payments to Lexon pursuant to the Focus-Lexon Heads of Terms.

[1575] The CMA has considered the witness evidence of [Focus Director 1] and [AMCo Director 2] as to why Focus originally agreed to the profit share clause, and then made payments under it in paragraphs 5.304 to 5.345. The CMA has also considered the witness evidence of [Focus Director 1] and [AMCo Director 2] as to why Focus continued to make profit share payments to Lexon, despite the absence of product in paragraphs 5.532 to 5.555. For the reasons set out in those sections, the CMA finds that those explanations do not adequately explain Focus' willingness to agree to the profit sharing clause with Lexon or to make payments to Lexon despite the absence of product received from Lexon/Medreich.

[1576] The CMA considers the Parties' representations on this point in paragraphs 5.545 to 5.554, in particular that the first and second profit share amendments undermine the CMA's finding in this respect. For the reasons set out there, the CMA has not seen any evidence of Focus revisiting or questioning the notion that payments would continue to be made to Lexon under the profit share clause notwithstanding the lack of product supplied by Lexon/Medreich.

5.644 Seventh, Focus did not expect to obtain commercial volumes of Prochlorperazine POM from Lexon and, relatedly, was aware that Medreich had not launched a product pursuant to the Market Exclusion Agreement.

5.644.1 Focus' forecasting expectations in June and July 2013 envisaged purchasing Prochlorperazine POM solely from Alliance (despite Focus also agreeing to have the exclusive rights to supply the product jointly developed by Lexon and Medreich). As set out in paragraph 5.638 above, the 22 June 2013 email did not envisage Focus purchasing Prochlorperazine POM from Lexon. This is supported by other documentary evidence. For example, the 18 July 2013 email in which [Focus Director 1] assumed all of Focus' purchases would be made from Alliance.[1577]

5.644.2 Despite entering into the Focus-Lexon Heads of Terms by 1 August 2013, Focus forecasted in November 2013 in its budget for 2014, covering the period January 2014 to December 2014, that its purchases of Prochlorperazine POM would be made exclusively from Alliance.[1578]

5.644.3 Focus' intended strategy did not change when the Medreich MA for Prochlorperazine POM tablets was actually granted on 9 January 2014. On 10 January 2014, Focus placed two further orders for Prochlorperazine with Alliance for 40,000 packs (at £5.65 / pack) for delivery by 1 May and 40,000 for delivery by 2 June.[1579]

5.644.4 Similarly, on 4 April 2014, three months after Medreich had obtained its MA for Prochlorperazine POM, Focus anticipated consistent orders being placed with Alliance during 2014 and 2015 (see paragraph 3.122 above).[1580]

[1577] See note 1563 above.

[1578] See Email [Focus Director 1] to [Focus Director 2] entitled '*FW: other OLS for budget*' 14 November 2013 (URN: PRO-E003759). This assumes that all purchases would be made at the supply price specified in the Alliance-Focus Agreement, as shown by the fact that the cost of goods (CoG) in the email chain was £5.65 (the price at which Focus purchased product from Alliance) for each month in 2014. The Parties' representations on this email and its significance as regards Focus' understanding are set out in paragraphs 5.487 to 5.489. In that section the CMA concludes that, given the contents of [Focus Director 1]'s emails to [Focus Director 2] at that time, Focus' expectation of purchasing all product from Alliance is evidence of the Market Exclusion Agreement.

[1579] Email [Focus employee] to [Alliance employee] and [Alliance Employee 1], cc [Focus employee] entitled '*New PO's 9165131 and 9165132*' 10 January 2014 (URN: PRO-E001099), attaching Focus Purchase Orders 10 January 2014 (URN: PRO-E001100).

[1580] *Focus Prochlorperazine Forecast – 04 04 14*' 4 April 2014 (URN: PRO-E001117). This is prior to communications between Lexon and Focus as to API issues relating to Prochlorperazine POM (see paragraph 3.126). The Parties' representations on Focus' forecast evidence generally and its significance as regards Focus' understanding is set out in paragraphs 5.487 to 5.489. In that section the CMA concludes that, in particular given the contents of [Focus Director 1]'s emails to [Focus Director 2] at that time, Focus' expectation of purchasing all product from Alliance is evidence of the Market Exclusion Agreement. The CMA rejects the specific submission in relation to Focus' 4 April 2014 forecast that Focus would have forecasted steady volumes and prices in a bid to present the business as performing steadily in advance of a potential sale later in 2014 (Advanz RSO, 1 August 2019, paragraph 3.227 (URN: PRO-C5111)). Advanz did not cite any contemporaneous evidence to support this assertion. In any event, on Focus' own case (see paragraphs 5.314 to 5.324) Focus expected to be able to purchase from Lexon more cheaply than from Alliance – and hence Focus should have been incentivised to show a cheaper supply source coming on stream.

5.644.5 Subsequent evidence from AMCo is clear that AMCo/Focus understood that Medreich had not launched a product pursuant to the Market Exclusion Agreement: a handwritten note within AMCo discussing Primegen stated in respect of Prochlorperazine POM '*profit share w/Medreich'* and '*Medreich could decide to launch w/ own MA*'[1581] and a notebook entry of [AMCo Employee 3] dated April 2016 stated in respect of Prochlorperazine POM and the Lexon profit share *'Make sure [Lexon Director 1] keeps on top of Medreich*'.[1582]

5.644.6 The above evidence demonstrates that Focus expected to supply only Alliance's Prochlorperazine POM, while continuing to make payments to Lexon, and was aware that Medreich was not launching a product, which further demonstrates Focus' awareness of the common objective and the conduct of Alliance, Lexon and Medreich in pursuit of it.

5.645 Eighth, subsequent evidence after AMCo acquired Focus, relating to the Primegen product development acquired by AMCo, is also supportive of Focus' awareness of the common objective. That evidence, relating to Focus, has been set out in detail in paragraphs 5.490 to 5.507 by way of support for the CMA's finding of the existence of the Market Exclusion Agreement agreed between Alliance and Lexon. The CMA has taken into consideration the witness evidence and Parties' representations relating to that evidence as set out at paragraphs 5.508 to 5.523, and has set out why it does not consider those representations to be persuasive. Given that this evidence emanates from Focus, and is informative of Focus' understanding and decision-making, it also shows that Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) of the common objective and the conduct of Lexon and Medreich in pursuit of it for the reasons set out below.

5.645.1 The second profit share renegotiation was prompted by the grant of the Primegen licence, rather than by any failure by Lexon to supply product, which is evidence supportive of the Market Exclusion Agreement.[1583] This evidence on the rationale for the second profit share renegotiation shows that Focus was aware of the premise and purpose of the Market Exclusion Agreement – namely that Lexon was receiving profit share in return for not

[1581] Advanz Hard Copy Document TXT021, page 1 (URN: PRO-E004055). The CMA's analysis of the Parties' representations on this document are set out in note 1344).

[1582] [AMCo Employee 3] Notebook EMN010, page 29 (URN: PRO-E004038). Advanz submitted that, rather than showing that Focus was aware that Medreich had not launched product pursuant to the Market Exclusion Agreement, this document in fact provides evidence of Focus chasing Lexon for product (Advanz RLF, 30 November 2021, paragraph 2.17.9 (URN: PRO-C7917)): the CMA's analysis in this respect is set out in paragraph 5.614.3(a).

[1583] Email [Focus Director 1] to [Lexon Director 1] entitled '*prochlorperazine 3mg Tabs*' 26 June 2015 (URN: PRO-E003877). Email [AMCo Director 2] to [Focus Employee 1] entitled '*RE: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757). Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg*' 26 June 2015 (URN: PRO-E001634).

entering the market with product that could be developed pursuant to the Medreich licence (see paragraph 5.500).

5.645.2 The concern of the vendors of Focus, [Focus Director 1] and [Focus Director 2], around the second profit share renegotiation as reflected in [Focus Director 1]'s email of 15 June 2015 evidences Focus' understanding that Lexon and Medreich were entitled to profit share under the Market Exclusion Agreement[1584] (see paragraphs 5.493 to 5.496); [Focus Director 1]'s specific referencing of Medreich in that email ('*If they push alliance [sic] or lexon/medriech [sic] too much it will end up being a car crash for all*') evidences Focus' awareness that Medreich was receiving part of the profits from Lexon paid to Lexon by Focus under the Focus-Lexon Heads of Terms, in line with the fact that the profit share payments represented compensation for Lexon not entering the market with the product it had developed with Medreich.

5.645.3 AMCo's internal contemporary analysis shows that it viewed the lack of product from Lexon by June 2015 as being a function of the Market Exclusion Agreement, rather than because of an inability to supply.[1585] The AMCo evidence relating to the second profit share re-negotiation between June 2015 and February 2016 shows that AMCo/Focus considered that the commercial consequences of launching its own Primegen product would be Lexon's entry. This shows that Focus was aware of the common objective and the conduct of Lexon in pursuit of it: namely that Lexon had agreed with Alliance that it would not supply commercial volumes of its/Medreich's product into the market whilst it was being compensated through the profit share (see paragraphs 5.497 to 5.499).

5.645.4 The reaction of [Focus Director 1] and [Focus Director 2] in late June 2015 when Lexon/Medreich sought to resist, at least in terms of timing, Focus' attempts to leverage the Primegen Prochlorperazine POM development project in the profit share renegotiation shows Focus' awareness of the common objective and Lexon and Medreich's conduct in pursuit of it. [Focus Director 1] wrote to [Focus Director 2] that Lexon had stated that Medreich was pushing back on the start date for the profit share amendment until the time of the Primegen licence grant.[1586] This

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[1584] Email [Focus Director 1] to [Focus Director 2] entitled '*Re: Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616).

[1585] Email [AMCo Employee 4] to various colleagues at AMCo entitled '*Project Capital – Ad Hoc PPRM_Agenda & Presentation*' 29 June 2015 (URN: PRO-E001635) attaching presentation entitled '*Project CAPITAL BD Workstream*' 30 June 2015 (URN: PRO-E001636). Advanz Hard Copy Document TXT021, page 1 (URN: PRO-E004055).

[1586] Email [Focus Director 1] to [Focus Director 2] entitled '*FW: Prochlorperazine 3mg*' 26 June 2015 (URN: PRO-E001634), in which [Focus Director 1] recorded: '*[Lexon Director 1] has been back on the phone the 50/50 wont [sic] start until licence grant – Medrich [sic] wont [sic] go for 1st Oct ! and [sic] looking at [AMCo employee]'s e mail [sic] it looks like the launch date is July 16 so I presume the licence was further away than [Primegen employee] suggested. So we wont see any upside this year*.'

communication of Medreich's position, and Focus's apparent acceptance of that position – despite the fact that Lexon/Medreich had not supplied any Prochlorperazine POM product in the year and a half after obtaining the licence on 9 January 2014 – are consistent with Focus being aware that Lexon was passing a proportion of the profit share to Medreich and that Medreich was being compensated for not supplying product. It therefore shows Focus was aware of the common objective and the conduct of Lexon and Medreich in pursuit of it.[1587]

5.645.5 AMCo used the Primegen licence as leverage in profit share re-negotiations with Lexon rather than to launch its own product (which would have been considerably cheaper than either the Alliance or Lexon product (see paragraphs 5.314 to 5.324 and paragraphs 5.501 to 5.504).[1588] The contemporaneous evidence is clear that Focus understood that, even if the negotiations were conducted with Lexon, these would also have an impact on, and be of commercial relevance to, Medreich given it was receiving profit share payments from Lexon.[1589] Later AMCo documentary evidence demonstrates that, following the second profit share re-

[1587] The CMA does not accept Cinven's representation that the email does not implicate Focus and, at best, simply shows that Focus understood Lexon and Medreich to have a partnership in relation to Prochlorperazine POM (Cinven RLF, 22 April 2021, paragraph 2.36(c) (URN: PRO-C7107)). This overlooks the fact that the email records Focus' reaction to the Lexon/Medreich push-back – one of acceptance, rather than incredulity – which is evidence of Focus' awareness of the common objective. This is also a response to Advanz's representation that the email only records Medreich's (and/or Lexon's) intentions, which are not imputable to Focus, and that nothing in the email suggests that AMCo was or could have been aware of a non-entry commitment by Lexon/Medreich to Alliance (Advanz RLF, 22 April 2021, paragraphs 4.135.1 and 4.159 (URN: PRO-C7112) and Advanz RLF, 30 November 2021, paragraph 2.17.5 (URN: PRO-C7917)). Advanz's representation that the email simply shows Medreich using the fact that Focus had no MA at that time and therefore had '*fewer options with respect to Prochlorperazine POM*' (Advanz RLF, 22 April 2021, paragraph 4.159 (URN: PRO-C7112)) does not explain how Medreich could have considered it had any leverage given it was, allegedly, failing to supply the product that was sought by Focus. Similarly, Advanz's representation that this was an attempt by Medreich/Lexon to exploit the fact that AMCo/Focus had no alternative source of supply at the time save for Alliance's product, which was significantly more expensive than the product AMCo expected to receive from Lexon/Medreich, ignores the fact that Lexon/Medreich had not supplied the product, and that the Lexon/Medreich product would be more expensive given the Focus price increases and the profit share clause in the Focus-Lexon Heads of Terms (see paragraphs 5.314 to 5.324) (Advanz RLF, 30 November 2021, paragraph 2.17.5, URN: PRO-C7917). The CMA also rejects Advanz's representation that the email does not show Focus accepting Medreich's position (Advanz RLF, 22 April 2021, paragraph 4.159 (URN: PRO-C7112): both [Focus Director 1]'s email and [Focus Director 2]'s response to it suggest that they do accept (or at least, do not dispute) the principle underlying the push-back by Lexon/Medreich.

[1588] Report entitled '*PPRM Report AUG 2015'* August 2015 (URN: PRO-E004024). Email [AMCo employee] to [AMCo Director 1], [AMCo Employee 2] and [AMCo employee], all AMCo entitled '*SDG Strategic Projects Monthly Report ([✂]) – August 15*' 21 September 2015 (URN: PRO-E001680) attaching *Strategic Projects Monthly Report – August 2015* 21 September 2015 (URN: PRO-E001681). Excel spreadsheet entitled '*PPRM Report September 2015*' 20 October 2015 (URN: PRO-E001705). Email [AMCo Employee 4] to [AMCo employee] and [AMCo employee] cc [AMCo Director 2] entitled '*Pipeline tracker updated – Prochlorperazine buccal tablets 3mg*' 9 December 2015 (URN: PRO-E001728). Email [AMCo Director 2] to [Focus Employee 1] entitled '*Re: Prochlorperazine Buccal Tabs*' 8 February 2016 (URN: PRO-E001757).

[1589] AMCo presentation entitled '*Pharma Pipeline Review Meeting – August 2015*' 25 August 2015, page 60 (URN: PRO-E001669) stating in respect of Prochlorperazine POM '*[AMCo employee] to confirm if we will launch given the situation with Focus / Medreich*' and AMCo excel spreadsheet entitled '*PPRM Report September 2015*' 20 October 2015 (URN: PRO-E001705) stating in respect of the launch plans for the Primegen Prochlorperazine POM '*No plans to launch for now. Launch plans pending outcome of discussions with Medreich*'. Advanz stated that these documents showed that Focus knew about the relationship between Lexon and Medreich, but did not show that Focus knew or otherwise understood about the role the CMA says Medreich played in the Market Exclusion Agreement (Advanz RLF, 30 November 2021, paragraphs 2.17.6 and 2.17.8 (URN: PRO-C7917)). However, the CMA considers it significant that Focus referenced Medreich in its analysis of whether or not it wished to launch its own Primegen product, indicating that Medreich was connected to the commercial negotiations that Focus/AMCo were having with Lexon at that point.

negotiation with Lexon, AMCo did not try to produce and market the Primegen product.[1590] This shows Focus' awareness that it would be more profitable to continue to share in the profits from the monopoly supply of Alliance product (on improved terms for AMCo) than it would be to market the Primegen product in competition with both Alliance and Lexon product (see paragraphs 5.505 and 5.506).

The Parties' representations regarding the significance of the 2014 Correspondence as regards Focus' awareness[1591]

5.646 Advanz[1592] and Cinven[1593] made extensive representations that three sets of correspondence between Focus and Lexon in 2014 (that is, the 2014 Correspondence:[1594] see paragraphs 5.582 to 5.620 above) provide evidence that:

5.646.1 Focus did expect to receive commercial volumes of product from Lexon;

5.646.2 Focus chased Lexon to obtain commercial volumes of product;

5.646.3 Focus and Lexon contemplated renegotiation of the profit share in April 2014 when Lexon had failed to supply product, and then actually renegotiated the profit share in November 2014 as a result of Lexon's failure to deliver product, which in turn paved the way for the second profit share renegotiation that concluded in February 2016;

5.646.4 as a result, the Focus-Lexon Heads of Terms cannot be seen simply as a way of transferring value from Focus to Lexon; and

5.646.5 to the extent that Lexon informed Focus that it had ordered product and was progressing its product development, Lexon was misleading Focus,

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[1590] Email [AMCo Employee 4] to [AMCo employee] and various others, cc [AMCo employee] entitled '*RE: Pipeline Tracker – Oct – [✂] comments*' 31 October 2016 (URN: PRO-E001925). Email [AMCo employee] to [AMCo employee] cc [AMCo employee] entitled '*Re: Prochlorperazine Tablets 24M Payment milestone*' 10 January 2017 (URN: PRO-E001967). Excel spreadsheet entitled '*PPRM Report – December 2016*' (URN: PRO-E002007).

[1591] The CMA sets out its analysis in relation to further representations made by the Parties as regards Focus' participation in Annex G:: namely the Parties' representations that the evidence provided by the leniency applicant, Medreich, does not implicate Focus, and the Parties' representations that it is necessary for the CMA to show that Focus attended meetings.

[1592] Advanz RSO, 1 August 2019, paragraphs 3.125.2(c), 3.180.8, 3.181, 3.210-3.213, 3.223 and 6.20-6.30 (URN: PRO-C5111). Advanz RLF, 30 November 2021, paragraphs 2.25 to 2.57 (URN: PRO-C7917).

[1593] Cinven RSO, 15 August 2019, paragraphs 4.52 to 4.55, 4.103 and 4.174 (URN: PRO-C5132). Cinven RLF, 30 November 2021, paragraphs 3.12 to 3.14 (URN: PRO-C7919).

[1594] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794). Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795). Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796). Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine [sic] 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811). Email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine [sic] 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812). Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine [sic] 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003813). Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832). Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

and this shows that Focus was unaware of the Market Exclusion Agreement.

5.647 The CMA has set out in detail its conclusion that the interpretation advanced by the Parties in this respect cannot be reconciled with surrounding documentary evidence or with the Parties' conduct, and that the 2014 Correspondence, when considered in the round and alongside the other evidence, does not therefore provide evidence that Focus expected and intended to obtain commercial quantities of product from Lexon (see paragraphs 5.617 to 5.620 above).

5.648 For the reasons set out in that analysis, the CMA finds that the 2014 Correspondence does not undermine its conclusion as regards Focus' awareness of the fact that, pursuant to the Market Exclusion Agreement, Lexon would not supply commercial volumes of the Prochlorperazine POM product it had jointly developed with Medreich to Focus in return for compensation in the form of a share of the profits from Focus on the sale of Alliance's product. By way of summary in so far as this evidence relates specifically to Focus' awareness of the common objective and the conduct of Lexon in pursuit of it, the CMA has found that:

5.648.1 the 2014 Correspondence itself cannot properly be regarded as Focus 'chasing' for product or for an update on product (see in particular paragraphs 5.601.3, 5.607.4 and 5.614 above);

5.648.2 to the extent that Focus could be said on the basis of the 2014 Correspondence to be contemplating placing an order for Prochlorperazine POM from Lexon, it is not credible that Focus was contemplating orders of multiple batches (that is, commercial volumes) of Prochlorperazine POM (see paragraph 5.601 above); to the extent that Focus and Lexon discussed Focus' '*requirements*' in terms of product, this is plausibly explained by being a reference to the time(s) at which Focus wished to take delivery of a single batch of product (see paragraph 5.608 and Annex F:);

5.648.3 in any case, insofar as [Lexon Director 1]'s email of 3 September 2014 does contemplate the order of multiple batches, there are in any case other plausible explanations for Lexon's reference to the lead times relevant to deliveries beyond a single order (see paragraph 5.608 and Annex F:);

5.648.4 outside the 2014 Correspondence, there is no other evidence[1595] of Focus (or AMCo) having approached Lexon regarding product supply, or having made enquiries regarding Lexon/Medreich's inability to supply,

[1595] At interview, [Focus Director 1] said he could not remember whether he had gone back to Lexon with details of Focus' requirements for Prochlorperazine POM (See interview [Focus Director 1], 2 October 2018, page 207, lines 10-11 (URN: PRO-C3294)). Advanz's 6 January 2020 response to the CMA's questions dated 26 November 2019, response to question 11 (URN: PRO-C5635). Interview [AMCo Director 2], 7 January 2020, page 129, lines 2-7 (URN: PRO-C5994).

notwithstanding the ongoing Focus quarterly payments to Lexon that increased in size until early 2017, had totalled over £4.37 million by the end of 2016 and ultimately totalled £7.86 million by the conclusion of the Market Exclusion Agreement at the end of July 2018; such approaches and enquiries would have been expected had Focus been unaware of the common objective and the conduct of Lexon in pursuit of it and actually been anxious to obtain stock from Lexon (see paragraph 5.614.3 above);

5.648.5 Focus' decision to continue paying profit share to Lexon (albeit on amended terms as agreed between Focus and Lexon in November 2014), despite the fact that it was well over a year since Focus and Lexon had entered into the Focus-Lexon Heads of Terms and Lexon/Medreich was yet to deliver any product to Focus, is reasonably explicable only in terms of Focus being aware of the common objective and the conduct of Lexon in pursuit of it (and intending to contribute to the common objective) (see paragraphs 5.525, 5.615 and 5.620 above); and

5.648.6 insofar as [Lexon Director 1] was, as Advanz and Cinven suggest, seeking to mislead [Focus Director 1] on 4 November 2014 regarding the placement of a single order, the CMA finds that [Lexon Director 1] was not motivated by a desire to hide from [Focus Director 1] the nature of the Market Exclusion Agreement, and his intention never to supply commercial volumes of product (see paragraphs 5.601, 5.607 and 5.614) and there is a plausible explanation as to why [Lexon Director 1] might have misled [Focus Director 1] on this issue notwithstanding the fact that Focus was a knowing participant in the Market Exclusion Agreement (see paragraphs 5.602, 5.608, 5.616 and Annex F:); in addition, the CMA has set out in those paragraphs an alternative plausible explanation regarding the information about the placement of an order which does not involve [Lexon Director 1] misleading [Focus Director 1].

Focus' intentional contribution to the common objective

5.649 As set out at paragraph 5.138 above, an undertaking's intention to contribute to the common objective pursued can be inferred from its participation in at least one element of the relevant conduct.

5.650 For the reasons set out below, the CMA concludes that Focus intentionally contributed, through its own conduct, to the common objective.

5.651 In order to implement the Market Exclusion Agreement, each of Alliance and Lexon entered into the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms, respectively, with Focus. Given the role of Focus in the implementation of the Market Exclusion Agreement, the CMA considers there was a clear

complementarity between the conduct of Alliance and Lexon (on the one hand) and of Focus (on the other) in pursuing the common objective.

5.652 In this respect, the CMA considers that Focus' role was instrumental to the implementation of the Market Exclusion Agreement (see paragraphs 5.190 to 5.202 above). As described at paragraph 5.201 and paragraphs 5.274 to 5.276 above, Focus became the exclusive supplier of Alliance's Prochlorperazine POM (by entering into the Alliance-Focus Agreement), and Focus shared the profits that it earned from its sales of Alliance's product with Lexon (as recorded in the Focus-Lexon Heads of Terms). In other words, Focus acted as the mechanism by which value was transferred from Alliance to Lexon under the Market Exclusion Agreement and, therefore, its conduct contributed to the common objective pursued.

5.653 As set out at paragraphs 5.638 to 5.644 above, and as is made clear in particular from the contents of [Focus Director 1]'s email of 22 June 2013[1596] referencing the fact that Focus would enter into agreements with each of Alliance and Lexon and that the deal between Focus and Lexon would have a 75% profit share in Lexon's favour, Focus entered into the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms with the knowledge that entering into those agreements was a critical part of the implementation of the Market Exclusion Agreement.

5.654 Accordingly, the CMA concludes that Focus intentionally contributed to the common objective.

Medreich's awareness

Summary of CMA's conclusion

5.655 The CMA concludes that from 5 February 2014 Medreich was aware (or could reasonably have foreseen it and was prepared to take the risk) that Alliance and Lexon had entered into an arrangement (the Market Exclusion Agreement) in which they agreed that:

5.655.1 Alliance would indirectly (through Focus) transfer value to Lexon by exclusively supplying Focus with its Prochlorperazine POM, and Focus sharing the profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon; and

5.655.2 in return for that value transfer, Lexon would not enter the market with the Prochlorperazine POM that it had jointly developed with Medreich.

[1596] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476). The CMA's consideration of the Parties' representations on this email are set out in paragraphs 5.227 to 5.253.

5.656 In this respect, the CMA also concludes that Medreich was aware (or could reasonably have foreseen it and was prepared to take the risk) of the following conduct engaged in by Alliance and Lexon in pursuit of the common objective:

5.656.1 Alliance's conduct in supplying Prochlorperazine POM to Focus at a fixed transfer price, which enabled Focus to earn a significant margin which could be shared with Lexon and ultimately Medreich; and

5.656.2 the fact that Lexon received payments from Focus through a profit share mechanism, which Lexon then shared with Medreich, in return for Lexon (and Medreich) not entering with their jointly developed Prochlorperazine POM product.

5.657 The CMA also concludes that Medreich was aware (or could reasonably have foreseen it and was prepared to take the risk) of the following conduct engaged in by Focus in pursuit of the common objective:

5.657.1 Focus' conduct in purchasing Prochlorperazine POM from Alliance at a fixed transfer price, enabling it to earn a significant margin which could be shared with Lexon and ultimately Medreich; and

5.657.2 the fact that Focus made payments to Lexon through a profit share mechanism, in return for Lexon (and Medreich) not entering the market with their jointly developed Prochlorperazine POM product.

Evidence relied on by the CMA as regards Medreich's awareness

The evidence of Medreich's awareness up to and including 5 February 2014

5.658 The evidence set out in the paragraphs below demonstrates that in the second half of 2013 through to the start of 2014, Medreich gained a developing awareness of the existence of the Market Exclusion Agreement and the common objective and the conduct of Alliance, Focus and Lexon in pursuit of it.

5.659 Pursuant to the Lexon-Medreich Agreement, Lexon was responsible for the commercialisation of the prochlorperazine products jointly developed by Lexon and Medreich. Shortly after Medreich received its MA for Prochlorperazine OTC, [Medreich Employee 1] informed [Lexon Director 1] of this and asked *'[w]hat is the plan now, to commercialise these; as we can start the planning for all three from now. I know you were negotiating something, so please can you update us perhaps some time in August'*.[1597] It follows that from 30 July 2013, Medreich was

[1597] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled *'Prochlorperazine'* 30 July 2013 (URN: PRO-E002619). [Lexon Director 1] in his witness statement provided in response to the Statement of Objections that he responded to this email by telephone asking [Medreich Employee 1] to proceed to order stock as soon as the licence was granted (see [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 68 (URN: PRO-C5092) and cited evidence which he said showed that he was consistently seeking product from Medreich after the grant of the licence on 9 January 2014 (paragraphs 67 – 106)). The CMA's reasoning as to why it does not find [Lexon Director 1]'s

(i) waiting for instructions from Lexon about how to proceed with the commercialisation of Prochlorperazine POM; and (ii) aware that [Lexon Director 1] was *'negotiating something'* that would have a bearing on the plans for the commercialisation of prochlorperazine.

5.660 [Medreich Employee 1] was provided with further details of the plan Lexon had put in place for the commercialisation of prochlorperazine during two telephone calls with [Lexon Director 1], the first of which occurred in *'probably around August, September,'*[1598] and the other *'probably sometime [in] January 2014.'*[1599] [Medreich Employee 1] told the CMA that during those calls he discussed with [Lexon Director 1] *'something to do with Alliance supplying some of the product, which they were selling anyway, to either Lexon or Focus, I'm not sure which, whereby Focus would make a margin and then the balance margin would be shared between Lexon and Medreich'* (emphasis added).[1600]

5.661 [Medreich Employee 1] recalled asking [Lexon Director 1] during the second telephone call whether the above arrangement was *'legal'*.[1601] In addition, whilst [Medreich Employee 1] told the CMA that *'Medreich didn't recognise it at the time',*[1602] he also told the CMA that:

> *'But I -- looking at it with hindsight, clearly Alliance in -- what I speculate is Alliance were giving up some of their profit by giving a quota of product to either Focus or Lexon - I don't, I don't know who they supplied it to; I've no idea - so that then some profit could be made there which was actually the profit normally made in Alliance. So, they were just giving up some profit in return for not having more quantity come into the market.'*[1603]

5.662 [Medreich Employee 1] also told the CMA that the arrangement proposed on the calls was brought to Medreich's executive committee,[1604] which he attended. He recalled that in that meeting *'[Medreich employee] … said, "We should get more of*

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evidence that he was consistently seeking Prochlorperazine POM product from Medreich to be persuasive is set out in paragraphs 5.456 to 5.468).

[1598] Interview [Medreich Employee 1], 12 July 2018, page 59, line 17 (URN: PRO-C3666). [Lexon Director 1] stated in his witness statement provided in response to the Statement of Objections that he would have explained to [Medreich Employee 1] that Lexon had appointed Focus to distribute the Medreich product (see [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 68 (URN: PRO-C5092)).

[1599] Interview [Medreich Employee 1], 12 July 2018, page 62, line 7 (URN: PRO-C3666).

[1600] Interview [Medreich Employee 1], 12 July 2018, page 62, lines 11-14 (URN: PRO-C3666). [Lexon Director 1] stated in his witness statement provided in response to the Statement of Objections that after 8 January 2014 he had explained the profit share provision in the Focus-Lexon Heads of Terms to Medreich (see Witness Statement of [Lexon Director 1] dated 31 July 2019, paragraph 78 (URN: PRO-C5092)). [Lexon Director 1] stated that he had made clear to [Medreich Employee 1] that although in the short term this was a good arrangement for Lexon and Medreich whilst Medreich was unable to supply, they would make much more money once they were able to supply Focus because [✂]. The CMA sets out in paragraph 5.430 its findings that [Lexon Director 1]'s evidence as regards the relative profitability of supplying the Medreich product as against receiving profit share from Focus on sales of the Alliance product is not correct.

[1601] Interview [Medreich Employee 1], 12 July 2018, page 73, line 5 (URN: PRO-C3666).

[1602] Interview [Medreich Employee 1], 12 July 2018, page 74, lines 3-4 (URN: PRO-C3666).

[1603] Interview [Medreich Employee 1], 12 July 2018, page 73, lines 18-24 (URN: PRO-C3666).

[1604] Interview [Medreich Employee 1], 12 July 2018, page 62, line 16 (URN: PRO-C3666).

this"'[1605] which [Medreich Employee 1] understood as referring to Medreich *'getting some payment but not actually having to manufacture a product.'*[1606]

5.663 As set out at paragraphs 3.204 to 3.206 above, on 7 January 2014, Medreich was provided with a Prochlorperazine POM profit share reconciliation spreadsheet by Lexon and asked to arrange for an invoice for 50% of the profit share payment received by Lexon from Focus to be sent to Medreich. The CMA infers from the contents of [Medreich Employee 1]'s email of 8 January 2014 that Medreich were also informed by Lexon that such payments would be made to Medreich quarterly and they were based on a *'Profit share on prochlorperazine licenses [sic]'*.[1607] Medreich arranged for the invoice to be issued to Lexon, and accepted that payment despite the fact that Medreich had not supplied any Prochlorperazine POM to Lexon; in fact, Medreich had not yet received its marketing authorisation for Prochlorperazine POM.[1608] This email demonstrates an awareness (and acceptance) by Medreich that the common objective involved receiving payments from Focus, through Lexon, without having to supply any Prochlorperazine POM as well as the conduct engaged in and the role of Focus in that regard.

5.664 The evidence set out in the paragraphs below demonstrates that by 4 February 2014, Medreich was aware of the existence of the Market Exclusion Agreement and the common objective and the conduct of Alliance, Focus and Lexon in pursuit of it.

5.665 On 4 February 2014, [Medreich Employee 1] emailed [Lexon Director 1] to ask about the strategy for the commercialisation of prochlorperazine:

> *'According to me the Focus deal is on the 3mg POM licence only? So we should start the work now to introduce the 3 mg P and the 5 mg in Medreich livery. I think we should also get ready to do the 3 mg POM as well, even if only so that Alliance cannot try to increase the Purchase price going forward. In fact their supply price is quite higher [sic] than the CGS, albeit we are extremely happy with the deal on the table!'*[1609]

[1605] Interview [Medreich Employee 1], 12 July 2018, page 62, line 22-23 (URN: PRO-C3666).

[1606] Interview [Medreich Employee 1], 12 July 2018, page 62, lines 23-24 (URN: PRO-C3666)

[1607] Email [Medreich Employee 1] to [Medreich employee], cc [Medreich Director 2] entitled *'FW:'* 8 January 2014 (URN: PRO-E002696). The email from [Medreich Employee 1] to [Medreich employee] was then forwarded on internally within Medreich by [Medreich Director 2] to [Medreich Director 1] (Email [Medreich Director 2] to [Medreich Director 1] entitled *'FW:'* 8 January 2014 (URN: PRO-E002698)).

[1608] This was a point made by [Medreich Director 2] in an email to [Medreich Employee 1] where he observed that *'I thought we are still waiting for the license [sic]. . [sic] Has he gone ahead and done the deal and we are getting paid without officially having the license [sic] … that's good then.'* See Email [Medreich Director 2] to [Medreich Employee 1] entitled *'FW: Prochlorperazine 3mg share profit'* 8 January 2014 (URN: PRO-E002687) and Email [Medreich Employee 1] to [Medreich employee], cc [Medreich Director 2] entitled *'FW:'* 8 January 2014 (URN: PRO-E002696).

[1609] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled *'Products'* 4 February 2014 (URN: PRO-E002744).

5.666 This email from 4 February 2014 demonstrates that by that point Medreich was aware, or could reasonably have foreseen it and was willing to take the risk, that:

5.666.1 there was a *'deal'* in place with Focus on the *'3mg POM licence'*;

5.666.2 Medreich understood the profit share arrangement also to involve Alliance, as it considered that the development of Medreich and Lexon's Prochlorperazine POM product could be used as leverage vis-à-vis Alliance (*'I think we should also get ready to do the 3 mg POM as well, even if only so that Alliance cannot try to increase the Purchase price going forward'*). That is, if Alliance tried to increase the price at which it sold Prochlorperazine POM (thus reducing the profits to be shared between Focus, Lexon and Medreich), the threat of entry of the Lexon and Medreich Prochlorperazine POM could be used as leverage against Alliance; and

5.666.3 Medreich were *'extremely happy with the deal on the table'*. That is, Medreich were, unsurprisingly, *'extremely happy'* to receive payments in relation to Prochlorperazine POM, despite the fact Medreich was not supplying the jointly developed Prochlorperazine POM product.

5.667 In response to [Medreich Employee 1]'s email, [Lexon Director 1] explained the agreement he had reached involved only supplying product for the purposes of the Sunset Clause applicable to the Medreich MA:

> *'The 3mg POM is best left alone as we make far much [sic] more as it is. I have agree [sic] that we make a batch every 3 years and drift it into the Alliance stock (can I have the batch size so I can plan)'.*[1610]

5.668 When asked by the CMA what he understood [Lexon Director 1] to have meant by the above statement, [Medreich Employee 1] stated *'Well, it must be referring to this distribution strategy with Alliance and Focus. So you know, that's the only thing it can be, isn't it?'*[1611]

[1610] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750). [Lexon Director 1]'s evidence in respect of this email has been set out in paragraphs 5.426 to 5.432 above. The CMA has found no reason to doubt the plain wording of [Lexon Director 1]'s email of 4 February 2014 that his instruction to Medreich was that the 3mg product was '*best left alone*'; in respect of [Lexon Director 1]'s respective counter-claims, the CMA has found that: (a) [Lexon Director 1]'s subsequent claims about relative profitability are not borne out: it was more profitable for Lexon to be party to the Market Exclusion Agreement (in line with the wording of his email) (see paragraph 5.430; (ii) [Lexon Director 1]'s subsequent claims that he had not (notwithstanding the wording of his email) reached an agreement are not credible (see paragraph 5.432); and (iii) Lexon did not order any Prochlorperazine POM product from Medreich until an order for a single batch was placed on 23 June 2015 (see paragraphs 5.434 to 5.455).

[1611] Interview [Medreich Employee 1], 12 July 2018, page 122, lines 8-9 (URN: PRO-C3666). Cinven submitted that Medreich had informed the CMA that its understanding of any agreement was based on speculation, for example quoting [Medreich Employee 1] in his interview that his understanding was '*formed by looking at the events "with hindsight" and that he "can only speculate" on what occurred, since "[w]e never discussed it"*' (Cinven RSO, 15 August 2019, paragraph 4.142 (URN: PRO-C5132) citing Interview [Medreich Employee 1], 12 July 2018, pages 73 and 116 (URN: PRO-C3666)). However, the CMA considers that [Medreich Employee 1]'s comments as quoted by Cinven related predominantly to the

5.669 Following this email, [Medreich Director 2] emailed [Medreich Employee 1] stating: *'Prochloroperazine [sic] 3mg (pom / p) – ok to go with his strategy, just need to make a batch as he agress [sic] also.'*[1612] [Medreich Employee 1] replied, in agreement: *'We should do exactly as you say. But we need to compile a spreadsheet to be updated monthly of the cost price and the sales and the profit share amount, just like [Lexon Director 1] does. We can circulate it quarterly. …'*.[1613] [Medreich Employee 1] then replied to [Lexon Director 1] on 5 February 2014 confirming that Medreich would take steps to introduce the 5mg prochlorperazine product but noting that *'3mg we leave to you for the time being'*.[1614]

5.670 Cinven submitted that the CMA should not place too much reliance on internal Medreich emails and emails between Medreich and Lexon. It submitted that [Medreich Director 2]'s internal email of 8 January 2014[1615] and [Medreich Employee 1]'s email to [Lexon Director 1] of 4 February 2014,[1616] read naturally and straightforwardly, showed that Medreich was pleased that Lexon had negotiated the Focus-Lexon Heads of Terms under which Lexon and Medreich would receive regular revenues in advance of having an MA for Prochlorperazine POM.[1617] However the CMA does not find Cinven's critique persuasive in this regard:

5.670.1 it is clear from [Medreich Employee 1]'s email of 4 February 2014 that he understood not just that Medreich would be paid *in advance* of having product, but that this strategy meant that Medreich *would not* produce product: hence [Medreich Employee 1]'s comments:

> *'So we should start the work now to introduce the 3 mg P and the 5 mg in Medreich livery. I think we should also get ready to do the 3 mg POM as well,* ***even if only so that Alliance cannot try to increase the Purchase price going forward****'* (emphasis added);[1618] and

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legality of the arrangements and that it is clear from the contemporaneous evidence (see paragraph 5.669) and from other parts of [Medreich Employee 1]'s interview (see for example paragraph 5.661) that Medreich was aware of the common objective that had been agreed between Alliance and Lexon and of the conduct of Alliance and Lexon in pursuit of it.

[1612] Email [Medreich Director 2] to [Medreich Employee 1] entitled '*FW: Products'* 5 February 2014 (URN: PRO-E002746).

[1613] Email [Medreich Employee 1] to [Medreich Director 2] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002747).

[1614] Email [Medreich Employee 1] to [Lexon Director 1] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002750). In [Lexon Director 1]'s reply of 5 February 2014 he did not raise any concerns with this proposed strategy, see Email [Lexon Director 1] to [Medreich Employee 1] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002751).

[1615] Email [Medreich Director 2] to [Medreich Employee 1] entitled *'FW: Prochlorperazine 3mg share profit'* 8 January 2014 (URN: PRO-E002687).

[1616] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled *'Products'* 4 February 2014 (URN: PRO-E002744).

[1617] Cinven RSO, 15 August 2019, paragraphs 4.136 and 4.137 (URN: PRO-C5132).

[1618] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled *'Products'* 4 February 2014 (URN: PRO-E002744).

5.670.2 in any event, Medreich is unambiguously made aware of the basis for the payment in [Lexon Director 1]'s reply email of 4 February 2014 (see paragraph 5.667 above),[1619] as demonstrated by:

(a) [Medreich Director 2]'s email to [Medreich Employee 1] of 5 February 2014: '*Prochloroperazine [sic] 3mg (pom / p) – ok to go with his strategy, just need to make a batch as he agress [sic] also;'*[1620] and

(b) [Medreich Employee 1]'s response of 5 February 2014 to Lexon: '*3mg we leave to you for the time being'*.[1621]

5.671 On the basis of the evidence referred to in paragraphs 5.659 to 5.669 above, the CMA has reached the conclusion that, by 5 February 2014, Medreich was aware (or could reasonably have foreseen it and was willing to take the risk) of the common objective and the conduct of each of Alliance, Focus and Lexon in pursuit of the common objective, namely that:

5.671.1 Lexon had entered into an agreement involving Alliance and Focus whereby Alliance would supply its Prochlorperazine POM to Focus, and Focus would share with Lexon and Medreich the profits Focus made from the sales of Alliance's product; and

5.671.2 in return for receiving those payments, Medreich was not required to produce commercial quantities of Prochlorperazine POM. Rather, Medreich were informed that *'3mg POM is best left alone'* and that Lexon had agreed to *'make a batch every 3 years and drift it into the Alliance stock'* (paragraph 5.667).

The evidence of Medreich's awareness subsequent to 5 February 2014

Documentary evidence

5.672 The CMA's conclusion that Medreich was aware (or could reasonably have foreseen it and was willing to take the risk) of the conduct engaged in by Lexon, Alliance and Focus in pursuit of the common objective is supported by subsequent documentary evidence.

5.673 On 28 March 2014, [Medreich Employee 1] sent an excel spreadsheet to [Medreich Director 1] which set out details of how the profit share functioned.[1622] In that email,

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[1619] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750). See note 1610 above.

[1620] Email [Medreich Director 2] to [Medreich Employee 1] entitled '*FW: Products'* 5 February 2014 (URN: PRO-E002746).

[1621] Email [Medreich Employee 1] to [Lexon Director 1] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002750).

[1622] Email [Medreich Employee 1] to [Medreich Director 1] cc [Medreich employee] and [Medreich Director 2] 28 March 2014 entitled '*RE: Prochlorperazine 3 mg x 50 Focus*' (URN: PRO-E002787) attaching Excel spreadsheet entitled *'Prochlorperazine 2014 budget.xlsx'* 28 March 2014 (URN: PRO-E002788).

[Medreich Employee 1] commented that: '*Talked to [Lexon Director 1] As [sic] per the attached we can budget our share of the profit share per year of £300k. There is an upside for our profit of £95k, if we can get a trade price increase.*' The attached spreadsheet recorded the *'cost from ALLIANCE'* that is, the price Focus purchased Prochlorperazine POM from Alliance, and recorded that *'Focus take 25%'* and that *'We [Medreich] split 75% of the profit with Lexon'*.[1623] The spreadsheet also records that '*June onwards increase the Trade price by £1, share 75% of that with Lexon'*. The spreadsheet does not indicate that the price at which Alliance sold product to Focus would increase when the trade price increased. This correspondence from [Medreich Employee 1] to [Medreich Director 1] shows that:

5.673.1 Medreich were aware (or could reasonably have foreseen it and was willing to take the risk) that Focus acquired Prochlorperazine POM from Alliance at a fixed price, and the details of how the profit share would operate; and

5.673.2 Medreich considered that its future annual budgets could be based on Medreich's share of the profits earned from Focus supplying the Alliance product, rather than on the basis of Medreich/Lexon launching their own Prochlorperazine POM product – therefore evidencing Medreich's awareness of the conduct engaged in by Lexon, Alliance and Focus in pursuit of the common objective.[1624]

5.674 On 7 April 2014 [Medreich Employee 1] asked [Medreich employee] to prepare a 'debit note' for the profit share and observed that *'the CGS was wrong last time, it is now a little higher. However in return the profit uplift from price increases, these are not to be shared with Alliance as that price is now fixed.'*[1625] When, in early 2014, the price Alliance charged Focus increased (from the initial batch price to the agreed price going forward – see paragraph 3.100), Medreich was aware (or could reasonably have foreseen it and was willing to take the risk) that this had implications for the share of profit Medreich could expect to receive. In an email to [Lexon Director 1] of 7 April 2014, [Medreich Employee 1] observed that:

> *'I have been asked for a detailed analysis of how the COGS has increased now to £5.47 against a cost last quarter of £4.85. This is a product that should cost some [✂], so we feel that Alliance are making still the lion's share at £1m a year profit, and we are getting about £220k each. Is there anything that can be used to help me corroborate the increase in the COGS from Focus perhaps. Could we see please the supplier invoices? I do not want to be difficult as it is a clever arrangement, but I am cutting a bit of a*

[1623] Excel spreadsheet entitled *'Prochlorperazine 2014 budget.xlsx'* 28 March 2014 (URN: PRO-E002788).

[1624] The Parties' representations on the significance of this document are set out in paragraphs 5.567 and 5.568.

[1625] Email [Medreich Employee 1] to [Medreich employee] cc [Medreich Director 1], [Medreich Director 2] and [Medreich employee] (all Medreich) entitled *'FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014'* 7 April 2014 (URN: PRO-E002795).

sorry figure with the management here, as I cannot explain how suddenly the supplier is going for this 13% cost increase.'[1626]

5.675 During an interview with the CMA, [Medreich Employee 1] was asked if he had *'any recollection of where … [the £1m a year] figure might have come from?'*[1627] [Medreich Employee 1] replied that he did not know, but he might have picked a figure *'to get across the fact that they're [i.e. Alliance] making -- I mean, honestly, it used to be all their profit, so they, clearly, surrendered some of the existing profit, to share it with three other parties.'*[1628] This again indicates that Medreich were aware (or could reasonably have foreseen it and was willing to take the risk) that the conduct engaged in by Alliance (i.e. selling to Focus at a fixed price and therefore allowing Focus to earn a significant margin) was pursuant to the common objective. Further, as noted in paragraph 5.570 above, [Medreich Employee 1]'s email cannot be reconciled with Medreich having regarded Alliance as being an independent supplier to Focus that was free to change its supply price without scrutiny from Lexon and/or Medreich.

5.676 Further evidence of Medreich's awareness of the common objective and the conduct of Focus and Lexon in pursuit of it derives from the time of the second profit share renegotiation between Focus and Lexon relating to the grant of the Primegen licence. After the profit share renegotiation had been agreed between AMCo and Lexon, [Lexon Director 1] emailed Medreich on 8 July 2016[1629] to explain to them why he considered the profit share split between Lexon and Medreich also needed to be varied. In his email of 8 July 2016, [Lexon Director 1] stated: '*…there is a new player and we need to accommodate that as per conversation with [Medreich Director 2] and [Medreich Director 1]*'. [Lexon Director 1]'s reference to Primegen as a '*new player*' that '*we need to accommodate*' provides evidence that Medreich would have understood that the level of payments that each undertaking received was linked to that undertaking's ability to supply Prochlorperazine POM, and to that extent represented compensation for not supplying it: that explained why, having acquired its own licence, against which Prochlorperazine POM would not be supplied, AMCo was entitled to receive a greater share of the payments. This therefore provides further evidence that

[1626] Email [Medreich Employee 1] to [Lexon Director 1] entitled *'FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014'* 7 April 2014 (URN: PRO-E002803). Advanz submitted in respect of this email that the CMA had not produced evidence that Lexon requested such corroborating evidence from Focus to show to Medreich, and that Medreich would have been aware of the mechanics of the profit share between Focus and Lexon (Advanz RSO, 1 August 2019, paragraph 3.135 (URN: PRO-C5111)). The CMA does not consider that these points negate the CMA's finding that the content of the email shows Medreich's awareness of the common objective, involving both Alliance and Focus.

[1627] Interview [Medreich Employee 1], 12 July 2018, page 142, lines 4-5 (URN: PRO-C3666).

[1628] Interview [Medreich Employee 1], 12 July 2018, page 142, lines 7-17 (URN: PRO-C3666).

[1629] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2], [Medreich employee] and [Lexon employee] entitled '*RE: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130).

Medreich was aware of the common objective and the conduct of Focus and Lexon in pursuit of it.[1630]

5.677 Medreich was provided with quarterly profit share reconciliations from January 2014 until December 2017 (see paragraph 3.124 above). During this period, Medreich was aware (or could reasonably have foreseen it and was willing to take the risk) that Lexon was providing the payments to Medreich not in return for the supply of Prochlorperazine POM, but in return for Medreich not supplying Prochlorperazine POM. Medreich's understanding of this was summarised by [Medreich Director 2] in 2017 on two separate occasions:

5.677.1 First, on 28 February 2017, in response to a question from [Meiji employee] asking for information in respect of Medreich products, [Medreich Director 2] described Prochlorperazine POM as falling within the category of '*Products which has [sic] not been ordered after being approved*':

'…On top of my head [sic], I only see Prochlorperazine 3mg as there is (was) only one other supplier. But that situation is changing as 2 more suppliers have come in… and we have placed order onto [sic] India which I believe has failed at India level. When we do profit share deals, there is no written agreement, it is gentleman [sic] word and invoices are raised based on off the record workings.'[1631]

5.677.2 Second, on 21 July 2017, in response to a question from [Meiji employee], in relation to why there was profit share income derived from Prochlorperazine POM despite the absence of supply, [Medreich Director 2] commented that:

'3mg has never been manufactured or supplied .. Profit share comes from 3mg only.

There is a deal in place that for Medreich Not [sic] to bring 3mg in market we get royalty …'.[1632]

[1630] [Lexon Director 1]'s evidence as regards the significance of his email to Medreich of 8 July 2016 is set out in paragraph 5.475. Other Parties' representations on this email are set out in paragraph 5.481. The CMA has found that these representations do not undermine the significance of this email as regards Medreich's awareness of the common objective and of Lexon's conduct in pursuit of it. Further, the fact that [Lexon Director 1] had had a conversation with [Medreich Director 2] and [Medreich Director 1] at Medreich is evidence that Lexon and Medreich did discuss the profit share arrangement, contrary to Cinven's representations in this respect (see Cinven RSO, 15 August 2019, paragraph 4.142 (URN: PRO-C5132)).

[1631] Email [Medreich Director 2] to [Meiji employee] and [Medreich employee], cc various others at Medreich entitled '*RE: Follow up on the meeting in January*' 28 February 2017 (URN: PRO-E003257). The CMA's analysis of the Parties' representations in relation to this email are set out in note 1463.

[1632] Email [Medreich Director 2] to [Meiji employee] entitled *'Re: Prochlorperazine – profit sharing'* 21 July 2017 (URN: PRO-E003351). [Medreich Director 2]'s own commentary on the contents of his email of 21 July 2017 is set out in paragraph 5.578; for the reasons set out there, the CMA has not found plausible [Medreich Director 2]'s claim that he did not know that a deal with Lexon had been done, but rather he 'assumed' this. The Parties' representations on the

Lexon and Medreich's delay in ordering Prochlorperazine POM product until 23 June 2015

5.678 The CMA has found that, despite [Lexon Director 1]'s (Lexon) claim that he placed an order for product in early February 2014,[1633] Lexon did not place an order for Prochlorperazine POM with Medreich until 23 June 2015 – that is, nearly a year and a half after Medreich received its MA on 9 January 2014 (see paragraphs 5.434 to 5.455). When the order was placed, that order was for a single batch of product, equating to [✂] packs of 50 tablets.[1634]

5.679 It is clear from Medreich's own conduct – given in particular the comparison with what it did as regards prochlorperazine 5mg tablets – that it understood that the delay in Lexon's submission of an order for Prochlorperazine POM reflected the existence of the Market Exclusion Agreement and the conduct of Lexon in pursuit of it, namely that Lexon was providing payments to Medreich not in return for the supply of Prochlorperazine POM, but in return for Medreich not supplying Prochlorperazine POM. Specifically:

5.679.1 as noted in paragraph 5.669 above, [Medreich Employee 1] had confirmed to Lexon that '*Prochlorperazine we will introduce 5 mg only for now …. 3 mg we leave to you for the time being*';[1635]

5.679.2 Medreich plc proceeded to launch prochlorperazine 5mg, by placing an internal order with Medreich Ltd, the manufacturing arm, for prochlorperazine 5mg tablets on 21 March 2014 and then producing a validation batch for prochlorperazine 5mg tablets in September/October 2014;[1636] and

5.679.3 by contrast, although Medreich plc could have placed an internal order for production of Prochlorperazine POM on 21 March 2014,[1637] it did not place an internal order for Prochlorperazine POM with Medreich Ltd, its

significance of [Medreich Director 2]'s email of 21 July 2017, and the CMA's consideration of them, are set out in paragraphs 5.579 to 5.581: for the reasons set out there, the CMA considers that [Medreich Director 2] did understand the arrangement and that it is appropriate to place weight on [Medreich Director 2]'s email. In any event, even if [Medreich Director 2] had been actually unaware of the deal with Lexon, based on the evidence available to [Medreich Director 2] above, the CMA considers that it was reasonably foreseeable that such a deal had been done and that, therefore, [Medreich Director 2], at least, should have been aware of it (that is that Medreich could reasonably have foreseen it and was willing to take the risk).

[1633] [Lexon Director 1] Witness Statement of 31 July 2019, paragraphs 81-82 (URN: PRO-C5092).

[1634] Email [Lexon Director 1] to [Medreich Director 2] entitled '*RE: FW: batch size*' 23 June 2015 (URN: PRO-E002980) and attachment entitled *'Lexon PO – 416174'* (URN: PRO-E002981).

[1635] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*RE: Products*' 5 February 2014 (URN: PRO-E002750).

[1636] Response of Medreich, dated 8 November 2021 to CMA questions of 22 October 2021 paragraphs 2.2, 2.3 and 3.1 (URN: PRO-C7817).

[1637] Response of Medreich, dated 8 November 2021 to CMA questions of 22 October 2021 paragraph 2.5 (URN: PRO-C7817).

manufacturing arm, until 23 June 2015 after receipt of Lexon's purchase order of the same date.[1638]

Medreich's intentional contribution to the common objective

5.680 As set out at paragraph 5.138 above, an undertaking's intention to contribute to the overall objective pursued can be inferred from its participation in at least one element of the relevant conduct.

5.681 For the reasons set out below, the CMA concludes that Medreich intentionally contributed, through its own conduct, to the common objective. Medreich's role was instrumental in ensuring that the product it had jointly developed with Lexon was not commercialised for the period of the Market Exclusion Agreement (and, thus, implementing the common objective): it refrained from producing the jointly developed product (other than the one batch required to avoid the application of the Sunset Clause) in return for receiving a share of the profits that Lexon had received through the profit share clause described at paragraph 5.296 above. It follows that the conduct engaged in by Alliance, Lexon and Focus, on the one hand, and Medreich on the other, clearly shared a common purpose and was complementary in nature.

5.682 Internal Medreich email correspondence confirms that Medreich intentionally contributed to that plan from 5 February 2014:

5.682.1 [Medreich Director 2] wrote to [Medreich Employee 1] on 5 February 2014 to inform him *'Prochloroperazine [sic] 3mg (pom / p) – ok to go with his strategy, just need to make a batch as he agress [sic] also.'*[1639]

5.682.2 [Medreich Employee 1] responded to [Medreich Director 2] in agreement: *'[w]e should do exactly as you say…'*.[1640]

5.683 The decision to *'go with his* [[Lexon Director 1]'s] *strategy'*[1641] was communicated to Lexon on 5 February 2014 when [Medreich Employee 1] informed [Lexon Director 1] that *'3mg we leave to you for the time being'*.[1642]

[1638] Response of Medreich, dated 8 November 2021 to CMA questions of 22 October 2021 paragraphs 4.1 and 4.2 (URN: PRO-C7817).

[1639] Email [Medreich Director 2] to [Medreich Employee 1] entitled *'FW: Products'* 5 February 2014 (URN: PRO-E002746).

[1640] Email [Medreich Employee 1] to [Medreich Director 2] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002747).

[1641] Email [Medreich Director 2] to [Medreich Employee 1] entitled *'FW: Products'* 5 February 2014 (URN: PRO-E002746).

[1642] Email [Medreich Employee 1] to [Lexon Director 1] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002750). In [Lexon Director 1]'s reply of 5 February 2014 he did not raise any concerns with this proposed strategy, see Email [Lexon Director 1] to [Medreich Employee 1] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002751).

5.684 Medreich's decision to implement the strategy agreed with Lexon by not progressing the commercialisation of Prochlorperazine POM and to instead *'make a batch every 3 years'*[1643] was recorded in other Medreich documents:

5.684.1 On 18 June 2015, [Medreich Director 2] stated in an internal email that he intended to place *'commercial orders'* for Prochlorperazine POM and asked to be advised of the *'lowest commercial batch possible in order to place orders'*.[1644]

5.684.2 On 24 June 2015, after the order for a single batch of Prochlorperazine POM had been placed by Lexon on Medreich and Medreich plc had ordered that batch from its manufacturing arm, Medreich Ltd, Medreich's executive committee meeting were informed that was *'the 1 batch required in order to keep the license [sic] active'*.[1645] That is, the batch was not ordered to allow Medreich to compete in the market, but only to keep Medreich's licence active.

5.685 Finally, Medreich's actual contribution is evident from the fact that Medreich accepted significant payments from Lexon which were generated from Focus' sales of Alliance's Prochlorperazine POM and paid to Medreich despite the fact that Medreich did not supply any Prochlorperazine POM (until November 2017). Between January 2014 and September 2017,[1646] Medreich received £2.77 million (before VAT) from Lexon (see Annex I:).

5.686 The CMA recognises that there are a number of later internal Medreich emails in which Medreich seeks updates about the delivery of Prochlorperazine POM and notes the importance of Prochlorperazine POM being delivered (see, for example, the evidence set out in paragraphs 3.267 and 3.268). That correspondence is consistent with the existence of the Market Exclusion Agreement and with Medreich's intentional contribution to the common objective. Medreich was only ever seeking to supply one batch of Prochlorperazine POM, consistent with the instructions they received from [Lexon Director 1] on 4 February 2014;[1647] but it was important both from a commercial perspective, in terms of the basis for Lexon/Medreich receiving payment pursuant to the Market Exclusion Agreement,

[1643] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'Products'* 4 February 2014 (URN: PRO-E002750) (see note 1610 above).

[1644] Email [Medreich Director 2] to [Medreich employee] cc [Medreich Employee 1] amongst others entitled *'FW: batch size'* 18 June 2015 (URN: PRO-E002974).

[1645] *'Minutes of the Meeting of the Executive Committee of Medreich PLC Held on 24th June 2015 at 10:30am in the Board Room of Medreich PLC Offices'* 29 June 2015 (URN: PRO-E002983 / PRO-E002985). The CMA addresses [Lexon Director 1]'s comments in respect of this evidence ([Lexon Director 1] Witness Statement of 31 July 2019, paragraph 92 (URN: PRO-C5092)) in 5.463.

[1646] This is the period before any Prochlorperazine POM was supplied to Lexon by Medreich.

[1647] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750). See note 1610 above.

and the avoidance of the Sunset Clause that Medreich was able to produce that one batch of product (see relatedly paragraph 5.464).

5.687 Cinven submitted that the fact that there was evidence showing that Medreich faced considerable difficulties in producing Prochlorperazine POM means that the CMA cannot safely conclude that non-production was linked to payments made by Focus under the Focus-Lexon Heads of Terms.[1648] In this respect, whilst there were regulatory and manufacturing difficulties encountered by Medreich as regards Prochlorperazine POM, these do not explain the conduct and action of Lexon and Medreich. In particular, the CMA has found that Medreich clearly accepted [Lexon Director 1]'s strategy that Prochlorperazine POM should be '*left alone*' (see paragraph 5.669 above) and then understood that the single batch ordered on 23 June 2015 was required for the purpose of the Sunset Clause (see paragraph 5.684). As a result, the fact that there were difficulties in producing Prochlorperazine POM does not undermine the CMA findings regarding Medreich's intentional contribution to the common objective.

Conclusion on Focus' and Medreich's participation in the Market Exclusion Agreement

5.688 Based on the evidence set out in the sections above, the CMA concludes that Focus (from 22 June 2013) and Medreich (from 5 February 2014) participated in the Market Exclusion Agreement, because:

5.688.1 there was an overall plan pursuing a common objective, which in this case, was the implementation of the Market Exclusion Agreement;

5.688.2 they each made an intentional contribution to the common objective; and

5.688.3 they were each aware of the conduct which was put into effect by Alliance and Lexon in pursuit of the common objective, or could reasonably have foreseen it and were prepared to take the risk, and they were also as a matter of fact in this case each aware of the conduct which was put into effect by each other in pursuit of the common objective.

Restriction of competition by object

Legal framework

5.689 To come within the Chapter I prohibition, an agreement must have '*as [its] object or effect*' the prevention, restriction or distortion of competition within the UK. It is settled case law that certain types of coordination between undertakings reveal a sufficient degree of harm to competition, such that there is no need to examine

[1648] Cinven RSO, 15 August 2019, paragraph 4.134 based on paragraphs 4.111 – 4.133 (URN: PRO-C5132).

their effects.[1649] 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.[1650]

5.690 The term *'object'* in the Chapter I prohibition refers to the sense of *'aim'*, *'purpose'*, or *'objective'* of the coordination between undertakings in question.[1651] 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.[1652]

5.691 An agreement may be regarded as having an anticompetitive object even if it does not have a restriction of competition as its sole aim but also pursues other legitimate objectives. The EU 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].'*[1653]

5.692 In order to determine whether an agreement objectively reveals a sufficient degree of harm such as to constitute a restriction of competition by object, regard must be had to:

5.692.1 the economic and legal context of which it forms a part;

5.692.2 its content; and

[1649] C-373/14 P *Toshiba v Commission*, EU:C:2016:26, paragraph 26; C-172/14 *ING Pensii*, EU:C:2015:484, paragraph 31 and C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 49. Contrary to representations by Lexon (Lexon RSO, 31 July 2019, paragraphs 33-34 and 39-40 (URN: PRO-C5091)) and Advanz (Advanz RSO, 1 August 2019, paragraphs 4.32.3, 5.115.3, 5.121-5.125, 6.114.3 (URN: PRO-C5111)) there is no requirement for the CMA to conduct a counterfactual analysis in order to find a restriction of competition by object. See, for example, C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraphs 139-143, upholding the judgment of the EU General Court in T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraphs 472-474. Unlike this case, the *MasterCard* case cited by Lexon concerned an infringement by effect, not by object. See C-382/12 P *MasterCard and Others v Commission* EU:C:2014:2201, paragraph 186.

[1650] C-373/14 P *Toshiba v Commission*, EU:C:2016:26, paragraph 26; and C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 50.

[1651] See, for example, respectively: C-56/64 *Consten & Grundig v Commission*, EU:C:1966:41, paragraph 343; C-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.

[1652] T-168/01 *GlaxoSmithKline Services Unlimited v Commission*, EU:T:2006:265, paragraph 77 (upheld on appeal in Joined cases C-501/06P etc *GlaxoSmithKline Services Unlimited v Commission*, EU:C:2009:610). See also C-614/16 P *Merck v Commission*, paragraph 92: *'characterisation as a 'restriction by object' does not require that parties to those agreements pursue an anticompetitive objective, even though such an objective may nevertheless be taken into consideration'*.

[1653] C-209/07 *Competition Authority v Beef Industry Development Society*, EU:C:2008:643, paragraph 21.

5.692.3 its objectives.[1654]

5.693 It is well established that an agreement need not be implemented to infringe the prohibition on anti-competitive agreements, including whether it amounts to a restriction of competition by object.[1655] However, evidence of the parties' conduct showing that the agreement was implemented may corroborate the assessment of its content and objectives.[1656] The European Commission's *Guidance on the Application of Article 101(3)* states: *'The way in which an agreement is actually implemented may reveal a restriction by object even where the formal agreement does not contain an express provision to that effect'*.[1657]

5.694 Although the parties' subjective intentions are not a necessary factor in determining whether an agreement is restrictive of competition, those intentions may be taken into account as corroboration of the objective assessment.[1658]

Market sharing and market exclusion

5.695 The Chapter I prohibition expressly applies in particular to agreements or practices which:

5.695.1 share markets or sources of supply; or

5.695.2 limit or control production, markets, technical development or investment.

5.696 The EU Court of Justice has consistently held that market sharing constitutes a particularly serious breach of the competition rules.[1659] It has also consistently held that agreements that aim to share markets have, in themselves, an object restrictive of competition, and that such an object cannot be justified by an analysis of the economic context of the anti-competitive conduct concerned.[1660]

[1654] 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.

[1655] C-277/87 *Sandoz v Commission,* ECLI:EU:C:1990:6; *WANO Schwarpulver*, OJ 1978 L322/26, [1979] 1 CMLR 403; Case 19/77 *Miller v Commission*, ECLI:EU:C:1978:19, paragraphs 7 to 10. See also COMP/37750 *French Beer*, [2006] 4 CMLR 577, paragraph 68.

[1656] C-49/92 P *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraph 81 to 88. 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, ECLI:EU:T:2006:265, paragraphs 82 to 83.

[1657] *European Commission Guidance on the Application of Article 101(3)*, recital 22.

[1658] 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.

[1659] C-373/14 *Toshiba Corporation v Commission*, EU:C:2016:26, paragraph 28; C-449/11 *Solvay Solexis v Commission*, EU:C:2013:802, paragraph 82; and C-408/12 *YKK and Others v Commission*, EU:C:2014:2153, paragraph 26.

[1660] 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.

5.697 The EU General Court has held that *'The exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production'* (emphasis added).[1661]

5.698 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 EU Court of Justice held:

> *'The BIDS arrangements are intended therefore, essentially, to enable several undertakings to implement a common policy which has as its object the encouragement of some of them to withdraw from the market and the reduction, as a consequence, of the overcapacity which affects their profitability by preventing them from achieving economies of scale.*
>
> *That type of arrangement conflicts patently with the concept inherent in the EC Treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market. Article 81(1) EC [now 101(1) 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…'.*[1662]

5.699 The EU Court of Justice concluded that the arrangements in question were a restriction by object. Advocate General Trstenjak, whose Opinion the Court followed, characterised the arrangements as '*the 'buying off' of competition*'.[1663]

[1661] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 435.

[1662] C-209/07 *Competition Authority v Beef Industry Development Society* , EU:C:2008:643, paragraphs 33 to 35.

[1663] Opinion of AG Trstenjak in C-209/07 *Competition Authority v Beef Industry Development Society*, EU:C:2008:467, paragraph 77. Compare T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 352*: 'where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, the Commission rightly took the view that it was possible to consider that such a limitation did not arise exclusively from the parties' assessments of the strength of the patents but rather was obtained by means of that payment …, constituting, therefore, a buying-off of competition'*. See also the European Commission's *International Removal Services* decision (Commission decision of 11 March 2008 in Case 38.543 *International Removal Services*): the Commission found that the payment of commissions by international removal companies to competitors in exchange for their issuing artificially high quotes for removal services amounted to a restriction by object. This legal assessment was confirmed by the EU General Court: T-208/08 and T-209/08, *Gosselin Group NV and Stichting Administratiekantoor Portielje v Commission*, EU:T:2011:287, paragraphs 67 to 71; explicitly upheld on this point in C-429/11 *Gosselin Group NV v Commission*,

5.700 In *Cartes Bancaires*, the EU Court of Justice explained that, *'[t]he object of the BIDS arrangements was … to change, appreciably, the structure of the market through a mechanism intended to encourage the withdrawal of competitors'*.[1664]

5.701 In the pharmaceutical industry, the European Commission and the CMA have issued a number of decisions finding that agreements involving incumbent pharmaceutical companies making 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*,[1665] *Perindopril (Servier)*[1666], *Fentanyl*[1667] and *Cephalon*[1668] in the EU and *Paroxetine*[1669] in the UK. These types of agreements are commonly known as 'pay for delay' agreements. They are essentially variations on 'classic' market exclusion agreements such as those in *Irish Beef* and *Toshiba*, with (in most cases) the additional complexity of a patent context.

5.702 Specifically, in its *Lundbeck* judgment, the EU General Court upheld a decision by the European Commission that so-called 'pay for delay' agreements entered into between a patent holder and potential generic entrants were, *'comparable to market exclusion agreements, which are among the most serious restrictions of competition'*.[1670] In its *Servier* judgment, the EU 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'*.[1671] In both the *Lundbeck* and *Servier* judgments the EU General Court characterised these agreements as, *'a buying-off of competition'*.[1672] In both cases, the EU General Court held that these agreements were restrictions by object.[1673]

5.703 Unlike the present case, *Lundbeck*, *Servier, Cephalon* and *Paroxetine* all concerned patent litigation. All four cases concerned originator companies with patented drugs, facing the threat of entry by generics and in some cases seeking to end patent litigation with those generics via settlement agreements. The Commission's analysis of the agreements in *Lundbeck* and *Servier* was

EU:C:2013:463, paragraphs 47 to 50. In its *Lundbeck* decision the European Commission explained that the competitors in *International Removal Services* paid each other not to compete, and as a result all undertakings fared better, at the expense of higher consumer prices: Commission decision of 19 June 2013 in Case 39.227 *Lundbeck*, footnote 1178.

[1664] C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 84.

[1665] Commission decision of 19 June 2013 in Case 39.227 *Lundbeck*.

[1666] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*.

[1667] Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*.

[1668] Commission decision of 26 November 2020 in Case AT.39686 *Cephalon*.

[1669] CMA decision in *Paroxetine* (CE-9531/11); *Paroxetine I* [2018] CAT 4.

[1670] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 435.

[1671] T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 233.

[1672] 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.

[1673] 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.

substantively upheld on appeal by the EU General Court and (in the case of *Lundbeck*) the EU Court of Justice,[1674] with the exception of the agreement between Servier and Krka, in respect of which the EU 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.[1675]

5.704 The patent context was a key factor in the CAT's decision to refer the *Paroxetine* case to the EU Court of Justice: although the CAT found that the agreements in question, *'amounted to a monopoly supplier … agreeing to share a significant but limited part of the market with independent distributors of its own product'*,[1676] it referred to the EU Court of Justice specific questions on whether the agreements amounted to infringements of competition law in circumstances where there were pending court proceedings relating to the validity and/or infringement of the relevant patent. In its judgment, the CAT noted that:

> *'the patent position cannot be ignored, and this situation cannot be equated to a simple agreement for exclusion of a potential competitor from the market or for market sharing'.*[1677]

5.705 Following the EU Court of Justice's judgment, the CAT upheld the CMA's findings that the agreements amounted to restrictions of competition by object.[1678]

5.706 For the purposes of assessing whether the agreements at issue in each of *Lundbeck*, *Perindopril (Servier)*, *Fentanyl* and *Cephalon* revealed in themselves a sufficient degree of harm to competition to amount to restrictions *'by object'*, the European Commission took into account:[1679]

5.706.1 the potential entrant and the incumbent were at least potential competitors;

5.706.2 the agreements involved a payment (or 'value transfer') from the incumbent to the potential entrant; and

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[1674] In T-472/13 *Lundbeck v Commission* EU:T:2016:449 and C-591/16 P *Lundbeck v Commission*, EU:C:2021:243; T-679/14 *Teva v Commission*, EU:T:2018:919; T-691/14 *Servier and Others v Commission,* EU:T:2018:922; T-677/14 Biogaran v Commission, EU:T:2018:910; T-680/14 *Lupin v Commission*, EU:T:2018:908; T-682/14 *Mylan Laboratories v Commission*, EU:T:2018:907; T-701/14 Niche Generics v Commission, EU:T:2018:921; and T-705/14 *Unichem Laboratories v Commission*, EU:T:2018:915. All cases (other than *Lundbeck v Commission*) currently on appeal to the EU Court of Justice.

[1675] T-684/14 *Krka Tovarna v Commission*, EU:T:2018:918 (currently on appeal to the EU Court of Justice).

[1676] *Paroxetine I* [2018] CAT 4, paragraph 303.

[1677] *Paroxetine I* [2018] CAT 4, paragraphs 244 and 303 (emphasis added).

[1678] *Paroxetine II* [2021] CAT 9, paragraphs 33-58.

[1679] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1154; Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 661; and Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 219; Commission decision of 26 November 2020 in Case AT.39686 *Cephalon*, paragraph 581.

5.706.3 in return, '*the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter into one or more…markets with a generic product*'.[1680]

5.707 The CMA took those factors into account in its *Paroxetine* decision, in which it found that GSK and two generic companies had entered into anti-competitive agreements by object. GSK made cash payments and other value transfers to the generic companies in return for which the generic companies accepted restrictions on their ability to enter the market independently.[1681]

5.708 These factors are relevant to establishing a market exclusion agreement, whether or not in a patent context. However, in the absence of a patent context (such as in the present case, which involves unbranded, generic drugs), establishing a restriction of competition by object where a potential competitor agrees not to enter the market is more straightforward.[1682]

Potential competition

5.709 The legal framework for potential competition is set out in paragraphs 5.39 to 5.65 above.

Payment or value transfer

5.710 As set out above, a relevant question is whether there was a payment, also known as a value transfer, to the potential entrants.

5.711 Such a payment, or value transfer, 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.[1683] In *Fentanyl*, the payments were expressed to relate to promotional activities, though their value far exceeded that of the minimal activities carried out.[1684] In *Paroxetine*, the CAT noted that the parties' descriptions of payments as *'marketing payments'* or *'promotional*

[1680] Or, in the *Fentanyl* case: *'due to the Agreement, the generic undertaking limited, for the duration of the Agreement, its independent efforts to enter the market with its generic product'* (Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 219).

[1681] CMA decision in *Paroxetine* (CE-9531/11), sections 6.E and 6.G.

[1682] Advanz submitted (Advanz RSO, 1 August 2019, paragraphs 4.29-4.30, 4.32, 5.115, 5.125, 6.114 (URN: PRO-C5111)) that a restriction by object can be excluded where an agreement has not impacted competition in the market *'because the undertakings did not actually compete originally'* or where '*there is simply not enough competition in the market to begin with*'. Such an interpretation would appear to exclude from the category of restrictions by object agreements between incumbents and potential entrants. This interpretation is not supported by the Advocate General's Opinion in *BIDS* cited by Advanz (see C-209/07 *Competition Authority v Beef Industry Development Society* EU:C:2008:467 paragraph 52 and footnotes 32-33). It is also entirely inconsistent with the case law concerning potential competition (see, for example, T-519/09 *Toshiba v Commission* EU:T:2014:263, paragraph 230) and decisional practice and case-law on 'pay-for-delay' arrangements discussed at paragraphs 5.701 to 5.708 above.

[1683] *Paroxetine I* [2018] CAT 4, paragraphs 179 to 180. See also *Paroxetine II* [2021] CAT 9, paragraph 47. Compare T-208/08 *Gosselin v Commission* EU:T:2011:287, paragraph 12, in which cartelists issued each other with invoices for common payments on rejected offers, or offers not made, *'referring to fictitious services'*.

[1684] The limited promotional activities are summarised at paragraph 274 of Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*.

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.'*[1685]

5.712 A value transfer may also take a *'more covert '* form than cash.[1686] For example, in *Cephalon*, in addition to certain cash payments, part of the consideration for non-entry included purchases of raw materials from Teva[1687] and granting by Cephalon of access to clinical data that were highly valuable to Teva for a different medicine.[1688]

5.713 In *Paroxetine* the agreements involved the supply of specified volumes of product for the potential entrants to sell on their own account. The CAT held that *'the CMA was correct to regard the margin which the generic company was likely to earn on the specified volumes supplied as part of the consideration'*.[1689] The CAT found that: *'So long as no other generic company was able to enter the market with an independent product, the generic companies could expect to sell the paroxetine supplied by IVAX for at least the PI price'*.[1690]

5.714 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).[1691] 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.[1692] In its judgment on Sun Pharmaceutical Industries and Ranbaxy's appeal, the EU General Court agreed with the Commission that these supplies were part of the consideration granted to Ranbaxy, and pointed out that the discount involved Lundbeck giving up the profits it would have made in selling the product itself.[1693] The EU Court of Justice upheld the EU General Court.

5.715 An incumbent may therefore pay a potential entrant in the form of a transfer of its margin on specified quantities of product: it pays by supplying product to the potential entrant to make a profit margin on resale.

[1685] *Paroxetine I* [2018] CAT 4, paragraphs 125, 179 to 180, and 185.

[1686] Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 660.

[1687] Commission decision of 26 November 2020 in Case AT.39686 *Cephalon*, paragraphs 783-811.

[1688] Commission decision of 26 November 2020 in Case AT.39686 *Cephalon*, paragraph 720-782.

[1689] *Paroxetine I* [2018] CAT 4, paragraph 184.

[1690] *Paroxetine I* [2018] CAT 4, paragraph 184.

[1691] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1578.

[1692] T-460/13 *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*, EU:T:2016:453, paragraphs 246-251.

[1693] T-460/13 *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission* , EU:T:2016:453, paragraph 249.

In return for non-entry (or delayed entry)

5.716 A further relevant factor is whether, in return for the value transfer, the potential entrant gave a commitment not to enter the market.

5.717 As is the case for any agreement (see paragraph 5.125 above), such a commitment need not be explicit, but can exist as a common understanding between the parties. In *Paroxetine*, for example, the CAT stated:

> *'Although under the IVAX Agreement there was no contractual restriction on IVAX entering the UK market independently (by contrast with the position under the GUK and Alpharma Agreements), we have no doubt that this was the intention and understanding of the parties.'*[1694]

Object of the Market Exclusion Agreement

5.718 The Market Exclusion Agreement had the object of restricting competition in the market for the supply of Prochlorperazine POM in the UK, having regard to its:

5.718.1 economic and legal context, in particular the fact that Alliance and Lexon were potential competitors (see paragraphs 5.79 to 5.114 above); and

5.718.2 content and objectives (see paragraphs 5.148 to 5.688 and 5.719 to 5.727).

5.719 The Market Exclusion Agreement had the object of sharing the market because Alliance agreed to (indirectly through Focus) transfer value to Lexon in return for Lexon agreeing not to enter the market with the Prochlorperazine POM it had jointly developed with Medreich. In other words, Lexon and Alliance agreed not to compete with one another.

5.720 Once an agreement on payment in return for non-entry is established, as the CMA has done in paragraphs 5.628 and 5.688, the analysis of the object of that agreement is straightforward. The exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production. Entry of the product jointly developed by Lexon and Medreich would have been, in principle, favourable to competition and would have contributed to the public interest in potentially lowering the cost of healthcare.

Alliance transferred value to Lexon, through Focus

5.721 As explained at paragraph 5.628, Alliance and Lexon agreed that Alliance would indirectly (through Focus) transfer value to Lexon by: exclusively supplying Focus with its Prochlorperazine POM, and Focus sharing the profits it earned from the

[1694] *Paroxetine I* [2018] CAT 4, paragraph 422.

sales of Alliance's Prochlorperazine POM with Lexon. The form of the value transfer was as follows:

5.721.1 Under the terms of the Alliance-Focus Agreement, Alliance agreed to supply Prochlorperazine POM to Focus at an initial transfer price of £4.85 for the first batch supplied, increasing to £5.65 for subsequent orders (see paragraph 3.100 above).[1695]

5.721.2 Alliance debranded its Prochlorperazine POM, Buccastem, in December 2013 (see paragraph 3.114). From that point, the price of Prochlorperazine POM was not subject to the PPRS or any other regulatory constraint. Alliance[1696] (and Focus[1697]) understood that, once the product was debranded, it would be possible significantly to increase the price of Prochlorperazine POM.

5.721.3 Rather than selling the unbranded product (Prochlorperazine POM) and increasing the price and margin Alliance would have earned prior to the anticipated competitive entry of Lexon/Medreich, an option which Alliance itself had previously considered,[1698] Alliance sold Prochlorperazine POM to Focus at a fixed price. In doing so, Alliance was forgoing a significant proportion of the profits that could be earned (and were earned by Focus) from the supply of the product for as long as Lexon/Medreich agreed to refrain from commercialising their product and Alliance retained its monopoly over the supply of Prochlorperazine POM. This transfer of profit margin from Alliance to Focus is a value transfer, with Alliance giving up the potential to earn these profits and enabling them to be earned instead by Focus.

5.721.4 On purchasing the product from Alliance, Focus could instead set and sustain a substantially increased price for Prochlorperazine POM. Focus proceeded to increase the selling price from £8 per pack in December

[1695] The supply price was subject to re-negotiation in January 2015 (see paragraph 3.175) when Focus and Alliance agreed an increased supply price of £6.10 per pack.

[1696] The evidence shows that Alliance had expected to increase the price of the product had it continued to supply it to wholesalers. For example, as early as 2010, Alliance described the *'opportunity'* of de-branding as follows: *'increase profit stream from x to y as a result of genericising the 50's pack, enabling a price increase strategy to be deployed. How much money can we make and how quickly?'* (Email [Alliance employee] to [Alliance employee] cc [Alliance employee] entitled *'Buccastem: Uk generic opportunity'* 8 April 2010 (URN: PRO-E000806) (see paragraph 3.65)). Further, following the approach from Lexon in 2013, Alliance's internal documentation from March 2013 had listed debranding as an option: *'De-brand Buccastem, launch generic prochlorperazine in to Category A and name price'* (Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled *'Buccastem/Prochlorperazine generic threat'* 21 March 2013 (URN: PRO-E000986)).

[1697] See for example [Focus Director 1]'s statement that *'Generic pricing will depend on market and Focus will set!'* (Email [Focus Director 1] to [Focus Director 2] entitled *'Fwd: Prochlorperazine IMS'* dated 22 June 2013 (URN: PRO-E001476)) and email [Focus Director 1] to [Focus Director 2] entitled *'Prochlorperazine 3mg Tabs'* 18 July 2013 (URN: PRO-E001478) which sets out a table of anticipated price increases by Focus.

[1698] See paragraph 3.76.

2013 to around £30 in December 2017 (with the price reaching nearly £35 in June 2017).[1699]

5.721.5 Focus shared the profits it earned from selling Alliance's Prochlorperazine POM with Lexon and Medreich. This profit sharing was effected through a clause in the Focus-Lexon Heads of Terms that provided for Focus to pay 75% of profits to Lexon (subsequently renegotiated to 50%[1700]) on Focus' sale of Prochlorperazine POM irrespective of the source of that Prochlorperazine POM.[1701]

5.721.6 Lexon, in turn, shared a proportion of the payments it received from Focus, with Medreich.

5.721.7 Accordingly, Alliance was providing Focus with the opportunity to earn the profits on the supply of Prochlorperazine POM over and above the agreed transfer price, unconstrained by competition from Lexon/Medreich, and to pay a proportion of those profits to Lexon and, in turn, Medreich. Between January 2014 and 31 July 2018, Focus earned £14.4 million which was generated from the supply of the Alliance product, of which Focus paid £7.86 million (before VAT) of its profits to Lexon, who in turn paid £2.90 million (before VAT) to Medreich.[1702]

5.721.8 The total estimated amounts of gross profits (that is, revenue minus cost of goods, but prior to any other operating expenses) earned by the relevant undertakings between December 2013 and July 2018 are shown in Figure 5 below.

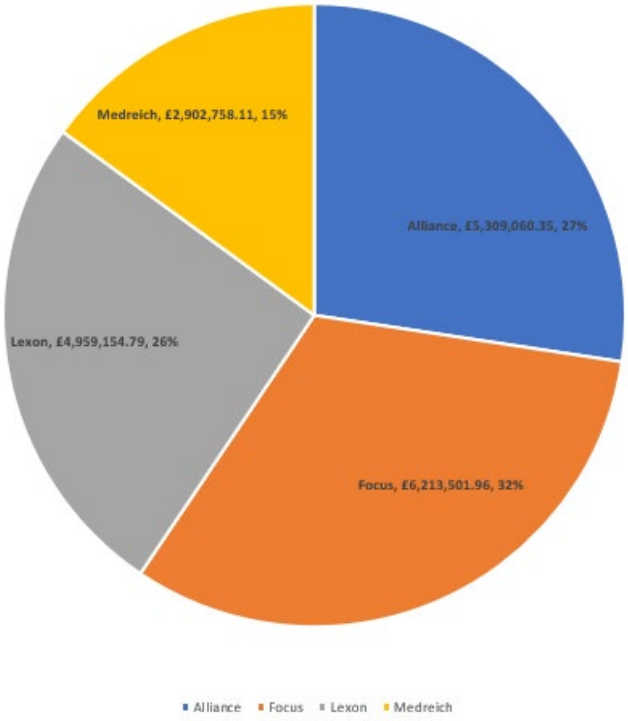
[1699] Based on the Focus' average selling price to wholesalers (see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150)).

[1700] See paragraphs 3.167, 3.181 to 3.184 and 3.189.

[1701] Lexon submitted that the CMA's *'real complaint'* was directed at the profit sharing clause in the Focus-Lexon Heads of Terms and the *'effect this had as matters developed',* and on this basis the CMA should have established the elements of an effects case (Lexon RSO, 31 July 2019, paragraphs 33-38 (URN: PRO-C5091)). The CMA does not accept Lexon's representation in this respect. The CMA sets out its finding as regards the existence of the Market Exclusion Agreement between Alliance and Lexon in paragraph 5.628.

[1702] Cinven stated that the CMA was suspicious that Alliance did not distribute genericised Prochlorperazine POM itself given the higher prices it could have charged absent the PPRS pricing restrictions and direct competition from other generic suppliers, and that the CMA's findings in this respect ignore evidence as to the limitations of Alliance's business model and distribution model when a market is expected to become genericised (Cinven RSO, 15 August 2019, paragraph 4.78 (URN: PRO-C5132)). The CMA's consideration of the value transfer from Alliance to Focus, including Alliance's decision to debrand and sell Prochlorperazine POM at a fixed price to Focus, is set out in paragraphs 5.277 to 5.295 and paragraphs 5.359 to 5.378.

Figure 5: Prochlorperazine POM gross profits by undertaking December 2013 to July 2018



Source: CMA analysis based on submissions from the parties[1703]

5.722 Put another way, Alliance (the incumbent supplier) was sharing the profits earned from the supply of Prochlorperazine POM with Lexon and Medreich, while allowing Focus to retain a margin for its part in the arrangement.[1704]

The value transfers were made in return for non-entry by Lexon/Medreich with the Prochlorperazine POM that they had jointly developed

5.723 As set out at paragraphs 5.628 and 5.688 above, the CMA finds that Lexon and Medreich agreed not to commercialise their jointly developed Prochlorperazine

[1703] Gross profits methodology:
(a) Lexon and Medreich: profit share receipts as set out in Annex I:. No cost of goods ('**COGs**') accounted for.
(b) Focus: total profits minus profit paid to Lexon as set out in Annex I:. This is a slight overestimate of profits given Focus' actual COGs was higher than the £5.65 reported in the reconciliation statements from April 2015 to July 2018, during which Focus paid Alliance a £6.10 transfer price (see note 260). Focus profits in this chart, as compared to the reconciliation statements, are reduced by the COGs differential times Focus' sales volumes for the period April 2015 to July 2018 as set out in the section 26 response of Advanz dated 21 December 2018, to the CMA Notice of 11 December 2018 (URN: PRO-C3149 and URN: PRO-C3150).
(c) Alliance: Revenue calculation equates to Prochlorperazine POM transfer price (£4.85 for the first 40,000 units (see paragraph 3.100), £5.65 for sales until March 2015 and £6.10 for sales from April 2015 to July 2018) multiplied by volumes as set out in the section 26 response of Advanz dated 21 December 2018, to the CMA Notice of 11 December 2018 (URN: PRO-C3149 and URN: PRO-C3150). COGs based on a price of £[✂] per pack across all units sold based on Alliance Pharmaceuticals Dechra Pharmaceuticals Contract Manufacturing Agreement (URN: PRO-E001318). No other costs are included in the analysis.

[1704] Alliance submitted that the CMA's presentation in Figure 5 of the gross profits earned by undertaking was misleading on the basis that, from Alliance's perspective, there was no *'universe of profits'* to be made (and therefore to be shared) (Alliance RSO, 1 August 2019, paragraph 4.11 (URN: PRO-C5096)). The CMA's finding about the transfer of value from Alliance to Lexon, through Focus, are set out in paragraphs 5.277 to 5.295.

POM product, on the understanding that they would receive a share of the profits that Focus earned from the supply of the Alliance product.

5.724 The value transfers that Alliance made to Lexon (via Focus) can be explained only on the basis that they served to compensate Lexon/Medreich for their agreement not to enter the market. Beyond that commitment not to enter, no other benefits were provided in return that can explain the substantial value transfers made by Alliance to Lexon (via Focus).

5.725 The CMA has considered the explanations for the value transfers that have been provided by the Parties and the explanations provided by witnesses. These explanations were premised on the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms being stand-alone vertical distribution agreements. For the reasons outlined in paragraphs 5.285 to 5.295, paragraphs 5.304 to 5.345 and paragraphs 5.532 to 5.555, those explanations cannot explain the transfers of value from Alliance to Lexon (via Focus).

Conclusion on the object of the Market Exclusion Agreement

5.726 The CMA concludes that the Market Exclusion Agreement had the object of sharing the market because Alliance agreed to (indirectly through Focus) transfer value to Lexon in return for Lexon agreeing not to enter the market with the Prochlorperazine POM it had jointly developed with Medreich. In other words, Lexon and Alliance agreed not to compete with one another.

5.727 The CMA concludes that the Market Exclusion Agreement reveals in itself a sufficient degree of harm to be characterised as a restriction of competition by object.

Duration

5.728 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.

5.729 As set out at paragraph 5.628 above, the CMA concludes that most likely by 7 June 2013, and by 22 June 2013 at the latest, Alliance and Lexon had agreed that they would enter into a form of pay for delay agreement. The CMA therefore finds that the Market Exclusion Agreement commenced by 7 June 2013 and persisted until 31 July 2018 (see paragraph 3.274) (the '**Infringement Period**').

5.730 As set out at paragraph 5.635 the CMA finds that Focus was aware, or could reasonably have foreseen it and was prepared to take the risk, of and participated in the Market Exclusion Agreement from 22 June 2013 until 31 July 2018 (see paragraph 3.274) (the '**Focus Infringement Period**').

5.731 As set out at paragraphs 5.655 and 5.671 above, Medreich subsequently became aware, or could reasonably have foreseen it and was prepared to take the risk, of and participated in the Market Exclusion Agreement from 5 February 2014, but served formal notice on Lexon to remove the supply of *'Prochlorperazine Maleate'* from the scope of the Lexon-Medreich Agreement, *'and all related arrangements (including payment of any profit share)'* on 15 February 2018[1705] (see paragraph 3.272). Accordingly, the CMA finds that Medreich participated in the Market Exclusion Agreement between 5 February 2014 and 15 February 2018 (the '**Medreich Infringement Period**').

[1705] Email [Medreich employee] to [Lexon Director 1] entitled *'Joint Venture and Management Responsibility'* 15 February 2018 (URN: PRO-E003647).

6. Other Aspects of the Legal Assessment

Appreciable restriction

Legal framework

6.1 An agreement that is restrictive of competition by 'object' will fall within the Chapter I prohibition only if it has as its object an appreciable prevention, restriction or distortion of competition.[1706]

6.2 The EU Court of Justice has clarified that an agreement that may affect trade between EU Member States and that has an anti-competitive object constitutes, by its nature, and independently of any concrete effect that it may have, an appreciable restriction on competition.[1707]

6.3 In accordance with section 60(A)(2) of the Act, this principle[1708] also applies in respect of the Chapter I prohibition and the UK. An agreement that may affect trade within the UK and that has an anti-competitive object therefore constitutes, by its nature and independently of any concrete effect that it may have, an appreciable restriction on competition.

Application

6.4 The CMA has found that the Market Exclusion Agreement had the object of restricting competition.[1709] Given that the effect on trade test is satisfied (see paragraphs 6.14 to 6.17 below) the CMA therefore concludes that the Market Exclusion Agreement constitutes, by its very nature, an appreciable restriction of competition in the supply of Prochlorperazine POM in the UK for the purposes of the Chapter I prohibition.

[1706] It is settled case law that an agreement between undertakings falls outside the prohibition in Article 101(1) TFEU 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.

[1707] 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.

[1708] Which predates 'IP completion day' (as defined as 31 December 2020 at 11.00 p.m. in section 39 of the European Union (Withdrawal Agreement) Act 2020) and was applicable immediately before IP completion day. Therefore, section 60A(2) Competition Act 1998 is applicable.

[1709] Cinven submitted (Cinven RSO, 15 August 2019, paragraph 9.2 (URN: PRO-C5132)) that the Market Exclusion Agreement does not have the object of preventing, restricting or distorting competition and, therefore, that it did not have as its object an appreciable restriction of competition. The CMA disagrees: the CMA has established at Chapter 5 above that the Market Exclusion Agreement does have the object of restricting competition.

6.5 In any event, and in the alternative, the CMA concludes that the Market Exclusion Agreement had an appreciable impact on competition for the supply of Prochlorperazine POM within the UK based on the CMA's findings that:

6.5.1 the geographical scope of the Market Exclusion Agreement covered the whole of the UK; and

6.5.2 the Market Exclusion Agreement allowed Alliance (through Focus) to retain a 100% share by volume and value of the relevant market until the entry of Morningside in 2017.

Exclusion or exemption

Legal framework

Exclusion

6.6 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.[1710] The CMA concludes that none of the relevant exclusions from the Chapter I prohibition set out in Schedules 1 to 3 of the Act applies in this case.

Exemption

6.7 Agreements falling within the scope of the Chapter I prohibition but which satisfy the criteria set out in section 9 of the Act are exempt from the Chapter I prohibition.

6.8 There are four cumulative criteria to be satisfied:

6.8.1 the agreement contributes to improving production or distribution, or promoting technical or economic progress;

6.8.2 while allowing consumers a fair share of the resulting benefit;

6.8.3 the agreement does not impose on the undertakings concerned restrictions which are not indispensable to the attainment of those objectives; and

6.8.4 the agreement does not afford the undertakings concerned the possibility of eliminating competition in respect of a substantial part of the products in question.

[1710] 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.

6.9 In considering whether an agreement satisfies the criteria set out in section 9 of the Act, the CMA will have regard to the Commission's Article 101(3) Guidelines.[1711]

6.10 Agreements which have as their object the prevention, restriction or distortion of competition are unlikely to benefit from individual exemption as such restrictions generally fail (at least) the first two conditions for exemption: they neither create objective economic benefits, nor do they benefit consumers. Moreover, such agreements generally also fail the third condition (indispensability).[1712] However, each case ultimately falls to be assessed on its merits.

6.11 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.[1713]

6.12 None of the Parties have claimed that an exemption should apply in this case. The CMA has concluded that the Market Exclusion Agreement had an anti-competitive object.

6.13 The CMA therefore concludes that no exemption applies in this case.

Effect on trade within the UK

6.14 For the reasons set out below, the CMA concludes that the Market Exclusion Agreement was capable of affecting trade within the UK.

6.15 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.[1714] 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.[1715]

6.16 Contrary to a representation from Cinven,[1716] to infringe the Chapter I prohibition, the conduct does not actually have to affect trade as long as it is capable of doing so.[1717] 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.[1718]

[1711] See Agreements and Concerted Practices (OFT401, December 2004), adopted by the CMA Board, paragraph 5.5 which provides that the CMA will have regard to the Commission Notice 'Guidelines on the Application of Article 81(3) of the Treaty' [2004] OJ C101/97 (Article 101(3) Guidelines) when considering the application of Section 9(1) of the Act.

[1712] Article 101(3) Guidelines, paragraph 46.

[1713] Section 9(2) of the Act. See also Article 101(3) Guidelines, see paragraphs 51 to 58.

[1714] Section 2(1) of the Act.

[1715] Section 2(7) of the Act.

[1716] Cinven RSO, 15 August 2019, paragraph 9.8 (URN: PRO-C5132).

[1717] See, for example, T-228/97 *Irish Sugar plc v Commission,* EU:T:1999:246, paragraph 170.

[1718] *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11, paragraphs 459 and 460.

6.17 The Market Exclusion Agreement was implemented in the UK and was capable of having an effect on the price paid in the UK for Prochlorperazine POM.[1719]

6.18 Accordingly, the CMA concludes that the Market Exclusion Agreement may have affected trade in the buying and selling of drugs within the whole or part of the UK.[1720]

[1719] For the reasons set out at footnote 1709 above, the CMA has rejected Cinven's representation that the Market Exclusion Agreement did not have as its object an appreciable restriction of competition. The CMA therefore also rejects Cinven's submission that the Market Exclusion Agreement did not have an effect on trade within the UK because the Market Exclusion Agreement did not have as its object an appreciable restriction of competition. Cinven RSO, 15 August 2019, paragraph 9.2, footnote 584 (URN: PRO-C5132).

[1720] Contrary to a representation by Advanz (Advanz RSO, 1 August 2019, paragraph 8.4 (URN: PRO-C5111)), when applying the Chapter I prohibition, the CMA is not obliged to define the relevant product or geographic market, unless it is impossible, without such a definition, to determine whether the agreement in question has as its object or effect the appreciable prevention, restriction or distortion of competition. (T-62/98 *Volkswagen v Commission* EU:T:2000:180, paragraph 230, and T-29/92 *SPO and Others v Commission* EU:T:1995:34, paragraph 74). As noted at paragraph 4.1 above, in the present case, the CMA considers that it is not necessary to reach a definitive view on market definition in order to determine whether there is an agreement between undertakings which has as its object the appreciable prevention, restriction or distortion of competition. See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, in which the CAT held, at paragraph 176, that in Chapter I cases *'determination of the relevant market is neither intrinsic to, nor normally necessary for, a finding of infringement'*.

7. Undertakings and Attribution of Liability

Legal framework

Undertakings

7.1 Competition law refers to the activities of 'undertakings'. An undertaking is any entity engaged in economic activity, regardless of its legal status and the way in which it is financed.[1721] An entity is engaged in 'economic activity' where it conducts any activity '*of an industrial or commercial nature by offering goods and services on the market*'.[1722]

7.2 The definition of an undertaking is therefore a functional one that is '*context-sensitive*'.[1723] In the context of the Chapter I and II prohibitions, the term 'undertaking' '*must be understood as designating an economic unit for the purpose of the subject-matter of the agreement [or conduct] in question, even if in law that economic unit consists of several persons, natural or legal*'.[1724]

7.3 It is thus well established that an undertaking does not correspond to the commonly understood notions of a legal entity or corporate group, for example under English commercial or tax law; and that a single undertaking may comprise one or more legal and/or natural persons.[1725]

Attribution of liability

7.4 Where an undertaking infringes the competition rules, it falls to that undertaking to answer for that infringement.[1726]

7.5 However, in order to enforce competition law it is necessary to attribute liability for the undertaking's infringement to legal entities.[1727]

7.6 The Act, the CMA Rules and the CMA's guidance do not stipulate which legal or natural person the CMA is obliged to hold responsible for the infringement or to punish by the imposition of a financial penalty.[1728]

[1721] C-41/90 *Hofner and Elser v Mactrotron*, EU:C:1991:161, paragraph 21; C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraph 54 and the case law cited.

[1722] C-118/85 *Commission v Italian Republic*, EU:C:1987:283, paragraph 7.

[1723] *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 360.

[1724] Case 170/83 *Hydrotherm*, EU:C:1984:271, paragraphs 11-12. See also C-217/05 *Confederación Española de Empresarios de Estaciones de Servicio v CEPSA*, EU:C:2006:784, paragraph 40; and *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 397: '*It is to be borne in mind that any relevant "undertaking" must relate to the restriction which is said to offend Article 101 [or the conduct which is said to breach Article 102] TFEU*'.

[1725] *Sepia Logistics Limited v Office of Fair Trading* [2007] CAT 13, paragraph 70.

[1726] T-372/10 *Bolloré II*, EU:T:2012:325, paragraph 52.

[1727] C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 54 to 57.

[1728] The same is true for the European Commission under the EU competition rules: see C-516/15 P *Akzo Nobel and Others v Commission*, EU:C:2017:314, paragraph 51 and the case-law mentioned there.

7.7 In *Sainsbury's Supermarkets Ltd v Mastercard*, the CAT concluded that '*In our view the current state of the law in this regard is most clearly expressed in the Advocate General's Opinion (endorsed by the Court of Justice) in Case C-231/11 P to C-233/11 P Commission v Siemens*'.[1729] The CAT quoted the following passage from the Advocate General:

> *'in the case of an undertaking made up of various legal persons, the persons who have participated in the cartel, as well as the ultimate parent company which exercises a decisive influence over them, may be regarded as legal entities collectively constituting a single undertaking for the purposes of competition law which may be held responsible for the acts of that undertaking. Consequently, if the Commission establishes that the undertaking has, either intentionally or negligently, committed an infringement of EU competition rules, it may determine the personal and collective liability of all the legal persons who make up the economic unit and who, by acting together, have participated, directly or indirectly, in the commission of the infringement.*
>
> *It is specifically for that reason that the Court has found it to be compatible with the principle of personal responsibility – as well as with the objective of the effective implementation of the competition rules – to require the legal persons who participated in the infringement and, along with them, the person who exercised decisive influence over them, to bear joint and several responsibility, specifically because those persons form part of a single economic unit and, therefore, form a single undertaking…'*[1730]

7.8 The CAT therefore went on to hold that: '*a legal person may be liable for a breach of competition law*:

> *(i) Because he, she or it has in some way participated in that breach, as a part of the single economic unit or "undertaking" that has infringed the law; and/or*
>
> *(ii) Because he, she or it has exercised decisive influence over one or more of the persons within the "undertaking" who have participated in the infringement.'*[1731]

7.9 When attributing liability, the starting point is therefore that those legal entities that directly '*participated in th[e] breach*' are liable.

7.10 Legal entities may also be held liable on the basis of parental liability, if they '*exercised decisive influence over one or more of the persons within the*

[1729] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(21).

[1730] Opinion of Advocate General Mengozzi in C-231/11 P *Commission v Siemens*, EU:C:2013:578, paragraphs 80-81 (emphasis added), quoted in *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(8).

[1731] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).

"undertaking" who have participated in the infringement'.[1732] An entity that exercises decisive influence over a directly infringing entity need not be a 'parent' in the literal sense of owning shares: the term 'parental' encompasses other forms of decisive influence.[1733]

7.11 Where a parent exercises decisive influence over a direct participant in an infringement, parent and subsidiary together form a single economic entity in relation to the infringement.[1734]

7.12 This means that the parent can be held jointly and severally liable for the infringement with the directly participating subsidiary and is deemed itself to have participated in the infringement:

> *'it cannot be disputed that the imputation to the parent company of the infringement committed by the subsidiary, on the ground that those companies form a single undertaking for the purposes of EU competition law and, therefore, that the parent company is regarded as having participated in the infringement on the same basis as its subsidiary, is also clearly apparent under EU law, according to the long-established case-law of the Court of Justice and this Court [the EU General Court].*
>
> *…*
>
> *the basis of the liability of the parent company … is not strict liability incurred on behalf of another but liability for its own misconduct and personal in nature.*
>
> *…*
>
> *If the parent company is part of that economic unit, it is regarded as jointly and severally liable with the other legal persons making up that unit for the infringements of competition law … In such a situation, the parent company*

[1732] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).

[1733] For example, the EU Court of Justice has confirmed that decisive influence can be exercised by a legal entity that holds the voting rights in a subsidiary (without necessarily holding the shares): C-595/18 P *Goldman Sachs v Commission*, EU:C:2021:73, paragraphs 29-36, upholding T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 50 to 52. Elsewhere, the courts have held that ownership is one, but not the only or a necessary reason for a finding of decisive influence. For example, in C-293/13 P *Fresh Del Monte v Commission*, EU:C:2014:2439, AG Kokott noted that the principles of decisive influence 'can also easily be applied to the case of a partnership' rather than a 'parent company-subsidiary relationship in the traditional sense', and that 'All the parties to the proceedings were in agreement on this point, and the EU General Court likewise rightly took that premiss as its starting point' (paragraph 75). The EU Court of Justice followed this Opinion, acknowledging that this involved classifying a partnership as equivalent to a parent-subsidiary relationship: C-293/13 P *Fresh Del Monte v Commission*, EU:C:2015:416, paragraphs 79-80.

[1734] See, for example, Opinion of AG Kokott in C-97/08 *Akzo Nobel v Commission*, paragraphs 42-45. The EU Court of Justice followed the Advocate General's Opinion. See also C-628/10 *Alliance One v Commission*, paragraphs 42-44; C-597/13 *Total v Commission*, paragraphs 32-35; C-516/15 *Akzo Nobel v Commission*, paragraphs 46-53.

is penalised for an infringement which it is deemed to have committed itself'.[1735]

7.13 Where a directly participating subsidiary is subject to the decisive influence of successive parents during an infringement period, that subsidiary and its successive parents form '*one and the same undertaking which, in its various successive configurations, committed the infringement at issue*' and can '*be held jointly and severally liable for payment of a single fine as entities forming part of one and the same undertaking to which the infringement at issue is imputable*.'[1736]

7.14 The EU Court of Justice summarised the legal framework for attributing liability to parents in *Akzo Nobel v Commission*:

> *'It is clear from settled case-law that the conduct of a subsidiary may be imputed to the parent company in particular where, although having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the market, but carries out, in all material respects, the instructions given to it by the parent company … having regard in particular to the economic, organisational and legal links between those two legal entities …*
>
> *That is the case because, in such a situation, the parent company and its subsidiary form a single economic unit and therefore a single undertaking … Thus, the fact that a parent company and its subsidiary constitute a single undertaking … enables the Commission to address a decision imposing fines to the parent company, without having to establish the personal involvement of the latter in the infringement'.*[1737,1738]

7.15 The legal test for parental liability is therefore that the 'parent' entity exercises '*decisive influence*' over a direct participant in an infringement. The question is

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[1735] T-372/10 *Bolloré II* [2012] OJ C235/13, paragraphs 37, 51 to 52 (emphasis added) and the case law cited. Compare T-69/04 *Schunk v Commission*, EU:T:2008:415, paragraphs 73 to 74. The principles of attributing liability to a parent apply equally, whether the underlying infringement is of the Chapter I prohibition / Article 101(1), or the Chapter II prohibition / Article 102. For example, these principles have been applied in a Chapter II/Article 102 context in cases such as: CE/1217-02 *Predation by Aberdeen Journals Limited,* CMA Decision of 16 September 2002, paragraph 11; *Aberdeen Journals* [2002] CAT 4, paragraph 4; C-6/72 *Europemballage Corporation and Continental Can Company* v *Commission,* EU:C:1973:22, paragraph 15; and Joined cases 6 and 7-73 *Istituto Chemioterapico Italiano and Commercial Solvents* v *Commission,* EU:C:1974:18, paragraphs 36 to 41.

[1736] C-823/18 P *Commission v GEA Group AG*, paragraphs 70 and 72.

[1737] C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 58 to 59 (emphasis added). See also C-516/15 P *Akzo Nobel v Commission*, EU:C:2017:314, paragraphs 52 to 58; C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 27 citing C-93/13 P and C-123/13 P *Commission and Others v Versalis and Others*, EU:C:2015:150, paragraph 40; C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraph 44; *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 15 to 22.

[1738] Applying this legal framework '*does not in any way constitute an exception to the principle of personal responsibility, but is the expression of that very principle. That is because the parent company and the subsidiaries under its decisive influence are collectively a single undertaking for the purposes of competition law and responsible for that undertaking*': *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(3), citing Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraphs 97 to 99. Nor does this legal framework infringe the right to be presumed innocent: T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 187 to 191. See also C-611/18 P *Pirelli v Commission*, EU:C:2020:868, paragraphs 70, 73 and 95.

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*'.[1739] If so, the parent forms part of the economic entity that committed the infringement and may be held jointly and severally liable with its subsidiary for that infringement:

> *'the parent company to which the unlawful conduct of its subsidiary is attributed is held individually liable for an infringement of the EU competition rules which it is itself deemed to have infringed, because of the decisive influence which it exercised over the subsidiary'.*[1740]

7.16 This does not require that the parent was involved in, or even aware of, the infringement by its subsidiary.[1741] However, evidence that the parent was aware of the infringement and did not intervene can be relevant.[1742]

The presumption of decisive influence (the Akzo presumption)

7.17 It is settled caselaw that where a parent company holds (directly or indirectly)[1743] 100% (or nearly 100%)[1744] of the shares or voting rights[1745] in a subsidiary which has infringed the competition rules, not only is that parent company able to exercise decisive influence over the conduct of its subsidiary, but there is a rebuttable presumption that the parent company does in fact exercise such decisive influence over the conduct of its subsidiary (the '***Akzo* presumption**'). The

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[1739] T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605, referring to the Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraphs 87 to 94. See also T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraph 70 and the caselaw cited.

[1740] C-516/15 P *Akzo Nobel v Commission*, EU:C:2017:314, paragraphs 56 to 58.

[1741] C-90/09 P *General Química SA v Commission*, EU:C:2011:21, paragraph 102: '*what counts is not whether the parent company encouraged its subsidiary to commit an infringement …, or whether it was directly involved in the infringement committed by its subsidiary, but the fact that those two companies constitute a single economic unit and thus a single undertaking … which enables the Commission to impose a fine on the parent company*'. See also C-97/08 *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 59 and 77, and T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraph 367 and the caselaw cited.

[1742] See, for example, Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, in which the facts that Mylan was aware of the relevant agreement involving its subsidiary Matrix Laboratories as part of its due diligence for the acquisition of that subsidiary, but did not raise any objections, were relevant factors in the Commission's decision to hold Mylan liable. The Commission found that based on its due diligence Mylan '*was aware that Matrix had agreed to stay out of the market with perindopril in return for a large sum of money*', and therefore knew, or ought to have known, that the relevant agreement was anti-competitive. However, Mylan never raised any objections to the agreement or took any measure aimed at terminating it, showing that '*Mylan tacitly approved the infringement and this, in itself, amounts to additional evidence that Mylan exercised decisive influence over the conduct of Matrix*': paragraphs 3041-3044. The Commission's attribution of liability to Mylan was upheld on appeal in T-682/14 *Mylan v Commission*, EU:T:2018:907. The EU General Court noted that '*The control exercised by the parent company over its subsidiary does not necessarily have to have a connection with the unlawful conduct*' and did not rely on this point for its finding that Mylan exercised decisive influence (since it held that the Commission had established this based on other factors) – but noted that '*that the applicants do not dispute that Mylan was aware of the Agreement at the time it acquired a majority shareholding in Matrix*' (paragraphs 349-368).

[1743] C-90/09 P *General Química and Others* v *Commission*, EU:C:2011:21, paragraphs 86 to 87.

[1744] T-217/06 *Arkema France, Altuglas International SA, Altumax Europe SAS v Commission* EU:T:2011:251, paragraph 53.

[1745] T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 50 to 52 and 64, upheld in C-595/18 P *Goldman Sachs v Commission*, paragraphs 35-36.

two entities can therefore be regarded as a single economic unit and held jointly and severally liable for the infringement and any resulting fine.[1746]

7.18 Where the *Akzo* presumption applies, it suffices for the purposes of attribution of liability. In such circumstances, it is for the party in question to rebut the presumption by adducing sufficient evidence.[1747]

7.19 The CMA may nonetheless also rely on additional economic, organisational and legal links to demonstrate the exercise of decisive influence, other than the parent's shareholding or voting rights in the subsidiary.[1748]

7.20 For example, in the *Power Cables*[1749] cartel case, the EU General Court upheld the European Commission's finding that Goldman Sachs exercised decisive influence over its fund's subsidiary Prysmian, applying the *Akzo* presumption and on the basis of additional links including:

7.20.1 The power to appoint and remove directors (albeit indirectly through its funds) and to call shareholder meetings;

7.20.2 Goldman Sachs' representation on the subsidiary's board;

7.20.3 The management powers of Goldman Sachs' board representatives; and

7.20.4 Goldman Sachs' receipt of regular updates and monthly reports.[1750]

7.21 The EU Court of Justice upheld the EU General Court and rejected Goldman Sachs' argument that these factors did not suffice to establish decisive influence.[1751]

Cases where the Akzo presumption does not apply

7.22 Where the *Akzo* presumption does not apply, because the parent owns less than (nearly) 100% of the shares or voting rights in the subsidiary, the '*principal question*' is whether the parent actually exercises decisive influence over the conduct of the subsidiary during the relevant period, since '*if it were to be established … that … the [parent] did in fact exercise decisive influence over the*

[1746] 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.

[1747] C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraph 47, citing C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraph 61; see also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 19 to 21; C-595/18 P *Goldman Sachs v Commission*, EU:C:2021:73, paragraph 40.

[1748] C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraph 49.

[1749] Commission Decision of 2 April 2014 in Case 39610 *Power Cables*.

[1750] T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445.

[1751] C-595/18 P *Goldman Sachs v Commission,* EU:C:2021:73.

conduct of [the directly infringing entity], that would necessarily imply that they were in a position to do so'.[1752]

7.23 Such decisive influence is not limited to and does not require influence on commercial conduct. The CAT has confirmed that: '*The factors to which the court may have regard, when considering the issue of decisive influence, are not limited to commercial conduct but cover a wide range as described by the Advocate General and the General Court [in Akzo].*'[1753] In that case, the EU Court of Justice approved the statement of Advocate General Kokott that: '*the absence of autonomy of the subsidiary in terms of its market conduct is only one possible connecting factor on which to base an attribution of responsibility to the parent company. It is not the only connecting factor*'.[1754]

7.24 Whether the parent exercises decisive influence therefore turns on the economic, organisational and legal links between the parent and subsidiary, which vary from case to case.[1755] The test focuses on substance over form and does not depend on technicalities of company law. Rather, it asks whether, as a matter of '*economic reality*' and in light of those economic, organisational and legal links, the parent can be said to have exercised decisive influence.[1756]

Economic, organisational and legal links indicating decisive influence

7.25 There is no exhaustive set of criteria or 'checklist' to complete in assessing the economic, organisational and legal links indicating decisive influence.[1757] The EU Court of Justice has also confirmed that '*The existence of an economic unit may … be inferred from a body of consistent evidence, even if some of that evidence,*

[1752] T-24/05 *Alliance One and Others v Commission*, EU:T:2010:453, paragraphs 165 to 167, upheld in C-628/10 P and C-14/11 P *Alliance One and Others v Commission*, EU:C:2012:479. See also T-104/13 *Toshiba Corp. v European Commission*, EU:T:2015:610, paragraph 95; and C-172/12 P *El du Pont de Nemours v Commission*, EU:C:2013:601, paragraph 44; and T-541/08 *Sasol v Commission*, EU:T:2014:628, paragraph 43.

[1753] *Durkan Holdings Limited v OFT* [2011] CAT 6, paragraph 22.

[1754] Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 87, approved in C-97/08 P *Akzo Nobel v Commission,* EU:C:2009:536, paragraphs 73 to 74: '*It is clear, as the Advocate General pointed out …, that the conduct of the subsidiary on the market cannot be the only factor which enables the liability of the parent company to be established, but is only one of the signs of the existence of an economic unit*'. See also T-24/05 *Alliance One & Others v Commission*, EU:T:2010:453, paragraph 170: '*It is also necessary to reject the applicants' argument that the decisive influence that a parent company must exercise in order to have liability attributed to it for the infringement committed by its subsidiary must relate to activities which form part of the subsidiary's commercial policy stricto sensu and which, furthermore, are directly linked to that infringement'*. See also T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraph 32, and T-682/14 *Mylan v Commission*, paragraph 347.

[1755] C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 72 to 74.

[1756] C-440/11 *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV,* EU:C:2013:514, paragraphs 66 to 68. The EU Court of Justice followed the Opinion of Advocate General Kokott, EU:C:2012:763, paragraphs 71 to 76: '*the decisive factor is ultimately economic reality, since competition law is guided not by technicalities, but by the actual conduct of undertakings*'. Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 46: '*In examining whether the parent company is able to exercise decisive influence over the market conduct of its subsidiary, account must be taken of all the relevant factors relating to the economic, organisational and legal links which tie the subsidiary to its parent company and, therefore, account must be taken of the economic reality*'. See also Joined cases C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, EU:C:2015:416, paragraph 76.

[1757] C-628/10 P *Alliance One*, EU:C:2012:479, paragraph 45; T-141/07 *General Technic-Otis v Commission*, paragraph 103.

taken in isolation, is insufficient to establish the existence of such a unit.'[1758]
Examples of links that have been considered to confer decisive influence include:

7.25.1 A majority shareholding;

7.25.2 Rights under a shareholders' agreement to determine the composition of the subsidiary's board and/or to veto strategic commercial decisions;

7.25.3 The presence of parent representatives on the subsidiary's board;

7.25.4 The receipt of information on strategic and commercial plans; and

7.25.5 The nature of the parent's business model, where relevant to its investment in the subsidiary.

A majority shareholding

7.26 Although a majority shareholding is not necessary to establish decisive influence, the EU General Court has confirmed that, if a parent holds a majority interest in the subsidiary's share capital, that can enable it to exercise decisive influence over its subsidiary and, in particular, over the subsidiary's market conduct.[1759]

Rights under a shareholders' agreement

7.27 The ability to exercise decisive influence may also be demonstrated on the basis of links other than a majority shareholding, such as the management powers that the parent has over the subsidiary.[1760] An agreement between parent companies in relation to management of their subsidiary is a relevant legal link for the assessment of decisive influence. Implementation of such an agreement is an indication that decisive influence is exercised.[1761]

7.28 For example, the EU General Court has held that:

> *'the ability to decide upon the composition of the board of directors of a company constitutes an objective factor which determines, in itself, whether it is possible to control the decisions that may be adopted by the board and, therefore, by the company concerned. The board of directors constitutes, by definition, the body responsible for administering and representing the company.'*[1762]

[1758] C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, paragraph 65.

[1759] T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 182; T-104/13 *Toshiba v Commission,* EU:T:2015:610, paragraph 96.

[1760] T-132/07 *Fuji Electric Co. Ltd v Commission,* EU:T:2011:344, paragraph 183.

[1761] T-314/01 *Avebe v Commission,* EU:T:2006:266, paragraph 138.

[1762] T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 91 (emphasis added).

7.29 Further, veto rights constitute an important legal link between the parent and the subsidiary, which can enable the parent to exercise decisive influence over the subsidiary.[1763] It is not necessary for veto rights *'to relate to measures connected with the day-to-day management of the business or, specifically, with the company's conduct on the market; it is enough for those rights of veto to afford the partner concerned, in very general terms, a sufficient influence over the company's commercial policy in the broadest sense'*.[1764]

7.30 The mere holding of a veto right over certain strategic decisions (such as the adoption of a business plan or budget) can in itself confer decisive influence.[1765] The holder need not actually veto decisions (though if it does, that is strong evidence). Where a parent holds a veto right and attends meetings at which it could veto decisions, that amounts to exercising its right, since its approval is a prerequisite.[1766] Even where decisions are taken by the subsidiary's management, '*the fact that the parent company or its representatives must approve those proposals and therefore has the right to reject them is, in fact, evidence of a decisive influence*'.[1767]

7.31 However, a parent may exercise decisive influence over a subsidiary even when it does not make use of any actual rights to determine its conduct and refrains from giving any specific instructions or guidelines to its subsidiary.[1768] The parent's influence over strategic decisions such as whether the subsidiary's business activities shall be expanded or down-sized, whether investments or acquisitions

[1763] For example, in T-104/13 *Toshiba v Commission,* EU:T:2015:610, factors in the EU General Court's finding that Toshiba exercised decisive influence over a joint venture company (upheld by the EU Court of Justice) included Toshiba's veto rights over: material investments; the formation, capital participation in or acquisition of a company or business for a price above a certain threshold; and the provision of loans over a certain threshold to subsidiary companies and other entities (paragraphs 106 to 113, upheld in C-623/15 P *Toshiba v Commission*, EC:C:2017:21).

[1764] Opinion of Advocate General Kokott in C-293/13 *Del Monte*, EU:C:2014:2439, paragraph 89 (followed by the EU Court of Justice).

[1765] C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67. Compare T-543/08 *RWE v Commission*, EU:T:2014:627, paragraphs 30 to 32: '*The conduct on the market of the subsidiary is under the decisive influence of the parent company, in particular, where the subsidiary carries out, in all material respects, the instructions given to it by the parent company in that respect … The subsidiary's conduct on the market is, in general, also under the decisive influence of the parent company where the latter retains only the power to define or approve certain strategic commercial decisions, where appropriate by its representatives in the bodies of the subsidiaries, while the power to define the commercial policy stricto sensu of the subsidiary is delegated to the managers responsible for its operational management, chosen by the parent company and representing and promoting the parent company's commercial interests*' (emphasis added). See also T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

[1766] Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 73: '*the holder of a right of veto over certain decisions of an undertaking must necessarily be consulted before the adoption of any decisions which it is capable of vetoing and must approve those decisions*'.

[1767] T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 114 and caselaw cited, upheld in C-595/18 P *Goldman Sachs v Commission*.

[1768] T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605. See also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraph 22(b). See also C-155/14 P *Evonik Degussa GmbH v Commission,* EU:C:2016:446, paragraph 41, citing C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce,* EU:C:2015:416, paragraphs 96-97.

shall be made and whether it shall be sold and for what price, can be particularly important.[1769]

The presence of parent company representatives on the subsidiary's board

7.32 The EU General Court has held that:

> *'the fact that, when acquiring a company, a company replaces some of the directors constitutes evidence that the acquiring company in fact exercises decisive influence over the conduct of the company that has been acquired'.*[1770]

7.33 The EU General Court has confirmed that appointee directors on a subsidiary board can act in more than one capacity, where the interests of parent and subsidiary are aligned. The fiduciary duties of directors to their company cannot determine the composition of a single economic unit any more than the separate legal personality of that company can. The EU General Court emphasised that the parent's conduct in appointing representatives '*would not have made sense if the applicant had intended that the supervisory board be composed of persons entirely independent from the applicant.*' Since the appointee directors could not be considered '*solely as [the applicant's] representatives*', they acted in a dual capacity.[1771]

7.34 A parent may therefore exercise decisive influence via the presence, in leading positions of the subsidiary, of individuals who occupy managerial posts within the parent company;[1772] or other personal links between the companies.[1773] Those individuals need not be representatives only of the parent, but may owe duties to multiple entities without risk of conflict where their interests align.

7.35 The presence on the subsidiary's board of directors of individuals who also hold managerial posts within the parent therefore constitutes an organisational and personal link between the two entities. The facts that these individuals may simultaneously be directors of many other companies, and may not be involved in

[1769] Commission Decision of 2 April 2014 in Case 39610 *Power Cables*, paragraph 779. The courts have therefore rejected the argument that '*residual control over 'strategic decisions' and financial supervision are not enough to found a conclusion that [a parent] actually exercised control over its subsidiary*': T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

[1770] T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 100; see also T-497/07 *CEPSA v Commission*, EU:T:2013:438, paragraph 176.

[1771] T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraphs 75-77.

[1772] T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 184; T-76/08 *EI du Pont de Nemours and Company, DuPont Performance Elastomers LLC and DuPont Performance Elastomers SA v Commission*, EU:T:2012:46, paragraphs 70 and 74.

[1773] C-440/11 *Commission v Stichting Administratiekantoor Portielje*, EU:C:2013:514, paragraphs 67 and 68.

day-to-day operations, are not inconsistent with a finding that this link enables the exercise of decisive influence.[1774]

7.36 The EU General Court has held that: '*Such an accumulation of posts necessarily places the parent company in a position to have a decisive influence on its subsidiary's market conduct since it enables members of the parent company's board to ensure, while carrying out their managerial functions within the subsidiary, that the subsidiary's course of conduct on the market is consistent with the line laid down at management level by the parent company'*. The Court confirmed that '*[t]hat objective can be attained even though member(s) of the parent company who take on managerial functions within the subsidiary do not have authority as agents of the parent company'*.[1775]

7.37 In *Toshiba* the EU Court of Justice therefore held that a parent exercised decisive influence over a subsidiary based among other things on the parent's appointment of four directors out of the total 10 on the subsidiary's board (one of whom simultaneously occupied a management position within the parent); and the appointment as the subsidiary's vice president and representative from time to time of individuals who had previously acted at a high management level within the parent, and who subsequently returned to it, showing that – as the EU General Court held, '*even if they had not retained contractual links with the [parent] and were no longer under its direct authority*' – they '*necessarily had thorough knowledge of Toshiba's policy and its commercial objectives and were in a position to cause the [subsidiary]'s policy and Toshiba's interests to converge*'.[1776]

7.38 Such personal links are not only relevant where there is '*an accumulation of posts*' with both parent and subsidiary concurrently. In *Goldman Sachs* the EU Court of Justice upheld the EU General Court and Commission's findings that Goldman Sachs exercised decisive influence over its fund's portfolio company Prysmian in part through the personal links Goldman Sachs had with two 'independent' non-executive directors on Prysmian's board, who were not directors, officers, employees or managers of Goldman Sachs. Their personal links to Goldman Sachs consisted of '*previous advisory services*' and '*consultancy agreements*'. The EU Court of Justice held that:

[1774] For example, where one such individual was simultaneously a board member of around 40 other companies, and was not '*hands-on'*, instead receiving mainly reports on finance and '*major moves*' from the relevant subsidiary's managing director around three times a year, that did not prevent the individual from '*dealing fairly intensively with*' the relevant subsidiary, or contributing to the finding that the parent exercised decisive influence. The courts have recognised that '*the position of member of the board of directors of a company entails, by its very nature, legal responsibility for the activities of the company as a whole, including the company's market conduct … Once [the relevant individuals] assumed those responsibilities, it is of little significance that they did not, in practice, deal with the undertaking's commercial strategy*': T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraphs 53 to 60; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

[1775] T-132/07 *Fuji Electric Co. Ltd v Commission,* EU:T:2011:344, paragraph 184.

[1776] C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 14-17. See also T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 116. The EU Court of Justice upheld the EU General Court's judgment (see in particular paragraph 77).

'The relevance of such personal links lies in the fact that they may suggest that a person, although active for a given company, actually pursues, in view of his or her links with another company, the interests of the latter.'[1777]

7.39 Even the presence of a single parent company representative on the board of the subsidiary can be a relevant link among others conferring the ability to exercise decisive influence.[1778]

The receipt of information on strategic and commercial plans

7.40 It is not necessary for the parent to have control over the subsidiary's day-to-day operations; rather, what counts is '*influence over the general strategy which defines the orientation of the undertaking*'.[1779]

7.41 The exercise of such influence may be supported (and demonstrated) by the parent's rights to obtain information about its subsidiary:

'a flow of information between a parent company and its subsidiary and, a fortiori, an obligation to report to the parent company, also constitutes an indication of the exercise of control over the subsidiary's decisions (see, to that effect, judgments of 20 January 2011, General Química and Others v Commission, C-90/09 P, EU:C:2011:21, paragraph 107; of 6 March 2012, FLSmidth v Commission, T-65/06, not published, EU:T:2012:103, paragraph 31; and the Opinion of Advocate General Mengozzi in Evonik Degussa and AlzChem v Commission, C-155/14 P, EU:C:2015:529, point 75). Such information and reports show organisational links between the parent company and its subsidiary and allow the parent company to monitor and control the activities of its subsidiary in order to take specific measures in relation to it.'[1780]

7.42 The provision by the subsidiary to the parent of information on '*the implementation stage of strategic and commercial plans*' is an indication that the parent '*exercised control*' over the decisions drawn up and executed by the subsidiary's executives.[1781]

[1777] C-595/18 P *Goldman Sachs v Commission*, EU:C:2021:73, paragraphs 89 and 93-95.

[1778] C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 76: '*it is in no way necessary for the accumulation of posts within both the parent company and the subsidiary to concern more than one individual in order to constitute one indication among others of that capacity*'. Compare C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraph 106: '*[the subsidiary's] sole director designated by [the parent] constituted, as a result of his consistent pattern of behaviour, a link between those two companies, by which the information concerning sales, production and financial results were communicated to [the parent]*'.

[1779] T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 121, referring to the Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 73.

[1780] T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraph 351.

[1781] C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraphs 104 to 107.

The nature of the parent's business model

7.43 The nature of the parent's business model may be a relevant factor demonstrating its exercise of decisive influence over the subsidiary.

7.44 In particular, financial investors that actively engage with their portfolio companies to effect change are likely to exercise decisive influence over them. For example, in *Gigaset v Commission*, the EU General Court took into account the fact that the parent's commercial strategy relied on buying and restructuring companies in order to sell them for a higher price (typically on a three- to five-year timeframe), noting that it was difficult to see how this could be achieved without exercising decisive influence over its subsidiary.[1782]

7.45 The EU General Court has limited the concept of a '*pure financial investor*' (potentially lacking decisive influence) to '*the case of an investor who holds shares in a company in order to make a profit, but who refrains from any involvement in its management and in its control'*.[1783] There may be cases of pure financial investors; but any such finding can only be made on a case by case basis.

7.46 For example, in response to an industry parent company's attempt to rebut the *Akzo* presumption by arguing that its subsidiary was purchased for investment purposes, the EU General Court held that:

> *'the purchase by an investment company with a view to sale can also argue in favour of the existence of an economic entity between the investment company and the subsidiary in question. The fact that the investment company seeks to improve the subsidiary's results over the short term implies, as a rule, that the parent company must involve itself in the subsidiary's activities. An effective and strict system of monitoring may offer better guarantees for increased profitability than a policy of non-intervention'.*[1784]

7.47 The courts, the European Commission and Member States' national competition authorities have, in a number of cases, held parent companies focused on financial investment to be liable for infringements committed by their portfolio companies. For example:

7.47.1 In its *Gigaset* decision, the Commission found that Gigaset exercised decisive influence over its subsidiary SKW Holding, including during the period when its shareholding decreased from 100% to 57%, on the basis

[1782] T-395/09 *Gigaset AG v Commission,* EU:T:2014:23, paragraphs 37 to 38.

[1783] T-392/09 *1. garantovaná a.s. v Commission*, EU:T:2012:674, paragraph 52, citing the Opinion of Advocate General Kokott in C-97/08 *Akzo Nobel v Commissio*n, EU:C:2009:262.

[1784] T-54/06 *Kendrion v Commission*, EU:T:2011:667, paragraph 66 (judgment only available in French and Dutch; English summary from the Opinion of Advocate General Sharpston in C-50/12 P *Kendrion v Commission*, EU:C:2013:350, paragraph 53).

of factors including: overlapping roles on the Gigaset and SKW boards; veto rights over particular transactions; and Gigaset's involvement in the appointment, dismissal and terms of remuneration of SKW's key management. The EU General Court upheld the Commission's conclusions.[1785]

7.47.2 In its *Servier* decision, the European Commission attributed liability to Unichem Laboratories for the infringement committed by its subsidiary Niche Generics, including during the period when it owned 60% of its shares, on the basis that Unichem exercised decisive influence over Niche through its: '*prevailing presence on Niche's Board of Directors*', the majority of whom were appointed by Unichem (and which included the chairman of Unichem's board); rights under a shareholders' agreement; monitoring of Niche's financial performance and approval of its business plan.[1786] The Commission dismissed Unichem's argument that it had been acting '*only as a passive investor in Niche much like a venture capitalist*', since these points showed that it had not refrained from any involvement in its subsidiary's management or control.[1787] The Commission also found that Mylan Laboratories exercised decisive influence over its majority-owned subsidiary Matrix Laboratories, on the basis of factors including Mylan's: access to strategic information and leverage over Matrix's decision making processes; rights to be consulted and to veto strategic decisions; and personal links via Mylan employees serving on Matrix's board, '*on deputation from Mylan*' – i.e. seconded from Mylan.[1788] The EU General Court upheld the Commission's analysis of both cases in two separate appeals.[1789] In relation to Mylan/Matrix, it found that '*the obligations as regards authorisation, consultation, reporting and consolidation of accounts as well as the cross-directorships between the subsidiary and its parent company*' were sufficient to establish decisive influence during the 20-month ownership period.[1790]

7.47.3 In its *Lundbeck* decision, the European Commission found AL Industrier AS liable for the infringement committed by its subsidiary Alpharma – despite its shareholding of between 23 and 27.8% – on the basis that AL Industrier exercised decisive influence in particular via the personal links between parent and subsidiary, comprising (among other things): that the parent had the right to appoint six out of nine members of the subsidiary's board; and that individuals had overlapping roles between parent and

[1785] T-395/09 *Gigaset AG v Commission,* EU:T:2014:23.

[1786] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraphs 3017-3019.

[1787] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 3016.

[1788] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraphs 3028-3036.

[1789] T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89; and T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 344-361. Currently on appeal to the EU Court of Justice: C-166/19 P and C-197/19 P.

[1790] T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 350 and 359.

subsidiary. In so doing the Commission expressly rejected the parent's argument that it was a mere financial investor.[1791] This aspect of the decision was not appealed.[1792]

7.47.4 In its *Power Cables* decision, the European Commission attributed liability to The Goldman Sachs Group, Inc. on the basis that it exercised decisive influence over its fund's portfolio company, Prysmian, for several years of the infringement period.[1793] During an initial period, Goldman Sachs held 100% of the voting rights in Prysmian, and the Commission applied the *Akzo* presumption as well as additional relevant factors including those referred to at paragraph 7.20 above. After Prysmian shares were sold off in a flotation, the Commission concluded that Goldman Sachs continued to exercise decisive influence via those factors. The EU General Court upheld the Commission's attribution of liability, noting that '*the exercise of voting rights regarding strategic decisions for the business conduct of the subsidiary, such as the appointment of top management and the approval of business and management plans, is evidence of a clear exercise of decisive influence rather than a purely temporary financial investment.*'[1794] The EU Court of Justice upheld the EU General Court in all respects.[1795]

7.47.5 The Dutch national competition authority, the Authority for Consumers and Markets, found entities within two investment groups, Bencis Capital Partners and CVC Capital Partners, liable as successive parents of Meneba B.V., the legal entity that entered into a market sharing agreement. CVC was found to have exercised decisive influence over Meneba notwithstanding its minority share of 41%. It did not appeal. Bencis was found to have exercised decisive influence over Meneba via its powers to appoint board members (which it exercised, including by appointing one of its founders and managing partners as Meneba's chairman), cast deciding votes in relation to the supervisory board, and influence business plans. Bencis appealed to the District Court of Rotterdam, which upheld the Authority's decision, confirming that Bencis

[1791] Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraphs 1274-1283.

[1792] In Alpharma's appeal, T-471/13 *Alpharma v Commission*, EU:T:2016:460, the Court noted: '*the Commission held that A.L. Industrier, which controlled Alpharma Inc., formed with that company a single undertaking that also included Alpharma ApS. Moreover, the applicants do not dispute that those three companies formed a single undertaking at the time of the conclusion of the agreement at issue*' (paragraph 389).

[1793] Commission Decision of 2 April 2014 in Case 39610 *Power Cables*, the Competition Commissioner stated, '*I would like to highlight the responsibility of groups of companies, up to the highest level of the corporate structure, to make sure that they fully comply with competition rules. This responsibility is the same for investment companies, who should take a careful look at the compliance culture of the companies they invest in.*' EU Commission: '*Introductory remarks on two cartel decisions: Power Cables and Steel Abrasives*' (URN: PAD085).

[1794] T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 180.

[1795] C-595/18 P Goldman Sachs v Commission, EU:C:2021:73.

had exercised decisive influence over Meneba via these economic, organisational and legal links.[1796]

Application to this case

7.48 In summary, for the reasons set out below, the CMA concludes that the following legal entities formed part of the undertakings Alliance, Focus, Lexon and Medreich and are liable for the Infringement during the periods and on the basis indicated:

Table 3: Legal entities forming part of the undertakings over time and basis of liability

Undertaking	Legal entity	Period	Basis of liability
Lexon	Lexon (UK) Limited	Entire Infringement Period	Direct participant
	Lexon UK Holdings Limited	1 March 2018 until the end of the Infringement Period	Parental liability
Medreich	Medreich plc	Entire Medreich Infringement Period	Direct participant
	Medreich Limited	Entire Medreich Infringement Period	Parental liability
	Meiji Seika Pharma Co. Ltd	12 February 2015 until the end of the Medreich Infringement Period	Parental liability
	Meiji Holdings Co. Ltd.	12 February 2015 until the end of the Medreich Infringement Period	Parental liability
Alliance	Alliance Pharmaceuticals Limited	Entire Infringement Period	Direct participant
	Alliance Pharma plc	Entire Infringement Period	Parental liability
Focus[1797]	Focus Pharmaceuticals Limited	Entire Focus Infringement Period	Direct participant
	Focus Pharma Holdings Limited	Entire Focus Infringement Period	Parental liability
	Mercury Pharma Group Limited	1 October 2014 until the end of the Focus Infringement Period	Parental liability
	The Cinven Entities (see paragraph 7.73 below)	1 October 2014 until 20 October 2015	Parental liability
	The Advanz Entities (see paragraph 7.73 below)	21 October 2015 until the end of the Focus Infringement Period	Parental liability

Lexon

7.49 The CMA concludes that the following legal entities formed part of an undertaking for the purposes of the Chapter I prohibition referred to as 'Lexon':

[1796] Decisions 6306_20/217_OV (20 November 2014) and 6306_20/259 (11 September 2015); District Court of Rotterdam judgment of 26 January 2017, NL:RBROT:2017:588.

[1797] The CMA has found that Focus participated in the Infringement from at least 22 June 2013 to 31 July 2018 (see paragraph 5.730).

7.49.1 For the entire Infringement Period:

(a) Lexon (UK) Limited; and

7.49.2 From 1 March 2018 until the end of the Infringement Period:

(a) Lexon UK Holdings Limited.

7.50 A description of the activities of these entities during the Infringement Period is set out at paragraphs 3.15 and 3.16 above. Throughout these periods, each of these entities was engaged in economic activities, including the sale of pharmaceutical products on the market (directly or through subsidiaries). From 1 March 2018 Lexon UK Holdings Limited became the sole parent of Lexon (UK) Limited, acquiring 100% of the shares from a number of individual shareholders.

Liability of Lexon (UK) Limited

7.51 Lexon (UK) Limited is held liable for the Infringement for the entire Infringement Period.

7.52 Lexon (UK) Limited was directly involved in this Infringement during the Infringement Period. Lexon (UK) Limited was the legal entity that, as party to the Lexon-Medreich Agreement, had the exclusive right to market any Prochlorperazine POM supplied by Medreich plc in the UK (see paragraphs 3.53 and 3.54). It was also the legal entity that entered into written Heads of Terms with Focus Pharmaceuticals Limited granting Focus the exclusive right to supply any Prochlorperazine POM supplied by Lexon/Medreich (see paragraph 3.106 above) and, through its [✂], [Lexon Director 1], entered into an unwritten agreement with Alliance Pharmaceuticals Limited (i.e. the Market Exclusion Agreement) whereby it would appoint Focus Pharmaceuticals Limited as a distributor, but would supply only one batch of product every five years in return for value transferred from Alliance Pharmaceuticals Limited through Focus Pharmaceuticals Limited (see Chapter 5 above). A detailed description of Lexon (UK) Limited's role, involvement in the Infringement and conduct is set out in Chapter 5 above, along with the CMA's findings that its conduct infringed the Chapter I prohibition. Accordingly, the CMA finds Lexon (UK) Limited liable for the Infringement in which Lexon (UK) Limited participated for the entire Infringement Period, and for the resulting financial penalties.

Liability of Lexon UK Holdings Limited

7.53 Lexon UK Holdings Limited is held liable for the Infringement from 1 March 2018 until the end of the Infringement Period.

7.54 As noted at paragraph 3.16 above, from 1 March 2018 until the end of the Infringement Period, Lexon (UK) Limited was directly wholly owned by Lexon UK

Holdings Limited. Lexon UK Holdings Limited therefore had the ability to exercise decisive influence over Lexon (UK) Limited during this period, and the CMA applies the *Akzo* presumption that it did actually exercise such influence. Lexon UK Holdings Limited has not disputed this and the *Akzo* presumption has therefore not been rebutted. The CMA therefore finds that Lexon UK Holdings Limited and Lexon (UK) Limited formed a single undertaking during this period.

7.55 The CMA therefore attributes liability to Lexon UK Holdings Limited for the Infringement from 1 March 2018 until the end of the Infringement Period, and for the resulting financial penalties, jointly and severally with Lexon (UK) Limited.

Medreich

7.56 The CMA concludes that the following legal entities formed part of an undertaking for the purposes of the Chapter I prohibition referred to as 'Medreich':

7.56.1 For the entire Medreich Infringement Period:

(a) Medreich plc;

(b) Medreich Limited; and

7.56.2 From 12 February 2015 until the end of the Medreich Infringement Period:

(a) Meiji Seika Pharma Co., Ltd; and

(b) Meiji Holdings Co. Ltd.

7.57 A description of the activities of these entities during the Medreich Infringement Period is set out at paragraphs 3.18 and 3.19 above. Throughout these periods, each of these entities was engaged in economic activities, including the sale of pharmaceutical products on the market (directly or through subsidiaries).

Liability of Medreich plc

7.58 Medreich plc is held liable for the Infringement, for the entire Medreich Infringement Period.

7.59 Medreich plc was directly involved in this Infringement during the Medreich Infringement Period. Medreich plc was the legal entity that, as party to the Lexon-Medreich Agreement, granted an exclusive right to Lexon (UK) Limited to market any Prochlorperazine POM supplied by Medreich Limited (see paragraphs 3.53 and 3.54). It participated in the Market Exclusion Agreement (see Chapter 5) through its own conduct by accepting the payments from Lexon (UK) Limited and agreeing to supply only the minimal quantity of Prochlorperazine POM necessary to avoid the application of the Sunset Clause. A detailed description of Medreich plc's role, involvement in the Infringement and conduct is set out in Chapter 5

above, along with the CMA's findings that its conduct infringed the Chapter I prohibition. Accordingly, the CMA finds Medreich plc liable for the Infringement in which Medreich plc participated for the entire Medreich Infringement Period and for the resulting financial penalties.

Liability of Medreich Limited

7.60 Medreich Limited is held liable for the Infringement, for the entire Medreich Infringement Period.

7.61 For the entire Medreich Infringement Period, Medreich plc was wholly owned by Medreich Limited.[1798] Medreich Limited therefore had the ability to exercise decisive influence over Medreich plc during this period, and the CMA applies the *Akzo* presumption that it did actually exercise such influence. Medreich Limited has not disputed this and the *Akzo* presumption has therefore not been rebutted. The CMA therefore finds that Medreich Limited and Medreich plc formed a single undertaking during this period.

7.62 The CMA therefore attributes liability to Medreich Limited for the Infringement for the entire Medreich Infringement Period, and for the resulting financial penalties, jointly and severally with Medreich plc.

Liability of Meiji Seika Pharma Co. Ltd. and Meiji Holdings Co. Ltd.

7.63 Meiji Seika Pharma Co. Ltd and Meiji Holdings Co. Ltd are held liable for the Infringement from 12 February 2015 until the end of the Medreich Infringement Period.

7.64 As noted at paragraph 3.19 above, from 12 February 2015 until the end of the Medreich Infringement Period, Medreich Limited, the 100% owner of Medreich plc, was directly wholly owned by Meiji Seika Pharma Co. Limited[1799] which, in turn, was directly wholly owned by Meiji Holdings Co. Limited. [1800] Each of Meiji Seika Pharma Co. Limited and Meiji Holdings Co. Limited therefore had the ability to exercise decisive influence over Medreich plc during this period, and the CMA applies the *Akzo* presumption that they did actually exercise such influence. The parties have not disputed this and the *Akzo* presumption has therefore not been rebutted. The CMA therefore finds that Meiji Seika Pharma Co. Limited, Meiji Holdings Co. Limited, Medreich Limited and Medreich plc formed a single undertaking during this period.

7.65 The CMA therefore attributes liability to Meiji Seika Pharma Co. Ltd. and Meiji Holdings Co. Limited for the Infringement in which Medreich plc participated from

[1798] Section 26 response of Medreich dated November 2017, to CMA Notice of 10 October 2017 (URN: PRO-C1301).

[1799] See Meji press release - https://www.meiji.com/global/news/2015/pdf/150213_01.pdf (URN: PAD082).

[1800] Meji press release - https://www.meiji.com/global/news/2015/pdf/150213_01.pdf (URN: PAD082); and Medreich plc Annual Report and Financial Statements for the year ended 31 March 2018, page 24 (URN: PAD021).

12 February 2015 until the end of the Medreich Infringement Period, and for the resulting financial penalties, jointly and severally with Medreich Limited and Medreich plc.

Alliance

7.66 The CMA concludes that the following legal entities formed part of an undertaking for the purposes of the Chapter I prohibition referred to as 'Alliance' for the entire Infringement Period:

7.66.1 Alliance Pharmaceuticals Limited; and

7.66.2 Alliance Pharma plc.

7.67 A description of the activities of these entities during the Infringement Period is set out at paragraphs 3.3 and 3.4 above. Throughout these periods, each of these entities was engaged in economic activities, including the sale of pharmaceutical products on the market (directly or through subsidiaries).

Liability of Alliance Pharmaceuticals Limited

7.68 Alliance Pharmaceuticals Limited is held liable for the Infringement for the entire Infringement Period.

7.69 Alliance Pharmaceuticals Limited was directly involved in this Infringement during the Infringement Period. Alliance Pharmaceuticals Limited was the legal entity that supplied Prochlorperazine POM to Focus Pharmaceuticals Limited pursuant to the Alliance-Focus Agreement (see Chapter 5 above) and entered into an unwritten agreement with Lexon (UK) Limited on the terms summarised in Chapter 5 above. A detailed description of Alliance Pharmaceuticals Limited's role, involvement in the Infringement and conduct is set out in Chapter 5 above, along with the CMA's findings that its conduct infringed the Chapter I prohibition. Accordingly, the CMA finds Alliance Pharmaceuticals Limited liable for the Infringement in which Alliance Pharmaceuticals Limited participated for the entire Infringement Period and for the resulting financial penalties.

Liability of Alliance Pharma plc

7.70 Alliance Pharma plc is held liable for the Infringement for the entire Infringement Period.

7.71 For the entire Infringement Period Alliance Pharmaceuticals Limited was directly wholly owned by Alliance Pharma plc.[1801] Alliance Pharma plc therefore had the ability to exercise decisive influence over Alliance Pharmaceuticals Limited during

[1801] Section 26 response of Alliance dated 2 November 2017, to CMA Notice of 16 October 2017, part 1 (URN: PRO-C0218).

this period, and the CMA applies the *Akzo* presumption that it did actually exercise such influence. Alliance Pharma plc has not disputed this and the *Akzo* presumption has therefore not been rebutted. The CMA therefore finds that Alliance Pharmaceuticals Limited and Alliance Pharma plc formed a single undertaking during this period.

7.72 The CMA therefore attributes liability to Alliance Pharma plc for the Infringement in which Alliance Pharmaceuticals Limited participated for the entire Infringement Period, and for the resulting financial penalties, jointly and severally with Alliance Pharmaceuticals Limited.

Focus

7.73 The CMA concludes that the following legal entities formed part of an undertaking for the purposes of the Chapter I prohibition referred to as 'Focus':

7.73.1 For the entire Focus Infringement Period:

(a) Focus Pharmaceuticals Limited; and

(b) Focus Pharma Holdings Limited;

7.73.2 From 1 October 2014 until the end of the Focus Infringement Period, Mercury Pharma Group Limited, Focus Pharmaceuticals Limited and Focus Pharma Holdings Limited (together the **Focus Companies**);

7.73.3 From 1 October 2014 until 20 October 2015:

(a) The Focus Companies;

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

(c) Cinven (Luxco 1) S.à.r.l. (formerly known as Cinven (Luxco 1) S.A.[1802]); and

(d) Cinven Partners LLP (together with Cinven Capital Management (V) General Partner Limited and Cinven (Luxco 1) S.à.r.l., the **Cinven Entities**).

7.73.4 From 21 October 2015 until the end of the Focus Infringement Period:

(a) The Focus Companies;

(b) Concordia Investment Holdings (UK) Limited;

[1802] The Cinven Entities have notified the CMA of this name change on 30 November 2021, see Cinven RLF, 30 November 2021, paragraph 1.1 (URN: PRO-C7919).

(c) Concordia Investments (Jersey) Limited; and

(d) Advanz Pharma Corp. Limited (formerly known as Concordia International Corp.[1803] and before that as Concordia Healthcare Corp.[1804]) (together with Concordia Investment Holdings (UK) Limited and Concordia Investments (Jersey) Limited, the **Advanz Entities**).

7.74 A description of the activities of these entities during the Infringement Period is set out at paragraphs 3.5 to 3.8 above. Throughout these periods, each of these entities was engaged in economic activities, including the sale of pharmaceutical products on the market (directly or through subsidiaries).

7.75 For the entire Focus Infringement Period, Focus Pharmaceuticals Limited was wholly owned by Focus Pharma Holdings Limited.[1805] On 1 October 2014, Mercury Pharma Group Limited indirectly acquired Focus Pharmaceuticals Limited[1806] by acquiring 100% of the shares of Focus Pharma Holdings Limited.[1807] Mercury Pharma Group Limited was majority owned by the Fifth Cinven Fund. From 1 October 2014 until 20 October 2015, the Cinven Entities exercised decisive influence over the Focus Companies for the reasons set out in paragraphs 7.85 to 7.275 below, such that the Cinven Entities and the Focus Companies formed a single undertaking.

7.76 On 21 October 2015, the Focus Companies were indirectly acquired by Concordia Investments (Jersey) Limited, a wholly owned subsidiary of the entity now known as Advanz Pharma Corp. Limited.[1808] From that date and, at least, until the end of the Focus Infringement Period, the entity now known as Advanz Pharma Corp.

[1803] See Prnewswire: *'Concordia International Corp. Announces Name Change to ADVANZ PHARMA Corp.'* (URN: PAD007).

[1804] Concordia Healthcare Corporation announced its name change to Concordia International Corporation on 28 June 2016. See Prnewswire: *'Concordia Healthcare Corp. Announces Name Change to Concordia International Corp. and Comments on Brexit's Impact on the Company's Business'*, accessed on 5 October 2017 (URN: PAD046).

[1805] See Focus Pharmaceuticals Limited's annual returns (URNs: PAD077-PAD081).

[1806] See Cinven press release https://www.cinven.com/media/news/141001-amco-announces-the-acquisition-of-focus-pharmaceuticals-limited/, accessed on 29 April 2019 (URN: PAD076) and Focus Pharma Holdings Limited's annual report dated 31 December 2014 (URN: PAD075).

[1807] See section 26 response of Advanz dated 20 February 2019, to CMA Notice of 6 February 2019 (URN: PRO-C3820 and PRO-C3803) and the Focus Pharma Holdings Limited annual report and financial statements dated 31 December 2014 (URN: PAD075).

[1808] See Concordia: *'Completes AMCo acquisition'* (URN: PAD045). Concordia Healthcare Corporation announced its name change to Concordia International Corporation on 28 June 2016: Prnewswire: *'Concordia Healthcare Corp. Announces Name Change to Concordia International Corp. and Comments on Brexit's Impact on the Company's Business'.* See Prnewswire: *'Concordia Healthcare Corp. Announces Name Change to Concordia International Corp. and Comments on Brexit's Impact on the Company's Business'*, accessed on 5 October 2017 (URN: PAD046). The structure of the group following its acquisition by Concordia International Corporation is shown in the document entitled *'Confidential Annex 5.1 – Corporate Structure Chart for the AMCo Group af....pdf'* (URN: PRO-E004579); the document entitled *'Confidential Annex 5.2 – Current Corporate Structure Chart of the AMCo G....pdf* (URN: PRO-E004580); and the document entitled *'Annex 2: Updated structure chart'* (URN: PRO-E004582).

Limited indirectly held 100% of the shares in the Focus Companies through the other Advanz Entities.[1809]

Liability of Focus Pharmaceuticals Limited

7.77 Focus Pharmaceuticals Limited is held liable for the Infringement for the entire Focus Infringement Period.

7.78 Focus Pharmaceuticals Limited was directly involved in the Infringement during the Focus Infringement Period. Focus Pharmaceuticals Limited was the entity that, through its [✂], [Focus Director 1], entered into the Alliance-Focus Agreement with Alliance Pharmaceuticals Limited giving it the exclusive right to distribute Prochlorperazine POM supplied by Alliance Pharmaceuticals Limited to the UK market (see paragraphs 3.100 and 3.104 above). It was also the entity that, again through [Focus Director 1], entered into the Focus-Lexon Heads of Terms with Lexon (UK) Limited through which it transferred significant value to Lexon (UK) Limited (see paragraphs 3.105 and 3.106 above). In entering the above agreements, Focus Pharmaceuticals Limited helped to implement and participated in the Market Exclusion Agreement (see paragraphs 5.635 to 5.654 above). A detailed description of Focus Pharmaceuticals Limited's role, involvement in the Infringement and conduct is set out in Chapter 5 above, along with the CMA's findings that its conduct infringed the Chapter I prohibition. Accordingly, the CMA finds Focus Pharmaceuticals Limited liable for the Infringement in which Focus Pharmaceuticals Limited participated for the entire Focus Infringement Period, and for the resulting financial penalties.

Liability of Focus Pharma Holdings Limited

7.79 Focus Pharma Holdings Limited is held liable for the Infringement for the entire Focus Infringement Period.

7.80 As noted at paragraph 7.75 above for the entire Focus Infringement Period Focus Pharmaceuticals Limited was directly wholly owned by Focus Pharma Holdings Limited.[1810] Focus Pharma Holdings Limited therefore had the ability to exercise decisive influence over Focus Pharmaceuticals Limited during this period, and the CMA applies the *Akzo* presumption that it did actually exercise such influence. Focus Pharma Holdings Limited has not disputed this and the *Akzo* presumption has therefore not been rebutted. The CMA therefore finds that Focus Pharma Holdings Limited and Focus Pharmaceuticals Limited formed a single undertaking during this period.

[1809] On 29 June 2017, Concordia International (Jersey) Limited (a wholly owned subsidiary of Concordia Investment Holdings (UK) Limited) was dissolved and its interest in the Focus Companies was transferred to Concordia Investment Holdings (UK) Limited, a wholly owned subsidiary of Concordia Investments (Jersey) Limited, itself a wholly owned subsidiary of Advanz Pharma Corp. Limited.

[1810] See note 1805.

7.81 The CMA therefore attributes liability to Focus Pharma Holdings Limited for the Infringement in which Focus Pharmaceuticals Limited participated for the entire Focus Infringement Period, and for the resulting financial penalties, jointly and severally with Focus Pharmaceuticals Limited.

Liability of Mercury Pharma Group Limited

7.82 Mercury Pharma Group Limited is held liable for the Infringement from 1 October 2014 until the end of the Focus Infringement Period.

7.83 Mercury Pharma Group Limited is held liable by application of the law on parental liability. As noted at paragraph 3.7 above, Mercury Pharma Group Limited acquired 100% of the shares of Focus Pharma Holdings Limited on 1 October 2014 and maintained this holding for the rest of the Focus Infringement Period. During this period Focus Pharma Holdings Limited wholly owned Focus Pharmaceuticals Limited. As a result, from 1 October 2014 until, at least, the end of the Focus Infringement Period, Mercury Pharma Group Limited indirectly held 100% of Focus Pharmaceuticals Limited through Focus Pharma Holdings Limited. Accordingly, Mercury Pharma Group Limited had the ability to exercise decisive influence over both Focus Pharma Holdings Limited and, indirectly, Focus Pharmaceuticals Limited, and the CMA applies the *Akzo* presumption that it did actually exercise such influence. Mercury Pharma Group Limited has not disputed this and the *Akzo* presumption has therefore not been rebutted. The CMA therefore finds that Mercury Pharma Group Limited, Focus Pharma Holdings Limited and Focus Pharmaceuticals Limited formed a single undertaking during this period.

7.84 The CMA therefore attributes liability to Mercury Pharma Group Limited for the Infringement in which Focus Pharmaceuticals Limited participated from 1 October 2014 until the end of the Focus Infringement Period, and for the resulting financial penalties, jointly and severally with Focus Pharma Holdings Limited and Focus Pharmaceuticals Limited.

Liability of the Cinven Entities

7.85 The Cinven Entities are held liable for the Infringement from 1 October 2014 until 20 October 2015.

7.86 From 1 October 2014 until 20 October 2015 (the '**Cinven Period**') each of the Focus Companies was indirectly majority owned by the Cinven private equity house ('**Cinven**'):[1811]

7.86.1 The Focus Companies were wholly owned by Amdipharm Mercury Limited ('**AML**') (formerly known as CCM Pharma Limited).

7.86.2 Cinven held more than 55% of the shares in AML (and therefore, ultimately, the Focus Companies) but less than 100%.

7.87 For the reasons set out in this section, the CMA concludes that as a result of the economic, organisational and legal links between the Cinven Entities and the Focus Companies, the Cinven Entities each exercised decisive influence over each of the Focus Companies throughout the Cinven Period.[1812] Throughout the Cinven Period, the Cinven Entities and the Focus Companies therefore formed an economic unit for the purpose of the Infringement committed by Focus.

7.88 The CMA therefore holds each of the Cinven Entities liable, jointly and severally with the Focus Companies, for Focus's participation in the Infringement, and for the resulting financial penalties, during the Cinven Period.

7.89 Before setting out the detail of the CMA's findings it is important to provide some context in order to explain why the CMA considers it appropriate to hold entities associated with Cinven liable and why the CMA has chosen the Cinven Entities (of the myriad legal entities associated with Cinven).

7.90 The CMA has structured its analysis of the decisive influence each Cinven Entity exercised in the sections below to reflect the multiple and cumulative links between the Cinven Entities and the AMCo Group (the CMA uses the phrase '**the AMCo Group**' to mean AML and all its wholly-owned subsidiaries under Cinven's ownership (including, from 1 October 2014 onwards, the Focus Pharma group[1813]). This analysis is necessarily detailed because of the complex way Cinven structured its investment in the AMCo Group.

7.91 This should not, however, detract from the simple points explained below: that Cinven publicly described its approach as one of making '*control investments*' and

[1811] Mercury Pharma Group Limited was majority owned by Cinven from 31 August 2012 onwards. However, Mercury Pharma Group Limited did not acquire the directly infringing entity in this case, Focus Pharmaceuticals Limited, until 1 October 2014. The Cinven Entities therefore cannot be held liable for the Infringement committed by Focus Pharmaceuticals Limited prior to that date. For this reason, the Cinven Period begins on 1 October 2014.

[1812] Cinven submitted that [✂] (Cinven RSO, 15 August 2019, Annex 1, paragraph 12.2 (URN: PRO-C5134) (in responding to the Statement of Objections in this case Cinven referred the CMA to its representations in Case 50395). This mischaracterises the CMA's findings. The links between the Cinven Entities are relevant (in showing, among other things, the alignment of their interests) but the CMA's findings relate to the economic, organisational and legal links between each Cinven Entity and the Focus Companies, which demonstrate the exercise of decisive influence by each Cinven Entity.

[1813] In this section, the CMA uses the phrase '**the Focus Pharma group**' to mean Focus Pharmaceuticals Limited and its parent company Focus Pharma Holdings Limited.

acting as *'a catalyst for change'*;[1814] that Cinven publicly described its investment in the AMCo Group as *'transformative'*;[1815] and that in achieving that transformation, three key Cinven Entities and in particular a handful of key Cinven individuals were involved, following what Cinven publicly described as *'a 'one team' approach'*.[1816]

7.92 In the sections that follow, the CMA first explains the approach Cinven takes to its investments, demonstrating that Cinven's approach generally, and specifically to its investment in and management of the AMCo Group, was centred around obtaining control and using that control to actively manage the portfolio business. The CMA goes on to explain the role the Cinven Entities played in Cinven's approach, following which the CMA explains why each of the Cinven Entities exercised decisive influence over the Focus Companies during the Cinven Period and is therefore jointly and severally liable with them for the Infringement committed by Focus.

7.93 Some of the evidence in the sections that follow pre-dates the Cinven Period (which, as explained above, begins in this case with the acquisition of the Focus Pharma group on 1 October 2014). This evidence is relevant to the analysis of Cinven's exercise of decisive influence during the Cinven Period in that it demonstrates a strategy for investment that began with the acquisition of the Mercury Pharma and Amdipharm groups in 2012 and continued with the acquisition of the Focus Pharma group in 2014. The acquisition of the Focus Pharma group, like that of the Mercury Pharma and Amdipharm groups, was devised by Cinven as part of a strategy of building the AMCo Group into a leading specialist in reaping profits from niche generic drugs. The economic, organisational and legal links that Cinven put in place with the AMCo Group continued during the Cinven Period, when the Focus Pharma group became part of the AMCo Group. Evidence relating to Cinven's investment in the AMCo Group prior to the Cinven Period is therefore relevant to the Cinven Period.

Cinven's approach to investment and creation of the AMCo Group

7.94 This section explains Cinven's approach to investment generally and specifically how that approach was implemented in relation to the AMCo Group, drawing on Cinven's own published and internal documents. It shows that to exercise decisive influence (or in Cinven's words, to *'leverage control ownership positions'*[1817]) by buying, restructuring, adding to, making profitable and then divesting companies is the essence of Cinven's business model, and it is the strategy it successfully

[1814] Document entitled *'Annex 1 - Cinven Annual Review 2011'*, page 22 (URN: PRO-E004553).

[1815] Cinven press releases: *'AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp'* (emphasis added) (URN: PAD043).

[1816] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 7 (URN: PRO-E004554).

[1817] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 26 (URN: PRO-E004554).

applied to this investment. It is for these reasons that the CMA considers it appropriate to hold entities associated with Cinven liable.

7.95 Cinven's own descriptions of its approach to investments confirm that it is not a '*pure financial investor*'.[1818] Its public documents describe it as *'an active and engaged investor in companies'*[1819] and explain '*The Cinven approach*' to investment as follows:

> *'Cinven creates value by making control investments in leading European companies and accelerating growth through the application of our sector expertise, global reach and active ownership model.*
>
> *…*
>
> *We act as a catalyst for change; driving revenue, EBITDA and margin growth through active engagement with our portfolio companies and their management.*[1820]
>
> *…*
>
> *We seek to improve all aspects of the companies we invest in, for the full duration of our ownership.'*[1821]
>
> *'A key differentiating factor in the Cinven offer is … the active investor model that we pursue with all our investments.'*[1822]

7.96 One of the *'Investment criteria for a typical Cinven company'* was *'Control positions, a path to control, or significant influence over the strategy and management'*.[1823] Cinven's approach is, in its own words, to *'acquire control positions in market-leading, cash generative companies with attractive market dynamics'*.[1824]

7.97 Cinven emphasised that its active ownership continued throughout the lifetime of an investment:

[1818] See paragraphs 7.22–7.47.5 above.

[1819] Cinven: *'Annual Review 2014'*, page 120 (URN: PAD055). In this document, the term *'Cinven' 'means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006) and/or funds managed or advised by any of the foregoing'*. See page 1.

[1820] Document entitled *'Annex 1 - Cinven Annual Review 2011'*, page 22 (URN: PRO-E004553) (emphasis added).

[1821] Cinven: 'Annual Review 2014', page 22 (URN: PAD055). As above, the term *'Cinven' 'means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006) and/or funds managed or advised by any of the foregoing'*. See page 1.

[1822] Document entitled *'Annex 1 - Cinven Annual Review 2011'*, page 19 (URN: PRO-E004553) (emphasis added).

[1823] Document entitled *'Annex 3 - Cinven Annual Review 2013'*, page 25 (URN: PRO-E004555).

[1824] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 23 (URN: PRO-E004554). See also page 26: *'We leverage control ownership positions'*.

'The Sector, Portfolio and Financing teams come together to evaluate opportunities, through the development of an investment case and strategy, from initial acquisition, through the ownership period and finally to ultimate exit.'[1825]

7.98 In this case, Cinven pursued its active investor model when acquiring the Amdipharm and Mercury Pharma groups, combining them to create the AMCo Group, acquiring and incorporating the Focus Pharma group, and ultimately divesting the AMCo Group. The contemporaneous documents demonstrate these aspects of Cinven's active ownership with respect to the AMCo Group, as further discussed below:

7.98.1 When developing the 'investment case and strategy';

7.98.2 'Through the ownership period'; and

7.98.3 When preparing for '*the ultimate exit*'.

Developing the 'investment case and strategy'

7.99 Cinven's investment case and strategy for the AMCo Group was to combine the Mercury Pharma and Amdipharm groups and bring them under single management, and to adopt for the combined group a strategy and business plan focussed on what it called '*off-patent, niche pharmaceuticals*' (see below).

7.100 Cinven stated publicly in relation to these investments:

'Creating a global force in niche pharmaceuticals

In 2012, Cinven acquired and brought together Mercury Pharma and Amdipharm, two complementary niche pharmaceutical companies, to create an international player of scale and a platform for continued consolidation in this fragmented market. The combined business is now called Amdipharm Mercury Company Limited (AMCo).

…

Our Healthcare sector team identified off-patent, niche pharmaceuticals as a particularly attractive sub-sector. It is insulated from the patent expiry issues which affect the broader pharmaceutical industry, has high entry barriers, and is a relatively fragmented market, offering opportunities for significant value creation through consolidation.'[1826]

[1825] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 7 (URN: PRO-E004554).

[1826] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 8 (URN: PRO-E004554).

7.101 In publicising its investments, Cinven therefore emphasised both its industry expertise and its understanding of the way niche generic drugs could be exploited for profit. Cinven's knowledge of the reimbursement system for generic drugs – in particular, the free pricing regime, which could be exploited where effective competition failed to materialise – was a key factor in its decision to invest in the Mercury Pharma and Amdipharm groups.

7.102 Cinven's Healthcare sector team was led by two Cinven Partners: [Cinven Partner], [✂], and [Cinven Partner], [✂].[1827] [Cinven Partner] was quoted in the press when the investment in the Amdipharm group was announced, explaining the rationale for the investment. The *Financial Times* wrote:

> *'Amdipharm buys up the rights to what Cinven calls "unloved generics" – legacy drugs that still have a solid base of patients in spite of being superseded by newer versions that have slightly different effects. Cinven is hoping to exploit the stable growth of these cheap off-patent medicines that are sold in low volumes and with limited risk of price competition.*
>
> *These relatively neglected drugs, which Cinven partner [✂] dubbed "little jewellery boxes", can still attract strong sales. Amdipharm generates annual revenues of more than £110m.*[1828]

7.103 [✂].[1829] [✂].

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

> *'Approximately 40% of the generics market in the UK is unbranded*
>
> - *The pricing of these unbranded products is not regulated because competition suppresses pricing across the market as a whole*
> - *However, for smaller, niche formulations, the competitive forces may not work to suppress prices as efficiently as for larger volume products and create room for price growth*
>
> *…*
>
> *Mercury therefore operates below the radar and capitalises on opportunities to achieve volume and pricing growth even in such a heavily regulated market'*
>
> *…*

[1827] Document entitled *'Annex 3 - Cinven Annual Review 2013'*, page 109 (URN: PRO-E004555).

[1828] FT: *'Cinven accelerates into UK healthcare'* (URN: PAD044) (emphasis added).

[1829] Cinven RSO, 15 August 2019, Annex 2, footnote 558 (URN: PRO-C5134), Cinven's RSSO in Case 50395.

Reimbursement for drug manufacturers is controlled by a small group within the DoH … The focus is on high volume drugs (patent and off-patent) as this is where the absolute quantum of savings is higher: niche products are typically below the radar'[1830]

7.105 The '*investment attraction*' of the Mercury Pharma group was therefore its ability to exploit the absence of effective regulation for niche generic drugs and increase prices while remaining '*below the radar*' of authorities.

7.106 [✂] The investment recommendation for Cinven's acquisition of the Amdipharm group stated:

'The primary growth levers for Amdipharm [✂][1831]

7.107 [✂].[1832]

7.108 As these documents make clear, the investment thesis and business plan for the combined AMCo Group were a continuation and expansion of the same strategy that the existing management of the Mercury Pharma group had already pursued – in particular under [AMCo Director 1], [✂]. Cinven has publicly stated that it cultivates an early relationship with portfolio company management so that *'when the time comes we already have a strong affinity with the management team and are able to move quickly'*.[1833] In its internal documents, Cinven noted that *[✂]*.[1834] The final recommendation for Cinven to acquire the Mercury Pharma and Amdipharm groups [✂] :

[✂]

[✂]

[✂].[1835]

7.109 On 13 November 2012 [AMCo Director 1] and [AMCo Employee 2], at that time [✂],[1836] gave a presentation to investors at a healthcare conference run by the Jefferies financial group. The presentation stated that a '*key strategic element*' of the merger between Amdipharm and Mercury was that their '*Portfolio comprises low-cost, off-patent products which are not the main focus of healthcare cost*

[1830] Minutes of a meeting of IC dated 2 July 2012, pages 6 and 8 (emphasis added) (URN: PRO-E004083).

[1831] Document '*Annex 2.2 - Memorandum to the IC entitled 'Amdipharm - initial investment recommendation*' dated 9 July 2012, page 4 (URN: PRO-E004084).

[1832] Document *'Ampule Confidential Information Memorandum_Draft_v08.pdf.pdf*', page 14 (URN: PRO-E004558).

[1833] Cinven: *'Annual Review 2014'*, page 21 (URN: PAD055).

[1834] Minutes of a meeting of IC dated 2 July 2012, page 2 (emphasis added) (URN: PRO-E004083).

[1835] Minutes of a meeting of the IC dated 30 July 2012, pages 5 (emphasis added) and 36 (emphasis in original) (URN: PRO-E004085).

[1836] See Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 64 of document / page 66 of pdf (URN: PRO-E004554).

reduction initiatives'. It went on to note: '*Pharmaceutical reimbursement contributed c.10% to the total NHS budget in 2012, so is not as material to overall healthcare spending as actual service provision, which is the primary focus of healthcare reform*'.[1837]

7.110 Both Cinven and AMCo Group senior management therefore shared a common strategy from the outset of Cinven's investment. In simple terms, this was to increase the prices of certain off-patent drugs where AMCo faced no or ineffective competition, and whose markets were small enough to avoid attention from the DHSC.

7.111 Cinven's investment case and strategy for the AMCo Group therefore involved two key elements that, if implemented, would each amount to the exercise of decisive influence:

7.111.1 The combining into a single group of two previously independent groups of companies, including installing a single management team at the top of that combined group which answered to Cinven. Only through exercising decisive influence over the Mercury Pharma and Amdipharm groups could this be achieved; and

7.111.2 The adoption for the combined AMCo Group of a business plan to be carried out by that management team, focussed on generating profit from the AMCo Group's portfolio of '*off-patent, niche pharmaceuticals*'. Again, only through exercising decisive influence over the AMCo Group could Cinven have achieved this.

7.112 The acquisition of the Focus Pharma group in October 2014 (effected through the parent company of the Mercury Pharma group, Mercury Pharma Group Limited) was a continuation of this strategy:

7.112.1 Cinven's internal recommendation to acquire the Focus Pharma group:

(a) Noted that [✂]. The recommendation therefore concluded [✂];

(b) Listed as the first investment attraction Focus's [✂] and stated that there was [✂]. Those [✂] are discussed above;

(c) Noted that: [✂]. [1838]

[1837] Phenytoin [2018] CAT 11, Transcript of hearing (Day 5) (URN: PAD084).

[1838] Document *'Focus Pharmaceuticals - Final Investment Recommendation'* dated 17 September 2014, pages 2-5 and 8 (URN: PRO-E004098).

'Through the ownership period'

7.113 Throughout the period in which Cinven owns a portfolio company, it ensures that its investment strategy is implemented, including through operational input, appointing senior managers, and regular reporting. Cinven's public documents state: *'we do guarantee our operational input, which is targeted, systematic and on-going throughout the entire period of our ownership.'*[1839]

7.114 This was the case for the AMCo Group. Cinven's investment strategy was implemented immediately and throughout the Cinven Period through ongoing and systematic strategic and operational oversight.

7.115 Once the Mercury Pharma and Amdipharm acquisitions were complete, Cinven's strategy was put into effect without delay. As explained in the sections that follow, Cinven immediately:

7.115.1 appointed two 'Investor Directors' to the board of AML to exercise its rights as majority shareholder in the AMCo Group and to oversee implementation of its strategy (see paragraph 7.182 below);

7.115.2 appointed key individuals to positions on the boards of numerous other AMCo Group companies to further entrench its influence (including Mercury Pharma Group Limited, the company that became the 100% owner of Focus Pharmaceuticals Limited and Focus Pharma Holdings Limited in October 2014) (see paragraph 7.186 below); and

7.115.3 put in place reporting lines to ensure the regular provision of strategic and operational information about the AMCo Group's performance, and used that information to direct the AMCo Group's conduct (see paragraph 7.203 below).

7.116 Immediately after acquiring the Amdipharm and Mercury Pharma groups, Cinven put in place a *'100 day action plan'* which included [✂] a single team led by [AMCo Director 1], to oversee *'UK portfolio optimisation: Price increases, De-branding, Cross-selling'*.[1840] Such a 100 day action plan was what Cinven generally put in place when it made an investment, as its 2012 annual review explained: the plan '*involves our Investment and Portfolio teams working closely with a company's management team and expert consultancies to develop <u>our strategy</u> into a detailed business plan'*.[1841] This immediate, in-depth oversight of the AMCo Group's

[1839] Cinven: *'Annual Review 2014'*, page 24 (URN: PAD055). As above, the term *'Cinven' 'means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006) and/or funds managed or advised by any of the foregoing'*. See page 1.

[1840] Document *'Review of investments and valuations at 31 December 2012'*, page 5 (URN: PRO-E004191).

[1841] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 28 (URN: PRO-E004554). (emphasis added). Pages 28-29 provide a case study of the activities of the Portfolio team in relation to another investment, CPA Global,

integration, management and strategy demonstrates that Cinven exercised decisive influence over its investment from the outset, in order to ensure its goals were achieved.

7.117 The combined AMCo Group prepared consolidated management accounts from January 2013 onwards, which were presented to Cinven by [AMCo Director 1].

7.118 Once Cinven has invested, every portfolio company also develops a longer-term *'Value Creation Plan'* in conjunction with Cinven, looking at *'all aspects of operational improvement, with a specific emphasis on Cinven's areas of functional expertise'*.[1842] Such a plan was also put in place for AMCo. In 2014, Cinven noted that:

> *'AMCo continued to execute its Value Creation Plan, characterised by international expansion and strong growth … The size and geographic presence of the combined business has allowed Cinven and AMCo's leadership team, to build a truly international platform in line with Cinven's buy and build and internationalisation strategies.*
>
> *AMCo has completed three acquisitions under Cinven's ownership, most recently it acquired Focus Pharmaceuticals in October 2014.*
>
> *… Cinven's deep experience of executing complex mergers, operational improvement and acquisitive growth, has created a new force in the global pharmaceuticals industry.'*[1843]

7.119 Throughout the Cinven Period, in addition to the 'follow-on' acquisitions (acquisitions by the AMCo Group of companies, such as the Focus Pharma group) that formed part of Cinven's '*buy and build*' strategy, under Cinven's ownership the AMCo Group also implemented Cinven's strategy by leveraging the absence of competition and weak regulation of niche generic drugs to increase prices. In fact, the '*buy and build*' strategy went hand in hand with the strategy of exploiting niche generics, as explained above in relation to the Focus Pharma group acquisition.

7.120 Cinven therefore implemented its investment strategy by exercising decisive influence over the AMCo Group's business, including through adopting a 100-day action plan and a Value Creation Plan, acquiring additional assets, appointing individuals to key positions on AMCo Group boards, putting in place reporting lines to ensure it was able effectively to monitor its investment, and overseeing the

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including reorganising sales and marketing functions; developing technical plans for its software to reduce customer churn; and *'instituting a formal and robust long-term strategic planning process'*.

[1842] Cinven: *'Annual Review 2014'*, page 24 (URN: PAD055).

[1843] Cinven: *'Annual Review 2014'*, page 25 (URN: PAD055). As above, the term *'Cinven' 'means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006) and/or funds managed or advised by any of the foregoing'*. See page 1.

AMCo Group's commercial conduct, ensuring that the AMCo Group continued the strategy to focus on '*niche drugs*'.

Preparing for the 'ultimate exit'

7.121 Finally, Cinven's divestment of the AMCo Group and its strategy and decisions in the run-up to that divestment demonstrate that it continued to explore and implement initiatives that continued its investment strategy for the AMCo Group. Statements made by Cinven and AMCo Group management when the divestment was announced demonstrate that the investment in the AMCo Group had been successful and that Cinven had played a decisive role in that success.

7.122 Cinven's '*AMCo exit paper*', prepared in February 2015, stated:

> *'We have worked with McKinsey to help to define AMCo's strategy … We have also identified the weaker areas of AMCo's business and are working to address these*
>
> *…*
>
> *While M&A would allow us to address these matters more quickly, given it involves external parties, it remains somewhat outside of our control*
>
> *…*
>
> *We have a Cinven friendly SHA [shareholders' agreement] in place, where we retain full control in exit (including information rights and controlling access to bidders)*
>
> *Management's interests are largely aligned with ours, although a later sale would likely be the preferred option by most of the management as it would increase their likely capital gain … We are aware of management's incentivisation and are continuing to monitor it closely. We have allowed the management team to meet a number of private equity funds'*.[1844]

7.123 The exit paper made clear that Cinven:

7.123.1 Was able to 'define AMCo's strategy';

7.123.2 Considered that internal initiatives (not involving third parties) were subject to its '*control*';

7.123.3 Retained full control in exit; and

[1844] Document entitled *'AMCo - Exit Paper'* dated 27 February 2015, pages 3, 11 and 13 (emphasis added) (URN: PRO-E004100). Compare to document *'Q4 PRC Paper on Amco dated December 2014'*, page 1 (URN: PRO-E004099): [✂].

7.123.4 Was aligned with AMCo Group management on exit strategy (but need not be: it was Cinven that made the call on when divestment would take place).

7.124 The paper also noted, under '*Strategic initiatives*', that:

> *'In order to improve the attractiveness of AMCo on exit we are working on a number of business initiatives. [✂].*[1845]

7.125 The exit paper therefore also made clear that the strategic business initiatives devised at the time of disposing of the AMCo Group were [✂].

7.126 Cinven succeeded in using its expertise to increase significantly the value of the AMCo Group. Cinven bought the Mercury Pharma group for £465 million and the Amdipharm group for £367 million,[1846] and sold the combined AMCo Group three years later for £2.3 billion,[1847] making a profit of £1.5 billion. Its (approximately three-year) investment *'returned cash proceeds of 3.5x cost'*.[1848] In its own press release announcing the sale to Concordia International (now Advanz), Cinven described the combination of the two businesses as '*transformative*' and emphasised its role in engineering it:

> *'Cinven created AMCo, which focuses on the sale of niche prescription off-patent products, in 2012 through the transformative merger of Mercury Pharma ('Mercury') and Amdipharm, both of which were acquired in bilateral transactions, in August and October 2012 respectively'.*

7.127 [Cinven Partner] commented:

> *'Cinven successfully created AMCo – through the combination of two businesses – as a result of bilateral transactions and our strong healthcare sector focus and track record. We saw an opportunity to create significant value through the consolidation of the relatively fragmented, off-patent, niche pharmaceuticals market and AMCo has certainly achieved that. We have worked closely with the highly capable management at AMCo, led by [AMCo Director 1], in further strengthening the senior team, internationalising the business, executing and integrating several acquisitions as part of our 'buy and build' strategy, and optimising AMCo's capital structure in order to most effectively achieve growth'.*

7.128 [AMCo Director 1] stated:

[1845] Document entitled *'AMCo - Exit Paper'* dated 27 February 2015, page 11 (emphasis added) (URN: PRO-E004100).

[1846] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 9 (URN: PRO-E004554).

[1847] Concordia paid USD1.2 billion in cash, USD700 million in shares and USD220 million in additional payments relating to the AMCo Group's future performance, as well as assuming its net debt. See FT article: *'Cinven to sell AMCo to Concordia in £2.3bn deal'* (URN: PAD050).

[1848] See Cinven: *'Annual Review 2015'*, page 4 (URN: PAD052).

'Cinven has been instrumental in the growth and success of the AMCo business, starting with the initial combination of Mercury Pharma with Amdipharm which made us a truly international player. Subsequently, they have provided considerable assistance in areas including international expansion, through their Portfolio team in Asia and Europe; and expertise in M&A, and integration to ensure we generated the most upside quickly from the acquisitions we made. They have been first class in their understanding of the healthcare sector and the dynamics and drivers of our business'.[1849]

7.129 The *Times* wrote:

'A private equity firm has made about £1.5 billion from buying and selling generic drug companies that exploit NHS rules to impose huge increases in the price of medicines

…

The combined strategy generated a massive profit for the private equity company when it sold AMCo last October in a deal valued at £2.3 billion, including almost £1 billion debt – five times the value of its original investment. [Cinven Partner], a partner in Cinven, said it was one of his most successful deals.'[1850]

7.130 Cinven submitted that [✂].[1851] However, as explained in paragraph 7.46 above, the EU Courts have limited the concept of a '*pure financial investor*' (potentially lacking decisive influence) to '*the case of an investor who holds shares in a company in order to make a profit, but who refrains from any involvement in its management and in its control*'.[1852] This was not the case with Cinven, as the documents discussed in this section demonstrate. In particular, case law shows that financial investors that actively engage with their portfolio companies to effect change – as Cinven did – are likely to exercise decisive influence over them.[1853] For this reason the courts, the Commission and Member States' national competition authorities have held parent companies focused on financial investment liable for infringements committed by their portfolio companies in numerous cases.[1854]

[1849] Cinven press releases: *'AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp'* (emphasis added) (URN: PAD043).

[1850] The Times article: '*Firm's £1.5bn drug profit is bitter pill for taxpayer*', June 2016 (emphasis added) (URN: PAD056).

[1851] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.1(b)(iv) and 12.79-12.85 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1852] T-392/09 1. *garantovaná a.s. v Commission*, EU:T:2012:674, paragraph 52, citing the Opinion of Advocate General Kokott in C-97/08 *Akzo Nobel v Commission*, EU:C:2009:262.

[1853] For example, T-395/09 *Gigaset AG v Commission,* EU:T:2014:23, paragraphs 37-38.

[1854] See, for example, T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, upheld in C-595/18 P *Goldman Sachs v Commission*; Commission decision of 19 June 2013 in Case 39226 *Lundbeck*, upheld in T-471/13 *Xellia Pharmaceuticals and Alpharma v Commission*, EU:T:2016:460; Commission decision of 9 July 2014 in Case 39.612

7.131 Cinven's *'active'* and *'engaged'* ownership;[1855] its *'targeted, systematic and on-going'* operational input;[1856] its instigation of *'the transformative merger'*[1857] of two corporate groups and the acquisitions of others including the Focus Pharma group; its success in generating a very substantial profit drawing on its knowledge of the pharmaceutical sector and in particular its understanding of the opportunities presented by the *'little jewellery boxes'* of *'unloved'* niche generic drugs,[1858] demonstrate that it was no pure financial investor in the AMCo Group. Cinven combined the Mercury Pharma and Amdipharm groups and placed them under a single management team; it put in place a strategy and business plan and ensured these were implemented and regularly reported on; it acquired and integrated the Focus Pharma group into the AMCo Group in pursuit and continuation of that strategy; and its investment in the AMCo Group was successful, with this success being attributable according to both [Cinven Partner] and [AMCo Director 1] to Cinven's active management of the AMCo Group.

7.132 For all these reasons, the CMA considers it appropriate to hold entities associated with Cinven liable for the Infringement committed by Focus during the Cinven Period and rejects Cinven's submission that [✂].[1859]

The roles of the Cinven Entities

7.133 It is therefore clear that Cinven exercised decisive influence over the AMCo Group.

7.134 The law requires that liability for the Infringement committed by Focus is attributed to legal persons on whom fines may be imposed.[1860] The CMA must therefore identify the legal entities within Cinven to which liability for the Infringement can be attributed.[1861]

Perindopril (Servier), upheld in T-705/14 *Unichem v Commission*, EU:T:2018:915 and T-682/14 *Mylan v Commission*, EU:T:2018:907; T-395/09 *Gigaset AG v Commission,* EU:T:2014:23; Dutch AGCM decisions in *Meneba*, Decisions 6306_20/217_OV (20 November 2014) and 6306_20/259 (11 September 2015); District Court of Rotterdam judgment of 26 January 2017, NL:RBROT:2017:588.

[1855] Cinven: *'Annual Review 2014'*, page 120 (URN: PAD055). Document entitled *'Annex 1 - Cinven Annual Review 2011'*, page 18 (URN: PRO-E004553).

[1856] Cinven: *'Annual Review 2014'*, page 24 (URN: PAD055).

[1857] Cinven press releases: *'AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp'* (URN: PAD043).

[1858] FT: *'Cinven accelerates into UK healthcare'* (URN: PAD044).

[1859] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.3 and 12.86 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1860] C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 54 to 57.

[1861] Cinven submitted that [✂] (Cinven RSO, 15 August 2019, Annex 2, paragraph 10.19 (URN: PRO-C5134), Cinven's RSSO in Case 50395). See also Cinven RSO, 15 August 2019, Annex 1, paragraph 12.40(f) (URN: PRO-C5134), Cinven's in RSO in Case 50395; Cinven RSO, 15 August 2019, paragraph 10.19 (URN: PRO-C5132). The CMA rejects this submission. It is clear from the contemporaneous evidence cited in the sections above that the Cinven private equity house exercised decisive influence over the Focus Companies. In the following sections, the CMA has set out how that decisive influence was exercised through specific legal entities, as the law requires.

7.135 Cinven bought the Amdipharm and Mercury Pharma groups and the Focus Pharma group, and sold the combined AMCo Group, through the Fifth Cinven Fund. [✂].[1862] [✂].

7.136 [✂].

Figure 6: [✂]

[✂]

7.137 As this diagram shows, the structure of the fund was complex. Despite this complexity, however, for the purposes of this case there are three core entities and a handful of core individuals through which Cinven exercised decisive influence over the Focus Companies:

7.137.1 [✂].[1863] [✂];

7.137.2 [✂];

7.137.3 [✂].

7.138 As noted at paragraph 7.73.3, in this Chapter the CMA refers to Cinven MGP, Luxco 1 and Cinven Partners together as the **Cinven Entities**.

7.139 Notwithstanding the complexity of the Fifth Cinven Fund, the Cinven Entities were structurally and – most importantly – personally connected:

7.139.1 [✂].[1864]

7.139.2 [✂].[1865] [✂].

7.139.3 [✂].[1866] [✂].

7.139.4 [✂].[1867]

[1862] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 9.7 (URN: PRO-E004435). See also document entitled *'Amended and Restated Limited Partnership Agreement'* dated 28 March 2013, clause 4.1.3 (URN: PRO-E004473), limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership: [✂].

[1863] [✂] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraphs 9.4-9.5 (URN: PRO-E004435). See also document entitled *'Amended and Restated Limited Partnership Agreement'* dated 28 March 2013, recital (1), definitions and clauses 4.1.1 and 4.2 (URN: PRO-E004473), the limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership (Annex 37 to the Section 26 response dated 2 November 2016 (URN: PRO-E004435)).

[1864] Document entitled *'Cinven Partners LLP Partnership Agreement'* dated 17 February 2012, clause 8 (URN: PRO-E004114). [✂].

[1865] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 9.12 (URN: PRO-E004435).

[1866] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 9.12 (URN: PRO-E004435).

[1867] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 9.14 (URN: PRO-E004435).

7.139.5 [✂].

7.140 These connections ensured that the Cinven Entities acted as one in relation to the AMCo Group investment.

7.141 Cinven publicly emphasised that its '*active ownership approach*' was *'underpinned'* by a *'complete alignment'* between the interests of its Partners, fund entities such as Cinven MGP and Luxco 1 and portfolio companies such as the Focus Companies. [✂] during the Cinven Period stated:

> *'there is a clear alignment of interest between investors, owners and portfolio companies, focused on creating value through growing sales and EBITDA*
>
> *…*
>
> *Partnership alignment:*
>
> *Cinven is a collegial partnership … Our incentives and remuneration are directly linked to the performance of our portfolio companies and funds. This complete alignment with our investing interests underpins our active ownership approach'.*[1868]

7.142 Cinven described this as a "*one team' approach*' that it followed throughout the lifetime of an investment:

> *This integrated, one team culture of trust and partnership lies at the heart of Cinven's success.*
>
> *…*
>
> *Cinven is wholly owned by its 25 Partners. A widely-spread, single pot incentive structure reinforces the one team ethos. Incentives are directly aligned with the performance of our Portfolio companies and the returns to our investors'*[1869]
>
> *'Ours is a 'one team' approach.'*[1870]

7.143 Cinven submitted that [✂].[1871] However, the CMA finds that the evidence shows that pursuant to this "'*one-team' approach*", the interests of each of the Cinven

[1868] Document entitled *'Annex 1 - Cinven Annual Review 2011'*, pages 4 and 7 (URN: PRO-E004553) (emphasis added).

[1869] Document entitled *'Annex 1 - Cinven Annual Review 2011'*, page 25 (URN: PRO-E004553) (emphasis added).

[1870] Document entitled *'Annex 2 - Cinven Annual Review 2012'*, page 7 (URN: PRO-E004554) (emphasis added). See also page 30: *'Our interests are directly aligned with our Limited Partner investors and our portfolio companies, building value'* (emphasis added).

[1871] Cinven RSO, 15 August 2019, Annex 2, paragraph 10.14(g) (URN: PRO-C5134), Cinven's RSSO in Case 50395.

Entities and the Focus Companies were aligned in pursuit of their common strategy of exploiting the profit opportunities presented by niche generic drugs.

7.144 Each of the Cinven Entities played a specific role in the AMCo Group investment, and was able to and did actually exercise decisive influence over the Focus Companies as will be explained in the sections that follow:

7.144.1 [✂];

7.144.2 [✂];

7.144.3 [✂].

The legal test for attributing liability to the Cinven Entities

7.145 Before explaining the CMA's legal analysis of the decisive influence exercised by each of the Cinven Entities, the CMA here responds to Cinven's representations on the legal test.

7.146 Cinven submitted that [✂]:

> [✂].[1872]

7.147 [✂].[1873]

7.148 This submission is misdirected.

7.149 The phrase '*a specific economic aim on a long-term basis*' derives from the EU General Court's description of an undertaking:

> *'Article [101] of the Treaty is aimed at economic units which consist of a unitary organisation of personal, tangible and intangible elements, which pursue a specific economic aim on a long-term basis and can contribute to the commission of an infringement of the kind referred to in that provision.'*[1874]

7.150 This is not, however, the legal test for attributing liability to parents. The assessment of whether a parent exercises decisive influence over a subsidiary turns on the organisational, economic and legal links between the two entities. A shared commercial policy may be inferred from the totality of such links. However, the test does not require a common economic aim in the sense of the parent's

[1872] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.1(a) (URN: PRO-C5134), Cinven's RSO in Case 50395. Cinven repeated this argument in Cinven RSO, 15 August 2019, Annex 2, paragraphs 10.4-10.8 (URN: PRO-C5134), Cinven's RSSO in Case 50395. See also Cinven RSO, 15 August 2019, paragraphs 10.6-10.15 (URN: PRO-C5132).

[1873] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.1(a) and 12.7-12.9 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1874] T-9/99 *HFB v Commission*, EU:T:2002:70, paragraph 54. See also T-11/89 *Shell v Commission*, paragraphs 308-312.

influence over commercial conduct or that the parent and subsidiary are active in the same commercial sector.[1875] This has been specifically confirmed in more recent caselaw. For example, in T-399/09 *Holding Slovenske v Commission* the EU General Court rejected HSE's argument that it could not be liable for an infringement committed by its subsidiary because it '*never shared any single economic aim*' with its subsidiary.[1876] The EU General Court held that:

> *'It can be seen from the reasoning of the latter judgment [T-112/05 Akzo v Commission] … that, contrary to what the applicant appears to believe, the expression in question ['a single economic aim on a long-term basis'] cannot be understood as meaning that there must be an affinity between the business sectors in which the various legal persons making up an economic unit are active, nor even that the existence of a single economic unit is incompatible with the existence of an activity in several different, entirely unrelated, sectors'.*[1877]

7.151 Similarly, in *Kendrion v Commission* the EU Court of Justice followed the Opinion of the Advocate General, who noted that:

> *'It cannot follow from the fact that a wholly-owned subsidiary is acquired as a financial investment and that its activities are outside the sphere of the parent company's normal operations that the two companies do not comprise the same undertaking. On the contrary: on the assumption that the purpose of an investment is to yield a return, it seems to me that, in order to ensure greater profitability from that investment, any parent company would have a strong incentive to exercise a decisive influence over its subsidiary's commercial policy'.*[1878]

7.152 Where a parent company exercises decisive influence over a subsidiary it forms a single undertaking with that subsidiary. That is the legal test to be applied to the Cinven Entities' relationship with the Focus Companies.[1879]

[1875] T-682/14 *Mylan v Commission*, paragraph 347 and the cases cited. *Durkan Holdings Limited v OFT* [2011] CAT 6, paragraph 22; Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 87, approved in C-97/08 P *Akzo Nobel v Commission,* EU:C:2009:536, paragraphs 73 to 74.

[1876] T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraphs 44 and 46.

[1877] T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraph 56 (emphasis added). See also paragraphs 49-50 and 54: '*What is relevant is the question whether … the applicant, during the infringement period, exercised a decisive influence over its subsidiary, with the result that they could be considered as constituting, during that period, an economic unit. Contrary to the applicant's submission, neither its alleged intention to sell its shareholding in [the subsidiary] to another investor nor the fact that the latter was active in an entirely different commercial sector from its own precludes the exercise of such decisive influence … the mere fact that the parent company and its subsidiary are active in different economic sectors, or even that the personnel of the parent company have no expertise in the specific commercial sector in which the subsidiary is active does not preclude the exercise of a decisive influence by the parent company over its subsidiary, even if the latter enjoyed a certain level of autonomy in the management of its business*'.

[1878] Opinion of Advocate General Sharpston in C-50/12 P *Kendrion v Commission*, EU:C:2013:350, paragraph 54, followed in C-50/12 P, EU:C:2013:771.

[1879] See C-97/08 *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 58-59.

7.153 In any event, in this case not only can a shared commercial policy be inferred indirectly from the totality of the organisational, economic and legal links between the Cinven Entities and the Focus Companies explained in the sections that follow; the evidence explained in the sections above directly shows that the Cinven Entities did share with the AMCo Group a specific economic aim throughout Cinven's ownership: to exploit the absence of regulation for niche generic drugs in order to extract high profits. That strategy was driven by Cinven.

7.154 Cinven's second submission was that [✂].[1880]

7.155 The CMA rejects this submission. As explained in paragraph 7.25 above, it is clear that there is no exhaustive set of criteria or 'checklist' to be completed when considering parental liability.[1881] Nor is any specific instruction from the parent required.[1882] The CMA considers in detail in the sections that follow an extensive range of economic, organisational and legal links between the Cinven Entities and the Focus Companies, many of which taken in themselves would be sufficient to establish the exercise of decisive influence (for example, the evidence that Cinven MGP edited and approved the AMCo Group budget).[1883] The evidence all points in the same direction.

Liability of Cinven MGP

7.156 Cinven MGP exercised decisive influence over the Focus Companies throughout the Cinven Period, as a result of the legal, organisational and economic links between Cinven MGP and the Focus Companies:

7.156.1 Cinven MGP had the ability to exercise decisive influence over the Focus Companies:

(a) The Focus Companies were wholly owned by AML throughout the Cinven Period.[1884] The CMA therefore concludes, on the basis of the

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[1880] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.6, 12.7 and 12.10-12.14 (URN: PRO-C5134), Cinven's RSO in Case 50395. Cinven RSO, 15 August 2019, Annex 2, paragraph 10.7 (URN: PRO-C5134), Cinven's RSSO in Case 50395.

[1881] See, for example, C-628/10 P *Alliance One v Commission*, EU:C:2012:479, paragraph 45: 'In order to establish whether a subsidiary determines its conduct on the market independently, the Commission is, as a general rule, bound to take into consideration the economic, organisational and legal links which tie that subsidiary to the parent company, which may vary from case to case and cannot therefore be set out in an exhaustive list'; T-141/07 *General Technic-Otis v Commission*, paragraph 103. See also C-179/12 P *Dow v Commission*, EU:C:2013:605, paragraph 54 and the case law cited: '*The Court of Justice has stipulated that account must be taken of all the relevant factors relating to the economic, organisational and legal links which tie the subsidiary to the parent company, which may vary from case to case and cannot therefore be set out in an exhaustive list*'.

[1882] T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605. See also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraph 22(b); C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 41, citing C-293/13 P *Del Monte v Commission*, EU:C:2015:416, paragraphs 96-97.

[1883] The mere holding of a veto right over certain strategic commercial decisions (such as the adoption of a business plan or budget) can in itself confer decisive influence: C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63-67.

[1884] Document entitled '*Annex 4 _ Structure chart of the Mercury Pharma group following _1110204_0*' (URN: PRO-E004440), structure chart of the Mercury Pharma group as at 31 August 2012; document '*Annex 5 _ Structure chart of*

Akzo presumption, that AML exercised decisive influence over the Focus Companies. The parties have not disputed this and the *Akzo* presumption has therefore not been rebutted.[1885]

(b) Cinven MGP had the ability to exercise decisive influence over AML (and through AML, over each of AML's wholly-owned subsidiaries, including the Focus Companies) through its: (i) control of Cinven's majority shareholding and voting rights in AML; and (ii) control of Cinven's rights (including veto rights) under an AML shareholders' agreement.[1886]

7.156.2 Cinven MGP did actually exercise decisive influence over the Focus Companies by:

(a) exercising Cinven's rights under that shareholders' agreement, including to appoint directors to the boards of AML and other AMCo Group companies, to approve the AMCo Group budget and specified matters such as material transactions, and to obtain strategic and operational information about the AMCo Group's performance; and

(b) overseeing the AMCo Group's commercial conduct as its management sought to implement the strategy of increasing the prices of niche generic drugs that Cinven and the AMCo Group shared.

Cinven MGP had the ability to exercise decisive influence over the Focus Companies

Cinven MGP's control of Cinven's majority shareholding and voting rights in AML

7.157 Cinven MGP controlled a majority of the shares and voting rights in AML [✂].[1887]

the Amdipharm group following the A_1110205_0' (URN: PRO-E004441), structure chart of the Amdipharm group as at 31 October 2012; document '*Annex 6 _ Structure chart of the Amdipharm Mercury combined grou_1113301*' (URN: PRO-E004442), structure chart of the Amdipharm Mercury combined group; document '*Annex 44 _ Organisational chart illustrating the structure of th_1110227_0*' (URN: PRO-E004480), and the Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 1.8 (URN: PRO-E004435).

[1885] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.4 (URN: PRO-C5134), Cinven's RSO in Case 50395: *'The Cinven [Entities] do not contest the decisive influence that AML held over its subsidiaries within the AMCo Group.'*

[1886] As explained below, the shareholders in AML were [✂]. Cinven MGP controlled those [✂], had exclusive authority to act on their behalf, and exercised their rights as shareholders in AML.

[1887] According to the structure charts submitted by Cinven (Document '*Annex 4 _ Structure chart of the Mercury Pharma group following _1110204_0*' (URN: PRO-E004440); document '*Annex 5 _ Structure chart of the Amdipharm group following the A_1110205_0*' (URN: PRO-E004441); document '*Annex 6 _ Structure chart of the Amdipharm Mercury combined grou_1113301*' (URN: PRO-E004442); and document '*Annex 44 _ Organisational chart illustrating the structure of th_1110227_0*' (URN: PRO-E004480), structure chart of the Fifth Cinven Fund) [✂] (Cinven MGP's stake at that point can be seen in document '*Annex 44 _ Organisational chart illustrating the structure of th_1110227_0*' (URN: PRO-E004480); Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 1.8 (URN: PRO-E004435).

7.158 The shareholders in AML were [✂].[1888] [✂].[1889] [✂].[1890] This made Cinven MGP equivalent to a majority shareholder in AML and the *de facto* holder [✂] over AML and, through it, the Focus Companies, deriving from that shareholding.[1891]

7.159 The stakes of the other shareholders were fragmented and none of them held any rights other than those typically granted to minority shareholders.[1892]

7.160 [✂].[1893]

7.161 [✂].[1894] [✂][1895] this meant that in practice Cinven MGP controlled the majority of voting rights in AML and no other shareholder could block any shareholder decisions Cinven MGP wanted to make in relation to AML, and therefore the Focus Companies.

7.162 Cinven MGP's control of Cinven's majority shareholding and voting rights in AML therefore enabled Cinven MGP to exercise decisive influence over AML, and in particular over AML's and the Focus Companies' market conduct.[1896]

7.163 [✂].[1897] [✂].[1898]

[1888] [✂].

[1889] [✂].

[1890] [✂].

[1891] The EU Court of Justice has confirmed that decisive influence can be exercised by a legal entity that holds the voting rights in a subsidiary (without necessarily holding the shares): C-595/18 P *Goldman Sachs v Commission*, paragraphs 29-36, upholding T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 50 to 52. Elsewhere, the courts have held that ownership is one, but not the only or a necessary reason for a finding of decisive influence. For example, in C-293/13 P *Fresh Del Monte v Commission*, EU:C:2014:2439, AG Kokott noted that the principles of decisive influence '*can also easily be applied to the case of a partnership*' rather than a '*parent company-subsidiary relationship in the traditional sense*', and that '*All the parties to the proceedings were in agreement on this point, and the General Court likewise rightly took that premiss as its starting point*' (paragraph 75). The EU Court of Justice followed this Opinion: C-293/13 P *Fresh Del Monte v Commission*, EU:C:2015:416, paragraphs 79-80.

[1892] [✂] Document entitled '*Annex 5 _ Structure chart of the Amdipharm group following the A_1110205_0*' (URN: PRO-E004441); document '*Annex 6 _ Structure chart of the Amdipharm Mercury combined grou_1113301*' (URN: PRO-E004442); and document '*Annex 44 _ Organisational chart illustrating the structure of th_1110227_0*' (URN: PRO-E004480).

[1893] Document '*Annex 9 _ Articles of Association of Amdipharm Mercury Limited*', clause 4.3.1(a) and 4.3.2(a) (URN: PRO-E004445). [✂].

[1894] Section 26 response of Cinven dated 28 July 2017, to the CMA Notice of 11 July 2017, question 1 (URN: PRO-E004510). [✂] (Document '*Annex 1 - CCM Pharma Limited Register of Members and Share Ledger'* dated 28 September 2012 (URN: PRO-E004512); document '*Annex 2 - Amdipharm Mercury Limited Register of Members and Share Ledger'* dated 1 May 2014 (URN: PRO-E004513); and document '*Annex 3 - Concordia International (Jersey) Limited Register of Members and Share Ledger'* dated 28 October (URN: PRO-E004514)).

[1895] Section 26 response of Cinven dated 28 July 2017, to the CMA Notice of 11 July 2017, question 1 (URN: PRO-E004510), Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraphs 9.3-9.5 and 9.7 (URN: PRO-E004435), and clause 4.1.1 of the Cinven Limited Partnerships' limited partnership agreements (for example, the document entitled [✂] (URN: PRO-E004473), the limited partnership agreement of Fifth Cinven Fund [✂].

[1896] As explained in the Legal Framework section above, the EU General Court has held that '*It is generally the case that if a parent company holds a majority interest in the subsidiary's share capital, that can enable it actually to exercise decisive influence on its subsidiary and, in particular, on the subsidiary's market conduct*'. T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 182; T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 96.

[1897] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.11 and 12.16 and footnote 685 (URN: PRO-C5134), Cinven's RSO in Case 50395. Cinven repeated these arguments in Cinven RSO, 15 August 2019, Annex 2, paragraphs 10.11-10.12 (URN: PRO-C5134), Cinven's RSSO in Case 50395.

[1898] Cinven RSO, 15 August 2019, Annex 1, footnote 696 (URN: PRO-C5134), Cinven's RSO in Case 50395.

7.164 The CMA nonetheless concludes that Cinven MGP was equivalent to a majority shareholder and that it is an appropriate entity to hold liable for the Infringement committed by the Focus Companies [✂].[1899] [✂].[1900]

Cinven MGP's control of Cinven's rights under the AML shareholders' agreement

7.165 During the Cinven Period, the relationship between the shareholders in AML was governed by a shareholders' agreement (the '**AML Shareholders' Agreement**').[1901]

7.166 The AML Shareholders' Agreement gave the Cinven Limited Partnerships important rights over AML and over the Focus Companies (both directly, where rights explicitly referred to the AMCo Group, and indirectly, through AML as the 100% owner of the Focus Companies). These rights were controlled by Cinven MGP because:

7.166.1 [✂].

7.166.2 [✂].[1902] [✂].[1903]

7.167 [✂].[1904] [✂].[1905]

7.168 [✂]

7.168.1 [✂][1906] [✂].[1907] [✂].

7.168.2 [✂].[1908]

7.168.3 [✂].[1909]

[1899] Section 26 response of Cinven dated 28 July 2017, to the CMA Notice of 11 July 2017, question 1 (URN: PRO-E004510); Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraphs 9.3-9.5 and 9.7 (URN: PRO-E004435).

[1900] [✂].

[1901] Document '*Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, clause 9.1.1 (URN: PRO-E004443). [✂] (Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraphs 3.1 (URN: PRO-E004435)).

[1902] Section 26 response of Cinven dated 28 July 2017, to the CMA Notice of 11 July 2017, question 1 (URN: PRO-E004510).

[1903] [✂].

[1904] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.21 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1905] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.24 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1906] [✂].

[1907] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, clause 9.1.1 (URN: PRO-E004443).

[1908] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, clause 9.3.1 (URN: PRO-E004443).

[1909] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, clause 9.4.1 (URN: PRO-E004443).

7.169 [✂].[1910] [✂].

7.170 These rights in themselves gave Cinven MGP the ability to exercise decisive influence over AML, whose board set the strategic direction for its wholly-owned subsidiaries, including the Focus Companies[1911] – and over all its subsidiaries, including the Focus Companies.[1912] As explained above, during the Cinven Period, Cinven described the AML Shareholders' Agreement as *'a Cinven friendly SHA [shareholders' agreement] … where we retain full control'*. [1913]

7.171 [✂].[1914]

7.171.1 [✂].[1915] [✂]

7.171.2 [✂].

7.171.3 [✂].

7.171.4 [✂].

7.171.5 [✂].[1916]

7.172 [✂].[1917] [✂].

7.173 [✂][1918] [✂].[1919] [✂]

7.173.1 [✂];

[1910] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, clause 9.2 (URN: PRO-E004443).

[1911] AMCo's '*Annual Review 2013*', page 16: '*The strategic direction of the AMCo Group is set by the board of its ultimate parent company Amdipharm Mercury Limited*' (URN: PAD034).

[1912] As explained above, the EU General Court has held that: '*the ability to decide upon the composition of the board of directors of a company constitutes an objective factor which determines, in itself, whether it is possible to control the decisions that may be adopted by the board and, therefore, by the company concerned. The board of directors constitutes, by definition, the body responsible for administering and representing the company.*' T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 91 (emphasis added). Upheld in C-595/18 P *Goldman Sachs v Commission*.

[1913] Document entitled *'AMCo - Exit Paper'* dated 27 February 2015, page 13 (URN: PRO-E004100).

[1914] Document '*Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, clauses 5.2, 6.1 and Schedule 7, Part A (URN: PRO-E004443). Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, in which Toshiba's veto rights over the joint venture's material investments, capital participation in or acquisition of a company or other business, and the provision of loans to subsidiary companies were relevant factors in the court's finding that it exercised decisive influence (paragraphs 71 to 72 of the judgment).

[1915] Document '*Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0*', clause 5.2 (URN: PRO-E004443).

[1916] Document '*Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0*', clause 6.1 and Schedule 7 Part A (URN: PRO-E004443).

[1917] Document '*Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0*', clauses 6.1 and 1.1 (URN: PRO-E004443).

[1918] [✂].

[1919] [✂].

7.173.2 [✂].[1920]

7.174 [✂].[1921] [✂].[1922]

7.175 [✂].[1923] [✂].[1924]

7.176 [✂][1925] [✂] Cinven MGP [✂] effectively had control of strategic commercial decisions with respect to the entire AMCo Group (and therefore the Focus Companies) [✂].[1926] [✂].

7.177 [✂].[1927] [✂]

7.177.1 [✂].[1928]

7.177.2 [✂].[1929]

7.177.3 [✂].[1930]

7.177.4 [✂].[1931]

7.177.5 [✂].[1932]

7.178 These information rights ensured that Cinven MGP was able to intervene to protect its investment whenever necessary.

7.179 Cinven MGP's control [✂] gave it the ability to exercise decisive influence over AML, and over each of its subsidiaries (including, during the Cinven Period, the Focus Companies).

[1920] [✂].

[1921] [✂].

[1922] [✂].

[1923] [✂].

[1924] [✂].

[1925] [✂].

[1926] Compare T-543/08 *RWE v Commission*, EU:T:2014:627, paragraphs 30 to 32; T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47 (upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006).

[1927] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, clauses 5.1 and 5.4 (URN: PRO-E004443).

[1928] Document '*Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, Schedule 6 Part A, paragraph 2.1 (URN PRO-E004443).

[1929] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0',* Schedule 6 Part A, paragraph 1 (URN: PRO-E004443).

[1930] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, Schedule 6 Part A, paragraph 3 (URN: PRO-E004443).

[1931] Document *'Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, Schedule 6 Part B, paragraph 5 (URN: PRO-E004443).

[1932] Document '*Annex 7 _ Investment and shareholders_ agreement as amended and _1110207_0'*, Schedule 6 Part A, paragraph 4.3 (URN: PRO-E004443).

Cinven MGP did actually exercise decisive influence over the Focus Companies

7.180 [✂].

Cinven MGP exercised the right to appoint directors to the boards of AML and other AMCo Group companies

7.181 Cinven MGP exercised the right to appoint directors to AML's board.

7.182 Cinven MGP [✂] appointed two Investor Directors to exercise the Majority Investors' rights under the AML Shareholders' Agreement: [✂].[1933] [✂].[1934]

7.183 The Investor Directors sat on the board of AML throughout the Cinven Period.[1935]

7.184 Further, throughout the Cinven Period, the board of AML was composed entirely of directors appointed by Cinven MGP. [✂][1936] [✂].[1937] [✂].[1938]

7.185 [✂].[1939] Cinven MGP therefore exercised decisive influence over AML, and through AML over the Focus Companies, '*through its prevailing presence on [AML]'s Board of Directors*'.[1940] As explained above, the Focus Companies were each 100% owned by AML throughout the Cinven Period, and Cinven has not disputed the application of the Akzo presumption between AML and the Focus Companies. The AMCo Group executive management, including [AMCo Director

[1933] Cinven: *'[Cinven Partner]'* (URN: PAD049).

[1934] Cinven: *'[Cinven Partner]'* (URN: PAD047).

[1935] List of AML directors between 31 August 2012 and 21 October 2015 (URN: PRO-E004540); Section 26 response of Cinven dated 28 July 2017, to the CMA Notice of 11 July 2017 (URN: PRO-E004510); clarification in respect of [Cinven Partner] in Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 7.2(a) (URN: PRO-E004494).

[1936] Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 7.1 (URN: PRO-E004494).

[1937] Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 5 (URN: PRO-E004494); Engagement letters dated 6 July 2012 (URN: PRO-E004505), 24 September 2012 (URN: PRO-E004506) and 5 November 2012 (URN: PRO-E004507).

[1938] Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 7.1 (URN: PRO-E004494).

[1939] [✂] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 3.12 (URN: PRO-E004435). As explained above, the presence on the subsidiary's board of directors of individuals who also hold managerial posts within the parent constitutes an organisational link between the two entities. The facts that these individuals may simultaneously be directors of many other companies, and may not be involved in day-to-day operations, are not inconsistent with a finding that this link enables the exercise of decisive influence. Even where one such individual was simultaneously a board member of around 40 other companies, and was not 'hands-on', instead receiving mainly reports on finance and 'major moves' from the relevant subsidiary's managing director around three times a year, that did not prevent the individual from 'dealing fairly intensively with' the relevant subsidiary, or contributing to the finding that the parent exercised decisive influence. T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraphs 53 to 60; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

[1940] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 3017, upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89. Currently on appeal to the EU Court of Justice: C-166/19 P. The EU General Court noted that '*the position of member of the board of directors of a company entails by its very nature legal responsibility for the activities of the company as a whole, including its conduct on the market*' (paragraph 77 and caselaw cited). Compare Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, in which the fact that AL Industrier AS had the right to appoint six out of 9 members of its subsidiary's board was a relevant factor in the Commission's decision to hold it liable (paragraph 1283).

1], [✂], did not sit on the AML board but reported to it. The board of AML met at least once every quarter, with additional meetings held as necessary to discuss specific points such as group restructurings, share transfers to AMCo Group managers and the sale of the AMCo Group to Concordia Healthcare Corporation (now Advanz).[1941]

7.186 [✂]. These directors were influential individuals whose appointment to multiple companies throughout the AMCo Group served further to entrench Cinven MGP's decisive influence:

7.186.1 In addition to their positions as Investor Directors on the board of AML, [Cinven Partner] and [Cinven Partner] were also appointed to the board of Mercury Pharma Group Limited, the immediate 100% parent of Focus Pharma Holdings Limited and indirect 100% parent of Focus Pharmaceuticals Limited, throughout the Cinven Period. Mercury Pharma Group Limited was also the immediate 100% parent of Amdipharm Mercury Company Limited (now Advanz Pharma Services (UK) Limited), the company that employed the AMCo Group management including [AMCo Director 1], [✂]. [Cinven Partner] was appointed to the boards of six other AMCo Group companies (both holding companies and operating companies) during the Cinven Period.[1942]

7.186.2 [✂].[1943]

7.187 Through the appointment of these individuals to key companies in the AMCo Group, Cinven MGP consolidated its decisive influence over the Focus Companies. As board members, they had legal responsibility for the activities of the companies to which they were appointed, including their conduct on the market.[1944] As explained in the section Liability of Cinven Partners, paragraphs 7.219-7.275 below, each of these individuals played an important role in devising and implementing Cinven's strategy for the AMCo Group, contributing in particular to the recommendations to acquire and combine the Mercury and Amdipharm groups; for the combined AMCo Group to make follow-on acquisitions, including of the Focus Pharma group; and for the Fifth Cinven Fund to divest the AMCo Group.

7.188 Cinven MGP also appointed non-executive directors supplied [✂] to the boards of several other companies in the AMCo Group.[1945]

[1941] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 3.4 (URN: PRO-E004435).

[1942] List of AML directors between 31 August 2012 and 21 October 2015 (URN: PRO-E004540).

[1943] Document '*Annex 56 _ List of directors appointed by Cinven to Mercury Phar_1113368_0* ' (URN: PRO-E004492).

[1944] T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraph 77 and caselaw cited.

[1945] List of AML directors between 31 August 2012 and 21 October 2015 (URN: PRO-E004540).

7.189 This '*accumulation of posts*' on the AML board and the boards of AMCo Group companies enabled Cinven MGP to ensure that the AMCo Group's conduct was consistent with Cinven's strategy.[1946]

7.190 [✂].[1947] [✂].

7.191 [✂].[1948] [✂].

7.192 [✂].[1949] [✂] it is not necessary for Cinven MGP's appointee directors to be closely involved in day-to-day business for their presence to constitute a personal and organisational link enabling the exercise of decisive influence.

Cinven MGP exercised the [✂] veto rights

7.193 Cinven MGP's exercise [✂] – in particular, over the AMCo Group budget – are in themselves sufficient to demonstrate that it exercised decisive influence over AML and the Focus Companies.[1950]

7.194 As explained in paragraph 7.30 above, where a parent holds a veto right and attends meetings at which it could veto decisions, that amounts (in law and as a matter of economic reality) to exercising its right, since its approval is a prerequisite.[1951] Even where decisions are taken by the subsidiary's management, '*the fact that the parent company or its representatives must approve those proposals and therefore has the right to reject them is, in fact, evidence of a decisive influence*'.[1952] The contemporaneous evidence shows that Cinven MGP exercised the veto rights it controlled in this way.

The AMCo Group budget

7.195 As explained above, Cinven MGP, [✂] controlled a veto right over the AMCo Group budget: it was to be submitted to the Investor Directors appointed by Cinven MGP [✂] and AMCo Group management were required to incorporate any amendments they made to it.

[1946] Compare T-132/07 *Fuji Electric Co. Ltd v Commission,* EU:T:2011:344, paragraph 184.

[1947] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.25-12.26 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1948] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.26 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1949] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.26 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1950] Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67.

[1951] Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 73: '*the holder of a right of veto over certain decisions of an undertaking must necessarily be consulted before the adoption of any decisions which it is capable of vetoing and must approve those decisions*'.

[1952] T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 114 and caselaw cited, upheld in C-595/18 P *Goldman Sachs v Commission*. See also T-682/14 *Mylan v Commission*, paragraph 350 (currently on appeal to the EU Court of Justice: C-197/19 P).

7.196 [✂].[1953] The documentary evidence shows that [Cinven Partner] and [Cinven Partner] (the Investor Directors appointed by Cinven MGP) reviewed drafts of that budget in detail and made edits prior to approving it.[1954]

7.197 The Investor Directors could at any time have vetoed the budget. Their approval of the budget, and close involvement in its preparation, demonstrates in itself that Cinven MGP, [✂] exercised decisive influence over AML, and through AML over the Focus Companies.[1955] Not only would the AMCo Group's management not have been able to pass a budget without the Investor Directors' approval, the Investor Directors were also deeply involved in the preparation of that budget and their proposals were all followed.

7.198 [✂].[1956] [✂].[1957] [✂].

Investor Consent

7.199 The obligation for a subsidiary to engage in prior consultation with its parent or to obtain its prior approval is a strong indication that the parent actually exercises decisive influence over its subsidiary. In particular, in a situation where the parent must approve its subsidiary's proposals, the fact that the subsidiary is required to obtain that approval and therefore the parent company has the right to refuse to give it is evidence of a decisive influence.[1958]

7.200 [✂].

7.201 Cinven MGP exercised this right in practice. For example:

7.201.1 [✂].[1959]

[1953] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 3.14 (URN: PRO-E004435).

[1954] For example, an email exchange relating to the minutes of an AMCo Group investor meeting in August 2013 – attended by the Investor Directors – includes a record of detailed discussions of the draft 2014 budget and the timeframe for approval: '*Budget/Planning … [AMCo employee] to present initial planning timetable to Cinven by 9th August. Suggestions (a) First cut in October (b) "Budget/3 year plan" meeting in mid-November (c) Reporting to banks by end December*'. Email between [AMCo employee], [AMCo Employee 2], [AMCo employee] and [AMCo Director 1] entitled '*RE: Minutes of the AMCo Investor meeting ... please add commentaryu where highlighted, and review/add/amend*' 1 August 2013 (URN: PRO-E004564). These minutes show that the Investor Directors were involved, on an ongoing basis, in the preparation of the AMCo Group's budget and business plan. Indeed, the Investor Directors requested detailed edits to the draft budget. In an email enclosing draft slides relating to the 2014 budget, [AMCo employee] noted, '*[w]e have now included support slides and included various commentaries. Most of the data requests that [Cinven Partner] has asked for (the pricing table is still missing but we will get that done on Monday morning)*'. Email between [AMCo employee] and [AMCo Director 1] entitled '*Draft 2014 Budget slides*' 22 November 2013 (URN: PRO-E004568). [✂]. Minutes of AML board meeting dated 29 January 2014 (URN: PRO-E004459). Although this evidence pre-dates the Cinven Period, it is representative of the approach followed throughout Cinven's ownership.

[1955] Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67. As explained below, the question of 'decisive influence' for the purposes of merger control, referred to at this point in *Toshiba*, is closely related to the question of decisive influence for the purposes of attributing liability for antitrust infringements.

[1956] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.24 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1957] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.37 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1958] T-682/14 *Mylan v Commission*, paragraph 345 (currently on appeal to the EU Court of Justice: C-197/19 P) and the caselaw cited.

[1959] Minutes of AML board meeting dated 23 September 2014, items 5.2 and 6.5 (URN: PRO-E004461): [✂].

7.201.2 [✂].[1960]

7.202 [✂].[1961]

Cinven MGP exercised the Cinven Limited Partnerships' rights to obtain strategic and operational information about the AMCo Group's performance

7.203 A flow of information between a parent and its subsidiary and, *a fortiori*, an obligation to report to the parent, also constitutes an indication of the exercise of control over the subsidiary's decisions. Such information and reports show organisational links between the parent and its subsidiary and allow the parent to monitor and control the activities of its subsidiary in order to take specific measures in relation to it.[1962]

7.204 [✂].

7.205 [✂]

7.205.1 [✂].[1963]

7.205.2 [✂].[1964]

7.205.3 [✂].[1965]

7.206 The provision of this information to Cinven MGP is an indication that Cinven MGP exercised decisive influence over the decisions taken by the AMCo Group's executives.[1966] [✂].[1967]

7.207 [✂].[1968] [✂].

[1960] [✂] Minutes of AML board meeting dated 15 October 2015 (URN: PRO-E004464).

[1961] Minutes of AML board meeting dated 25 February 2015, paragraph 5 (URN: PRO-E004463): [✂] Minutes of AML board meeting dated 20 August 2015, item 2 (URN: PRO-E004464).

[1962] T-682/14 *Mylan v Commission*, paragraph 351 (currently on appeal to the EU Court of Justice: C-197/19 P) and the caselaw cited.

[1963] Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 6.3 (URN: PRO-E004494).

[1964] Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 6.4 (URN: PRO-E004494).

[1965] Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 6.2 (URN: PRO-E004494).

[1966] The EU Court of Justice has held that the provision by a subsidiary to a parent of information on the implementation of strategic and commercial plans is an indication that the parent exercised control over the decisions drawn up and executed by the subsidiary's executives: C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraphs 104 to 107. Compare Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, in which the parent's monitoring of its subsidiary's financial performance was a relevant factor in the attribution of liability (paragraph 3019), upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89.

[1967] See, for example, Minutes of Cinven MGP board meeting dated 2 April 2015 (URN: PRO-E004465) and 21 May 2015 (URN: PRO-E004466), [✂].

[1968] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.29 (URN: PRO-C5134), Cinven's RSO in Case 50395.

7.208 [✂].[1969] [✂].[1970]

7.209 [✂].[1971] [✂].[1972] [✂].[1973] The EU Court of Justice has recently confirmed that the existence of directors' duties to their company does not preclude their acting as a link through which a parent exercises decisive influence over that company.[1974]

Cinven MGP oversaw the AMCo Group's commercial conduct and strategy

7.210 As explained at paragraph 7.23 above, decisive influence does not require influence on a subsidiary's commercial conduct: this is not the only factor that is relevant.[1975] However, where such influence can be demonstrated (whether indirectly, from the totality of the economic, legal and organisational links between the parent and subsidiary,[1976] or directly from positive evidence of a shared commercial strategy) that is strong evidence of decisive influence.[1977] In particular, influence over '*the company's commercial policy in the broadest sense*',[1978] and over strategic commercial decisions such as whether its business activities shall be expanded or down-sized, whether investments or acquisitions shall be made and whether it shall be sold and for what price, can be particularly important.[1979]

7.211 Cinven MGP exercised decisive influence over the AMCo Group's commercial conduct and strategy (and therefore that of the Focus Companies). This is apparent not only from the positive evidence of a shared commercial strategy discussed in paragraphs 7.99-7.120 above, but also from the organisational links between Cinven MGP and the Focus Companies:

7.211.1 The board of AML set the strategic direction for its wholly-owned subsidiaries, including the Focus Companies.[1980] As explained above,

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[1969] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.20-12.31 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1970] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.34 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1971] [✂] (Cinven RSO, 15 August 2019, Annex 1, paragraph 12.32 (URN: PRO-C5134), Cinven's RSO in Case 50395). [✂].

[1972] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.34(c) (URN: PRO-C5134), Cinven's RSO in Case 50395 (emphasis added).

[1973] See, eg, T-395/09 *Gigaset AG v Commission,* EU:T:2014:23.

[1974] C-595/18 P *Goldman Sachs v Commission*, paragraphs 77, 94-95 and 100.

[1975] See further, for example, Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, confirming that decisive influence does not depend only on influence over commercial policy *stricto sensu*, but can include influence over strategy (paragraph 3032), upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89.

[1976] T-682/14 *Mylan v Commission*, paragraph 347 (currently on appeal to the EU Court of Justice: C-197/19 P) and the cases cited.

[1977] *Durkan Holdings Limited v OFT* [2011] CAT 6, paragraph 22; *Akzo Nobel*, EU:C:2009:356, paragraphs 73-74, approving the Opinion of Advocate General Kokott, EU:C:2009:262, paragraph 87. See also T-24/05 *Alliance One & Others v Commission*, EU:T:2010:453, paragraph 170; and *Holding Slovenske*, EU:T:2013:647, paragraph 32.

[1978] Opinion of Advocate General Kokott in C-293/13 *Del Monte*, EU:C:2014:2439, paragraph 89 (followed by the EU Court of Justice).

[1979] *Power Cables*, paragraph 779. The courts have therefore rejected the argument that '*residual control over "strategic decisions" and financial supervision are not enough to found a conclusion that [a parent] actually exercised control over its subsidiary*': T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

[1980] AMCo's '*Annual Review 2013*', page 16: '*The strategic direction of the AMCo Group is set by the board of its ultimate parent company Amdipharm Mercury Limited*' (URN: PAD034).

Cinven MGP controlled the board of AML. The AMCo Group's executive management – including [AMCo Director 1], [AMCo employee] and [AMCo Employee 2] – were not directors of or employed by AML but by Advanz Pharma Services (UK) Limited (formerly Amdipharm Mercury Company Limited), its wholly-owned subsidiary. They regularly reported to the AML board.[1981]

7.211.2 Implementation of strategy for the AMCo Group's principal UK operating subsidiaries was delegated to Mercury Pharma Group Limited.[1982] [✂].

7.212 The CMA therefore concludes, on the basis of the totality of organisational, legal and economic links between Cinven MGP and the Focus Companies considered throughout the sections above (many of which in themselves would suffice), that Cinven MGP exercised decisive influence over the Focus Companies during the Cinven Period.

Liability of Luxco 1

7.213 [✂].[1983] Luxco 1 therefore had the ability to exercise decisive influence over Cinven MGP, and the *Akzo* presumption that it did in fact exercise such decisive influence applies.

7.214 Cinven submitted that [✂].[1984]

7.215 The CMA does not consider that the evidence adduced by Cinven suffices to rebut the Akzo presumption.

7.216 First, it is settled case law that establishing decisive influence does not require proof of intervention in a subsidiary's commercial conduct or policy. A parent may exercise decisive influence over a subsidiary even where it does not make use of any actual rights to determine its conduct, and refrains from giving any specific instructions or guidelines to its subsidiary.[1985] For this reason the courts have consistently rejected attempts to rebut the *Akzo* presumption on the basis that the parent is not involved in the business of the subsidiary. For example:

[1981] See, eg, Minutes of AML board meeting dated 5 November 2014 (URN: PRO-E004462); Minutes of AML board meeting dated 27 January 2015 (URN: PRO-E004462); Minutes of AML board meeting dated 24 April 2015 (URN: PRO-E004463); Minutes of AML board meeting dated 22 July 2015 (URN: PRO-E004464).

[1982] AMCo's '*Annual Review 2013*', page 16: '*The board of Amdipharm Mercury Limited delegates the implementation of the strategy for the principal operating subsidiaries of the group to the board of Mercury Pharma Group Limited*' (URN: PAD034).

[1983] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 9.11 (URN: PRO-E004435), and structure chart of the Fifth Cinven Fund, document '*Annex 44 _ Organisational chart illustrating the structure of th_1110227_0*' (URN: PRO-E004480).

[1984] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.42-12.43 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1985] T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605. See also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraph 22(b). See also C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 41, citing *Del Monte*, EU:C:2015:416, paragraphs 96 and 97.

7.216.1 In *Stichting Gosselin*, the EU Court of Justice reversed the EU General Court's conclusion that the parent company had succeeded in rebutting the *Akzo* presumption. The facts that the parent company's only influence on its subsidiary was through its voting rights and no meeting of shareholders was held were not sufficient to prove that the parent and its subsidiary did not form an economic unit.[1986]

7.216.2 Similarly, in *Team Relocations*, an assertion that the subsidiary had managerial autonomy failed to rebut the *Akzo* presumption.[1987]

7.216.3 In *Del Monte*, the EU Court of Justice noted that *'the fact that Del Monte was legally precluded from involvement in the management of Weichert's day-to-day business and that its veto rights did not allow it, inter alia, to impose a particular budget does not mean that Del Monte was precluded altogether from being able to exert decisive include over Weichert's conduct on the relevant market'*.[1988]

7.217 Secondly, the fact [✂].[1989] [✂].[1990]

7.218 The CMA therefore concludes, on the basis of the *Akzo* presumption, that Luxco 1 exercised decisive influence over Cinven MGP and, through Cinven MGP, over the Focus Companies throughout the Cinven Period.

Liability of Cinven Partners

7.219 In identifying the legal entities that exercised decisive influence over the Focus Companies during the Cinven Period, the CMA also finds that Cinven Partners did so, and that liability for the infringement committed by Focus should be attributed to it. [✂].[1991]

7.220 Formally, [✂].[1992]

7.221 As a matter of economic reality, however, Cinven Partners' role in the AMCo Group investment was in practice far more significant than the contractual terms of its appointment would suggest.[1993]

[1986] C-440/11 *Commission v Stichting Administratiekantoor Portielje*, EU:C:2013:514, paragraphs 62-68.

[1987] T-204/08 *Team Relocations v Commission*, EU:T:2011:286, paragraph 152.

[1988] C-293/13 P *Del Monte v Commission*, EU:C:2015:416, paragraph 88.

[1989] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.42-12.43 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[1990] Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67 and 73; T-682/14 *Mylan v Commission*, paragraphs 345 and 350 (currently on appeal to the EU Court of Justice: C-197/19 P) and the caselaw cited; T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 114 (upheld in C-595/18 P *Goldman Sachs v Commission*) and caselaw cited.

[1991] [✂].

[1992] Document *'Annex 48 _ Investment Advisory Agreement in relation to Cinven M_1110231_0'*, clause 2.4 (URN: PRO-E004484).

[1993] [✂].

7.222 The CMA concludes that as a matter of economic reality, Cinven Partners – as well as Cinven MGP and Luxco 1 – exercised decisive influence over the Focus Companies and formed an economic unit for the purpose of the Infringement committed by Focus with the Focus Companies, Cinven MGP and Luxco 1, in particular through the personal links between those legal entities. The common strategy they pursued, of exploiting the absence of effective regulation for niche generic drugs, was devised and overseen by Cinven Partners staff and is attributable to Cinven Partners.

7.223 In making this finding, the CMA draws on established principles of the law on attribution of liability, which the CMA explains here before setting out below how they apply.[1994]

7.224 As explained in paragraph 7.22 above, when attributing liability the '*principal question*' is whether one entity exercises decisive influence over the other in practice, since '*if it were to be established … that … [one entity] did in fact exercise decisive influence over the conduct of [the other], that would necessarily imply that they were in a position to do so*'.[1995] The test focuses on substance over form. For example, in C-440/11 *Stichting Gosselin* Advocate General Kokott stated:

> *'the decisive factor is ultimately economic reality, since competition law is guided not by technicalities, but by the actual conduct of undertakings'*

7.225 It is therefore '*of decisive importance, leaving aside all the formal deliberations on company law, to examine the actual effects of the personal links between [the relevant entities] on everyday business activities*'.[1996]

7.226 The EU Court of Justice followed the Advocate General, holding that:

> *'the fact that a finding that the author of the infringement and its holding entity form an economic unit does not necessarily presuppose the adoption of formal decisions by statutory organs and that, on the contrary, that unit may also have an informal basis, consisting inter alia in personal links between the legal entities comprising such an economic unit.'*[1997]

7.227 The CMA is therefore entitled to rely, as an objective factor, on Cinven Partners' level of representation on AMCo Group company boards in order to show that

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[1994] [✂].

[1995] T-24/05 *Alliance One and Others v Commission*, EU:T:2010:453, paragraphs 165 to 167, upheld in C-628/10 P and C-14/11 P *Alliance One and Others v Commission*, EU:C:2012:479. See also T-104/13 *Toshiba Corp. v European Commission*, EU:T:2015:610, paragraph 95; and C-172/12 P *El du Pont de Nemours v Commission*, EU:C:2013:601, paragraph 44; and T-541/08 *Sasol v Commission*, EU:T:2014:628, paragraph 43.

[1996] Opinion of Advocate General Kokott in C-440/11 *Commission v Stichting Administratiekantoor Portielje*, EU:C:2012:763, paragraphs 71 to 76.

[1997] C-440/11 *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV,* EU:C:2013:514, paragraphs 66 to 68. Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 46. See also Joined cases C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, EU:C:2015:416, paragraph 76.

Cinven Partners was in a position to, and did in fact, exercise decisive influence over the Focus Companies.[1998]

7.228 As explained in the Legal Framework section, paragraphs 7.1-7.47 above, the EU Courts have held that decisive influence may be demonstrated by the presence of parent representatives on the subsidiary's board ('*even though member(s) of the parent company who take on managerial functions within the subsidiary do not have authority as agents of the parent company*'):

> *'Such an accumulation of posts necessarily places the parent company in a position to have a decisive influence on its subsidiary's market conduct since it enables members of the parent company's board to ensure, while carrying out their managerial functions within the subsidiary, that the subsidiary's course of conduct on the market is consistent with the line laid down at management level by the parent company'.*[1999]

7.229 An '*accumulation of posts*' in the sense of overlapping, simultaneous roles with parent and subsidiary is not required in order to demonstrate the exercise of decisive influence. Such influence may also be demonstrated by informal personal links between parent and subsidiary.[2000]

7.230 Where individuals *'had previously acted at a high management level within [the parent] and subsequently returned to it',* they *'necessarily had thorough knowledge of [the parent's] policy and its commercial objectives and were in a position to cause the [subsidiary's] policy and [the parent's] interests to converge'*. This is the case '*even if they had not retained contractual links with [the parent] and were no longer under its direct authority*'.[2001] For example, in *Goldman Sachs* the EU Court of Justice upheld the EU General Court and Commission's findings that Goldman Sachs exercised decisive influence over its fund's portfolio company Prysmian in part through the personal links Goldman Sachs had with two 'independent' non-executive directors on Prysmian's board, who were not directors, officers, employees or managers of Goldman Sachs. Their personal links to Goldman

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[1998] T-419/14 *Goldman Sachs v Commission*, paragraph 109, upheld in C-595/18 P *Goldman Sachs v Commission*.

[1999] T-132/07 *Fuji Electric Co. Ltd v Commission,* EU:T:2011:344, paragraph 184. See also T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 354-355.

[2000] C-595/18 P *Goldman Sachs v Commission*, paragraphs 93-95. The EU Court of Justice has held that even the presence of a single parent company representative on the board of the subsidiary can be a relevant factor among others conferring the ability to exercise decisive influence: '*it is in no way necessary for the accumulation of posts within both the parent company and the subsidiary to concern more than one individual in order to constitute one indication among others of that capacity'*. C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 76. Compare C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraph 106: '*[the subsidiary's] sole director designated by [the parent] constituted, as a result of his consistent pattern of behaviour, a link between those two companies, by which the information concerning sales, production and financial results were communicated to [the parent]*'.

[2001] C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 15. As explained above, the EU Court of Justice found the exercise of decisive influence by a parent on the basis of (among other factors) the appointment to the subsidiary of individuals who had previously acted at a high management level within the parent, and who subsequently returned to it. The EU Court of Justice upheld the EU General Court's finding in T-104/13 *Toshiba v Commission*, EU:T:2015:610. The relevant factors are summarised in paragraphs 14-17 of the EU Court of Justice's judgment. The quotation relating to contractual links is from paragraph 116 of the EU General Court judgment.

Sachs consisted of '*previous advisory services*' and '*consultancy agreements*'. Notwithstanding Goldman Sachs' arguments that these links were subject to the directors' duties of independence and to Prysmian's confirmation to regulatory authorities that it considered them independent, the EU Court of Justice held that:

> *'The relevance of such personal links lies in the fact that they may suggest that a person, although active for a given company, actually pursues, in view of his or her links with another company, the interests of the latter. That may also be the case were a person who sits on the board of directors of a company is connected to another company by means of 'previous advisory services' or 'consultancy agreements', as the General Court noted in paragraph 106 of the judgment under appeal.'*[2002]

7.231 The principles established in these cases apply to the individuals appointed by Cinven MGP to AMCo Group roles: the Investor Directors [Cinven Partner] and [Cinven Partner], and the additional director [Cinven Partner] (see paragraphs 7.182-7.186 above). Each of these individuals was seconded from Cinven Partners to perform his role in the AMCo Group. Together, these Cinven Partners individuals enabled Cinven Partners to ensure that the AMCo Group's conduct was consistent with the strategy set by Cinven Partners.[2003]

7.232 In making this finding, the CMA has also had regard to the European Commission's Consolidated Jurisdictional Notice under Regulation 139/2004 (the '**EU Jurisdictional Notice**'), which states:

> *'The investment company usually exercises control by means of the organisational structure, e.g. by controlling the general partner of fund partnerships, or by contractual arrangements, such as advisory agreements, or by a combination of both. This may be the case even if the investment company itself does not own the company acting as a general partner, but their shares are held by natural persons (who may be linked to the investment company) or by a trust.'*[2004]

7.233 This passage of the EU Jurisdictional Notice concerns the issue of whether an investment company acquires '*control*' for the purposes of the European merger control regime. This is a different issue from attributing liability for antitrust infringements.

7.234 However, the point of principle set out in the EU Jurisdictional Notice is relevant to the present case. The concept of '*control*' in merger control refers to the possibility of exercising decisive influence on an undertaking.[2005] While it relates to a different

[2002] C-595/18 P *Goldman Sachs v Commission*, paragraphs 89 and 93-95.

[2003] [✂].

[2004] EU Jurisdictional Notice, paragraph 15.

[2005] Article 3(2) of Regulation 139/2004.

regime, that is clearly a related concept to the question of whether a parent exercises decisive influence over a subsidiary for the purposes of attributing liability. For example, in the *Toshiba* case, the parties accepted that the EU Jurisdictional Notice was relevant to the question of decisive influence for attribution of liability.[2006] The CMA must therefore have regard to the EU Jurisdictional Notice by virtue of section 60A(3) of the Act.[2007]

7.235 The EU Jurisdictional Notice goes on to state:

> *'Contractual arrangements with the investment company, in particular advisory agreements, will become even more important if the general partner does not have any own resources and personnel for the management of the portfolio companies, but only constitutes a company structure whose acts are performed by persons linked to the investment company. In these circumstances, the investment company normally acquires indirect control within the meaning of Article 3(1)(b) and 3(3)(b) of the Merger Regulation, and has the power to exercise the rights which are directly held by the investment fund.'*[2008]

7.236 [✂].[2009]

7.237 All of the Cinven individuals appointed to the AMCo Group were appointed by Cinven MGP and their actions are attributable to Cinven MGP, as explained above. However, their actions are also attributable to Cinven Partners. In particular, and as further set out in the sections that follow:

7.237.1 They were all members or employees of Cinven Partners [✂].[2010]

7.237.2 They set Cinven's strategy for its investment in the AMCo Group in their capacity as Cinven Partners staff – before they were appointed to AML and AMCo Group companies by Cinven MGP.

7.237.3 Cinven Partners oversaw the implementation of that strategy through those individuals, who were seconded from Cinven Partners to serve on the boards of AML and AMCo Group companies and acted not only for Cinven MGP/Luxco 1 and the AMCo Group boards on which they served,

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[2006] C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 67. See also the EU General Court judgment, paragraphs 107 to 111: the EU Jurisdictional Notice's '*relevance to the present case is not disputed by the parties*'.

[2007] [✂].

[2008] EU Jurisdictional Notice, paragraph 15.

[2009] [✂] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, paragraph 9.14 (URN: PRO-E004435). Paragraph 15 of the EU Jurisdictional Notice specifically refers to the general partner being owned by '*natural persons (who may be linked to the investment company)*' as being relevant to the question of control.

[2010] Cinven has confirmed that *'all of the individuals involved with the investment [in the AMCo Group] were either members of or employed by Cinven Partners',* which was the only entity that paid their remuneration. Section 26 response of Cinven dated 13 June 2018, to the CMA Notice of 16 May 2018, paragraphs 1.2, 8.4 and 9.2 (URN: PRO-E004078).

but also for Cinven Partners, in pursuit of their common strategy and interests. [✂].

7.237.4 Through those individuals, Cinven Partners drove the decision to divest the AMCo Group. They returned to Cinven Partners when the sale completed.

7.238 The decisive influence that Cinven MGP (and Luxco 1 through Cinven MGP) exercised over the Focus Companies through those individuals is therefore equally attributable to Cinven Partners.

The Investor Directors and other key individuals appointed to AMCo Group company boards were Cinven Partners staff

7.239 As explained above, Cinven MGP [✂] appoint directors to key AMCo Group company boards. In particular, Cinven MGP appointed:

7.239.1 Two Investor Directors, [Cinven Partner] and [Cinven Partner], to the board of AML, the Focus Companies' ultimate 100% owner. The Investor Directors exercised the rights of the Majority Investors, including to edit and approve the AMCo Group budget. The AMCo Group executive management, including [✂] [AMCo Director 1], did not sit on the AML board but reported to it;

7.239.2 [Cinven Partner], [Cinven Partner] and another senior individual, [Cinven Partner], to the board of Mercury Pharma Group Limited, the immediate 100% parent of the company that employed the AMCo Group management including [AMCo Director 1], [✂], and the company that became the immediate 100% parent of Focus Pharma Holdings Limited and indirect 100% parent of Focus Pharmaceuticals Limited after the acquisition of the Focus Pharma group; and

7.239.3 [Cinven Partner] to the boards of six other AMCo Group companies.

7.240 These individuals were all partners or employees of Cinven Partners during the Cinven Period. Cinven has confirmed that *'all of the individuals involved with the investment [in the AMCo Group] were either members of or employed by Cinven Partners LLP'*:[2011]

7.240.1 [✂].[2012] [✂].[2013] [✂].[2014]

[2011] Section 26 response of Cinven dated 13 June 2018, to the CMA Notice of 16 May 2018, paragraphs 1.2, 8.4 and 9.2 (URN: PRO-E004078).

[2012] Cinven: '*[Cinven Partner]*' (URN: PAD049).

[2013] Document entitled *'[Cinven Partner]'s partner letter dated 17 February 2012'* (URN: PRO-E004122).

[2014] According to Companies House.

7.240.2 [✂].[2015] [✂].[2016] [✂].[2017]

7.240.3 [✂].[2018]

7.241 These individuals were seconded from Cinven Partners to their roles in the AMCo Group [✂].[2019] [✂].[2020]

7.242 As Cinven Partners staff, the actions of these individuals are attributable to Cinven Partners:

7.242.1 The CAT has confirmed that an employee '*will typically be part of the undertaking that employs him or her*' and that the acts of employees can be attributed to their employer.[2021] All that is required is that the employee is authorised generally to act on the employer's behalf – i.e. that he or she act within the powers given to him or her by their employment.[2022] [✂].[2023] [✂].[2024] [✂].

7.242.2 The actions of [Cinven Partner], as an LLP member of Cinven Partners during the Cinven Period, are also attributable to Cinven Partners:

(a) [✂].[2025]

(b) The EU Court of Justice has held that: *'for Article 101 TFEU to apply, it is not necessary for there to have been action by, or even knowledge on the part of, the partners or principal managers of the undertaking concerned; action by a person who is authorised to act on behalf of the undertaking suffices'*.[2026] Not only was [Cinven Partner]

[2015] Cinven: '*[Cinven Partner]*' (URN: PAD047).

[2016] Section 26 response of Cinven dated 2 November 2016, to CMA Notice of 20 October 2016, footnote 20 (URN: PRO-E004435).

[2017] According to Companies House.

[2018] Cinven: '*[Cinven Partner]*' (URN: PAD048).

[2019] Document '*Annex 48 _ Investment Advisory Agreement in relation to Cinven M_1110231_0*', clauses 2.2.3, 2.2.4 and 8.1.1 (URN: PRO-E004484).

[2020] Section 26 response of Cinven dated 13 June 2018, to the CMA Notice of 16 May 2018, paragraphs 8.4 and 9.2 (URN: PRO-E004078).

[2021] *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 358. See also *Tesco v OFT* [2012] CAT 31, paragraph 62 and the cases cited: '*Since an undertaking comprising a body corporate can only act through the individuals employed by it, the acts or conduct of an undertaking are inevitably performed by those individuals. It follows that any act by any employee could, potentially, lead to an infringement attributable to their corporate employer, with whom they comprise the same undertaking*'.

[2022] See e.g. C-100/80 *Musique Diffusion v Commission*, paragraphs 97-98; C-40/73 *Suiker Unie v Commission*, paragraphs 539 and 542; C-68/12 *Slovenska sporitelna v Commission*, paragraph 25; T-588/08 *Dole v Commission*, paragraphs 581-582; T-56/99 *Marlines v Commission*, paragraph 60. See also the CMA decision in *Paroxetine* (CE-9531/11), paragraph 9.19.

[2023] [✂] (URN: PRO-E004119).

[2024] [✂].

[2025] Document entitled *'Cinven Partners LLP Partnership Agreement'* dated 17 February 2012, clause 13.1.2 (URN: PRO-E004114).

[2026] C-68/12 *Slovenská sporiteľňa*, EU:C:2013:71, paragraph 25; and Joined cases C-100/80 to 103/80 *Musique Diffusion française and Others* v *Commission,* EU:C:1983:158, paragraph 97 (see also T-588/08 *Dole v Commission*,

an LLP member of Cinven Partners; he was also an 'Authorised Signatory' of Cinven Partners,[2027] with [✂].[2028] He was equivalent to a director, a position which *'entails by its very nature legal responsibility for the activities of the company [or in this case, partnership] as a whole'*.[2029]

(c) Further, the members of an LLP such as Cinven Partners are deemed in law to be agents of the LLP.[2030] The EU Courts have held that '*where an agent works for his principal, he can in principle be regarded as an auxiliary organ forming an integral part of the latter's undertaking and bound to carry out the principal's instructions and thus, like a commercial employee, forms an economic unit with his undertaking*'.[2031] The CMA finds, on the basis of the evidence set out in this section, that [Cinven Partner] was acting for Cinven Partners (as well as the AMCo Group boards on which he sat) in administering the AMCo Group investment.[2032]

Cinven Partners set the strategy for the AMCo Group investment through those individuals

7.243 As explained in paragraph 7.40 above, the EU General Court has held that it is not necessary for the purposes of demonstrating the exercise of decisive influence that the parent have control over day-to-day operations; rather, what counts is '*influence over the general strategy which defines the orientation of the undertaking*'.[2033]

7.244 As explained in the section on Cinven's approach to investment and creation of the AMCo Group, paragraphs 7.94-7.132 above, Cinven's strategy for its investments in the Mercury Pharma and Amdipharm groups, and their combination to create the AMCo Group, was to exploit *'niche formulations'* where *'the competitive forces may not work to suppress prices'* and which *'are typically below the radar'* of the DHSC and NHS.[2034] Bringing the Mercury Pharma and Amdipharm groups together in

EU:T:2013:130, paragraph 581). Although action by principal managers is therefore not required, where it is present this is a strong factor establishing liability of the undertaking they manage.

[2027] Section 26 response of Cinven dated 7 November 2018, to the CMA Notice of 6 November 2018, paragraph 3.1 (URN: PRO-E004552).

[2028] Document entitled *'Cinven Partners LLP Partnership Agreement'* dated 17 February 2012, clauses 18.1 and 18.2 (URN: PRO-E004114).

[2029] T-705/14 *Unichem v Commission*, paragraph 77. See also T-77/92 *Parker Pen v Commission*, paragraphs 78-82.

[2030] Section 6(1) of the Limited Liability Partnerships Act 2000 states that: '*Every member of a limited liability partnership is the agent of the limited liability partnership*'.

[2031] T-56/99 *Marlines v Commission*, EU:T:2003:333, paragraph 60 and caselaw cited; and C-40/73 *Suiker Unie v Commission,* EU:C:1975:78, paragraph 480.

[2032] Compare C-595/18 P *Goldman Sachs v Commission*, paragraphs 89 and 93-95.

[2033] T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 121, referring to the Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 73.

[2034] Minutes of a meeting of IC dated 2 July 2012, pages 3, 6 and 8 (URN: PRO-E004083).

pursuit of this strategy was designed to secure Cinven's longer-term objective of increasing the value of both groups for sale.

7.245 Cinven's strategy – and especially its implementation through a merged group under the management of [AMCo Director 1], Mercury Pharma's [✂] with extensive experience of this business model – is attributable to Cinven Partners. It was devised by individuals acting in their capacity as Cinven Partners staff:

7.245.1 The investment recommendation for Cinven's acquisition of the Mercury Pharma group, discussed at paragraphs 7.104-7.105 above, which explained that the '*investment attraction*' of the Mercury Pharma group was its ability to exploit the absence of effective regulation for niche generic drugs and increase prices while remaining '*below the radar*' of authorities, and also the plan to bring Mercury Pharma and Amdipharm together under the management of [AMCo Director 1] [✂] was authored by [✂] individuals. It was dated 2 July 2012.[2035]

7.245.2 The investment recommendation for Cinven's acquisition of the Amdipharm group, discussed at paragraph 7.106 above, which referred to [✂] and stated that *'The primary growth levers for Amdipharm* [✂] was prepared by [✂] individuals. It was dated 9 July 2012 and was prepared on Cinven Partners headed paper.[2036]

7.245.3 The final recommendation for Cinven's acquisition of the Mercury Pharma and Amdipharm groups, discussed at paragraph 7.108 above, [✂] was also authored by [✂] individuals. It was dated 30 July 2012.[2037]

7.246 These recommendations were all prepared before Cinven had acquired either the Mercury Pharma or Amdipharm groups. They were also prepared (with the exception of the final recommendation[2038]) before any of these individuals was appointed to roles on the boards of AML and other AMCo Group companies. The work of those individuals in preparing the investment recommendations, and the strategy they set out, are therefore attributable to Cinven Partners.

[2035] Minutes of a meeting of IC dated 2 July 2012, page 2 (URN: PRO-E004083).

[2036] Document '*Annex 2.2 - Memorandum to the IC entitled* 'Amdipharm - *initial investment recommendation'* dated 9 July 2012, page 4 (URN: PRO-E004084). Compare C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, in which the fact that most of the documents found during the Commission's inspections were on the letterhead of Knauf Gips KG, with its address and details, was one relevant factor in the Court's finding that Knauf Gips KG should be liable for the infringement (paragraphs 104 to 106).

[2037] Minutes of a meeting of the IC dated 30 July 2012, pages 5 and 36 (URN: PRO-E004085).

[2038] [✂] List of AML directors between 31 August 2012 and 21 October 2015 (URN: PRO-E004540); [✂] Section 26 response of Cinven dated 18 November 2016, to the CMA Notice of 11 November 2016, paragraph 7.2(a) (URN: PRO-E004494).

7.247 This was made particularly clear in the Cinven press release announcing the sale of the AMCo Group to Concordia Healthcare Corporation (now Advanz) in September 2015. [Cinven Partner] – described as '*Partner at Cinven*'[2039] – stated:

> *'Cinven successfully created AMCo – through the combination of two businesses – as a result of bilateral transactions and our strong healthcare sector focus and track record. We saw an opportunity to create significant value through the consolidation of the relatively fragmented, off-patent, niche pharmaceuticals market and AMCo has certainly achieved that.'*[2040]

7.248 The press release noted that Cinven created the AMCo Group in 2012, and that:

> *'Cinven's Healthcare team identified the opportunity to consolidate the niche pharmaceutical market more than two years prior to this'*[2041]

7.249 [✂], which is not a Fifth Cinven Fund team. That team '*identified the opportunity to consolidate the niche pharmaceutical market more than two years prior*' to the acquisitions of the Mercury Pharma and Amdipharm groups in 2012 – before the Fifth Cinven Fund was set up and began fundraising.

7.250 The recommendations for the two acquisitions were prepared and submitted to the Investment Committee of Cinven Partners. [✂].[2042] It was made up [✂].[2043] As explained above, the investment case for the Amdipharm and Mercury Pharma group acquisitions was not a proposal for a passive investment, but a plan to combine two previously independent pharmaceutical groups, bring them under a single management team, and pursue a strategy of focussing on '*niche*' generic drugs. A plan, in other words, to actively set the business plan and strategy of the combined AMCo Group.

7.251 On the basis of those recommendations, that committee agreed to recommend that the Fifth Cinven Fund make binding offers for the two groups.[2044] Although the decision to make those offers was for Cinven MGP to take (as the general partner managing the limited partnerships into which passive investors had moved their funds and therefore the manager of those funds that were used, alongside loans, to acquire them), Cinven MGP only had the option to do so because Cinven

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[2039] Compare the description of [Cinven Partner] as '*a partner in Cinven*' in *The Times'* account of the sale, The Times article: '*Firm's £1.5bn drug profit is bitter pill for taxpayer*', June 2016 (URN: PAD056).

[2040] Cinven press releases: *'AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp'* (URN: PAD043).

[2041] Cinven press releases: *'AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp'* (emphasis added) (URN: PAD043).

[2042] [✂].

[2043] Section 26 response of Cinven dated 13 June 2018, to the CMA Notice of 16 May 2018, question 3 (URN: PRO-E004078).

[2044] Minutes of a meeting of the IC dated 30 July 2012, item 2 (URN: PRO-E004085); Minutes of a meeting of IC dated 2 July 2012, item 2 (URN: PRO-E004083).

Partners had devised the investment thesis and put it forwards. Cinven Partners determined the terms of those offers, including the maximum price to be paid. [✂].

Cinven Partners oversaw the implementation of that strategy through those individuals

7.252 Once the Mercury Pharma and Amdipharm groups had been acquired and combined, Cinven Partners continued to oversee the implementation of the strategy its staff had devised. It did so through its secondees on the AML and AMCo Group company boards, who acted not only for Cinven MGP/Luxco 1 and the AMCo Group boards on which they served, but also for Cinven Partners, in pursuit of their common strategy and interests.

7.253 [Cinven Partner], [Cinven Partner] and [Cinven Partner] [✂].[2045] [✂].[2046]

7.254 As explained in paragraphs 7.228-7.230 above, where individuals who have acted at a high management level within a parent are present on the subsidiary's board, this places them in a position to cause the subsidiary's policy and the parent's interests to converge. This is the case even where those individuals do not retain contractual links with the parent, are no longer under its direct authority, and do not have authority as its agents.[2047] In this case, however, these individuals did in fact retain contractual links with Cinven Partners; did have authority as agents of Cinven Partners; and remained under Cinven Partners' authority during the Cinven Period.

7.255 As explained in paragraphs 7.243-7.251 above, as Partner ([Cinven Partner]); Principal ([Cinven Partner]) and employee ([Cinven Partner]) of Cinven Partners, these individuals had played key roles in devising Cinven Partners' strategy for the AMCo Group investment. They had thorough knowledge of Cinven Partners' policy and commercial objectives. As directors on AMCo Group company boards, they were in a position to cause the AMCo Group's policy and Cinven Partners' interests to converge. In particular:

7.255.1 As explained in the Liability of Cinven MGP section, paragraphs 7.156-7.212 above, the Investor Directors sat on the board of the ultimate 100% owner of all the Focus Companies and the company that employed the AMCo Group's executive management. They held (and exercised) veto rights over the AMCo Group's business plan and commercial conduct.

[2045] [Document entitled *[✂].*]

[2046] [✂].

[2047] T-132/07 *Fuji Electric Co. Ltd v Commission,* EU:T:2011:344, paragraph 184; T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 116, upheld in C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 15 and 76; C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraph 106; C-595/18 P *Goldman Sachs v Commission*, paragraphs 89 and 93-95; T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 354-355.

7.255.2 As [✂] would naturally be expected to discharge his duties as an Investor Director on the AML board with an eye to the broader interests of Cinven Partners and its goal of attracting further investment in its healthcare portfolio. If the investment in the AMCo Group was successful, this was not only to the benefit of the investors in the Fifth Cinven Fund, whose interests Cinven MGP represented, but also of Cinven Partners, whose reputation would be enhanced (as is evident from the positive press after Cinven divested AMCo) which would assist in obtaining future investments.

7.256 [✂].

7.257 [✂]. This meant that in practice, they were required to advance the interests of each of:

7.257.1 The AMCo Group companies whose boards they served and to which they owed fiduciary duties;

7.257.2 The Majority Investors of the Fifth Cinven Fund, whose managing partner Cinven MGP appointed them; and

7.257.3 Cinven Partners, their employer or partnership.

7.258 Cinven submitted [✂].[2048]

7.259 The law on parental liability (like competition law in general) depends not on contractual or company law technicalities but on economic reality.[2049] The CMA finds that as a matter of economic reality – notwithstanding the terms of their appointment on paper – the Investor Directors also acted for Cinven Partners.

7.260 Cinven submitted [✂].[2050] However, there is nothing unusual about this situation. Company directors often serve on multiple boards and owe duties to each of them. Directors of a subsidiary company often also serve on the parent's board. In such a

[2048] Cinven RSO, 15 August 2019, Annex 1, paragraphs 12.47-12.50 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[2049] C-440/11 *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV*, EU:C:2013:514, paragraphs 66-68. See also Opinion of Advocate General Kokott, EU:C:2012:763, paragraphs 71-76: Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 46. See also Joined cases C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, EU:C:2015:416, paragraph 76.

[2050] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.56 (URN: PRO-C5134), Cinven's RSO in Case 50395.

situation they owe duties to both parent and subsidiary and are required to advance the interests of both.[2051] [✂].[2052]

7.261 The CMA finds that such a distinction is artificial in this case, particularly given that those interests were aligned. As explained in the section on Cinven's approach to investment and creation of the AMCO group, paragraphs 7.94-7.132 and the section on The roles of the Cinven Entities, paragraphs 7.133-7.144 above, the interests of all the Cinven Entities, AML and the Focus Companies were aligned in pursuit of their common strategy of exploiting the profit opportunities presented by niche generic drugs, and each of the Cinven Entities stood to gain if the investment in the AMCo Group was a success.[2053] Cinven did not suggest any way in which the interests of the Cinven Entities and the AMCo Group were not aligned. These individuals were therefore perfectly able to discharge their overlapping duties.

7.262 The evidence shows that they did so in practice.

7.263 The investment recommendations for AMCo Group follow-on acquisitions during the Cinven Period were prepared by the individuals Cinven Partners seconded to the AMCo Group in their capacity as Cinven Partners staff, for consideration and approval by the Cinven Partners Investment and Portfolio Review Committees.[2054] [✂] This gave Cinven Partners, through the individuals it seconded to the AMCo Group, control over the pipeline of investments for the Fifth Fund and the AMCo Group.[2055]

7.264 Cinven Partners exercised that control to ensure that strategic and material acquisitions by the AMCo Group were consistent with its investment strategy. For example, an update for the Portfolio Review Committee on the prospective acquisition of the Focus Pharma group was prepared by [Cinven Partner], [Cinven Partner] and [Cinven Partner] in August 2014. [✂].[2056] The final investment recommendation, discussed in paragraph 7.112 above, was also prepared by [Cinven Partner], [Cinven Partner], [Cinven Partner] and three other individuals. It

[2051] The EU General Court has confirmed that appointee directors on a subsidiary board can act in more than one capacity, where the interests of parent and subsidiary are aligned. Their fiduciary duties to the subsidiary do not necessarily conflict with their continued role as representatives of the parent. The court also noted that the parent's appointment of directors to the subsidiary's supervisory board '*would not have made sense if the [parent] had intended that the supervisory board be composed of persons entirely independent from the [parent]*'; and that '*the [parent] affirms that the members which it appointed to [the subsidiary]'s supervisory board could not be considered 'solely as [its] representatives', thereby admitting that they also acted in that capacity*': T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraphs 75-77.

[2052] Cinven RSO, 15 August 2019, Annex 1, paragraph 10.14(e) (URN: PRO-C5134), Cinven's RSSO in Case 50395 (emphasis in original).

[2053] [✂].

[2054] [✂].

[2055] See, for example, Minutes of the Cinven MGP quarterly Board Meeting dated 27 August 2015, page 5 (URN: PRO-E004112): [✂], Minutes of the Cinven MGP quarterly Board Meeting dated 22 November 2012 (URN: PRO-E004111), and Minutes of the Cinven MGP Quarterly Board meeting dated 14 February 2013 (URN: PRO-E004532).

[2056] Document entitled *'Focus Pharmaceuticals - AMCo bolt-on'* dated 6 August 2014 (URN: PRO-E004096).

noted that Focus had an [✂].[2057] These proposals were prepared by the individuals Cinven Partners seconded to the AMCo Group in their capacity as Cinven Partners staff: the proposals are on Cinven Partners headed paper.

7.265 During the course of the Cinven Period, regular papers on the AMCo Group investment were submitted to the Cinven Partners Portfolio Review Committee (see paragraph 7.205 above).[2058] The Portfolio Review Committee papers included a [✂] with a summary of risks and opportunities.

7.266 Once approved, investment recommendations were presented by Cinven Partners staff to the board of Cinven MGP. [✂].

7.267 [✂].[2059]

7.268 [✂].[2060]

7.269 The Cinven Partners individuals seconded to AMCo Group company boards therefore continued to oversee implementation of the strategy they had devised for the investments in the Mercury Pharma, Amdipharm and Focus Pharma groups, in their capacity as Cinven Partners staff.

Cinven Partners drove the decision to divest the AMCo Group through those individuals

7.270 The evidence also shows that although the ultimate sale of the AMCo Group was formally approved by Cinven MGP as managing general partner of the Fifth Cinven Fund, the decision to sell was driven by Cinven Partners, in particular through the individuals it seconded to AMCo Group company boards.

7.271 A recommendation for an AMCo Group follow-on acquisition was prepared for the Cinven Partners Investment Committee in October 2013. [✂]. The recommendation [✂].[2061] This statement makes clear that even as early as 2013, the decision to sell the AMCo Group would be based on Cinven Partners' broader perspective on the various Cinven funds, and the need to raise capital for the next fund.

[2057] Document entitled *'Focus Pharmaceuticals - Final Investment Recommendation'* dated 17 September 2014, page 3 (URN: PRO-E004098).

[2058] See, for example, document entitled *'Q4 PRC Paper on AMCo'* dated December 2014 (URN: PRO-E004099). As explained above, the EU Court of Justice has held that the provision by a subsidiary to a parent of information on the implementation of strategic and commercial plans is an indication that the parent exercised control over the decisions drawn up and executed by the subsidiary's executives: C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraphs 104 to 107. Compare Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, in which the parent's monitoring of its subsidiary's financial performance was a relevant factor in the attribution of liability (paragraph 3019), upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89.

[2059] Document entitled '*AMCo bolt-on M&A opportunities*' dated 1 April 2015, pages 12 and 13 (URN: PRO-E004384).

[2060] Minutes of Cinven MGP board meeting dated 2 April 2015, page 2 (URN: PRO-E004465).

[2061] Document entitled '*AMCo add-on acquisition - Initial investment recommendation'* dated 31 October 2013, pages 2, 3 and 4 (emphasis added) (URN: PRO-E004087).

7.272 The '*AMCo exit paper*' prepared in February 2015 and discussed in paragraphs 7.122-7.125 above was authored by [Cinven Partner], [Cinven Partner], [Cinven Partner] and one other individual, on Cinven Partners headed paper. It was presented to the Cinven Partners Portfolio Review Committee.[2062] The document makes clear that Cinven Partners was the entity that devised the plan for divestment, just as it had devised the plan for investment. As explained above, the paper referred to initiatives to improve the attractiveness of the AMCo Group on exit [✂]. It recommended that Cinven look to sell the AMCo Group to a trade buyer in 2015 and noted that '*We have a Cinven friendly SHA in place, where we retain full control in exit (including information rights and controlling access to bidders)*'. [✂].

7.273 In July 2015 [Cinven Partner], [Cinven Partner], [Cinven Partner] and two other individuals prepared a briefing for the Cinven Partners Investment and Portfolio Review Committees, on Cinven Partners headed paper, on an offer for the AMCo Group from Concordia Healthcare (now Advanz). The briefing stated, [✂]. Under [✂].[2063] These statements demonstrate that it was Cinven Partners that evaluated the strength and terms of the offer to purchase the AMCo Group and engaged with the potential buyer, in part on the basis of its view that its strategy of increasing the prices of niche generic drugs had now reaped the [✂].

7.274 The recommendation for the sale of the AMCo Group prepared in August 2015 was authored by [Cinven Partner], [Cinven Partner], [Cinven Partner] and two other individuals, on Cinven Partners headed paper. It was presented to the Cinven Partners Portfolio Review Committee by [Cinven Partner] and [Cinven Partner] for unanimous approval before it was presented to Cinven MGP.[2064] [✂].[2065] [✂].

7.275 Cinven submitted [✂].[2066] However, this is not the right way to approach the evidence. As explained in paragraph 7.25 above, the EU Court of Justice has confirmed that '*The existence of an economic unit may … be inferred from a body of consistent evidence, even if some of that evidence, taken in isolation, is insufficient to establish the existence of such a unit*'.[2067] The CMA finds that the documentary evidence, taken together and as a whole, demonstrates the exercise of decisive influence by Cinven Partners.

[2062] Document entitled *'AMCo - Exit Paper'* dated 27 February 2015 (URN: PRO-E004100).

[2063] Document entitled *'AMCo CRX Offer'* dated 15 July 2015, pages 2 and 4 (URN: PRO-E004103). See also *'AMCo CRX Offer updated'* dated 21 August 2015 (URN: PRO-E004104).

[2064] Email from [Cinven Partner] to PRC Members and others (Cinven) entitled '*RE:AMCo*' 26 August 2015 (URN: PRO-E004417); Email from [Cinven Partner] to PRC Members entitled '*RE:AMCo*' 26 August 2015 (URN: PRO-E004419).

[2065] Minutes of Cinven MGP board meeting dated 27 August 2015, paragraph 5, pages 2 and 3 (URN: PRO-E004537).

[2066] Cinven RSO, 15 August 2019, Annex 1, paragraph 12.59 (URN: PRO-C5134), Cinven's RSO in Case 50395.

[2067] C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, paragraph 65.

Liability of the Advanz Entities

7.276 The Advanz Entities are held liable for the Infringement from 21 October 2015 until the end of the Focus Infringement Period.

7.277 The Advanz Entities are held liable by application of the law on parental liability. As noted at paragraph 3.11 above, each of the Advanz Entities directly or indirectly acquired 100% of Mercury Pharma Group Limited on 21 October 2015 and maintained this holding for the rest of the Focus Infringement Period. During this period Mercury Pharma Group Limited indirectly held 100% of Focus Pharmaceuticals Limited (through Focus Pharma Holdings Limited) as set out at paragraphs 7.82 and 7.83 above. As a result, from 21 October 2015 until, at least, the end of the Focus Infringement Period, the Advanz Entities indirectly held 100% of each of the Focus Companies. Accordingly, each of the Advanz Entities had the ability to exercise decisive influence, indirectly, over the Focus Companies, and the CMA applies the *Akzo* presumption that they did actually exercise such influence. The Advanz Entities have not disputed this and the *Akzo* presumption has therefore not been rebutted. The CMA therefore finds that the Advanz Entities, Mercury Pharma Group Limited, Focus Pharma Holdings Limited and Focus Pharmaceuticals Limited formed a single undertaking during this period.

7.278 The CMA therefore attributes liability to each of the Advanz Entities for the Infringement in which Focus Pharmaceuticals Limited participated from 21 October 2015 until the end of the Focus Infringement Period, and for the resulting financial penalties, jointly and severally with Mercury Pharma Group Limited, Focus Pharma Holdings Limited and Focus Pharmaceuticals limited.

8. The CMA's Action

The CMA's decision

8.1 On the basis of the evidence and analysis set out in this Decision, the CMA has made a decision that the Parties have infringed the Chapter I prohibition by participating in the Market Exclusion Agreement as described in this Decision. The Market Exclusion Agreement had as its object the prevention, restriction or distortion of competition within the UK. Specifically:

8.1.1 From 7 June 2013 to 31 July 2018, Alliance and Lexon infringed the Chapter I prohibition by participating in the Market Exclusion Agreement;

8.1.2 From 22 June 2013 to 31 July 2018 Focus infringed the Chapter I prohibition by participating in the Market Exclusion Agreement; and

8.1.3 From 5 February 2014 to 15 February 2018, Medreich infringed the Chapter I prohibition by participating in the Market Exclusion Agreement.

8.2 On the basis of the evidence and analysis set out in this Decision, the CMA has made a decision to hold the entities to whom liability is attributed in Chapter 7 *(Undertakings and Attribution of Liability)* of this Decision liable for the Infringement committed by Alliance, Lexon, Focus and Medreich.

Directions

8.3 Section 32(1) of the Act provides that if the CMA has made a decision that an agreement infringes the Chapter I prohibition, it may give to such person or persons as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.

8.4 The CMA has not made a finding that the Infringement is ongoing at the time of this Decision. Therefore, it is not necessary to give directions to any Party in this case.

Financial penalties

The CMA's power to impose a penalty

8.5 Section 36(1) of the Act provides that, if the CMA makes a decision that an agreement has infringed the Chapter I prohibition, the CMA may require undertakings party to the agreement to pay the CMA a penalty in respect of the infringement.

8.6 However, pursuant to section 36(3) of the Act the CMA may impose a penalty under section 36(1) only if it is satisfied that the infringement has been committed intentionally or negligently by the undertaking.

8.7 For the reasons set out in paragraphs 8.22 to 8.69 below, the CMA finds that the Infringement was committed intentionally or at the very least negligently. The CMA has therefore imposed financial penalties in respect of the Infringement for which liability is attributed in line with Section 7 above.

8.8 The penalties have been calculated in accordance with the CMA's published guidance in force[2068] and relevant legislation.[2069]

The CMA's margin of appreciation in determining the appropriate penalty

8.9 The CMA has a margin of appreciation when determining the appropriate amount of a penalty under the Act.[2070] The CMA is not bound by its decisions in relation to whether to impose financial penalties or the calculation of any such penalties in previous cases under the Act. It makes assessments on a case-by-case basis,[2071] having regard to all relevant circumstances and the objectives of its policy on financial penalties. This is in line with its statutory requirements and the twin objectives of the CMA's policy on financial penalties, as reflected in the CMA Penalties Guidance.[2072] These objectives require the CMA to reflect the seriousness of the infringement and ensure the deterrence of the undertaking on which the penalty is imposed and to deter others from engaging in agreements or conduct that infringes the prohibitions(s) under the Act.[2073]

8.10 The CMA has concluded that it is appropriate in the circumstances of this case to exercise its discretion under section 36(1) of the Act to impose substantial financial penalties on the Alliance, Lexon, Focus and Medreich undertakings in respect of the Infringement.

8.11 The Infringement was a market exclusion agreement which concerned a widely-used product, covered the entire supply of Prochlorperazine POM in the UK for the large part of its duration, removed the first (and for a period of time, only) source of

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[2068] Guidance as to the appropriate amount of a penalty (CMA73), published April 2018 (the '**CMA Penalties Guidance**'). On 16 December 2021, the CMA published updated Guidance as to the appropriate amount of the penalty (CMA73) which applies from the date of its publication to new CA98 cases and to ongoing CA98 cases in which a Draft Penalty Statement or, if there are ongoing settlement discussions, a draft penalty calculation has not yet been issued. Since in this case the Draft Penalty Statement was issued prior to that date, the applicable penalties guidance is the version of CMA73 that was published on 18 April 2018.

[2069] The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000/309) ('**the 2000 Turnover Order**') and the Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004 (SI 2004/1259).

[2070] Provided that any penalty that the CMA imposes under the Act is within the range of penalties permitted by section 36(8) of the Act, calculated in accordance with the 2000 Turnover Order, and calculated having regard to the CMA penalties guidance in accordance with section 38(8) of the Act. The CMA's margin of appreciation is referred to in, for example, *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 168, and *Umbro Holdings, Manchester United, JJB Sports and Allsports v OFT* [2005] CAT 22, paragraph 102.

[2071] See, for example, *Kier Group and Others v OFT* [2011] CAT 3, paragraph 116: '*other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent*'. See also *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 97: '*[d]ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case*'. See also CMA Penalties Guidance, paragraph 2.6.

[2072] CMA Penalties Guidance, paragraph 1.3.

[2073] The Act, section 36(7A); CMA Penalties Guidance, paragraph 1.3.

potential competition in the supply of that drug and had the potential to significantly harm competition. Market exclusion agreements are among the most serious types of infringement and are very likely, by their nature, to cause harm to competition. A substantial penalty is also appropriate in these circumstances from a general deterrence point of view. The CMA considers that there is a need to send a strong message to deter similar conduct both by the Parties and other undertakings in the future.

8.12 The Parties have argued that no penalty, or only a nominal penalty, should be imposed in this case, including, they argue, based on 'uncertainty' or 'excusable error'. The CMA disagrees with the Parties' arguments, which are discussed in detail at paragraphs H.8 to H.17 and H.61 to H.62. There was no scope for 'uncertainty' or 'excusable error' at the time of the Infringement that an agreement aimed at preventing or delaying a competing supplier from entering the market was anti-competitive in nature.

Small agreements

8.13 The CMA considers that section 39 of the Act (which provides for limited immunity from penalties in relation to the Chapter I prohibition) does not apply in the present case on the basis that the combined applicable turnover of the Parties exceeded the relevant threshold.[2074]

Intention and negligence

8.14 If the CMA takes a decision that an undertaking's conduct has infringed the Chapter I prohibition, the CMA may require the undertaking concerned to pay a penalty in respect of the infringement if it is satisfied that the infringement has been committed intentionally or negligently.[2075] The CMA is not, however, obliged to specify whether it considers the infringement to be intentional or negligent.[2076]

8.15 The CAT has defined the terms 'intentionally' and 'negligently' as follows:

> *'an infringement is committed intentionally for the purposes of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition.*
>
> *[…]*

[2074] Regulation 3 of the Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000 (SI/2000/262) provides that the category of agreements for which no penalty may be imposed under section 9 of the Competition Act 1998 comprises '*all agreements between undertakings the combined applicable turnover of which for the business year ending in the calendar year preceding one during which the infringement occurred does not exceed £20 million*'.

[2075] Section 36(1) and 36(3) of the Act.

[2076] *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraphs 453 to 457. See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 221.

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'.[2077]

8.16 Intention or negligence relates to the anti-competitive nature of the conduct concerned, not the law. The CMA is not required to show that an undertaking knew that its conduct infringed the Act – what matters is not whether the undertaking was aware of '*any specific legal characterisation*' of its conduct, '*but whether it was aware of its anti-competitive nature*'.[2078]

8.17 This is consistent with the well-established approach taken by the EU Court of Justice[2079] which has stated:[2080]

'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'.

8.18 These principles were applied by the Court of Appeal in *Ping v CMA*.[2081] The CAT recently confirmed in *Paroxetine* that the principles set out at paragraphs 8.14 to 8.17 above are the principles applicable for the purpose of section 36(3) of the Act, noting that the question is whether the relevant undertakings '*knew or should have known'* that the agreements in question '*were anti-competitive in nature*'.[2082] This will be the case where an undertaking is aware or cannot be unaware of the 'essential facts' underpinning the legal finding of infringement found to have been committed by the relevant undertaking.[2083]

[2077] *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 221. See also *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, paragraph 117. On the meaning of 'negligently', see also 27/76 *United Brands Co and United Brands Continental BV v Commission*, EU:C:1978:22, paragraphs 298-301 and *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraph 457.

[2078] *Royal Mail Plc v Office of Communications* [2019] CAT 27, paragraph 782, citing T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 762 ('*it is settled case-law that that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty*'). See also *Napp*, paragraph 456.

[2079] Which predates 'IP completion day' (as defined as 31 December 2020 at 11.00 p.m. in section 39 of the European Union (Withdrawal Agreement) Act 2020) and was applicable immediately before IP completion day. Therefore, section 60A(2) Competition Act 1998 is applicable. See also *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading*, paragraph 455, where the CAT stated that section 60(2) Competition Act 1998 applied to interpreting the concepts of intention and negligence.

[2080] C-280/08 P *Deutsche Telekom v Commission*, EU:C:2010:603, paragraph 124, referring to Judgment in *NV IAZ International Belgium and Others v Commission* C-96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, EU:C:1983:310, paragraph 45 and Judgment in *NV Nederlandsche Banden-Industrie Michelin v Commission* C-322/81, EU:C:1983:313, paragraph 107.

[2081] *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, paragraph 117.

[2082] *Paroxetine II* [2021] CAT 9, paragraphs 117 and 121.

[2083] Case C-322/81 *NV Nederlandsche Banden-Industrie Michelin v Commission*, EU:C:1983:313, paragraph 107: '*In that respect it must be emphasized that Michelin NV was aware of the factual elements justifying both the finding of the existence of a dominant position on the market and the assessment of the contested discounts system as an abuse of that position*'.

8.19 Ignorance or a mistake of law is no bar to a finding of intentional (or, *a fortiori*, negligent) infringement, even where such ignorance or mistake is based on independent legal advice.[2084]

8.20 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.[2085]

8.21 Further, the fact that doubts as to the legality of an agreement or agreements similar to that agreement have been expressed by an actual or potential contractual partner of an undertaking, or a member of staff employed by an undertaking can support a finding that the undertaking could not be unaware of the anti-competitive nature of its conduct.[2086]

Application to Alliance

8.22 Applying the principles set out at paragraphs 8.14 to 8.21 above, and based on the evidence set out in this Decision, the CMA concludes that the undertaking Alliance cannot have been unaware or ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature, whether or not it was aware that it was infringing the competition rules. In particular Alliance cannot have been unaware or ought to have known that:

8.22.1 Lexon and Medreich, working together, were its potential competitors;

8.22.2 it was, indirectly through Focus, transferring value to Lexon;

8.22.3 those value transfers were in return for Lexon not entering the market with the product it had jointly developed with Medreich;

and, therefore, that the Market Exclusion Agreement was anti-competitive in nature.

8.23 Alliance made numerous representations challenging the CMA's conclusion that Alliance committed the infringement intentionally or, at the very least, negligently.

[2084] *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, paragraph 117. See also Judgment in *Deutsche Telekom v Commission* C-280/08 P, EU:C:2010:603, paragraph 124 and the EU Court of Justice's comments in Judgment in *Bundeswettbewerbsbehörde v Schenker & Co.* AG C-681/11, EU:C:2013:404, paragraph 38: '*the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine in so far as it could not be unaware of the anti-competitive nature of that conduct*'; and paragraph 41: '*[i]t 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*'.

[2085] *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraph 456.

[2086] See, to that effect, the comments of the CAT in *Paroxetine II* [2021] CAT 9, paragraph 127. See also C-591/16 P *H. Lundbeck A/S and Lundbeck Ltd v European Commission*, EU:C:2021:243, paragraph 164 and C-614/16 P *Merck KGaA* v *European Commission*, EU:C:2021:246, paragraph 132.

The CMA rejects these arguments. Alliance's representations, together with the CMA's response, are set out in Annex H: (paragraphs H.20 to H.27).

Potential competitor

8.24 Alliance cannot have been unaware or ought to have known that Lexon and Medreich, working together,[2087] were potential competitors to Alliance when Alliance entered into the Market Exclusion Agreement in June 2013.

8.25 Evidence of this includes, for example:

8.25.1 In March 2013, an internal Alliance email recorded that Lexon had communicated to Alliance that it would be launching a generic Prochlorperazine POM product.[2088]

8.25.2 Having been informed that Lexon's '*affiliate Medreich was in the process of obtaining a PL for Prochlorperazine POM*'[2089] and that Lexon intended to enter the market for Prochlorperazine POM, Alliance held internal discussions about how best to respond to the threat of generic entry, including the possibility of either Alliance, '*sell[ing] Lexon product in Alliance livery*' or Alliance agreeing to, '*supply Lexon with generic product*'.[2090]

8.25.3 Alliance reported internally on 14 March 2013 that the licence applied for in Medreich's name was expected in 6 weeks, '*[Alliance Employee 1] has had discussions with contacts at Lexon on threat of generic prochlorperazine… Not approved yet, they have said coming out in 6 weeks*'.[2091]

8.25.4 Senior management at Alliance took the competitive threat posed by Lexon's entry so seriously that they informed the [✂], [Alliance Director 1], of the threat and re-assured him that they were working on a '*defence strategy*' to address that threat: [Alliance Director 2] emailed [Alliance Director 1] on 21 March 2013 to inform him that *'…unfortunately the*

[2087] As set out at paragraphs 5.81 to 5.84 of this Decision, Lexon and Medreich must be considered together for the purposes of determining whether they were potential competitors in the supply of Prochlorperazine POM.

[2088] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*RE: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

[2089] Section 26 response of Alliance, part two, paragraph 17, dated 16 November 2017, to CMA Notice dated 16 October 2017 (URN:PRO-C0367).

[2090] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*RE: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

[2091] Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' meeting dated 14 March 2013 09:00 – 12:00 (URN: PRO-E000971). A different document also entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' recording the minutes of the meeting held on 14 March 2013 (URN: PRO-E000979) records the minutes differently, noting that: '*[Alliance Employee 1] contact at Lexon has confirmed they have a product coming out in 6 weeks, not on Rama yet. All of Lexon's licenses are PLPI; this would be less of a threat. Options would be to do nothing, do a deal on Buccastem or launch Alliance generic (project Cobra); this would take 8-12 weeks. [Alliance Employee 2] and [Alliance Employee 1] will monitor closely and keep dialogue open with Lexon open.*'

Buccastem threat would appear to be real, and not a PI threat. We are working on our defence strategy accordingly and I'll keep you informed as this is pulled together.' [2092]

8.25.5 By May 2013, Alliance was progressing a strategy to de-brand Buccastem in response to the threat posed by Lexon. For example, the minutes of the Alliance 'Community and Consumer Products Report' held in May 2013 noted that, '*Progressing launch of generic Prochlorperazine to combat the anticipated launch of competitor product by Lexon…*'.[2093]

8.26 For completeness, the fact that Alliance entered into an agreement with Lexon (at a time when Lexon and Medreich, working together, were not yet supplying Prochlorperazine POM) provides a further indication of Alliance's awareness of the competitive threat posed by Lexon.[2094]

Value transfers

8.27 Alliance cannot have been unaware or ought to have known that it was, indirectly through Focus, transferring value to Lexon.

8.28 Alliance and Lexon agreed that Alliance would, through Focus, transfer value to Lexon by exclusively supplying Focus with a de-branded version of Alliance's Prochlorperazine POM at a fixed selling price, and Focus sharing with Lexon the profits it earned from the sales of Alliance's Prochlorperazine POM.[2095] By way of example:

8.28.1 First, in the [Alliance Director 1] notebook entry it was recorded that Lexon would use '*Focus to distribute*'[2096] but that it would supply only the one batch needed to avoid the application of the Sunset Clause rather than enter the market with commercial volumes of the Prochlorperazine POM that it had developed with Medreich. Absent an intention on Alliance's part to compensate Lexon for not entering the market, Lexon would have had no reason to deny itself the opportunity to profit from the sale of its newly developed product. Lexon's commitment not to enter the market can therefore only have been communicated to Alliance, as recorded in [Alliance Director 1] notebook, on the basis that it had received assurances from Alliance that it would transfer value to Lexon. Consistent with this, the fact that the [Alliance Director 1] notebook entry of 11 June 2013 refers to an agreement between Lexon and Focus, despite Lexon

[2092] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*FW: Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000988).

[2093] Community and Consumer Products Report, dated 13 May 2013, page 5 (URN: PRO-E001008).

[2094] See C-307/18 *Generics (UK) and others v CMA*, paragraphs 55 to 57; See also C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraph 78. See paragraph 5.104.

[2095] See paragraph 5.628 based on the evidence set out in paragraphs 5.148 to 5.627.

[2096] [Alliance Director 1] Notebook entry CXH005 page 36 (URN: PRO-E003980).

intending to supply only one batch of product, is evidence that Alliance and Lexon had agreed that Lexon would be paid from the profits earned by Focus.

8.28.2 Second, [Lexon Director 1]'s involvement in the negotiation of the terms on which Alliance would supply Focus (as evidenced by the 22 June 2013 email[2097] and [Focus Employee 1]'s later reference to Lexon *'help[ing] set up'* the exclusive agreement between Alliance and Focus[2098]) is credibly explained only on the basis that Lexon and Alliance understood that those terms were of relevance to Lexon's own profitability and their intention having been to ensure that the agreed pricing and volume terms would enable Focus to fund compensation payments of a sufficient level. There is no other credible explanation for the involvement of Lexon (a potential competitor) in agreeing the terms on which Alliance (the incumbent) would proceed to supply its Prochlorperazine POM to Focus.

8.29 Alliance subsequently entered into the Alliance-Focus Agreement which provided for a significant value transfer from Alliance to Focus (which in turn could then be shared with Lexon pursuant to the Market Exclusion Agreement).[2099] Under the Alliance-Focus Agreement, Alliance supplied Focus on fixed price terms that would enable Focus to retain substantial profits from the supply of Alliance's de-branded product. By the end of July 2018, Focus had earned gross profits of £14.4 million on its sales of Prochlorperazine POM, a significant proportion of which were shared with Lexon (and, in turn, Medreich).

8.30 Alliance's intention was to transfer value from Alliance to Focus to enable Focus to compensate Lexon for its agreement not to enter the market.

8.30.1 By entering into a fixed price distribution contract, and at the same time de-branding its product, Alliance denied itself the opportunity to profit from any price increases that could be realised by de-branding and removing the product from the constraints of the PPRS, and instead enabled Focus to realise the benefit of those price increases.[2100]

8.30.2 The significant margins that Alliance permitted Focus to earn on the distribution of its product were far greater than would ordinarily be afforded to other suppliers appointed by Alliance to distribute its product, and are

[2097] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[2098] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030). The CMA's analysis of [Focus Employee 1]'s evidence and the Parties' associated representations on this email are set out in paragraph 5.556 to 5.561 above.

[2099] See paragraphs 5.277 to 5.280.

[2100] See paragraph 5.282.

consistent with Alliance and Focus having intended that the margins be used to compensate Lexon for its agreement not to enter the market.[2101]

8.30.3 Evidence from the Aspirin Agreement does not suggest that the margin provided for in the supply of Prochlorperazine POM was in any way conventional, and instead indicates that such margins are associated with agreements that involve a competing product no longer being marketed.[2102]

8.31 Alliance's decision to de-brand Buccastem POM (such that it was no longer subject to the price and profit controls of the PPRS or any other regulatory constraint) represents further evidence that Alliance intended to transfer value from Alliance to Focus to enable Focus to compensate Lexon for its agreement not to enter the market.[2103] Alliance denied itself the potential to inflate the price above its prevailing level, or to benefit from Focus' inflation of the price, and in doing so denied itself this key benefit of de-branding its product.[2104] De-branding did though involve significant disadvantages, including the loss of the assured sales derived from 'closed prescriptions', and an expected decrease in sales volumes due to the de-branding.[2105] Alliance's decision to de-brand can be explained only on the basis that its intention was to transfer value from Alliance to Focus to enable Focus to compensate Lexon for its agreement not to enter the market.[2106]

8.32 Further documentary evidence confirms that Alliance and Lexon had agreed that Lexon would not enter the market in return for value transfers from Alliance, indirectly through Focus. Absent value having been transferred to Lexon in return for not entering the market, Lexon would have had no reason not to enter and to deny itself the opportunity to profit from the sale of the product it had jointly developed with Medreich. Alliance cannot have been unaware or ought to have known that value was being transferred to Lexon.

8.32.1 Alliance's internal documents from the period from March to June 2013 make clear that Alliance had been highly concerned about the specific competitive threat caused by the prospect of market entry by Lexon. However, following the decision by Alliance to appoint Focus, and to supply Focus with Alliance's de-branded product, there are no further references expressing concern on the part of Alliance about the

[2101] See further paragraph 5.283.

[2102] See further paragraph 5.284.

[2103] See further paragraphs 5.359 to 5.378.

[2104] Alliance understood that, once the product was de-branded, it would be possible significantly to increase the price of Prochlorperazine POM (and indeed, the evidence shows that Alliance had expected to increase the price of the Prochlorperazine POM product had it continued to supply it to wholesalers). See further paragraph 5.279 and footnote 856.

[2105] See further paragraph 5.361.

[2106] See further paragraphs 5.359 to 5.378.

competitive threat posed by Lexon.[2107] Other Alliance internal documents are consistent with Alliance having considered that, having entered into the Market Exclusion Agreement, the Lexon threat had been removed. [Alliance Employee 1] observed in his performance appraisal that *'[t]he management of external companies and individuals has ensured the value will be maintained in Prochlorperazine (EP biggest product going into 2014)'* (emphasis added) [2108] and that *'margin generation for this product should be stable'*[2109] during 2014.[2110]

8.32.2 Alliance's sales forecasts after having entered into the Market Exclusion Agreement also demonstrate that Alliance did not expect that Lexon's product would be launched on to the market. In contrast to Alliance's documented concerns in Spring 2013 regarding entry by Lexon, Alliance's sales forecasts for 2014 and 2015 foresaw no entry by Lexon in either 2014 or 2015 and while, from November 2014, Alliance did forecast market entry in 2016, the expected entrant was not Lexon.[2111]

In exchange for non-entry

8.33 Alliance cannot have been unaware or ought to have known that the value transfers it made under the Market Exclusion Agreement were in return for Lexon not entering the market[2112] with the Prochlorperazine POM that it had jointly developed with Medreich.

8.34 Alliance and Lexon agreed that, in return for the value transfers by Alliance to Lexon, through Focus,[2113] Lexon would not enter with the Prochlorperazine POM that it had jointly developed with Medreich.[2114] Alliance was aware that Lexon would appoint Focus to distribute its product but that it would supply Focus with only the single batch necessary to avoid the application of the Sunset Clause. By way of example:

8.34.1 First, in the [Alliance Director 1] notebook it was recorded that Lexon would '*use Focus to distribute*' but that it would supply only the one batch needed to avoid the application of the Sunset Clause rather than enter the

[2107] See further paragraph 5.408.

[2108] [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014, page 18 (URN: PRO-E001103).

[2109] [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014, page 12 (URN: PRO-E001103). Although the relevant passage does not refer to Prochlorperazine POM directly, it is evident from the reference to the drug moving from brand to generic in the latter half of 2013 that the passage does refer to Prochlorperazine POM.

[2110] See paragraphs 5.407 and 5.409 to 5.416.

[2111] See paragraphs 5.379 to 5.405.

[2112] Lexon only supplied limited volumes required to avoid the application of the Sunset Clause. See, for example, paragraphs 5.422 to 5.433, 5.433 and 5.462.

[2113] By Alliance exclusively supplying Focus with a de-branded version of Alliance's Prochlorperazine POM at a fixed selling price, and Focus sharing with Lexon the profits it earned from the sales of Alliance's Prochlorperazine POM.

[2114] See paragraph 5.628 based on the evidence set out in paragraphs 5.148 to 5.627.

market with commercial volumes of the Prochlorperazine POM that it had developed with Medreich.[2115]

8.34.2 Second, [Lexon Director 1]'s involvement in the negotiation of the terms on which Alliance would supply Focus (as evidenced by the 22 June 2013 email[2116] and [Focus Employee 1]'s later reference to Lexon *'help[ing] set up'* the exclusive agreement between Alliance and Focus[2117]) is credibly explained only on the basis that Lexon and Alliance understood that those terms were of relevance to Lexon's own profitability and their intention having been to ensure that the agreed pricing and volume terms would enable Focus to compensate Lexon for agreeing not to enter the market. There is no other credible explanation for the involvement of Lexon (a potential competitor) in agreeing the terms on which Alliance (the incumbent) would proceed to supply its Prochlorperazine POM to Focus.

8.35 As noted at paragraphs 8.30 and 8.31 above, the significant margins that Alliance enabled Focus to earn on the supply of its product, and Alliance's decision to de-brand while denying itself the potential to benefit from price increases, can only be explained on the basis that its intention was to transfer value from Alliance to Focus to enable Focus to compensate Lexon for its agreement not to enter the market.

8.36 Further, as noted above at paragraph 8.32 above, Alliance's internal documents from the period from March to June 2013 make clear that Alliance had been highly concerned about the specific competitive threat caused by the prospect of market entry by Lexon. However, following the decision by Alliance to appoint Focus, and to supply Focus with Alliance's de-branded product there are no further references expressing concern on the part of Alliance about the competitive threat posed by Lexon.[2118] Other Alliance internal documents are also consistent with Alliance having considered that, having entered into the Market Exclusion Agreement, the Lexon threat had been removed. [Alliance Employee 1] observed in his performance appraisal that *'[t]he management of external companies and individuals has ensured the value will be maintained in Prochlorperazine (EP*

[2115] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980). See paragraphs 5.190 to 5.194 and in particular paragraphs 5.194.2 and 5.194.4.

[2116] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[2117] Email [Focus Employee 1] to [AMCo employee] entitled *'RE: Well Pharmacy price amendments – Focus lines'* 23 March 2017 (URN: PRO-E002030).

[2118] See further paragraph 5.408 above.

biggest product going into 2014)' (emphasis added) [2119] and that *'margin generation for this product should be stable'*[2120] during 2014.[2121]

8.37 Alliance's sales forecasts after having entered into the Market Exclusion Agreement also demonstrate that Alliance did not expect that Lexon's product would be launched on to the market. In contrast to Alliance's documented concerns in Spring 2013 regarding entry by Lexon, Alliance's sales forecasts for 2014 and 2015 foresaw no entry by Lexon in either 2014 or 2015 and while, from November 2014, Alliance did forecast market entry in 2016, the expected entrant was not Lexon.[2122]

8.38 The CMA has also found that the value transfers from Alliance to Focus are not adequately explained on the bases advanced by the Parties and by witnesses.[2123] Rather, the CMA finds that the value transfers were made to enable Focus to pay compensation to Lexon for Lexon's agreement not to enter the market.[2124] The absence of any other credible explanation for the value transfers supports the finding that, as agreed between Alliance and Lexon, the value transfers were compensation for Lexon not entering the market with the Prochlorperazine POM that it had jointly developed with Medreich and that Alliance cannot have been unaware of, or ought to have known this.

8.39 In light of the factors set out at paragraphs 8.24 to 8.38 above, and in light of the evidence set out in this Decision, the CMA finds that the undertaking Alliance cannot have been unaware or at least ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature.[2125]

[2119] [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014, page 18 (URN: PRO-E001103).

[2120] [Alliance Employee 1] 2013 Appraisal, dated 3 February 2014, page 12 (URN: PRO-E001103). Although the relevant passage does not refer to Prochlorperazine POM directly, it is evident from the reference to the drug moving from brand to generic in the latter half of 2013 that the passage does refer to Prochlorperazine POM.

[2121] See paragraphs 5.407 and 5.409 to 5.416.

[2122] See paragraphs 5.379 to 5.405.

[2123] See paragraphs 5.285 to 5.294.

[2124] See paragraphs 5.281 to 5.284 and 5.295.

[2125] The CMA's conclusion is further supported by doubts of Alliance staff over the legality of arrangements similar in nature to the Market Exclusion Agreement. In interviews with the CMA, both [Alliance Director 2] and [Alliance Employee 1] recognised that two options for Alliance to respond to the threat of generic entry could have raised legal concerns. One option involved de-branding Buccastem and Alliance gaining '*supply of generic from Lexon*', who, at that time, was a potential competitor to Alliance and selling the '*Lexon product in Alliance livery*'. Another option involved Alliance supplying its potential competitor, Lexon, with generic prochlorperazine. (See paragraph 5.164).These options involved direct forms of co-ordination between Alliance and Lexon, which envisaged that only one of Alliance or Lexon's products would be supplied to the market, and which would enable them to share the profits from the monopoly supply of a single product as opposed to both undertakings competing on price in the market. [Alliance Director 2] stated that '*supplying a competitor with product would strike me, without stepping back and putting too much thought into it, as quite, er, a tricky situation*. Interview [Alliance Director 2], 5 October 2018, page 85, lines 1-3 (URN: PRO-C2941). [Alliance Employee 1] observed that '*if they don't have a licence, you can supply a generic to someone but that doesn't work as soon as they get their licence, because that's … not compliant. So looking at this now, you know, these were options. The last two options would never have got past Legal*'. Interview [Alliance Employee 1], 4 October 2018, part 1, page 97, lines 20-24 (URN: PRO-C2909). Alliance therefore must have been aware, could not have been unaware, or at least ought to have known that entering into an indirect arrangement, such as the Market Exclusion Agreement, which was similar in nature, was anti-competitive in nature.

Application to Lexon

8.40 Applying the principles set out at paragraphs 8.14 to 8.21 above and based on the evidence set out in this Decision, the CMA concludes that the undertaking Lexon cannot have been unaware or ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature, whether or not it was aware that it was infringing the competition rules. In particular, Lexon cannot have been unaware or ought to have known that:

8.40.1 it and Medreich, working together, were potential competitors to Alliance;

8.40.2 it was receiving value transfers, indirectly through Focus, from Alliance;

8.40.3 those value transfers were in return for Lexon not entering the market with the product it had jointly developed with Medreich

and, therefore, that the Market Exclusion Agreement was anti-competitive in nature.

Potential competitor

8.41 Lexon cannot have been unaware or ought to have known when it entered into the Market Exclusion Agreement in June 2013 that it and Medreich, working together,[2126] were potential competitors to Alliance in the supply of Prochlorperazine POM and that it and Medreich, working together, had real concrete possibilities of entering the market.

8.42 As explained at paragraphs 5.87 to 5.114 above, at the time Lexon entered into the Market Exclusion Agreement, Lexon and Medreich had jointly invested the necessary resources to apply for an MA for Prochlorperazine POM, expected to receive that MA imminently, and were taking the necessary steps to plan the launch of the jointly developed product, meaning that Lexon would have been able to launch the product within a reasonable period of the date on which the Market Exclusion Agreement was concluded.

8.43 During 2012, Lexon and Medreich exchanged a number of emails about the anticipated commercialisation of the jointly developed Prochlorperazine POM and OTC in the UK which show that Lexon and Medreich were considering what steps to take to commercialise the product[2127] and that Medreich had told Lexon that Medreich had responded to all outstanding requests for information by the

[2126] As set out at paragraphs 5.81 to 5.84, Lexon and Medreich must be considered together for the purposes of determining whether they were potential competitors in the supply of Prochlorperazine POM.

[2127] Email [Medreich Director 2] to [Lexon Director 1] cc [Medreich Employee 1] entitled '*Prochlorperazine and Bisoprolol*' 28 May 2012 (URN: PRO-E002535); Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine and Bisoprolol*' 28 May 2012 (URN: PRO-E002536); Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*Prochlorperazine and Bisoprolol'* 1 June 2012 (URN: PRO-E002543); Email [Medreich Director 2] to [Lexon Director 1] cc [Medreich Employee 1] entitled '*Prochlorperazine and Bisoprolol*' 28 May 2012 (URN: PRO-E002544).

MHRA.[2128] During 2013, [Lexon Director 1] was provided with a number of further updates from Medreich. For example, on 5 March 2013, [Lexon Director 1] was informed that artworks had been prepared for the various prochlorperazine products[2129] and on 16 April 2013, [Medreich Director 2] informed [Lexon Director 1] that the grant of the MAs for Prochlorperazine POM and OTC was '*imminent*'.[2130] Further, in March 2013, Lexon communicated to Alliance that it would be launching a generic Prochlorperazine POM product[2131] and that the Lexon licence was expected in six weeks.[2132]

8.44 As Alliance was the incumbent (and only) supplier of Prochlorperazine POM in the UK market Lexon also cannot have been unaware or ought to have known that it would be competing with Alliance in the market for Prochlorperazine POM.

Value transfers

8.45 Lexon cannot have been unaware or ought to have known that it was receiving value transfers, indirectly through Focus, from Alliance.

8.46 Lexon and Alliance agreed that Alliance would, through Focus, transfer value to Lexon by Alliance exclusively supplying Focus with a de-branded version of Alliance's Prochlorperazine POM at a fixed selling price, and Focus sharing with Lexon the profits it earned from the sales of Alliance's Prochlorperazine POM.[2133]

8.47 Contemporaneous evidence from Lexon shows that in September 2013, [Lexon Director 1] expected to obtain revenues from Prochlorperazine POM even though Medreich was yet to obtain a licence. On 12 September 2013, [Lexon Director 1] informed the Lexon Board that '*Prochlorperazine is due to be launched next month from which healthy returns are expected*'.[2134]

8.48 Further, following the commencement of Focus' sales of Alliance's Prochlorperazine POM in December 2013, Lexon received the first of a series of quarterly 'reconciliation' statements from Focus in January 2014 for Focus' sales of

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[2128] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine*' 7 July 2012 (URN: PRO-E002552).

[2129] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*Fwd: Prochlorperazine 3mg and 5mg*' 05 March 2013 (URN: PRO-E002578).

[2130] Email [Medreich Director 2] to [Lexon Director 1] entitled '*FW: Prochlorperazine*' 16 April 2013 (URN: PRO-E002587).

[2131] Email [Alliance employee] to [Alliance Employee 2] and [Alliance Employee 1] cc [Alliance Director 2] entitled '*Buccastem/Prochlorperazine generic threat*' 21 March 2013 (URN: PRO-E000986).

[2132] Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' meeting dated 14 March 2013 09:00 – 12:00 (URN:PRO-E000971). A different document also entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' recording the minutes of the meeting held on 14 March 2013 (URN: PRO-E000979) records the minutes slightly differently, noting that: '*[Alliance Employee 1] contact at Lexon has confirmed they have a product coming out in 6 weeks, not on Rama yet. All of Lexon's licenses are PLPI; this would be less of a threat. Options would be to do nothing, do a deal on Buccastem or launch Alliance generic (project Cobra); this would take 8-12 weeks. [Alliance Employee 2] and [Alliance Employee 1] will monitor closely and keep dialogue open with Lexon open.*'

[2133] See paragraph 5.628 based on the evidence set out in paragraphs 5.148 to 5.627.

[2134] See paragraphs 3.107 and 5.419. Meeting minutes entitled *'Lexon (UK) Limited Board meeting minutes'* 12 September 2013, page 2 (URN: PRO-C0054).

Alliance's Prochlorperazine POM which stated: '*Please find attached the reconciliation for Dec sales of Prochlorperazine 3mg Tabs . [sic] Moving forward this will be done on a quarterly basis as per the agreement . [sic] Can you please raise an invoice on Focus for £80,631.56 and mark for the attention of [Focus employee] or myself .*'[2135]

8.49 This reconciliation statement set out for Alliance's Prochlorperazine POM by month for the previous quarter the volume of the product sold, the net turnover, the cost of goods, the profit and then the 75% share of that profit '*owed to Lexon*'. [Lexon Director 1] forwarded this email to colleagues at Lexon, stating, '*We also need to accrue half of this for Medreich*'.[2136] Following the commencement of Focus' sales of Alliance's Prochlorperazine POM in December 2013 and Lexon's receipt of the reconciliation statement in January 2014, the Lexon Board Minutes from 14 January 2014 record that (despite the fact that the Medreich licence had only recently been granted and no Medreich Prochlorperazine POM had been produced), '*[Lexon Director 1] discussed the status of drug development. Prochlorperazine has now been launched ….*'[2137]

8.50 The profit share reconciliation pattern – whereby Focus would email Lexon at the start of a quarter (January, April, July, October), with a reconciliation statement for the previous quarter, and Lexon would then email Medreich with an apportionment for Medreich's share – continued until December 2017.[2138] Lexon continued to receive profits on Focus's sales of Alliance's Prochlorperazine POM until the expiry of the Focus-Lexon Heads of Terms on 31 July 2018.[2139] By the end of July 2018, Lexon had received from Focus payments totalling some £7.86 million, £2.90 million of which Lexon passed to Medreich, despite the fact that Lexon had not provided any product to Focus with the exception of a single batch (of [✂] packs, for which Lexon invoiced Focus £49,522.25 and which represented in volume less than 1% of Focus' total supply of Alliance's product to that point) in March 2018.[2140]

[2135] See paragraphs 3.115 and 5.245; Email [Focus Director 1] to [Lexon Director 1] cc [Focus employee] entitled '*FW: Prochlorperazine Reconciliation December 2013*' 3 January 2014 (URN: PRO-E000346) and attachment entitled '*Prochlorperazine Reconciliation December 2013*', 3 January 2014 which showed the cost of goods being deducted from a net revenue figure to generate profit with '*75% Profit Share owed to Lexon'* (URN: PRO-E000347).

[2136] See paragraph 3.115; Email [Lexon Director 1] to [Lexon employee] and [Lexon employee] entitled '*FW: Prochlorperazine Reconciliation December 2013*' 3 January 2014 (URN: PRO-E000348). Lexon subsequently raised an invoice for its 75% share of the profits from Focus Email [Lexon employee] to [Lexon employee], [Lexon Director 1], [Focus Director 1], cc [Focus employee], entitled '*RE: Prochlorperazine Reconciliation December 2013*' 7 January 2014 (URN: PRO-E003772).

[2137] See paragraphs 3.118 and 5.419; *Lexon Board Minutes*, dated 14 January 2014, page 3 (URN: PRO-E000374).

[2138] See paragraph 3.124; Section 26 response of Lexon, dated 27 November 2018, to CMA Notice of 7 November 2018, question 3(b) (URN: PRO-C2977). See also email [Medreich employee] to [Lexon Director 1] entitled '*Joint Venture and Management Responsibility*' 15 February 2018 (URN: PRO-E003647).

[2139] See paragraph 3.124; Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 3(b) (URN: PRO-C3149). See also Annex I:.

[2140] See Annex I: and paragraph 5.154.10.

In exchange for non-entry

8.51 Lexon cannot have been unaware or ought to have known that the value transfers from Alliance, indirectly through Focus, were in exchange for Lexon not entering the market with the Prochlorperazine POM that it had jointly developed with Medreich.

8.52 Lexon and Alliance agreed that, in return for the value transfers by Alliance to Lexon, through Focus,[2141] Lexon would not enter the market with the Prochlorperazine POM that it had jointly developed with Medreich.[2142] For example:

8.52.1 In the [Alliance Director 1] notebook it was recorded that Lexon would '*use Focus to distribute*' but that it would supply only the one batch needed in relation to the Sunset Clause rather than enter the market with commercial volumes of the Prochlorperazine POM that it had jointly developed with Medreich.[2143]

8.52.2 The email from [Focus Director 1] to [Focus Director 2] on 22 June 2013[2144] records inter alia a '*Deal between Focus and [Lexon Director 1]. 25/75 % profit share in Lexon favour (as it is his licence)*' i.e. that Focus and Lexon had agreed that Focus would pass the majority of its profits (75%) from the sale of Alliance's Prochlorperazine POM to Lexon, on the basis that Lexon had (with Medreich) an MA for the same product.[2145]

8.53 As set out at paragraph 8.47 above, contemporaneous evidence from Lexon shows that in September 2013, [Lexon Director 1] expected to obtain revenues (*'healthy returns')* from Prochlorperazine POM even though Medreich was yet to obtain a licence.[2146]

8.54 Following the commencement of Focus' sales of Alliance's Prochlorperazine POM, and at a stage where Medreich was yet to obtain a licence, Lexon received the first quarterly 'reconciliation' statement from Focus in January 2014 which set out, *inter alia*, the 75% share of that profit '*owed to Lexon*'. [Lexon Director 1] forwarded this email to colleagues at Lexon, stating, '*We also need to accrue half of this for*

[2141] By Alliance exclusively supplying Focus with a de-branded version of its Prochlorperazine POM at a fixed selling price, and Focus sharing with Lexon the profits it earned from the sales of Alliance's Prochlorperazine POM.

[2142] See paragraph 5.628 based on the evidence set out in paragraphs 5.148 to 5.627.

[2143] [Alliance Director 1] Notebook entry CXH005, page 36 (URN: PRO-E003980). See paragraphs 5.190 to 5.194 and in particular paragraphs 5.194.2 and 5.194.4.

[2144] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[2145] See paragraphs 5.195 to 5.199.

[2146] See paragraphs 3.107 and 5.419; Meeting minutes entitled *'Lexon (UK) Limited Board meeting minutes'* 12 September 2013, page 2 (URN: PRO-C0054).

Medreich'.[2147] Lexon continued to receive such 'reconciliation' statements on a quarterly basis until December 2017 and continued to receive profits on Focus's sales of Alliance's Prochlorperazine POM until the expiry of the Focus-Lexon Heads of Terms on 31 July 2018, despite not having supplied any product to Focus with the exception of the single batch (see paragraphs 8.48 to 8.50 above).

8.55 The Lexon Board Minutes from 14 January 2014 record that (despite the fact that the Medreich licence had only recently been granted and no Medreich Prochlorperazine POM had been produced), '*[Lexon Director 1] discussed the status of drug development. Prochlorperazine has now been launched ….*'[2148]

8.56 In an email from [Lexon Director 1] to [Medreich Employee 1] dated 4 February 2014, [Lexon Director 1] responded to a suggestion from Medreich that it should get ready to introduce its Prochlorperazine POM product by stating that the product would be '*best left alone*' as Lexon and Medreich '*make far much [sic] more as it is*'.[2149]

8.57 By the end of July 2018, Lexon had received from Focus payments totalling some £7.86 million, £2.90 million of which Lexon passed to Medreich, despite the fact that Lexon had not provided any product to Focus with the exception of a single batch (of [✂] packs, for which Lexon invoiced Focus £49,522.25 and which represented in volume less than 1% of Focus' total supply of Alliance's product to that point) in March 2018.[2150]

8.58 The CMA has also found that the value transfers from Focus to Lexon are not adequately explained on the bases advanced by the Parties and by witnesses.[2151] The absence of any other credible explanation for the value transfers (which were enabled by Alliance's de-branding) supports the finding that, as agreed between Alliance and Lexon, the value transfers were compensation for Lexon not entering the market with the Prochlorperazine POM that it had jointly developed with Medreich) and that Lexon cannot have been unaware of or ought to have known this.

8.59 In light of the factors set out at paragraphs 8.41 to 8.58 above, and in light of the evidence set out in this Decision, the CMA finds that the undertaking Lexon cannot

[2147] See paragraph 3.115; Email [Lexon Director 1] to [Lexon employee] and [Lexon employee] entitled '*FW: Prochlorperazine Reconciliation December 2013*' 3 January 2014 (URN: PRO-E000348). Lexon subsequently raised an invoice for its 75% share of the profits from Focus Email [Lexon employee] to [Lexon employee], [Lexon Director 1], [Focus Director 1], cc [Focus employee], entitled '*RE: Prochlorperazine Reconciliation December 2013*' 7 January 2014 (URN: PRO-E003772).

[2148] See paragraphs 3.118 and 5.419; *Lexon Board Minutes*, dated 14 January 2014, page 3 (URN: PRO-E000374).

[2149] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled *'RE: Products'* 4 February 2014 (URN: PRO-E002750).

[2150] Annex I:and paragraph 5.154.10.

[2151] See paragraphs 5.304 to 5.345 and 5.532 to 5.555.

have been unaware or at least ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature.

Application to Medreich

8.60 Applying the principles set out at paragraphs 8.14 to 8.21 above, the CMA concludes that the undertaking Medreich cannot have been unaware or ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature, whether or not it was aware that it was infringing the competition rules.

8.61 Medreich cannot have been unaware or ought to have known:

8.61.1 that Alliance and Lexon had entered into the Market Exclusion Agreement;[2152]

8.61.2 of Alliance and Lexon's conduct in implementing the Market Exclusion Agreement;[2153] and

8.61.3 of Focus's conduct in implementing the Market Exclusion Agreement.[2154]

8.62 Medreich had an instrumental role in implementing the Market Exclusion Agreement. Medreich ensured that the product it had jointly developed with Lexon was not commercialised for the period of the Market Exclusion Agreement. Medreich refrained from producing the product that it had jointly developed with Lexon (other than the one batch required to avoid the application of the Sunset Clause) in return for receiving a share of the profits that Lexon had received through the profit share clause. Medreich understood that the payments from Lexon represented compensation for not entering the market.[2155] Medreich accepted significant payments from Lexon which were generated from Focus' sales of Alliance's Prochlorperazine POM and paid to Medreich despite the fact that Medreich did not supply any Prochlorperazine POM during the Infringement Period with the exception of a single batch of product supplied to Lexon in November 2017.[2156]

[2152] See paragraphs 5.655 and 5.658 to 5.679.

[2153] See paragraphs 5.656 and 5.658 to 5.679.

[2154] See paragraph 5.657 and 5.658 to 5.677.

[2155] See paragraph 5.679. See also Email [Medreich Director 2] to [Meiji employee] entitled *'Re: Prochlorperazine – profit sharing'* 21 July 2017 (URN: PRO-E003351).

[2156] Between January 2014 and September 2017 (that is, before any Prochlorperazine POM was supplied to Lexon), Medreich received £2.77 million (before VAT) from Lexon (see Annex I:).

8.63 The body of evidence relating to Medreich's awareness of both the Market Exclusion Agreement and the conduct of Alliance, Lexon and Focus implementing that agreement is set out in full in Chapter 5 of the Decision. In particular:

8.63.1 Statements from [Medreich Employee 1] in his interview with the CMA, confirm his understanding that Lexon was entering into an arrangement that would involve '*Alliance*,' '*whereby Focus would make a margin and then the balance margin would be shared between Lexon and Medreich*'[2157] and that it involved Medreich '*getting some payment but not actually having to manufacture a product*'.[2158]

8.63.2 Internal Medreich emails on 8 January 2014 demonstrate Medreich's awareness and acceptance that the common objective involved receiving payments from Focus, through Lexon, based on a *'Profit share on prochlorperazine licenses [sic]'* without having to supply any Prochlorperazine POM. [2159]

8.63.3 The email from [Medreich Employee 1] on 4 February 2014, demonstrates Medreich's awareness that there was a '*deal*' in place with Focus on the '*3mg POM licence*', that the profit share arrangement also involved Alliance and that Medreich were '*extremely happy*' with the deal on the table.[2160]

8.63.4 The email from [Lexon Director 1] to [Medreich Employee 1] on 4 February 2014 notes that '*The 3mg POM is best left alone*,'[2161] making clear to Medreich they should not produce Prochlorperazine POM ('*left alone'*) to which [Medreich Employee 1] replied on 5 February 2014 confirming that '*3mg we leave to you for the time being*'.[2162]

8.63.5 An internal Medreich email of 28 March 2014 between [Medreich Employee 1] and [Medreich Director 1] attaching an excel spreadsheet which set out details of how the profit share functioned recorded that '*Focus take 25%*' and that '*We [Medreich] split 75% of the profit with Lexon*'. That email showed that, following a discussion with [Lexon Director 1], Medreich considered it was able to budget on future receipt of profit share of £300,000 per year based on Focus' sale of the Alliance

[2157] See paragraph 5.660; Interview [Medreich Employee 1], 12 July 2018, page 62, lines 11-14 (URN: PRO-C3666).

[2158] See paragraph 5.662; Interview [Medreich Employee 1], 12 July 2018, page 62, lines 23-24 (URN: PRO-C3666).

[2159] See paragraph 5.663; Email [Medreich Employee 1] to [Medreich employee], cc [Medreich Director 2] entitled *'FW:'* 8 January 2014 (URN: PRO-E002696) and Email [Medreich Director 2] to [Medreich Employee 1] entitled *'FW: Prochlorperazine 3mg share profit'* 8 January 2014 (URN: PRO-E002687).

[2160] See paragraphs 5.665 to 5.666; Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled *'Products'* 4 February 2014 (URN: PRO-E002744).

[2161] See paragraph 5.667; Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled 'RE: Products' 4 February 2014 (URN: PRO-E002750).

[2162] See paragraph 5.669; Email [Medreich Employee 1] to [Lexon Director 1] entitled *'RE: Products'* 5 February 2014 (URN: PRO-E002750).

product, rather than on profits received on the sale of Medreich's own product.[2163]

8.63.6 An email from [Medreich Employee 1] to [Lexon Director 1] of 7 April 2014 demonstrates Medreich's awareness that, further to what [Medreich Employee 1] described as the '*clever arrangement*' that was in place, the price Alliance charged Focus had implications for the share of profit Medreich could expect to receive. In particular, it recorded that: '*I have been asked for a detailed analysis of how the COGS has increased now to £5.47 against a cost last quarter of £4.85. This is a product that should cost some [✂], so we feel that Alliance are making still the lion's share at £1m a year profit, and we are getting about £220k each*'.[2164]

8.63.7 Medreich was provided with quarterly profit share reconciliations from January 2014 until December 2017 and understood during this period that Lexon was providing the payments to Medreich not in return for the supply of Prochlorperazine POM, but in return for Medreich not supplying Prochlorperazine POM. For example, in an email on 21 July 2017 from [Medreich Director 2] responding to a question from [Meiji employee] in relation to why there was profit share income derived from Prochlorperazine POM despite the absence of supply, [Medreich Director 2] stated that '*3mg has never been manufactured or supplied .. Profit share comes from 3mg only…There is a deal in place that for Medreich Not [sic] to bring 3mg in market we get royalty …*'.[2165]

8.64 In light of the evidence set out in Chapter 5 of this Decision and summarised above, the CMA finds that the undertaking Medreich cannot have been unaware or at least ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature.

Application to Focus

8.65 Applying the principles set out at paragraphs 8.14 to 8.21 above, the CMA concludes that the undertaking Focus cannot have been unaware or ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature, whether or not it was aware that it was infringing the competition rules.

[2163] See paragraph 5.673; Email [Medreich Employee 1] to [Medreich Director 1] cc [Medreich employee] and [Medreich Director 2] 28 March 2014 entitled '*RE: Prochlorperazine 3 mg x 50 Focus*' (URN: PRO-E002787) attaching Excel spreadsheet entitled *'Prochlorperazine 2014 budget.xlsx'* 28 March 2014 (URN: PRO-E002788). Excel spreadsheet entitled *'Prochlorperazine 2014 budget.xlsx'* 28 March 2014 (URN: PRO-E002788).

[2164] See paragraph 5.674; Email [Medreich Employee 1] to [Lexon Director 1] entitled *'FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014'* 7 April 2014 (URN: PRO-E002803).

[2165] See paragraph 5.677.2; Email [Medreich Director 2] to [Meiji employee] entitled *'Re: Prochlorperazine – profit sharing'* 21 July 2017 (URN: PRO-E003351).

8.66 Focus cannot have been unaware or ought to have known:

8.66.1 that Alliance and Lexon had entered into the Market Exclusion Agreement;[2166]

8.66.2 of Alliance and Lexon's conduct in implementing the Market Exclusion Agreement;[2167] and

8.66.3 that Medreich held the MA for the Prochlorperazine POM in which Lexon had a commercial interest and of Medreich's conduct in implementing the Market Exclusion Agreement.[2168]

8.67 Focus had an instrumental role in implementing the Market Exclusion Agreement. It was the intermediary between Alliance and Lexon. Focus was the exclusive supplier of Alliance's Prochlorperazine POM. Focus then shared with Lexon the profits that Focus earned from selling Alliance's product, and sent Lexon quarterly 'reconciliation' statements for Focus's sales of Alliance's Prochlorperazine POM.[2169] In return Lexon agreed not to enter the market with the Lexon/Medreich Prochlorperazine POM.[2170] Focus entered into the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms knowing full well that those agreements implemented the Market Exclusion Agreement.[2171]

8.68 The body of evidence relating to Focus' awareness of both the Market Exclusion Agreement and the conduct of Alliance, Lexon and Medreich implementing that agreement is set out in full in Chapter 5 of the Decision. In particular:

8.68.1 An internal Focus email of 22 June 2013 from [Focus Director 1] to [Focus Director 2] demonstrates that Focus understood an agreement to have been reached between Alliance and Lexon. In particular, [Focus Director 1] understood that Lexon had reached an agreement with Alliance as to the price at which Focus would purchase Prochlorperazine POM from Alliance ('*[Focus Director 2] In case [Alliance Employee 1] rings you, the agreement [Lexon Director 1] made was we [Focus] initially buy at 25% off their [sic] [Alliance's] trade price*') and that there would be a profit share arrangement in place between Focus and Lexon.[2172]

[2166] See paragraphs 5.635 and 5.638 to 5.648.

[2167] See paragraphs 5.636 and 5.638 to 5.648.

[2168] See paragraph 5.637 and 5.638 to 5.648.

[2169] See paragraphs 3.115, 3.123 and 3.124.

[2170] See paragraph 5.628 and evidence referred to in Chapter 5.

[2171] See, paragraph 5.653 and Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[2172] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476). Despite the reference to a profit share, the email does not make any reference to Focus purchasing Prochlorperazine POM from Lexon. See paragraph 5.638.

8.68.2 An email dated 23 March 2017 from [Focus Employee 1] to [AMCo employee] states that '*The only reason that Lexon gets Prochlorperazine Buccal Tablets is because they helped set up the supply agreement with Alliance Pharma (who also make our Aspirin EC 300mg)*',[2173] illustrating Focus' understanding as to the Market Exclusion Agreement, and Lexon's role in helping to 'set up' the agreement between Alliance and Focus.[2174]

8.68.3 Internal Focus emails[2175] indicate that Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) that Focus would be supplied at a fixed price by Alliance in circumstances which enabled Focus to increase the price significantly at which it supplied Prochlorperazine POM to wholesalers in the UK.[2176]

8.68.4 An email from [Focus Director 1] to [Lexon Director 1][2177] and comments of a Focus witness in interview[2178] indicate that Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) that there was a relationship between Lexon and Medreich, where Medreich held the MA for the Prochlorperazine POM product in which Lexon would have commercial involvement.[2179]

8.68.5 Internal Focus emails[2180] indicate that Focus was aware (or could reasonably have foreseen it and was prepared to take the risk) that, pursuant to the Market Exclusion Agreement, Focus would share the profits it made from the sale of Alliance's Prochlorperazine POM with Lexon, without Lexon being required to supply any of the Prochlorperazine POM product that it had jointly developed with Medreich.[2181]

8.68.6 Focus chose to enter into and maintain two apparently conflicting agreements with Alliance and Lexon i.e. the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms. These agreements together required Focus only to supply the Alliance product and to share a significant proportion of its profits on those sales with Lexon in circumstances when Lexon was not providing Focus with any goods or

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[2173] Email [Focus Employee 1] to [AMCo employee] entitled '*RE: Well Pharmacy price amendments – Focus lines*' 23 March 2017 (URN: PRO-E002030).

[2174] See paragraph 5.639.

[2175] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476) and Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478).

[2176] See paragraph 5.640.

[2177] Email [Focus Director 1] to [Lexon Director 1] entitled '*Fwd: Rama as requested*' 10 July 2013 (URN: PRO-E000326)

[2178] Interview [Focus Director 1], 2 October 2018, page 46, line 8 (URN: PRO-C3294)

[2179] See paragraph 5.641.1.

[2180] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476); Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478)

[2181] See paragraph 5.641.2.

services. As a party to both contracts, Focus would, or at least should, have been fully aware of the terms of both agreements and the conflict between their terms.[2182]

8.68.7 Pursuant to the terms of its agreement with Lexon, Focus agreed to pay a substantial share of its profits on the sale of Prochlorperazine POM to Lexon for no offsetting income or benefit and without a requirement to supply it with any product. In practice, Focus paid Lexon some £7.86 million (before VAT) over a four and a half year period but received only a single batch of product in March 2018.[2183]

8.68.8 Focus' forecasting expectations[2184] and other Focus internal emails[2185] and documents[2186] indicate that Focus did not expect to obtain commercial volumes of Prochlorperazine POM from Lexon, and, relatedly, that Focus was aware that Medreich had not launched a product pursuant to the Market Exclusion Agreement.[2187]

8.69 In light of the evidence set out in Chapter 5 of this Decision and summarised above, the CMA finds that the undertaking Focus cannot have been unaware or at least ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature.

8.70 Cinven and Advanz made numerous representations challenging the CMA's conclusion that Focus committed the infringement intentionally or, at the very least, negligently. The CMA rejects these arguments. The Parties' representations, together with the CMA's response, are set out in Annex H: (paragraphs H.3 to H.19 and paragraphs H.28 to H.34).

Penalty calculation

8.71 When setting the amount of a penalty in respect of an infringement of the Chapter I prohibition, the CMA must have regard to the guidance on penalties in force at the time of setting the penalty.[2188] The CMA Penalties Guidance sets out a six-step approach for calculating the penalty.

[2182] See paragraph 5.642.

[2183] See paragraph 5.643. This represented in volume less than 1% of Focus' total supply of the Alliance product to that point and Focus paid Lexon just £49,522.25. Focus had supplied over one million packs of the Alliance product to the end of February 2018 (see section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150)).

[2184] See Email [Focus Director 1] to [Focus Director 2] entitled '*FW: other OLS for budget*' 14 November 2013 (URN: PRO-E003759); *Focus Prochlorperazine Forecast – 04 04 14*' 4 April 2014 (URN: PRO-E001117).

[2185] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[2186] Advanz Hard Copy Document TXT021, page 1 (URN: PRO-E004055); [AMCo Employee 3] Notebook EMN010, page 29 (URN: PRO-E004038).

[2187] See paragraph 5.644.

[2188] Section 38(8) of the Act.

Step 1 – Starting point

8.72 The starting point for determining the level of financial penalty which will be imposed on an undertaking is calculated with regard to (i) the relevant turnover of the undertaking and (ii) the seriousness of the infringement and the need for general deterrence.[2189]

8.72.1 The relevant turnover is the turnover of the undertaking in the relevant product market and geographic market affected by the infringement in the undertaking's last business year.[2190]

8.72.2 The CMA will apply a percentage rate of up to 30% to an undertaking's relevant turnover to reflect the seriousness of the particular infringement.

Relevant Turnover

8.73 The CMA has found that the relevant product and geographic market affected by the Infringement is no wider than the supply of Prochlorperazine POM in the UK[2191] and that a market definition that is limited to Prochlorperazine POM constitutes a conservative approach for the purposes of calculating any financial penalties.[2192]

8.74 The CMA has used the relevant turnover in the market for Prochlorperazine POM in the UK in the financial year preceding the date when the Infringement ended.

8.75 Relevant turnover is a measure of the scale and impact of infringing activity for the purposes of calculating the appropriate penalty.[2193] Generally the CMA will base relevant turnover on figures from an undertaking's audited accounts, but in exceptional circumstances it may be appropriate to use a different figure as reflecting the true scale of an undertaking's activities in the relevant market.[2194]

8.76 Where an undertaking's income from Prochlorperazine POM in the UK during the last financial year prior to the Infringement ending derives solely from sales of Prochlorperazine POM in the UK, the CMA has calculated that undertaking's relevant turnover by reference to the revenue from those sales.

8.77 However, where an undertaking's sales of Prochlorperazine POM in the UK during the last financial year prior to the Infringement ending do not reflect the true scale of income that the undertaking derived from Prochlorperazine POM in the UK, the CMA does not consider it appropriate to calculate that undertaking's relevant

[2189] CMA Penalties Guidance, paragraphs 2.3–2.15.

[2190] CMA Penalties Guidance, paragraphs 2.11–2.15. Paragraph 2.11 of the CMA Penalties Guidance provides that the undertaking's last business year is the financial year preceding the date when the infringement ended.

[2191] See paragraphs 4.1–4.7.

[2192] See paragraph 4.4.

[2193] *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 44.

[2194] CMA Penalties Guidance, paragraph 2.12; See *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraphs 44 to 59.

turnover by reference solely to the revenue from those sales. Where an undertaking obtains additional income which is directly linked to, and is a significant part of (or indeed comprises the entirety of) the revenue that it receives as a result of its activities in relation to the relevant market, the CMA considers it appropriate to include that income in the relevant turnover of the undertaking.[2195] The CMA considers that any calculation of relevant turnover which did not include this other income would not reflect or be an appropriate measure of the true scale and impact of the infringing activity in which the undertaking was engaged.

8.78 The CMA has found that the:

8.78.1 Alliance undertaking participated in the Infringement from at least 7 June 2013 until 31 July 2018;[2196]

8.78.2 Lexon undertaking participated in the Infringement from at least 7 June 2013 until 31 July 2018;[2197]

8.78.3 Medreich undertaking participated in the Infringement from at least 5 February 2014 until 15 February 2018;[2198] and

8.78.4 Focus undertaking participated in the Infringement from at least 22 June 2013 until 31 July 2018.[2199]

Alliance

8.79 The CMA has calculated the relevant turnover for the Alliance undertaking's involvement in the Infringement by reference to its total revenue from the sales of Prochlorperazine POM in the UK during the last financial year prior to the Infringement ending, which was the financial year ended 31 December 2017. Alliance's relevant turnover in that financial year amounted to £976,000[2200] and was derived from sales made to Focus.

8.80 Alliance's relevant turnover in its last business year of the Infringement (£976,000) is significantly less than its equivalent turnover during each of its preceding three full business years during the Infringement.[2201] Alliance's relevant turnover used at Step 1 of this penalty calculation is approximately half (53.8%) of its average turnover in the relevant market for the previous three years. Alliance's relevant

[2195] See the CMA's decision in *Paroxetine* (Case CE-9531/11), 12 February 2016, paragraphs 11.33-11.35 and the judgment of the CAT in *Paroxetine II* [2021] CAT 9, paragraph 161.

[2196] See paragraph 5.729.

[2197] See paragraph 5.729.

[2198] See paragraph 5.731.

[2199] See paragraph 5.730.

[2200] Section 26 response of Alliance dated 14 May 2021, to the CMA Notice of 7 May 2021 (URN: PRO-C7211 and URN: PRO-C7212).

[2201] In its business years ending 31 December 2014, 2015 and 2016, Alliance's turnover in the relevant market was respectively £1,813,437, £1,916,547 and £1,708,000. (Section 26 response of Alliance, dated 14 May 2021, to the CMA Notice of 7 May 2021 (URN: PRO-C7211 and URN: PRO-C7212).

turnover was therefore unusually low in its last business year of the Infringement. The CMA has taken account of Alliance's unusually low relevant turnover at Step 4 of its penalty calculation (see paragraphs 8.212 to 8.216).

Lexon

8.81 The CMA has calculated the relevant turnover for the Lexon undertaking's involvement in the Infringement by reference to the last financial year prior to the Infringement ending, which was the financial year ended 30 April 2018. Lexon supplied very limited quantities (with a value of £49,522.25[2202]) of the Lexon/Medreich Prochlorperazine POM product during that financial year[2203] – namely the one batch of Prochlorperazine POM product required to be produced for the purpose of the Sunset Clause and which was supplied by Lexon to Focus on 29 March 2018 (see paragraph 3.273).

8.82 The CMA considers that Lexon's sales of Prochlorperazine POM do not reflect the true scale of income that Lexon derived from Prochlorperazine POM in the UK. This is because, in the financial year ended 30 April 2018, Lexon received, under the Market Exclusion Agreement, profit share payments from the sale by Focus of Alliance's Prochlorperazine POM as compensation for not commercialising the Lexon/Medreich product. The CMA considers that this income was derived by Lexon directly from its activities on the relevant market and falls to be considered as part of the revenue of Lexon in relation to its activities in the relevant market.[2204] The CMA considers that any calculation of relevant turnover which did not include this profit share income would not reflect the true scale of Lexon's activities in relation to the relevant market and would not be an appropriate measure of the scale and impact of the infringing activity in which Lexon was engaged.[2205] Accordingly, in calculating the relevant turnover of Lexon, the CMA has included in Lexon's relevant turnover Lexon's profit share receipts from Focus in the financial year ended 30 April 2018 which amounted to £1,706,003.18.[2206]

8.83 Lexon's total turnover in the relevant market for the year ending 30 April 2018 is therefore £1,755,525.43.

[2202] Section 26 response of Lexon dated 14 May 2021, to the CMA Notice of 7 May 2021, question 3 (URN: PRO-C7218, PRO-C7222, and PRO-C7225).

[2203] As a wholesaler, Lexon purchased Prochlorperazine POM from Focus to distribute to its retail pharmacy customers. However, such sales were made pursuant to Lexon's position as a wholesale customer to Focus, rather than its position (working together with Medreich) as a potential competitor in the supply of the Lexon/Medreich Prochlorperazine POM product.

[2204] See in this respect *Paroxetine II* [2021] CAT 9, paragraph 161.

[2205] See in this respect *Paroxetine II* [2021] CAT 9, paragraph 161.

[2206] Section 26 response of Lexon dated 14 May 2021, to the CMA Notice of 7 May 2021, question 1 (URN: PRO-C7218, PRO-C7220, and PRO-C7223).

Medreich

8.84 The CMA has calculated the relevant turnover for the Medreich undertaking's involvement in the Infringement by reference to the last financial year before the Medreich undertaking's involvement in the Infringement ended, which was the financial year ended 31 March 2017.[2207] Medreich did not make any sales of Prochlorperazine POM during that financial year.[2208]

8.85 Under the Infringement, however, Medreich received through Lexon profit share payments from the sales by Focus of Alliance's Prochlorperazine POM as compensation for not commercialising the Lexon/Medreich product. The CMA considers that this income was therefore derived by Medreich directly from its activities on the relevant market and falls to be considered as the revenue of Medreich in relation to its activities in the relevant market.[2209] The CMA considers that any calculation of relevant turnover which did not include this profit share income would not reflect the true scale of Medreich's activities in relation to the relevant market and would not be an appropriate measure of the scale and impact of the infringing activity in which Medreich was engaged.[2210] Accordingly, in calculating the relevant turnover of Medreich, the CMA has included Medreich's profit share receipts from Lexon in the financial year ended 31 March 2017 which amounted to £1,221,397.65.[2211]

Focus

8.86 The CMA has calculated the relevant turnover for the Focus undertaking's involvement in the Infringement by reference to its revenue from the sales of Prochlorperazine POM in the UK during the last financial year prior to the Infringement ending, which was the financial year ended 31 December 2017. Focus' relevant turnover is £5,156,944.72.[2212]

8.87 Advanz and Cinven each submitted that the CMA should have diverged from the approach set out in the CMA Penalties Guidance when calculating Focus' relevant turnover.

[2207] In the particular circumstances of the case (including that Medreich's participation in the Infringement ceased during the financial year ended 31 March 2018, and Medreich declined to receive any profit share relating to Prochlorperazine sold after 31 December 2017 – see paragraphs 3.272 and 5.731), the CMA considers that the appropriate approach is to use the financial year ended 31 March 2017 as the basis for determining Medreich's relevant turnover.

[2208] Medreich submission dated 11 May 2021, in response to the CMA questions of 7 May 2021, question 2 (URN: PRO-C7206 and PRO-C7207).

[2209] See in this respect *Paroxetine II* [2021] CAT 9, paragraph 161.

[2210] See in this respect *Paroxetine II* [2021] CAT 9, paragraph 161.

[2211] Medreich submission dated 11 May 2021, in response to the CMA questions of 7 May 2021, question 1 (URN: PRO-C7206 and PRO-C7207).

[2212] Section 26 response of Advanz dated 21 December 2018, to the CMA Notice of 11 December 2018 (URN: PRO-C3150) as confirmed by the section 26 response of Advanz dated 21 May 2021, to the CMA Notice of 7 May 2021 (URN: PRO-C7232 – PRO-C7235).

8.88 Advanz submitted that the relevant turnover identified by the CMA '*does not reflect the economic reality*' of the Infringement and the CMA should have instead calculated relevant turnover by reference to average turnover over the period of the Infringement in line with *'[t]he decisional practice of the Commission'*. Advanz's view is that the CMA's approach results in a starting point that is *'improperly inflated'*.[2213]

8.89 Advanz further submitted that the CMA is wrong to conclude that Focus' relevant turnover is *'equal to its entire revenue from Prochlorperazine POM in 2017'* noting that it shared a proportion of its profits with Lexon under the terms of the Focus-Lexon Heads of Terms.[2214] Advanz argued that by not deducting the profit share amounts from Focus' relevant turnover the CMA *'artificially overstated the economic reality of the Alleged Infringement'*.[2215]

8.90 Cinven argued that the use of 2017 Focus turnover figures to calculate the starting point with respect to its period of ownership *'infringes the principle that the penalty imposed should be specific to the offence and the offender'*.[2216] Cinven further argued that the *'necessary corollary'* of the principle of personal responsibility is that *'liability for conduct following the sale of a subsidiary cannot be imputed to a former parent company'*[2217] and the CMA *'must take account of the particular Focus undertaking alleged to have existed*' at each of the Focus periods of ownership.[2218] Cinven submitted that the CMA should have calculated relevant turnover in this case individually for each ownership period by reference to the turnover generated in the last business year of each of the different ownership periods.[2219] Accordingly, Cinven submitted that the Focus undertaking with respect to its period of ownership *'ceased to exist on 21 October 2015'* and that the CMA should have used the Focus undertaking's 2014 turnover as the relevant turnover in relation to its ownership period as 2014 was the year preceding the end of the Infringement of the undertaking that comprised the *'Cinven Addressees, Mercury Pharma Group Limited and the Focus Entities.'*[2220]

8.91 The CMA concludes that in this case it is appropriate to apply the approach set out in the CMA Penalties Guidance when calculating relevant turnover with respect to the Focus undertaking.

8.92 The CMA considers that the relevant turnover figure it has identified for Focus reflects the true scale of Focus' activity in the relevant market and does not

[2213] Advanz RDPS, 7 July 2021, paragraph 6.7 (URN: PRO-C7481).
[2214] Advanz RDPS, 7 July 2021, paragraph 6.8 (URN: PRO-C7481).
[2215] Advanz RDPS, 7 July 2021, paragraph 6.8 (URN: PRO-C7481).
[2216] Cinven RDPS, 7 July 2021, paragraph 3.6(a) (URN: PRO-C7439).
[2217] Cinven RDPS, 7 July 2021, paragraph 3.5(a) (URN: PRO-C7439).
[2218] Cinven RDPS, 7 July 2021, paragraph 3.4 (URN: PRO-C7439).
[2219] Cinven RDPS, 7 July 2021, paragraph 3.6(a) (URN: PRO-C7439).
[2220] Cinven RDPS, 7 July 2021, paragraphs 3.6(a) and 3.8 (URN: PRO-C7439).

consider there is '*something out of the norm*' to justify departing from the CMA Penalties Guidance[2221] with respect to Focus.[2222]

8.93 Further, the fact that an alternative approach to the determination of relevant turnover was taken in a number of UK[2223] and EU cases in the past is of limited precedent value in this context, since the decision to adopt the approach in the CMA Penalties Guidance, or to depart from it needs to be made on a case-by-case basis, taking into account all relevant facts and circumstances of a case.

8.94 The CMA also rejects Advanz's view that it ought to deduct the profit share amounts paid to Lexon from Focus's relevant turnover. In the comparable scenario in *Paroxetine*, in which GSK made cash payments to potential competitors that had committed not to enter the market, the CAT concluded that it was not necessary to deduct such payments from GSK's relevant turnover. It observed that *'there is no justification for reducing that net sales figure* [GSK's total sales of paroxetine in its financial year ended 31 December 2003, after the deduction of sales rebates, VAT and other turnover-related taxes] *on the ground that GSK shared its high profits by making payments to competitors under agreements that infringed competition law. Nor is there any discrimination against GSK in this approach'*.[2224]

8.95 The CMA disagrees with Cinven's view that a different Focus undertaking existed at each period of ownership and that the CMA should have established separate starting points for each of the different Focus ownership periods in this case.[2225]

[2221] CMA Penalties Guidance, paragraph 2.11.

[2222] This point was recently confirmed by the CAT: *'The Penalty Guidance does not require the CMA to calculate the average of the turnovers over the period of an infringement which lasted more than one year. Accordingly, the normal position is that one does not take an average figure. […] it is clear that the CMA is entitled to depart from this aspect of the Penalty Guidance when it is appropriate to do so. It is not helpful to try to define the cases in which it would be appropriate to depart from the usual approach. […] All one can usefully say is that the Penalty Guidance is to be applied in the normal case so that there must be something out of the norm to justify departing from it and using an average of the turnovers for the whole period of the infringement (or some other approach).'* See *FP McCann Limited v CMA* [2020] CAT 28, paragraphs 178 and 179. An infringer's turnover will usually be variable over a period of time. Focus' relevant turnover figures in the Infringement period were £2.5m in 2014, £4.3m in 2015, £6.5m in 2016 and £5.2m in 2017. These figures do not show such volatility in turnover as to require a departure from the guidance.

[2223] For example, CMA decision of 19 December 2016 (Case CE/9691/12) - *Galvanised steel tanks for water storage – Information exchange* - is one of the few cases where the CMA departed from the standard approach of using the turnover from the business year preceding the end of the infringement. Instead, the CMA used the 12 months immediately preceding the infringement. The reason for this was that Balmoral was a new entrant that was growing quickly. To take the last financial year before the end of the infringement would not have represented its true economic situation. The CMA has also departed from the standard approach in a small number of other cases due to difficulties calculating turnover for the last business year. See for example CMA decision of 14 December 2017 (Case 50283) - *Cleanroom laundry services and products: anti-competitive agreement* - where the company's last business year lasted 18 months and so to calculate relevant turnover on a 12-month basis, the CMA considered it appropriate to pro-rate by two-thirds.

[2224] *Paroxetine II* [2021] CAT 9, paragraph 159.

[2225] The CMA considers that the Focus undertaking's involvement in the Infringement was that of a single undertaking throughout the Infringement, the configuration of which changed over time as successive parent companies joined and left it. This is consistent with the statement of the EU Court of Justice in its recent *GEA* judgment (C-823/18 P *GEA*, EU:C:2020:955, paragraphs 66 and 70) and is also supported by the Opinion of AG Pitruzzella in C-823/18 P *Commission v GEA Group AG*, EU:C:2020:426, which states that where the composition of an 'undertaking' changes over time as different companies join it and exit it (like in the present case), *a single fine* should be imposed on *a single undertaking* in its various and successive forms: *'The undertaking may, in fact, assume different forms during its participation in an infringement, depending on the different entities joining or leaving it. Such changes, which are liable to occur particularly where, as in the present case, the infringement continues for a long period, do not call into question*

The CMA's calculation of the relevant turnover for the Focus undertaking is entirely consistent with the CMA Penalties Guidance and accordingly no reduction on account of the calculation of relevant turnover is necessary at Step 4.

8.96 The CMA considers that its chosen approach to relevant turnover is also in line with the Court of Appeal and CAT's judgments in the *Toys* case. The Court of Appeal accepted the CAT's view that where there was more than one possible methodology for determining the relevant turnover, the overarching question ('overriding safeguard') was whether the *'overall figure resulting from the totality of the calculation is appropriate to the infringement in question'*.[2226] The CMA considers that in this case the overall figure resulting from the penalty calculation ensures a fair calculation of the fine payable by each liable undertaking.

8.97 The CMA therefore calculates the relevant turnover for the Alliance, Lexon, Medreich and Focus undertakings during the last financial year prior to the Infringement ending as set out in Table 4: Relevant turnover below.

Table 4: Relevant turnover

Undertaking	Date undertaking's involvement in the Infringement ended	Relevant business year	Basis for turnover	Relevant turnover
Alliance	31 July 2018	1 January to 31 December 2017	Sales of Prochlorperazine POM to Focus	£976,000
Lexon	31 July 2018	1 May 2017 to 30 April 2018	Receipt of profit share from Focus and supply of one batch of Lexon / Medreich Prochlorperazine POM product to Focus	£1,755,525
Medreich	15 February 2018	1 April 2016 to 30 March 2017	Receipt of profit share from Lexon	£1,221,398
Focus	31 July 2018	1 January to 31 December 2017	Sales of Prochlorperazine POM	£5,156,945

either the fact that there is a single undertaking to which an infringement is imputable, or the fact that a single fine is imposed on it.' (see paragraphs 48 and 49 of the Opinion – emphasis added by the CMA).

[2226] *Argos/Littlewoods* [2006] EWCA Civ 1318, paragraph 231.

Seriousness of the Infringement

8.98 The CMA will apply a starting point of up to 30% to an undertaking's relevant turnover in order to reflect adequately the seriousness of the particular infringement.[2227] The particular circumstances of each undertaking's unlawful conduct are taken into account at other steps.[2228]

8.99 Taking into account the nature of the Infringement, the specific circumstances of the case, and the need for general deterrence, the CMA considers that the starting point of 30% of relevant turnover should be applied in this case. The following factors are relevant to the CMA's assessment of seriousness:

8.99.1 Likelihood of the Infringement by its nature, to harm competition: The EU Court of Justice has consistently held market exclusion agreements, an extreme form of market sharing, to be a particularly serious breach of the competition rules.[2229] As set out in paragraphs 5.149 of this Decision, the CMA has found the Market Exclusion Agreement to be a market exclusion agreement. The CMA has found that Lexon and Medreich, working together, were potential competitors to Alliance in the supply of Prochlorperazine POM,[2230] and that Lexon agreed not to enter the market for Prochlorperazine POM in exchange for Alliance indirectly (through Focus) transferring value to Lexon by exclusively supplying Focus with its Prochlorperazine POM, and Focus sharing the profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon.[2231] Focus and Medreich participated in the Infringement.[2232] Market exclusion agreements are among the most serious types of infringement and are very likely, by their nature, to cause harm to competition.

8.99.2 Nature of the product: Prochlorperazine 3mg buccal tablets are widely used in the treatment of nausea and vomiting as well as to treat migraines and dizziness due to ear problems and other causes.[2233] Given its wide usage and the importance of generic competition to ensuring that it is priced competitively, the CMA considers that a high starting point is appropriate where, as in this case, the potential for generic competition in its supply is entirely eliminated.

8.99.3 Structure of the market: The Infringement covered the entire supply of Prochlorperazine POM in the UK for the large part of its duration. At the

[2227] CMA Penalties Guidance, paragraph 2.4.

[2228] CMA Penalties Guidance, paragraph 2.10.

[2229] As set out in paragraphs 5.696.

[2230] See paragraphs 5.85-5.114.

[2231] See paragraph 5.273-5.356.

[2232] See paragraph 5.629-5.688.

[2233] See paragraph 3.22.

start of the Infringement, Alliance was the sole supplier of the branded version of Prochlorperazine POM (Buccastem POM) in the UK. It remained the sole supplier of Buccastem POM and (following de-branding) Prochlorperazine POM, notwithstanding the grant of MAs to Medreich on 9 January 2014 and Primegen on 2 February 2016, until Morningside Healthcare was granted a MA in April 2017.[2234] For the majority of the duration of the Infringement, Alliance therefore was a monopolist supplier of Prochlorperazine POM in the UK. The significant coverage of the Infringement increases the seriousness of an infringement aimed at eliminating the only potential competition that existed at the time.

8.99.4 Potential effect on competitors: Medreich was the first pharmaceutical company to have obtained an MA for supplying Prochlorperazine POM tablets in the UK other than Alliance and was the first and – for more than two years – the only source of potential competition to Alliance in the supply of Prochlorperazine POM. The CMA has found that Lexon and Medreich, working together, were potential competitors to Alliance[2235] and that Lexon agreed not to enter the market with the Prochlorperazine POM that it had jointly developed with Medreich, removing the potential constraint on Alliance.[2236] The CMA considers that the removal of the first and, for a period of time, only source of potential competition places the Infringement at the upper end of seriousness and that a high starting point is therefore appropriate.

8.99.5 Potential effect on end customers: As the CMA has found that the Infringement is an object infringement, the CMA is not required to make a formal assessment of the actual harm caused for the purposes of establishing an infringement.[2237] Nevertheless, the CMA considers that the potential harm to competition is very high in circumstances where a potential entrant is paid by a sole supplier not to enter the market. As pharmacies that receive a prescription for Prochlorperazine POM are required to dispense it, and pharmacies can only drive price competition between competing suppliers where there is a choice of Prochlorperazine POM supplier, the elimination of generic competition in the supply of such medicines is therefore highly significant. A market exclusion agreement can cause severe public harm when it enables the incumbent to sustain its position as the sole supplier of a drug and, unconstrained by competition, the implementation of significant price increases at a cost to the NHS and ultimately the taxpayer. The cost of funding Prochlorperazine POM

[2234] See paragraphs 3.53, 3.156, 3.196, 5.490-5.523.

[2235] See paragraphs 5.85–5.114

[2236] See paragraphs 5.273–5.356.

[2237] *Consten and Grundig v Commission*, 56/64 and 58/64, EU:C:1966:41, page 342; see also *Cityhook Limited v OFT* [2007] CAT 18, paragraph 269.

prescriptions increased significantly during the course of the Infringement and the parties shared the substantial profits generated over the Infringement period (see paragraph 5.721.8 above).[2238]

8.99.6 Need to deter other undertakings: Penalties imposed by the CMA for breaches of the Act aim to deter other undertakings from engaging in similar infringements.[2239] The Infringement concerns one of the most serious types of infringement: the exclusion of a competitor from the market and an extreme form of market sharing. The CMA has recent experience of multiple market sharing infringements[2240] and a high starting point is appropriate to deter further recurrence of such infringements. Further, this Infringement is a horizontal market exclusion agreement that was implemented via two separate agreements with a common third party, Focus (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected and appropriate enforcement action being taken. A high starting point is appropriate to deter other businesses from engaging in similar conduct.

8.100 All of the foregoing factors, taken in the round, informed the CMA's assessment that a 30% starting point is appropriate in this case.

The Parties' representations

8.101 The Parties each submitted that the starting point percentage applied by the CMA is too high[2241] arguing that the 30% starting point is *'excessive'*,[2242] *'without precedent'*,[2243] *'inconsistent with recent and very analogous infringement decisions*

[2238] See paragraph 3.23 and Table 1: UK Prescriptions of Prochlorperazine 3mg Buccal tablets 2014-18.

[2239] CMA penalties guidance, paragraphs 2.4 and 2.9.

[2240] Case 50277 – *Hydrocortisone*; Case 50455 – *Fludrocortisone acetate*; Case 50507.2 – *Nortriptyline*; Case 50283: *Cleanroom laundry services and products*; Case 50299 – *Pre-cast concrete drainage products*.

[2241] Lexon RDPS, 2 July 2021, paragraph 2.1 (URN: PRO-C7416).

[2242] Alliance RDPS, 7 July 2021, paragraph 4.2 (URN: PRO-C7461).

[2243] Advanz RDPS, 7 July 2021, paragraph 2.19.1 (URN: PRO-C7481). A lack of precedent *'in the factual circumstances'* does not preclude the CMA from applying a 30% starting point noting the limited precedent value of previous cases. Moreover, it is precisely the specific facts of *this* case on which the CMA finds it appropriate to adopt a 30% starting point noting the factors it has set out in paragraphs 8.99 to 8.100, which make the Infringement a serious breach of competition law with the potential to cause severe public harm. Accordingly, the CMA rejects Advanz's argument that the specific circumstances of the case justify a *'significantly lower starting point'* (Advanz RDPS, 7 July 2021, paragraph 6.14 (URN: PRO-C7481)). Advanz also submitted that the CMA may be *'calculating its starting point to arrive at a figure that would in its mind make good the damage the CMA maintains has been suffered by the NHS'* (Advanz RDPS, 7 July 2021, paragraph 6.15 (URN: PRO-C7481)). As set out in paragraphs 8.98 to 8.100 of this Decision, while the CMA's calculation of the starting point has been made by reference to the seriousness of the type of infringement including the impact on the NHS of the repeated price increases that it entailed, the CMA has not sought in its penalty calculation to '*make good the damage*' to the NHS. For the avoidance of doubt, the CMA plays no role in compensating the NHS, an end customer. Fines imposed by the CMA are paid into the Consolidated Fund and not directly to the NHS.

in the pharmaceutical industry',[2244] and *'does not appear to have been arrived at by means of any objective assessment'*.[2245]

8.102 The CMA rejects the Parties' contention that the starting point should be lower on the basis of comparisons with other CMA and Commission cases. The CMA assesses penalties on a case-by-case basis,[2246] and is not bound by previous decisional practice. It only needs to ensure that there is broad consistency in its approach to the CMA Penalties Guidance. As set out above, the CMA considers that 30% is appropriate in this case taking into account the nature of the Infringement, the specific circumstances of the case, and the need for general deterrence.

8.103 Each of Cinven and Medreich made representations that the nature of the product does not justify a 30% starting point:

8.103.1 Cinven submitted that Prochlorperazine POM is *'not widely prescribed'.*[2247]

8.103.2 Medreich submitted that Prochlorperazine POM is not a vital or lifesaving drug.[2248]

8.104 The CMA rejects Cinven and Medreich's respective representations. As outlined above, each of the factors set out by the CMA in paragraphs 8.99.1 to 8.99.6 of this Decision are taken in the round to inform the CMA's assessment of seriousness with no individual factor being determinative. The CMA is not required to demonstrate that each factor individually warrants the starting point reached but in any event notes that the lifesaving nature of a product is not a pre-requisite of a high starting point. The CMA considers that comparison to products in other cases is of limited value given the variation in the factual circumstances of each case and the CMA's consideration of the need for general deterrence at the time of the Decision. The CMA's view remains that, when considered in the round with the other factors listed above (see paragraphs 8.98 to 8.100), the elimination of generic competition in the supply of this widely used drug merits a starting point of 30%.

[2244] Medreich RDPS, 7 July 2021, paragraph 3.3 (URN: PRO-C7444).

[2245] Cinven RDPS, 7 July 2021, paragraph 3.17 (URN: PRO-C7439).

[2246] See, for example, *Kier Group and Others v OFT* [2011] CAT 3, paragraph 116, where the CAT noted that *'other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent'*. See also *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 97, where the CAT observed that *'[d]ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case'*. The CAT recently confirmed that very limited assistance can be obtained from previous OFT and CMA decisions when assessing seriousness, since seriousness depends on a number of factors and each case is very different (see *Paroxetine II* [2021] CAT 9, paragraph 151, and *Roland v CMA* [2021] CAT 8, paragraphs 87 and 90 on the value of previous decisional practice and the individual assessment of case-specific factors). See also the CMA Penalties Guidance, paragraph 2.6.

[2247] Cinven RDPS, 7 July 2021, paragraph 3.23(a) (URN: PRO-C7439).

[2248] See Medreich RDPS, 7 July 2021, paragraph 3.5 (URN: PRO-C7444) in which Medreich argues that *'the conduct of the addressees of the Fludrocortisone Decision appears to be objectively of a more serious nature than that alleged of Medreich'* in particular with respect to the nature of the drugs concerned.

8.105 Cinven and Alliance made representations regarding the structure of the market that in their view justified a lower starting point percentage:

8.105.1 Cinven submitted that the CMA's view that the Infringement covered the entire supply of Prochlorperazine POM in the UK for a large part of its duration was *'hardly remarkable in a market where there was only one actual competitor with a proven capability to supply the product during [Cinven's period of ownership]'*. Further, Cinven submitted that the CMA is incorrect to assert for a period of two years Medreich was the only source of potential competition, noting the regulatory issues that Medreich encountered prevented it from entering for a period of nine of the twelve months of Cinven's ownership of Focus.[2249]

8.105.2 Alliance submitted that *'the extent of harm derived (…) is considerably more limited'* than set out above on account of Morningside's entry to the relevant market in 2017 *'such that the market was now more competitive'* and should be reflected in a lower starting point.[2250]

8.106 The CMA does not accept that any supply challenges faced by Medreich justify a lower starting point. It remains the case that the Market Exclusion Agreement had the object of preventing competition because Alliance agreed to (indirectly) transfer value to Lexon in return for Lexon agreeing not to enter the market with the Prochlorperazine POM it had jointly developed with Medreich, so sustaining Alliance's position as sole supplier of the drug. Removing the only source of competition in the supply of Prochlorperazine POM ensured that Alliance would not face any constraint on its sales volumes or prices. Further, it is not accepted that the temporary and unforeseen issues of the type encountered by Medreich should lessen the seriousness of an infringement that aimed to extinguish competition in the supply of Prochlorperazine POM noting that the issues Medreich encountered did not change its status as a potential competitor.

8.107 The CMA also does not consider it appropriate to reduce the starting point percentage on account of Morningside's entry in 2017. As set out in paragraph 8.99.3 the Infringement covered the entire supply of Prochlorperazine POM in the UK for the large part of its duration and the CMA considers it would be inappropriate to reduce the starting point on account of third party entry that was of relevance only to a very limited proportion of the Relevant Period.

8.108 Cinven, Lexon and Alliance submitted representations regarding the effects of the Infringement:

8.108.1 Cinven submitted that the CMA has alleged serious effects on end customers arising from pricing without having established that the

[2249] Cinven RDPS, 7 July 2021, paragraph 3.23(b) (URN: PRO-C7439).

[2250] Alliance RDPS, 7 July 2021, paragraphs 4.7 and 4.9 (URN: PRO-C7461).

Prochlorperazine POM price increases were a result of the Infringement, or that prices would have decreased or remained stable absent the Infringement. Cinven also noted that the CMA has not claimed that the price increases were excessive or unlawful and its statement regarding the effects of the Infringement is of *'very limited value'* in justifying the maximum possible starting point.[2251]

8.108.2 Cinven also claimed that the fact that Medreich and Lexon were not supplying Prochlorperazine POM may have had an *'incentivising effect'* on other potential competitors who retained the *'prospect of being second to market and achieving greater sales than subsequent generic entrants'*. Cinven argued that such incentives also mean that the harm resulting from the Infringement is *'highly unclear'*.[2252]

8.108.3 Lexon submitted that *'[g]iven the MHRA's delays in completing the licensing process and the well-documented difficulties involved in the manufacture of the Product, the likelihood of harm to competition and consumers is very low, and arguably non-existent.'*[2253]

8.108.4 Alliance referred to the CAT's views in *FP McCann* and *Paroxetine* and submitted that *'where the CMA is given evidence that the infringement did not have an adverse effect on competition, the CMA should consider the appropriate response to that evidence in the context of setting any fine, and that it should adopt an appropriate counterfactual which reflects the reality of the situation.'*[2254] Alliance also submitted that the Focus-Lexon Heads of Terms *'stands independently and should be assumed in any event'* and that in the counterfactual Alliance would have '*debranded Buccastem POM and signed an exclusive distribution agreement with Focus in any event'* on a *'fixed supply price model'* in response to possible generic entry.[2255]

8.109 The Parties' representations on effects are misconceived. First, the CMA has found that the Market Exclusion Agreement had the object of restricting competition in the market for the supply of Prochlorperazine POM in the UK.[2256] As an object restriction, the CMA is not required to make a formal assessment of the actual harm caused. However, when fixing a penalty, the CMA is entitled to have regard to the likelihood of harm resulting from that infringement and to take the view, that on the facts of the particular case, the infringement amounts to one of the most serious infringements, even where it has not been implemented or has

[2251] Cinven RDPS, 7 July 2021, paragraph 3.23(c) (URN: PRO-C7439).
[2252] Cinven RDPS, 7 July 2021, footnote 60 (URN: PRO-C7439).
[2253] Lexon RDPS, 2 July 2021, paragraph 2.3 (URN: PRO-C7416).
[2254] Alliance RDPS, 7 July 2021, paragraph 4.6 (URN: PRO-C7461).
[2255] Alliance RDPS, 7 July 2021, paragraph 8.4 (URN: PRO-C7461).
[2256] See paragraphs 5.726-5.727

had no actual adverse effect on competition.[2257] Second, when assessing the potential harm for the purposes of seriousness the CMA considers that it is appropriate to have regard to the information available to the Parties and their perception of the market at the time they decided to adopt a particular course of conduct and enter into and/or participate in the Market Exclusion Agreement, so that subsequent and unforeseen issues cannot therefore reasonably be regarded as lessening the seriousness of the Parties' conduct.[2258]

8.110 The CMA has found that the Market Exclusion Agreement was structured to delay the prospect of Lexon's market entry with the Medreich product, and to ensure that the Alliance product could be supplied in the absence of competition in the supply of Prochlorperazine POM. Free from competition, Focus foresaw that it could implement a series of prices increases (see paragraphs 5.279 and 5.640). At the time the Market Exclusion Agreement was entered into, it was anticipated that Lexon would have otherwise entered the market soon after Medreich acquired its MA, and such entry could reasonably have been expected to put downward pressure on market prices.

8.111 The CMA does not consider it appropriate to reduce the starting point percentage on the basis that the Infringement may have incentivised other potential competitors. The aim of the Infringement was plainly to restrict competition, and it is this infringing conduct that is the subject of the penalty. Further, there is no evidence that the Infringement incentivised new entry and, even if there was, the CMA finds that it would be inappropriate to decrease a penalty on the basis that a restriction of competition, and the price rises that the Infringement was structured to provide, served ultimately to incentivise other entrants to seek a share of the inflated market profits.

8.112 The CMA considers that the licensing and manufacturing issues encountered by Medreich do not alter its assessment of the likelihood of harm to competition and consumers and the seriousness of the Infringement. The issues that Medreich encountered were temporary, unforeseen and unrelated to the conduct of the Parties in entering into the Market Exclusion Agreement, and cannot reasonably be regarded as lessening the seriousness of the Parties' conduct in entering into (and/or participating in) an agreement that aimed to extinguish competition in the supply of Prochlorperazine POM.

8.113 The CMA does not accept the submissions advanced by Alliance concerning the conduct that would otherwise have been pursued by Alliance, Focus and Lexon. The evidence outlined at paragraphs 5.277 to 5.295 and 5.359 to 5.378 is entirely at odds with its submission that, absent the Market Exclusion Agreement, Alliance

[2257] *FP McCann Limited v CMA* [2020] CAT28, paras 111, 114 and 118.

[2258] The CMA note here the views of the EU General Court in *Lundbeck* that *'it is solely on the basis of the information available to them [the Parties] at the time and their perception of the market at that time that they decided to adopt a particular course of conduct and concluded the agreements at issue.'* Paragraph 139.

would have acted in the same manner and de-branded its product while supplying Focus at a fixed supply price. Similarly, absent the Market Exclusion Agreement, Lexon and Medreich would have been incentivised to bring its product to market as soon as possible, and there can be no expectation that they would otherwise have been paid by Focus not to do so.

8.114 Each of Cinven and Advanz also submitted that a 30% starting point was not required for the purposes of general deterrence:

8.114.1 Advanz argued that the publicity relating to this case meant that '*any necessary general deterrence objective was achieved long ago*'.[2259] Advanz also argued that *'the CMA's and the Commission's ongoing and very public investigations in the pharmaceutical sector'* are sufficient to generally deter such that no additional deterrence requiring the CMA to adopt a 30% starting point is necessary.[2260]

8.114.2 Cinven argued that *'it is not clear why the CMA believes that a fine of 21% or 25% would not be sufficient to deter other businesses from engaging in disguised infringements'* and noted that the CMA has applied lower starting points in previous cases without concern of dampening the deterrence effect of its decision.[2261]

8.115 The CMA rejects Advanz's submission that publicity relating to this case has been sufficient to satisfy the objective of general deterrence. The Infringement concerns one of the most serious types of infringing activity and there is a clear need to ensure general deterrence with respect to these types of infringement, including within the pharmaceutical industry. Where a penalty is not recognised by other undertakings as sufficiently high to have real impact on the infringing undertaking, other undertakings may form the view that the risk of penalties for competition infringements is not a significant business risk to which their management (including their top-level management) should give their attention. This would undermine the effectiveness of competition law.

8.116 Furthermore, the fact that there have been and continue to be a number of investigations in the pharmaceutical sector by the CMA and the European Commission does not detract from the seriousness of the Infringement set out in this Decision. It cannot be accepted that, in circumstances where the CMA detects

[2259] Advanz RDPS, 7 July 2021, paragraph 6.26.4 (URN: PRO-C7481).

[2260] Advanz RDPS, 7 July 2021, paragraph 2.19.3 (URN: PRO-C7481). Advanz also submitted that a duration multiplier of over 5 years is in itself a sufficient *'uplift'* such that general deterrence is satisfied without the need for an increase of the starting point percentage for general deterrence. See Advanz RDPS, 7 July 2021, paragraphs 4.50-4.51 (URN: PRO-C7481). The CMA rejects this submission. General deterrence is considered by reference to the seriousness of an infringement independent of an assessment of duration. Duration is a relevant factor in determining the appropriate penalty to apply to an infringing undertaking and a reduction of the starting point percentage based on a specific duration multiplier would undermine the role that the duration of an infringement has in that determination. In any event, the CMA at Step 4 has regard to whether an adjustment is required to achieve an overall result which is proportionate considering the decisions it has taken in the preceding steps of its penalty calculation.

[2261] Cinven RDPS, 7 July 2021, paragraph 3.23(d) (URN: PRO-C7439).

infringements in a sector that has already been subject to such scrutiny, there is no need for setting the starting point at a level that achieves general deterrence. The fact that the Infringement in this case has been identified in these circumstances of itself demonstrates that general deterrence *is* still necessary. The CMA also notes that the aim of general deterrence is not only to deter undertakings from the same sector from engaging in the same or similar conduct but also to deter undertakings more broadly from engaging in the same or similar conduct.[2262]

8.117 The CMA has ensured that it has assessed the seriousness[2263] of the Infringement by considering the factors set out in paragraphs 8.99.1 to 8.99.6. Its application of the maximum starting point percentage is based on an objective assessment of all the facts and specific circumstances of the case, of which general deterrence is an important one, but with no individual factor being determinative. Contrary to Cinven's representations and for the reasons set out in paragraph 8.99.6, the CMA does not consider that a lower starting point would be sufficient for the purposes of deterring others from engaging in the same or similar conduct. Furthermore, as set out in paragraph 8.102, the CMA considers the starting point percentages applied in other cases to be of limited precedent value and this remains the case when considering general deterrence.

8.118 Each of Advanz and Cinven submitted that the CMA has failed to apply equal treatment at Step 1 by treating Focus' '*involvement in the [Market Exclusion] Agreement'* as the same as the other parties despite its '*more limited nature'*[2264] and '*notwithstanding the material differences in the respective roles the CMA claims Alliance/Lexon and Focus had*'[2265] in the Market Exclusion Agreement.

8.119 The CMA notes that its assessment of seriousness at Step 1 is intended to reflect the seriousness of the infringement at issue (rather than the particular circumstances of each undertaking's unlawful conduct, which are taken into account at other steps).[2266] As a result, the CMA expects to adopt the same percentage starting point for each undertaking to the infringement,[2267] a position accepted by the CAT.[2268]

[2262] CMA Penalties Guidance, paragraph 2.9.

[2263] CMA Penalties Guidance, paragraphs 2.4–2.10.

[2264] Cinven RDPS, 7 July 2021, paragraph 1.13(e) (URN: PRO-C7439).

[2265] Advanz RDPS, 7 July 2021, paragraph 2.19.2 (URN: PRO-C7481).

[2266] Lexon submitted that the *'[n]o account is taken [by the CMA] of the beneficial role played by Lexon in the supply of pharmaceuticals to the NHS generally'* in its determination of the relevant starting point. See Lexon RDPS, 2 July 2021, paragraph 2.4 (URN: PRO-C7416). As set out here, the CMA's assessment at Step 1 is intended to reflect the seriousness of the infringement at issue and is intended to be consistent for each undertaking involved. Accordingly, no assessment of the broader role that Lexon has played as a supplier of pharmaceuticals to the NHS has been considered as this is not a relevant consideration.

[2267] CMA Penalties Guidance, paragraph 2.10.

[2268] *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 80.

8.120 Cinven made representations that the CMA's application of the 30% starting point was unwarranted considering the relevant circumstances of the case during Cinven's ownership period of Focus:

8.120.1 Cinven argued that the CMA is '*wrong*' to conclude that Medreich was Alliance's only source of competition for more than two years as, Cinven has claimed, neither Lexon nor Medreich were able to enter the market for nine of the twelve months of Cinven's ownership of the Focus Entities.[2269]

8.120.2 Cinven noted that *'the most substantial price rises took place'* after Cinven's period of ownership and argued that it is inappropriate for the CMA to determine the starting point *'on the basis of conduct that largely took place outside'* of Cinven's period of ownership.[2270]

8.121 As set out in paragraph 8.95, the CMA does not agree with Cinven's view that a different Focus undertaking existed at each period of ownership. In any event, the starting point is intended to reflect the seriousness of the infringement at issue. Cinven's observations are therefore immaterial to the CMA's assessment at Step 1. As set out in 8.112 the issues that Medreich encountered were temporary, unforeseen and unrelated to the conduct of the Parties in entering into the Market Exclusion Agreement, and cannot reasonably be regarded as lessening the seriousness of an infringement that aimed to extinguish competition in the supply of Prochlorperazine POM. Further, as set out in paragraph 8.109 the CMA has found that the Market Exclusion Agreement was structured to provide for price increases of Prochlorperazine POM. Such price increases were implemented during Cinven's period of ownership.

Calculation at the end of Step 1

8.122 The starting point for determining the level of financial penalty which will be imposed on each undertaking is set out in Table 5.

Table 5: Calculation at the end of Step 1

Undertaking	Relevant turnover	Percentage rate	Penalty after Step 1
Alliance	£976,000	30%	£292,800
Lexon	£1,755,525		£526,658
Medreich	£1,221,398		£366,419
Focus	£5,156,945		£1,547,083

[2269] Cinven RDPS, 7 July 2021, paragraph 3.23(b) (URN: PRO-C7439).

[2270] Cinven RDPS, 7 July 2021, paragraph 3.23(c) (URN: PRO-C7439).

Step 2 - Duration

8.123 The CMA may adjust the starting point reached at the end of Step 1 to take into account the duration of an infringement. Where the total duration of an infringement is more than one year, the CMA will (in most cases) round up part years to the nearest quarter year, although the CMA may in exceptional cases decide to round up the part year to a full year.[2271]

8.124 The CMA has apportioned liability for the penalties amongst the legal entities which formed each undertaking by reference to the period during which each formed a part of that undertaking as set out in Table 3: Legal entities forming part of the undertakings over time and basis of liability.

Alliance

8.125 The CMA has found that Alliance participated in the Infringement from at least 7 June 2013 until 31 July 2018 (5 years, 1 month and 25 days).[2272] The CMA has therefore applied a duration multiplier of 5.25 years.

Lexon

8.126 The CMA has found that Lexon participated in the Infringement from at least 7 June 2013 until 31 July 2018 (5 years, 1 month and 25 days).[2273] The CMA has therefore applied a duration multiplier of 5.25 years.

8.127 The CMA holds Lexon UK Holdings Limited jointly and severally liable with Lexon (UK) Limited for its period of ownership from 1 March 2018 until 31 July 2018 (5 months) only.[2274] The penalty will therefore be apportioned by reference to the entities' periods of ownership as explained at Step 4 of the penalty calculation (see paragraph 8.208 below).

Medreich

8.128 The CMA has found that Medreich participated in the Infringement from at least 5 February 2014 until 15 February 2018 (4 years and 11 days).[2275] The CMA has therefore applied a duration multiplier of 4.25 years.

8.129 The CMA holds Meiji Seika Pharma Co and Meiji Holdings Co Ltd jointly and severally liable with Medreich plc and Medreich Ltd for their period of ownership

[2271] CMA Penalties Guidance, paragraph 2.16.

[2272] See paragraph 5.729.

[2273] See paragraph 5.729.

[2274] See paragraphs 7.53-7.55.

[2275] See paragraph 5.731.

from 12 February 2015 until 15 February 2018 (3 years and 4 days) only.[2276] The penalty will therefore be apportioned by reference to the entities' periods of ownership as explained at Step 4 of the penalty calculation (see paragraph 8.208 below).

Focus

8.130 The CMA has found that Focus participated in the Infringement from at least 22 June 2013 until 31 July 2018 (5 years, 1 month and 10 days).[2277] The CMA has therefore applied a duration multiplier of 5.25 years.

8.131 The CMA holds Mercury Pharma Group Limited, the Cinven Entities and the Advanz Entities jointly and severally liable with the Focus Entities for their period of ownership only:

8.131.1 Mercury Pharma Group Limited and the Cinven Entities from 1 October 2014 to 20 October 2015 (1 year and 20 days);[2278] and

8.131.2 Mercury Pharma Group Limited and the Advanz Entities from 21 October 2015 to 31 July 2018 (2 years, 9 months and 10 days).[2279]

8.132 The penalty will therefore be apportioned by reference to the entities' periods of ownership as explained at Step 4 of the penalty calculation (see paragraph 8.208 below).

Calculation at the end of Step 2

8.133 At the end of the Step 2, the penalty for the Infringement to be imposed on each undertaking is set out in **Table 6** below.

Table 6: Calculation at the end of Step 2

Undertaking	Duration multiplier	Penalty after Step 2
Alliance	5.25 years	£1,537,200
Lexon	5.25 years	£2,764,953
Medreich	4.25 years	£1,557,282
Focus	5.25 years	£8,122,188

[2276] See paragraphs 7.63–7.65.

[2277] See paragraph 5.730.

[2278] See paragraphs 7.82–7.93

[2279] See paragraphs 7.276–7.278

Step 3 – Aggravating and mitigating factors

8.134 The CMA may, at Step 3, increase a penalty where there are aggravating factors and/or decrease it where there are mitigating factors. The CMA considers whether any adjustments are appropriate for each undertaking based on the specific circumstances of the infringement.[2280]

Aggravating factors

Involvement of directors or senior managers

8.135 The CMA concludes that the involvement of directors and senior management within the Alliance, Lexon, Medreich and Focus undertakings in the Infringement – during, for Lexon and Medreich, each of the two periods of ownership, and, for Focus, each of the three periods of ownership – should be considered an aggravating factor at Step 3.

Alliance

8.136 Directors and senior managers within the Alliance undertaking involved in the Infringement include:[2281]

8.136.1 [Alliance Director 1], [✂] at Alliance from the start of the Infringement until [✂]; and

8.136.2 [Alliance Director 2], [✂] at Alliance from start of the Infringement until [✂] and [✂] until the end of the Infringement.

8.137 The CMA finds that [Alliance Director 1] was aware of and approved the Market Exclusion Agreement.

8.137.1 [Alliance Director 1] was aware by at least March 2013 that Lexon intended to launch a generic version of Buccastem and that [Alliance Employee 1] was in direct contact with Lexon about the '*threat*'.[2282]

8.137.2 [Alliance Director 1] was aware by March 2013 that [Alliance Employee 1], [Alliance Director 2] and others were '*working on a defence strategy*' to that threat, about which he would be kept '*informed*'.[2283]

[2280] CMA Penalties Guidance, paragraphs 2.17-2.19, including a non-exhaustive list of aggravating and mitigating factors.

[2281] See paragraph 3.20.

[2282] See paragraphs 3.73, 5.160-5.161, 5.166. The minutes of the Alliance 'UK Review & Planning Meeting' held on 14 March 2013 record that [Alliance Director 1] attended, where [Alliance Employee 1]'s contact with Lexon was discussed. See Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' dated 14 March 2013 09:00 – 12:00, pages 1 and 8 (URN: PRO-E000971).

[2283] See paragraphs 3.78 and 5.166

8.137.3 [Alliance Director 1]'s '*direction*' on Alliance's proposed '*[d]efence plan*' as '*worked up*' by [Alliance Employee 1] was sought by [Alliance Director 2] on 7 June 2013.[2284]

8.137.4 The CMA has found that [Alliance Director 1] recorded Alliance's proposed defence plan in his notebook during a meeting with [Alliance Employee 1] on 11 June 2013, in which [Alliance Employee 1] set out the agreement he had reached in principle with [Lexon Director 1], i.e. the Market Exclusion Agreement.[2285]

8.137.5 Given that [Alliance Director 1]'s approval for Alliance's defence plan (i.e. the Market Exclusion Agreement) was sought[2286] and the Market Exclusion Agreement was implemented,[2287] the CMA infers that [Alliance Director 1] approved the Market Exclusion Agreement.

8.138 The CMA finds that [Alliance Director 2] was aware of and involved in implementing the Market Exclusion Agreement.

8.138.1 [Alliance Director 2] was aware by at least March 2013 that Lexon intended to launch a generic version of Buccastem and that [Alliance Employee 1] was in direct contact with Lexon about the '*threat*'.[2288]

8.138.2 [Alliance Director 2], with [Alliance Employee 1] and others, worked on a '*defence strategy*' to that threat from at least March 2013, on which he provided updates to [Alliance Director 1].[2289]

8.138.3 By 7 June 2013, [Alliance Director 2] was '*comfortable*' with Alliance's proposed '*[d]efence plan*' as '*worked up*' by [Alliance Employee 1] and sought [Alliance Director 1]'s '*direction*'.[2290]

8.138.4 [Alliance Director 2] signed the Alliance-Focus Agreement on 26 August 2013, which partially implemented the Market Exclusion Agreement.[2291]

8.139 Alliance has submitted that [Alliance Director 1] and [Alliance Director 2] were neither aware of the Market Exclusion Agreement nor respectively approved or implemented it.[2292] Alliance does not dispute that the evidence cited by the CMA

[2284] See paragraphs 3.88 and 5.190.

[2285] See paragraphs 3.90-3.93, 5.191-5.194, 5.202 and 5.269-5.270 See also paragraphs 5.204-5.226.

[2286] See paragraphs 3.88 and 5.190.

[2287] See paragraphs 5.273-5.356.

[2288] See paragraphs 3.73, 3.75-3.78, 5.160-5.161, 5.166. The minutes of the Alliance 'UK Review & Planning Meeting' held on 14 March 2013 record that [Alliance Director 2] attended this meeting, where [Alliance Employee 1]'s contact with Lexon was discussed. See Meeting notes entitled '*UK Review & Planning Meeting – Alliance Pharmaceuticals*' dated 14 March 2013 09:00 – 12:00, pages 1 and 8 (URN: PRO-E000971).

[2289] See paragraphs 3.78 and 5.166.

[2290] See paragraphs 3.88 and 5.190.

[2291] See paragraphs 3.104, 5.295 and 5.628. See also Alliance-Focus Agreement, p.11 (URN: PRO-C0369)

[2292] Alliance RDPS, 7 July 2021, paragraphs 1.5.1(d) and 6.1-6.2 (URN: PRO-C7461).

demonstrates [Alliance Director 1]'s and [Alliance Director 2]'s awareness of and involvement in Alliance's conduct in relation to Prochlorperazine POM but submits that neither [Alliance Director 1] nor [Alliance Director 2] were aware of or involved in the Market Exclusion Agreement on the basis of Alliance's submission that no such agreement existed.[2293]

8.140 The CMA rejects this submission. As set out in Chapter 5 of this Decision, the CMA has found that Alliance entered into the Market Exclusion Agreement with Lexon and, as described in paragraphs 8.137 and 8.138 of this Decision, Alliance's entry into that agreement occurred with the knowledge, approval and involvement of [Alliance Director 1] and [Alliance Director 2].

8.141 The CMA concludes that an uplift of 15% is therefore appropriate to reflect the involvement of [Alliance Director 1] and [Alliance Director 2] in the Infringement.

Lexon

8.142 The director within the Lexon undertaking involved in the Infringement was [Lexon Director 1], Director at Lexon (UK) Limited throughout the Infringement Period and at Lexon UK Holdings Limited from [✂] until the end of the Infringement Period.[2294]

8.143 The CMA finds that [Lexon Director 1] was directly and centrally involved in devising, establishing, implementing and maintaining the Market Exclusion Agreement:

8.143.1 [Lexon Director 1] was involved in Lexon and Medreich's plans to market generic prochlorperazine in the UK[2295] and in 2013 informed Alliance of the threat the product would pose to Alliance's branded Buccastem.[2296]

8.143.2 The CMA has found that [Lexon Director 1] met with [Alliance Employee 1] on 12 April 2013[2297] and in May or June 2013,[2298] during which they, respectively, discussed a supply deal in relation to Prochlorperazine POM[2299] and proceeded to reach an agreement in principle that Lexon would not compete with Alliance in return for being paid in the form of an indirect transfer of value via Focus, i.e. the Market Exclusion Agreement.[2300]

[2293] Alliance RDPS, 7 July 2021, paragraphs 6.3-6.9 (URN: PRO-C7461). See also Alliance RSO, 1 August 2019, paragraphs 1.7-1.11 (URN: PRO-C5096).

[2294] See paragraph 3.20.

[2295] See paragraphs 3.55 to 3.61.

[2296] See paragraphs 3.73, 3.75 and 3.76.

[2297] See paragraph 3.81 and 5.169.

[2298] See paragraph 3.87 and 5.171.

[2299] See paragraphs 5.174 and 5.188.

[2300] See paragraphs 5.174 and 5.188.

8.143.3 The CMA has found that [Lexon Director 1]:

(a) communicated to Focus the agreement reached between Lexon and Alliance at the Second Meeting between [Lexon Director 1] and [Alliance Employee 1] in May or June 2013, including the terms on which Alliance would supply Focus,[2301] and

(b) told [Focus Director 1] on 24 June 2013 he would '*chase*' [Alliance Employee 1] in relation to that supply agreement, i.e. the Alliance-Focus Agreement.[2302]

8.143.4 [Lexon Director 1] agreed the Focus-Lexon Heads of Terms with Focus, which the CMA has found partially implemented the Market Exclusion Agreement.[2303]

8.143.5 [Lexon Director 1] instructed Medreich by 4 February 2014 not to commercialise its Prochlorperazine POM[2304] and received profit share from Focus from January 2014, as per the Market Exclusion Agreement, and instructed colleagues to transfer half to Medreich.[2305]

8.143.6 [Lexon Director 1] renegotiated the terms of the profit share with Focus in November 2014[2306] and then renegotiated them again in February 2016 to '*accommodate*' the '*new player*', i.e. Focus Pharmaceuticals Limited's sister company, Primegen, with an MA for Prochlorperazine POM.[2307]

8.143.7 [Lexon Director 1] sent an order to Medreich on 23 June 2015 to commercialise only a single batch of Prochlorperazine POM, which was necessary to ensure that Medreich's MA did not expire under the Sunset Clause.[2308]

8.144 Lexon has submitted that the CMA's application of an uplift in light of [Lexon Director 1]'s involvement in the Infringement is '*unfair*' and '*discriminatory*' as Lexon – in contrast to larger companies – is a family business, with management responsibilities falling to one person, [Lexon Director 1].[2309]

[2301] See paragraphs 3.95, 5.195, 5.197-5.198 and 5.269-5.270. See also paragraphs 5.227-5.247.

[2302] See paragraphs 3.96, 5.196.1 and 5.199.1 and 5.269-5.270. See also paragraphs 5.248-5.253.

[2303] See paragraphs 3.105-3.106 and 5.356.

[2304] See paragraphs 3.202 and 3.207-3.213. See also paragraph 5.455. Except for one batch to be produced every three years to avoid the application of the Sunset Clause to its MA, as per the Market Exclusion Agreement. See paragraphs 5.191, 5.194 and 5.270.

[2305] See paragraphs 3.115, 3.124, 3.204-3.206 and 5.628.

[2306] See paragraphs 3.168 and 3.170.

[2307] See paragraphs 3.155, 3.158, 3.181-3.184, 3.189 and 3.192.

[2308] See paragraph 3.234 and 5.434. See also paragraphs 5.191, 5.194 and 5.270.

[2309] Lexon RDPS, 2 July 2021, paragraphs 2.5-2.6 (URN: PRO-C7416).

8.145 This submission is misconceived. In *Ping*, the CAT rejected the suggestion that it would be '*wrong in principle*' for the CMA to '*treat director involvement as an aggravating factor*' given the '*size of Ping's organisation*', which made it more likely that directors would be involved in certain decisions. As the CAT affirmed, company directors have a special responsibility, beyond that of other employees, not to infringe the law irrespective of the size of the company.[2310] The CMA therefore rejects Lexon's submission.

8.146 The CMA concludes that an uplift of 15% is therefore appropriate to reflect the involvement of [Lexon Director 1] in the Infringement.

Medreich

8.147 Directors and senior managers within the Medreich undertaking involved in the Infringement include:[2311]

8.147.1 [Medreich Director 2], Director at Medreich plc from [✂] until [✂][2312] as well as [✂] at Medreich plc from the start of the Medreich Infringement Period until at least [✂] and [✂] from at least [✂] until he left the company on [✂].[2313]

8.147.2 [Medreich Employee 1], [✂] from the start of the Medreich Infringement Period until [✂].

8.148 The CMA finds that [Medreich Director 2] was aware of and instrumental in implementing the Market Exclusion Agreement.

8.148.1 [Medreich Director 2] was aware that Lexon was providing quarterly profit share reconciliations to Medreich from January 2014 at least until he left the company in [✂] and he was aware from February 2014 that these payments were in return for Medreich not supplying Prochlorperazine POM.[2314]

8.148.2 [Medreich Director 2] was directly involved from February 2014 in ensuring that the Prochlorperazine POM product Medreich had jointly developed with Lexon was not commercialised during the period of the Market Exclusion Agreement, except for a single batch as per the Market Exclusion Agreement.[2315]

[2310] *Ping* [2018] CAT 13, paragraphs 243-244.

[2311] See paragraph 3.20.

[2312] [Medreich Director 2], Companies House available at [✂].

[2313] Medreich plc organogram (URN: PRO-C1302).

[2314] See paragraphs 5.663, 5.665-5.667 and 5.669. See also paragraphs 3.204-3.206, 3.208-3.213, 3.260 and 3.263-3.264 as well as 3.191 and 3.252.

[2315] See paragraphs 5.669, 5.682 and 5.684.

8.148.3 [Medreich Director 2] was directly involved in 2015 to 2017 in ensuring that a single batch of Prochlorperazine POM was manufactured to avoid Medreich's MA expiring under the Sunset Clause.[2316]

8.148.4 [Medreich Director 2] described the '*deal*' that had been made by Lexon in his internal email to [Meiji employee], [✂] of Medreich plc, on 21 July 2017.[2317]

8.149 The CMA finds that [Medreich Employee 1] was aware of and instrumental in implementing the Market Exclusion Agreement.

8.149.1 [Medreich Employee 1] was aware that:[2318]

(a) Lexon was providing quarterly profit share reconciliations to Medreich from January 2014 at least until he left the company in [✂] and he was aware from February 2014 that these payments were in return for Medreich not supplying Prochlorperazine POM;

(b) those payments were from Focus sharing the profits it earned from the sales of Alliance's Prochlorperazine POM supplied at a fixed price; and

(c) Medreich and Lexon's Prochlorperazine POM product could be used as leverage vis-à-vis Alliance to ensure that Alliance did not increase the price at which it sold its Prochlorperazine POM to Focus, which would have reduced the profits to be shared between Focus, Lexon and Medreich.

8.149.2 [Medreich Employee 1] told [Lexon Director 1] in February 2014 that Medreich was '*extremely happy with the deal*',[2319] which he later described in April 2014 as a '*clever arrangement*'.[2320]

8.149.3 [Medreich Employee 1] arranged for Medreich's invoices to be raised with Lexon from January 2014 for the profit share on Prochlorperazine POM.[2321]

8.149.4 [Medreich Employee 1] was directly involved in ensuring that the product Medreich had jointly developed with Lexon was not commercialised during

[2316] See paragraphs 3.232-3.236, 3.241-3.242, 3.244, 3.246-3.247, 3.257-3.259, 3.264, 3.267.
[2317] See paragraph 5.577 and 5.677. See also Medreich plc organogram (URN: PRO-C1302).
[2318] See paragraphs 5.659-5.662, 5.665-5.669, 5.673-5.675.
[2319] See paragraph 5.665-5.669.
[2320] See paragraph 5.569.
[2321] See paragraph 5.663, 3.191, 3.202-3.204.

the period of the Market Exclusion Agreement whilst he was employed at Medreich.[2322]

8.150 The CMA concludes that an uplift of 15% is therefore appropriate to reflect the involvement of [Medreich Director 2] and [Medreich Employee 1] in the Infringement.

Focus

8.151 Directors and senior managers within the Focus undertaking involved in the Infringement include:[2323]

8.151.1 [Focus Director 1], [✂] of Focus Pharmaceuticals Limited from the start of the Focus Infringement Period until [✂];

8.151.2 [Focus Director 2], [✂] of Focus Pharmaceuticals Limited from the start of the Focus Infringement Period until [✂]; and

8.151.3 [AMCo Director 2], Director of Focus Pharmaceuticals Limited from [✂] to [✂][2324], with roles within the AMCo Group and then Concordia (now Advanz Pharma) including:

(a) [✂],

(b) [✂], and

(c) [✂] until the end of the Focus Infringement Period.

8.152 The CMA finds that [Focus Director 1] was centrally involved in establishing Focus' participation in the Market Exclusion Agreement as well as instrumental in implementing the Market Exclusion Agreement.

8.152.1 The CMA has found that, by at least 22 June 2013, [Focus Director 1] understood that an agreement had been reached between Alliance and Lexon that:[2325]

(a) Alliance would exclusively supply Focus at Alliance's '*trade price*', enabling Focus to increase the price at which it supplied Prochlorperazine POM to wholesalers; and

(b) Focus would share the profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon.

[2322] See paragraphs 5.667-5.669.

[2323] See paragraph 3.20.

[2324] [AMCo Director 2], Companies House available at [✂].

[2325] See paragraphs 5.195 and 5.197. See also 5.227-5.247, 5.269-5.270 and 5.628.

8.152.2 [Focus Director 1] understood the terms agreed between Alliance and Lexon on which Alliance would supply Focus with Prochlorperazine POM and on 22 August 2013 signed the Alliance-Focus Agreement which the CMA has found partially implemented the Market Exclusion Agreement.[2326]

8.152.3 [Focus Director 1] concluded with Lexon the Focus-Lexon Heads of Terms by 1 August 2013 which the CMA has found partially implemented the Market Exclusion Agreement.[2327]

8.152.4 [Focus Director 1] initiated the transfer of profit to Lexon on 3 January 2014, explaining that Focus would send a '*reconciliation*' statement for Focus' sales of Alliance's Prochlorperazine POM to Lexon each quarter.[2328]

8.153 The CMA finds that [Focus Director 2] was aware of the Market Exclusion Agreement. The CMA has found that by at least 22 June 2013 [Focus Director 2] understood that:[2329]

8.153.1 an agreement had been reached between Alliance and Lexon that Alliance would exclusively supply Focus at Alliance's '*trade price*', enabling Focus to increase the price at which it supplied Prochlorperazine POM to wholesalers; and

8.153.2 Focus would share the profits it earned from the sales of Alliance's Prochlorperazine POM with Lexon.

8.154 The CMA finds that [AMCo Director 2] was aware of and instrumental in maintaining the Market Exclusion Agreement. [AMCo Director 2] was involved in:[2330]

8.154.1 AMCo's evaluation from June 2015 onwards of whether to launch its Primegen Prochlorperazine POM or continuing to supply Alliance's Prochlorperazine POM whilst paying profit share to Lexon;

8.154.2 AMCo's decision to renegotiate the terms of Focus' profit share with Lexon in February 2016 by '*leverag[ing] the license*' held by Focus' sister company Primegen; and

[2326] See paragraphs 3.103-3.104, 5.295 and 5.628. See also Alliance-Focus Agreement, p.11 (URN: PRO-C0369).
[2327] See paragraphs 3.105-3.106, 5.356 and 5.628.
[2328] See paragraphs 3.115 and 3.124
[2329] See paragraphs 5.195 and 5.197. See also 5.227-5.247, 5.269-5.270 and 5.628.
[2330] See paragraphs 3.134, 3.140-3.145, 3.153-3.158, 3.161 and 3.189. See also paragraphs 5.490-5.523.

8.154.3 a meeting with [Lexon Director 1] in February 2016 to finalise AMCo's renegotiation of the terms of Focus' profit share with Lexon following the grant of the Primegen MA.

8.155 Both Advanz and Cinven have submitted that they do not accept that [Focus Director 1], [Focus Director 2], and [AMCo Director 2] were involved in the Infringement.[2331] Advanz and Cinven's submission rests on their contention that Focus was unaware of the Market Exclusion Agreement and, on that account, [Focus Director 1], [Focus Director 2] and [AMCo Director 2] could not have been aware of or involved in that agreement. Advanz has additionally submitted that the CMA has only found that [Focus Director 2] understood that Focus had entered into two distribution agreements but did not have '*any involvement […] in or knowledge of*' the Market Exclusion Agreement.[2332] Cinven has further submitted that the CMA's finding that [Focus Director 2] was '*aware of*' the Market Exclusion Agreement does not mean that he was involved in the Infringement.[2333]

8.156 Advanz has further submitted that any involvement by directors and senior managers is, in any event, a '*neutral, not an aggravating factor*':[2334]

8.156.1 First, Advanz argues that Focus' and Advanz's directors '*consistently acted in good faith*' and in '*accordance with applicable regulations and best practices*' and had competition law compliance training in place.[2335]

8.156.2 Second, Advanz contends that Focus' conduct necessarily required the involvement of directors and/or senior managers because Focus is '*a small or medium sized pharmaceutical company*' and submits that their involvement should therefore have '*no bearing on Focus's culpability in this case*'.[2336]

8.156.3 Third, Advanz submits that the CMA has '*engaged in improper double counting*' by applying the '*maximum possible*' starting point at Step 1 as well as a 15% uplift to reflect the involvement of directors and senior management at Step 3. Advanz contends that the situations that the CMA Penalty Guidance suggests warrant a 30% starting point might only take place with the knowledge of senior management and it would therefore not be appropriate to apply an additional uplift for their involvement in these circumstances.[2337]

[2331] Advanz RDPS, 7 July 2021, paragraphs 6.33-6.38 (URN: PRO-C7481); Cinven RDPS, 7 July 2021, paragraph 3.28 (URN: PRO-C7439).

[2332] Advanz, RDPS, 7 July 2021, paragraph 6.35 (URN: PRO-C7481).

[2333] Cinven RDPS, 7 July 2021, footnote 68 (URN: PRO-C7439).

[2334] Advanz RDPS, 7 July 2021, paragraph 6.32 (URN: PRO-C7481).

[2335] Advanz RDPS, 7 July 2021, paragraph 6.32.1 (URN: PRO-C7481).

[2336] Advanz RDPS, 7 July 2021, paragraph 6.32.2 (URN: PRO-C7481).

[2337] Advanz RDPS, 7 July 2021 paragraph 6.32.3 (URN: PRO-C7481).

8.157 Cinven has similarly submitted that, '*[g]iven the size of the Focus Entities*', it is '*unsurprising*' that senior management were involved in entry into the Alliance-Focus Agreement and Focus-Lexon Heads of Terms. Cinven has argued that, if '*director-level knowledge of a significant commercial agreement alone were treated as an aggravating factor*', then Focus' involvement in these agreements could – citing *Ping* – '*never have been considered anything other than aggravated*'. Cinven has asserted that this '*cannot, as a matter of law, be correct*' as Step 3 would '*no longer constitute a genuine "aggravating" factor but a default, reflexive uplift*'.[2338]

8.158 Cinven has additionally submitted that, in any event, an uplift of 15% is unjustified in the specific circumstances of this case.[2339]

8.158.1 First, according to Cinven, the CMA has unlawfully treated '*different situations in the same way*' by applying the same director uplift (15%) for all undertakings despite concluding that the Lexon director was '*directly and centrally involved in devising, establishing, implementing and maintaining*' the Market Exclusion Agreement while, by contrast, there is no suggestion that [Focus Director 1], [Focus Director 2] or [AMCo Director 2] were instigators of the Market Exclusion Agreement.[2340]

8.158.2 Second, Cinven further contends that the CMA has acknowledged that there were three separate Focus undertakings during the Relevant Period, with Cinven forming a distinct undertaking with the Focus Entities and Mercury Pharma Limited during its period of ownership. In Cinven's submission, this means that the CMA cannot rely on director involvement which falls outside of its ownership period. Cinven has claimed that there was no involvement of AMCo directors during its ownership period and no involvement of Cinven directors or senior managers.[2341]

8.159 The CMA rejects these submissions.

8.160 As set out in paragraphs 5.635 to 5.637 of this Decision, the CMA has found that Focus participated in the Market Exclusion Agreement and, as described at paragraphs 8.152 to 8.154 of this Decision, that participation occurred with the knowledge and involvement of [Focus Director 1], [Focus Director 2] and [AMCo Director 2].

8.161 In relation to [Focus Director 2], the CMA observes that:

8.161.1 [Focus Director 2] was aware that Alliance and Lexon had agreed the terms on which Alliance would supply Focus Prochlorperazine POM and

[2338] Cinven RDPS, 7 July 2021, paragraph 3.29 (URN: PRO-C7439), citing *Ping* [2018] CAT 13, paragraph 247.
[2339] Cinven RDPS, 7 July 2021, paragraph 3.30 (URN: PRO-C7439).
[2340] Cinven RDPS, 7 July 2021, paragraph 3.31 (URN: PRO-C7439).
[2341] Cinven RDPS, 7 July 2021 paragraph 3.32 (URN: PRO-C7439).

was aware that Focus would pass on the majority of the profits from its sale of Alliance's Prochlorperazine POM to Lexon (see paragraph 8.155 above). The CMA therefore disagrees with Advanz's submission that [Focus Director 2] did not have '*any involvement […] in or knowledge of*' the Market Exclusion Agreement.[2342]

8.161.2 As established by the CAT, '*society has a greater expectation that senior management will lead by example and abide by the law*'. It is therefore appropriate for a penalty to be increased where '*director-level staff permit or coordinate the wrongdoing*'.[2343] As set out in paragraph 8.153 of this Decision, [Focus Director 2], a Director at Focus when the Market Exclusion Agreement was entered into and implemented, was aware of the Infringement and yet did not prevent it. [Focus Director 2]'s at least tacit approval of Focus' participation in the Infringement would, in itself, justify an uplift at Step 3 of Focus' penalty calculation.

8.161.3 [Focus Director 2] was, in any event, not the only director involved in the Infringement. As set out at paragraphs 8.152 and 8.154 of this Decision, both [Focus Director 1] and [AMCo Director 2] were instrumental in, respectively, establishing Focus' participation in and implementing the Market Exclusion Agreement as well as maintaining the Market Exclusion Agreement.

8.162 In relation to Advanz's additional submissions:

8.162.1 First, the evidence set out at paragraphs 8.152 to 8.154 above directly contradicts Advanz's submission that the Focus directors had '*acted in good faith*' and in '*accordance with applicable regulations and best practices*'.[2344] Ensuring the existence of competition law compliance training cannot be relevant to the assessment of whether senior management involvement should be considered an aggravating factor, where those senior managers have not only failed to ensure competition compliance, but have actively contributed to the Infringement.

8.162.2 Second, and as set out at paragraph 8.145 above, company directors have an additional responsibility, beyond that of other employees, not to infringe the law, regardless of the size of the company or structure of senior management.[2345]

8.162.3 Third, the application of a 30% starting point and a separate uplift for director involvement are neither mutually exclusive, nor do they amount to

[2342] Advanz, RDPS, 7 July 2021, paragraph 6.35 (URN: PRO-C7481).
[2343] *Ping* [2018] CAT 13, paragraph 246.
[2344] Advanz RDPS, 7 July 2021, paragraph 6.32.1 (URN: PRO-C7481).
[2345] *Ping* [2018] CAT 13, paragraph 244.

improper double-counting. The determination of the starting point at Step 1 and any uplift at Step 3 for the involvement of directors or senior management have very different purposes. The CMA's assessment at Step 1 considers the seriousness of the infringement, rather than particular circumstances of each undertaking's unlawful conduct.[2346] The CMA's assessment at Step 3 considers the conduct of the infringer, specifically here where directors and/or senior managers were involved in the undertaking's unlawful conduct.[2347] The CMA also does not accept Advanz's submission that activities that warrant a 30% starting point could take place only with the knowledge of senior management: this will depend on the facts of the case in question.[2348]

8.163 The CMA also rejects Cinven's submission that if '*director-level knowledge of a significant commercial agreement alone were treated as an aggravating factor*', then Focus' involvement in these agreements could – citing *Ping* – '*never have been considered anything other than aggravated*'. First, as set out in paragraphs 8.152 and 8.154 of this Decision, the Focus directors [Focus Director 1] and [AMCo Director 2] did not just have '*knowledge alone*' of the Alliance-Focus Agreement and Focus-Lexon Heads of Terms, but were respectively instrumental in establishing Focus' participation in and implementing the Market Exclusion Agreement as well as maintaining the Market Exclusion Agreement.[2349] Second, the CAT's observations in *Ping* must be interpreted in the context in which they were made, in particular the fact that the CAT drew a distinction between director involvement in the specific circumstances of *Ping* and their involvement in cases concerning a '*secret cartel*', where director involvement is likely to be treated as an aggravating factor. The circumstances of this case are akin to those of a secret cartel and are not comparable to the exceptional circumstances in *Ping*. Unlike *Ping*, this Infringement was not public and did not relate to a central element of Focus' way of doing business. Therefore, this is not an infringement that could not have occurred without director-level knowledge, let alone involvement. Moreover, unlike Ping, Focus' directors were not seeking to pursue a policy that they '*considered […] legitimate and ultimately benefitted consumers*'.[2350]

[2346] CMA Penalties Guidance, paragraph 2.10 (emphasis added).

[2347] CMA Penalties Guidance, paragraph 2.18

[2348] The CMA has applied a high percentage starting point at Step 1 reflecting the seriousness of the infringement and not increased the penalty at Step 3 where the Infringement has not involved directors and/or senior management. See, for example, the CMA's decisions in *Ophthalmology* (CE/9784-13), *Paroxetine* (CE-9531/11) and *Privately-funded ophthalmology services* (50782-1). Equally, the CMA has, where appropriate, previously applied a high percentage starting point at Step 1 reflecting the seriousness of the infringement as well as an increase at Step 3 due to the involvement of directors and/or senior management. See for example, the CMA's decision in *Online sales of posters and frames* (50223), *Phenytoin* (CE/9742-13), *Modelling* (CE/9859-14), *Galvanised steel tanks* (CE/9691/12), *Drawer fronts* (CE/9882-16), *Design, construction and fit-out services* (50481), *Pre-cast concrete drainage products* (50299), *Residential estate agency services* (50543) and *Nortriptyline – Market sharing* (50507.2

[2349] *Ping* [2018] CAT 13, paragraphs 246-247.

[2350] *Ping* [2018] CAT 13, paragraphs 246-247.

8.164 In relation to Cinven's additional submissions:

8.164.1 First, as set out at paragraphs 8.152 and 8.154 of this Decision, the CMA has concluded that [Focus Director 1] and [AMCo Director 2] were not only aware of the Market Exclusion Agreement but were respectively personally involved in establishing Focus' participation in and implementing the Market Exclusion Agreement as well as maintaining it. In other words, [Focus Director 1] and [AMCo Director 2] were centrally involved in Focus' conduct in relation to the Infringement. In these circumstances, the CMA finds that an uplift of 15% is appropriate for the Focus directors and that it is appropriate to apply the same percentage uplift as applied to Lexon. Moreover, it is not the case that a 15% uplift for the involvement of senior management and/or directors can only be applied where the senior managers and/or directors concerned were the instigators of an infringement.

8.164.2 Second, the CMA observes that, as described at paragraphs 8.154 of this Decision, [AMCo Director 2]'s involvement in the Infringement occurred in part during Cinven's period of ownership. Further,

(a) For the avoidance of doubt and contrary to Cinven's submissions, the CMA considers Focus to constitute a single undertaking throughout the Infringement Period, which changed over time as successive parent companies (Cinven and Advanz) acquired and sold it (see paragraph 7.73 of this Decision).[2351]

(b) For this aggravating factor to apply, it is not necessary to demonstrate the direct involvement of parent companies (at director level or otherwise); it is the involvement of senior managers and/or directors within the undertaking during that parent's period of ownership that is relevant.

8.165 The CMA concludes that an uplift of 15% is therefore appropriate to reflect the involvement of [Focus Director 1], [Focus Director 2] and [AMCo Director 2] in the Infringement.

[2351] C-823/18 P *Commission v GEA*, EU:C:2020:955, paragraphs 66 and 70. See also Opinion of AG Pitruzzella in C-823/18 P *Commission v GEA*, EU:C:2020:426, cited in paragraph 66.

Mitigating factors

Compliance

Alliance

8.166 The CMA finds that the evidence presented for Alliance's compliance activities does not merit a discount to its penalty.

8.167 Alliance's submissions show that, since the CMA's investigation was opened in 2017, Alliance has:

8.167.1 [✂];[2352]

8.167.2 [✂];[2353] and

8.167.3 [✂]:

(a) [✂];[2354]

(b) [✂];[2355]

(c) [✂];[2356] and

(d) [✂].[2357]

8.168 [✂].

8.169 [✂].

8.170 [✂].

8.171 In the light of the above, the CMA considers that Alliance has not demonstrated that adequate steps have been taken to achieve a clear and unambiguous commitment to compliance throughout the undertaking such as to merit a reduction in its penalty.

Lexon

8.172 The CMA finds that Lexon's compliance activities merit a discount of 10% to its penalty.

[2352] Alliance RDPS, 7 July 2021, paragraph 7.11.2 (URN: PRO-C7461).
[2353] Alliance RDPS, 7 July 2021, paragraphs 7.11.3-7.11.6 (URN: PRO-C7461).
[2354] Alliance RDPS, 7 July 2021, Appendix 4, page 2 (URN: PRO-C7465).
[2355] Alliance RDPS, 7 July 2021, Appendix 4, pages 6-11 (URN: PRO-C7465).
[2356] Alliance RDPS, 7 July 2021, Appendix 4, pages 9 and 11 (URN: PRO-C7465).
[2357] For examples, see Alliance RDPS, 7 July 2021, Appendix 4, pages 7 and 12 (URN: PRO-C7465).

8.173 Lexon's submissions show that, since the CMA's investigation was opened in 2017, Lexon has:

8.173.1 [✂];[2358]

8.173.2 [✂] updated its whistleblowing policy to include reference to the CMA and European Commission whistleblowing helplines;[2359]

8.173.3 [✂];[2360]

8.173.4 [✂];[2361]

8.173.5 [✂];[2362]

8.173.6 [✂];[2363]

8.173.7 [✂][2364].

8.173.8 [✂];[2365]

8.173.9 [✂];[2366] and

8.173.10 published a statement of its commitment to competition law compliance on its website.[2367]

8.174 Taking these considerations in the round, the CMA concludes that Lexon has provided sufficient evidence of compliance activities to warrant a reduction in penalty of 10%.

[2358] Lexon's letter to the CMA dated 3 November 2020, page 1, point 1 and Annex 1 (URN: PRO-C6386) and Lexon's letter to the CMA dated 25 January 2022, page 1 (URN: PRO-C8011).

[2359] Lexon's letter to the CMA dated 3 November 2020, page 2, point 8 (URN: PRO-C6386) and see http://www.lexonuk.com/userfiles/HR%20Policy%2018%20Rev%2003%20-%20Whistleblowing%20Policy%202.pdf, paragraph 3.2.

[2360] Lexon's letter to the CMA dated 3 November 2020, page 2, point 13 and Annex 4 (URN: PRO-C6386).

[2361] Lexon's letter to the CMA dated 3 November 2020, page 2, points 2-3 13 and Annex 2, pages 12-13, paragraph 8.10 (f)(iii) (URN: PRO-C6386). See also Lexon's further submission to the CMA of 28 September 2021, tab 5, page 67 (URN: PRO-C7736).

[2362] Lexon's letter to the CMA dated 3 November 2020, page 3 (URN: PRO-C6386).

[2363] Lexon's letter to the CMA dated 3 November 2020, page 2, points 2-3 and Annex 2, page 11, para 8.6 (URN: PRO-C6386).

[2364] Lexon's letter to the CMA dated 3 November 2020, page 2, point 6 (URN: PRO-C6386) and Lexon's letter to the CMA dated 25 January 2022 (URN: PRO-C8011) with attached draft PowerPoint presentation (URN: PRO-C80112)

[2365] Lexon's letter to the CMA dated 3 November 2020, page 2, point 4 (URN: PRO-C6386). See also, Lexon's further submissions, tab 4, pages 25-41 (URN: PRO-C7736).

[2366] Lexon's letter to the CMA of 3 November 2020, page 2, point 14 (URN: PRO-C6386).

[2367] See http://www.lexonuk.com/userfiles/Competition%20Law%20Compliance.pdf. The CMA notes that although Lexon has not published its statement in an adequately visible location on its website, Lexon's compliance activities considered together merit a 10% compliance discount.

Medreich

8.175 The CMA finds that Medreich's compliance activities merit a discount of 5% to its penalty.

8.176 Medreich's submissions show that, since the CMA's investigation was opened in 2017, Medreich has:

8.176.1 [✂];[2368]

8.176.2 [✂];[2369]

8.176.3 [✂];[2370]

8.176.4 [✂];[2371]

8.176.5 [✂];[2372] and

8.176.6 [✂].[2373]

8.177 [✂][2374] [✂].

8.178 Taking these considerations in the round, the CMA concludes that Medreich has provided sufficient evidence of compliance activities to warrant a reduction in penalty of 5%.

Focus – Advanz

8.179 The CMA finds that Advanz's compliance activities merit a discount of 5% to the parts of the penalty for which Advanz, or any members of the Advanz Group as it currently exists[2375] are liable.

[2368] Medreich's submission on compliance, dated 17 September 2021, page 3, paragraph 3.5(d) (URN: PRO-C7680) and Annex 2, page 24 (URN: PRO-C7687).

[2369] Medreich's submission on compliance, dated 17 September 2021, page 3, paragraph 3.5(e) (URN: PRO-C7680) and Annex 11 (URN: PRO-C7683).

[2370] Medreich's submission on compliance, dated 17 September 2021, pages 2-3, paragraph 3.5(b) (URN: PRO-C7680) and Annex 2, pages 24-27 (URN: PRO-C7687).

[2371] Medreich's submission on compliance, dated 17 September 2021, Annex 2, pages 15 and 24, point 28 (URN: PRO-C7687). See also Medreich's submission on compliance, dated 17 September 2021, page 2, paragraph 3.4 (URN: PRO-C7680) and Annex 1 (URN: PRO-C7681).

[2372] Medreich's submission on compliance, dated 17 September 2021, page 3, paragraphs 3.5(f) and 3.6 (URN: PRO-C7680) and Annex 13 (URN: PRO-C7685).

[2373] Medreich's submission on compliance, dated 17 September 2021, page 2, paragraph 3.5(a) (URN: PRO-C7680). See also, Annex 10, pages 3-4, paragraph 6 (URN: PRO-C7682) and Annex 8 (URN: PRO-C7693) and Medreich Oral Hearing, 21 July 2021, page 25, line 14 to page 26, line 20 (PRO-7635).

[2374] The CMA notes that Meiji has a general compliance statement on its website committing to comply with '*laws, regulations and social rules of each country in order to ensure all transactions are proper and to promote fair, transparent, and free competition*'. [✂]. https://www.meiji.com/global/investors/governance/compliance.html.

[2375] Including the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities.

8.180 Submissions from Advanz show that, since the CMA's investigation was opened in 2017, it has:

8.180.1 [✂]

(a) [✂];[2376]

(b) [✂];[2377] and

(c) [✂];[2378]

8.180.2 [✂];[2379]

8.180.3 made a clear public commitment to compliance with competition law on its website;[2380] and

8.180.4 [✂].[2381]

8.180.5 [✂].[2382]

8.181 Taking these considerations in the round, the CMA concludes that Advanz has provided sufficient evidence of compliance activities to warrant a reduction in penalty of 5%.

Focus – Cinven

8.182 The CMA finds that the evidence presented for Cinven's compliance activities [2383] does not merit a discount to the part of the penalty for which Cinven is liable.

8.183 [✂]

8.183.1 [✂][2384]

8.183.2 [✂];[2385]

[2376] [✂].

[2377] [✂].

[2378] [✂].

[2379] Advanz RDPS, 7 July 2021, paragraph 6.41.5 (URN: PRO-C7481) and Advanz Annex III Code of Conduct dated 11 August 2020, paragraph 6.1 (URN: PRO-C7472)*;* also available at https://www.advanzpharma.com/media/uploads/2020_08_11_Code-of-Conduct.doc.pdf.

[2380] Advanz Annex III Code of Conduct dated 11 August 2020 (URN: PRO-C7472)*;* also available at https://www.advanzpharma.com/media/uploads/2020_08_11_Code-of-Conduct.doc.pdf.

[2381] Advanz Annex III Code of Conduct dated 11 August 2020, paragraph 6.3 (URN: PRO-C7472).

[2382] As set out in CMA Penalties Guidance paragraph 2.19 and footnote 33, in order to merit a discount, an undertaking's compliance activities will generally be expected to include *'conducting periodic review of its compliance activities, and reporting that to the CMA*'.

[2383] Cinven RDPS, 7 July 2021, paragraphs 3.39 (URN: PRO-C7439) and Appendix 1 (URN: PRO-C7440). See also Cinven's subsequent letter regarding its compliance activities to the CMA dated 18 August 2021 (URN: PRO-C7609).

[2384] Cinven RDPS, 7 July 2021, Appendix 1, paragraph 3.1 (URN: PRO-C7440). [✂].

[2385] Cinven RDPS, 7 July 2021, Appendix 1, paragraphs 3.3-3.34 (URN: PRO-C7440). [✂].

8.183.3 [✂].[2386]

8.184 [✂].

8.185 [✂].[2387] [✂].[2388]

8.186 [✂][2389] [✂].

8.187 [✂].[2390]

8.188 [✂].

8.189 [✂].

8.190 In the light of the above, the CMA considers that Cinven has not demonstrated that adequate steps have been taken to achieve a clear and unambiguous commitment to compliance throughout the undertaking, from the top down, such as to merit a reduction in its penalty.

Other mitigating factors

8.191 The Parties have made further representations in relation to other factors which they have submitted should be considered mitigating factors at Step 3 of the CMA's penalty calculation. The CMA has set out its response to these representations in Annex H of this Decision.

Calculation at the end of Step 3

8.192 At the end of Step 3, the penalty for the Infringement to be imposed on each undertaking is set out in Table 7.

[2386] Cinven RDPS, Appendix 1, paragraphs 3.18-3.20 (URN: PRO-C7440). [✂].

[2387] [✂].

[2388] Cinven's submission on compliance activities dated 18 August 2021, paragraph 6(a) (URN: PRO-C7609); Cinven submission on compliance activities dated 11 January 2022 (URN: PRO-C7967), including Annexes 1 and 2 (URN: PRO-C7968) and (URN: PRO-C7969) (also available at cinven-esg-2020-aw.pdf); and Cinven's submission on compliance activities dated 25 January 2022 (URN: PRO-C8010).

[2389] Cinven RDPS, Appendix 1, paragraph 3.28 (URN: PRO-C7440). See Cinven RDPS, Annex 11, p.22 (URN: PRO-C7441.11). Cinven submission on compliance activities dated 11 January 2022 (URN: PRO-C7967), including Annexes 1 and 2 (URN: PRO-C7968) and (URN: PRO-C7969).

[2390] Cinven's submission on compliance activities dated 18 August 2021, paragraph 6(b) (URN: PRO-C7609).

Table 7: Calculation at the end of Step 3

Undertaking	Adjustment at Step 3[2391]	Penalty after Step 3
Alliance	Senior management involvement – 15% increase	£1,767,780
Lexon	Senior management involvement – 15% increase Compliance – 10% decrease	£2,903,200
Medreich	Senior management involvement – 15% increase Compliance – 5% decrease	£1,713,010
Focus	Senior management involvement – 15% increase Compliance – 5% decrease to be applied to the Advanz Group only (and not the Cinven Entities) at the start of Step 4 (see Table 8)	£9,340,516[2392]

Step 4 – Adjustment for specific deterrence and proportionality

CMA Approach to Step 4

8.193 As set out in the CMA Penalties Guidance, the CMA may adjust the penalty at Step 4 for specific deterrence (that is, to ensure that the penalty imposed on the infringing undertaking/s will deter it/them from engaging in anti-competitive practices in the future) and/or proportionality having regard to appropriate indicators of the size and financial position of the relevant undertaking(s) at the time the penalty is being imposed as well as any other relevant circumstances of the case.[2393] Adjustments at Step 4 may result in either an increase or a decrease to the penalty.

8.194 The CMA's assessment of the need to adjust the penalty is made on a case-by-case basis for each individual undertaking on which the CMA proposes to impose penalties.[2394]

[2391] The percentage increases and decreases are applied separately to the penalties at the end of Step 2, with the resulting figures added or subtracted to that figure at the end of Step 2.

[2392] This figure includes the application of the 15% increase for the involvement of senior management but does not include the 5% decrease for compliance as this is applied to the Advanz Group only (and not the Cinven Entities) at the start of Step 4 (see Table 8).

[2393] CMA Penalties Guidance, paragraph 2.20.

[2394] CMA Penalties Guidance, paragraph 2.21. See also C-189/02 P *Dansk Rørindustri v Commission*, EU:C:2005:408, paragraph 292.

8.195 Specific deterrence (as distinct from general deterrence) should ensure that the penalty is specific to the offence and the offender.[2395]

8.196 The objective of pursuing a specific deterrent effect through a financial penalty is '*essentially to control, in the future, the conduct of the economic entity to which the [CMA] decision is addressed. Such an effect must necessarily be produced on the undertaking in the state [in] which it exists at the time when that decision is adopted*'.[2396]

Specific deterrence and proportionality

8.197 The penalty reached after Steps 1 to 3 may be increased to ensure that the penalty to be imposed on the relevant undertakings will deter them from breaching competition law in the future given their size, financial position and any other relevant circumstances of the case.[2397]

8.198 Specific deterrence increases are generally limited to situations in which an undertaking has a significant proportion of its turnover outside the relevant market, or where the CMA has evidence that the undertaking has made an economic or financial benefit from the infringement that exceeds the penalty reached at the end of Step 3.[2398]

8.199 The penalty imposed for infringing competition rules pursues not only a preventative but also a '*punitive […] objective*'. Consequently, where the CMA has evidence that an undertaking has made a financial benefit from the infringement, the penalty cannot be set at a level which '*merely negates the profits*' of the infringement.[2399] Simply asking a company to repay the minimum level of its unlawful direct gains (or a small percentage more) would not be enough to deter the company from taking the risk of committing the unlawful conduct again in future.[2400] Any penalty imposed in relation to the infringement should therefore

[2395] C-247/11 P *Areva v Commission*, EU:C:2014:257, paragraphs 127 and 131.

[2396] C-408/12 P *YKK v Commission*, EU:C:2014:153, paragraph 91. In that case, the infringing subsidiary no longer existed as an independent economic entity at the time the contested decision was adopted, having been acquired by the YKK group. The EU Court of Justice held at paragraph 92 that: '*Consequently, the pursuit of a deterrent effect by means of the fine had necessarily to apply to the YKK group, of which [the subsidiary] was now part, regardless of the fact that [the parents] had not participated in the infringement in the period [prior to the acquisition of the subsidiary]*' and paragraph 87: '*[T]he fact that [the parent companies, post-acquisition] are not held jointly and severally liable for the infringement committed by [the subsidiary] for the period prior to [the acquisition] has no bearing on the determination of a deterrence multiplier*'. See also C-668/11 P *Alliance One v Commission*, EU:C:2013:614, paragraph 64, and the Order in C-421/11 P *Total et Elf Aquitaine v Commission*, EU:C:2012:60, paragraph 82.

[2397] CMA Penalties Guidance, paragraph 2.21.

[2398] CMA Penalties Guidance, paragraph 2.21.

[2399] T-410/09 *Almamet v Commission*, EU:T:2012:676, paragraph 271. This is particularly the case given the possibility that future unlawful conduct may not be detected or subject to enforcement.

[2400] See T-471/13 *Alpharma v Commission*, EU:T:2016:460, paragraph 429: The '*purpose of a fine is not simply to remove the benefits that an undertaking has obtained through its anticompetitive conduct, but also to deter that undertaking and other undertakings from engaging in such conduct*', as upheld by the EU Court of Justice in C-611/16 P *Alpharma v Commission*, EU:C:2021:245.

exceed the financial benefit from the infringement by a material amount in order to be a meaningful deterrent.

8.200 More significant adjustments may also be appropriate where the relevant turnover did not accurately reflect the scale of an undertaking's involvement in the infringement or the likely harm to competition.[2401]

8.201 The CMA may also take account of any other relevant circumstances of the case.[2402]

8.202 In considering the appropriate level of any adjustment for specific deterrence, the CMA ensures that it does not result in a disproportionate or excessive penalty having regard to the undertaking's size and financial position and the nature of the infringement.[2403]

8.203 At this step, the CMA assesses whether, in its view, the overall penalty for the infringement is appropriate in the round, with regard to the undertaking's size and financial position at the time the penalty is being imposed as well as the nature of the infringement, the role of the undertaking in the infringement and the impact of its infringing activity on competition.[2404]

8.204 Where the legal entities which were part of an undertaking at the time of the Infringement no longer form part of the same undertaking today (see paragraphs 8.206 to 8.208 and 8.304 to 8.305 below), the CMA has separately considered at Step 4 the penalties imposed on:

8.204.1 the undertaking as it exists at the date of this Decision; and

8.204.2 those legal entities that no longer form part of the undertaking at the date of this Decision.

Distribution of penalties between entities which are liable for the infringement in different periods

8.205 In determining how the total penalty is distributed between entities which are liable for the Infringement in different periods, the CMA has had regard to the principle that a penalty needs to be specific to the offender and the offence.[2405]

8.206 Where an infringing subsidiary is owned by successive parents during the Infringement Period, each parent is jointly and severally liable with that subsidiary

[2401] CMA Penalties Guidance, paragraph 2.22.

[2402] CMA Penalties Guidance, paragraph 2.21

[2403] CMA Penalties Guidance, paragraph 2.23.

[2404] CMA Penalties Guidance, paragraph 2.24.

[2405] C-247/11 P *Areva v Commission*, EU:C:2014:257, paragraphs 127 and 131.

only for the penalty in relation to its ownership period and cannot be jointly and severally liable with the other parent companies for the totality of the penalty.[2406]

8.207 The penalties are therefore calculated on a per-Period basis from Step 4 onwards, in each case starting with the apportionment of the penalty after Step 3 between the relevant Periods.[2407]

8.208 Table 8 sets out how the total duration of the Infringement is apportioned to each specific period of ownership at the end of Step 3 / start of Step 4.

8.209 The CMA's approach allows each successive parent company to know its own liability for the penalty which it is required to pay.[2408]

Parties' representations

8.210 The Parties have made representations in relation to the CMA's approach to its assessment at Step 4 of its penalty calculation. Where appropriate, these have been referenced and responded to in the analysis set out below. The CMA has set out its response to the remaining representations in Annex H of this Decision.

Table 8: Calculation at the end of Step 3 / start of Step 4

Undertaking	Period and legal entities liable jointly and severally	Duration-based apportionment	Penalty after Step 3
Alliance	Alliance Pharmaceuticals Limited Alliance Pharma plc	100%	£1,767,780
Lexon	**Lexon Period 1**[2409] Lexon (UK) Limited	4.82 years (91.87% of 5.25 years[2410])	£2,667,055
	Lexon Period 2[2411] Lexon (UK) Limited and Lexon UK Holdings Limited	0.43 years (8.13% of 5.25 years[2412])	£236,145
Medreich	**Medreich Period 1**[2413] Medreich plc and Medreich Ltd	1.07 years (25.27% of 4.25 years[2414])	£432,907

[2406] C-247/11 P *Areva v Commission*, EU:C:2014:257, paragraphs 126 to 142.

[2407] With regard to Focus, the CMA has also adjusted at Step 4 for the 5% compliance discount which applies to the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities but not to the Cinven Entities after the penalty has been apportioned.

[2408] C-247/11 P *Areva v Commission*, EU:C:2014:257, paragraph 135.

[2409] 7 June 2013 to 28 February 2018.

[2410] The precise figure is 1728/1881 days.

[2411] 1 March 2018 to 31 July 2018.

[2412] The precise figure is 153/1881 days.

[2413] 5 February 2014 to 11 February 2015.

[2414] The precise figure is 372/1472 days.

Undertaking	Period and legal entities liable jointly and severally	Duration-based apportionment	Penalty after Step 3
	Medreich Period 2[2415] Medreich plc, Medreich Ltd, Meiji Seika Pharma Co and Meiji Holdings Co Ltd	3.18 years (74.73% of 4.25 years[2416])	£1,280,103
Focus	**Focus Period 1**[2417] Focus Entities (Including application of Advanz's 5% discount for compliance at Step 3)	1.31 years (24.97% of 5.25 years[2418])	£2,231,208
	Focus Period 2[2419] Focus Entities, Mercury Pharma Group Limited and the Cinven Entities (Including application of 5% discount for compliance for the Focus Entities and Mercury Pharma Group Limited for at Step 3, but not for Cinven)	1.08 years (20.63% of 5.25 years[2420])	£1,927,170 (without application of compliance discount) of which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable for £1,843,380 after the application of 5% discount for compliance at Step 3[2421]
	Focus Period 3[2422] Focus Entities, Mercury Pharma Group Limited and the Advanz Entities (Including application of Advanz's 5% discount for compliance at Step 3)	2.86 years (54.39% of 5.25 years[2423])	£4,859,819

[2415] 12 February 2015 to 15 February 2018.

[2416] The precise figure is 1100/1472 days.

[2417] 22 June 2013 to 30 September 2014

[2418] The precise figure is 466/1866 days.

[2419] 1 October 2014 to 20 October 2015.

[2420] The precise figure is 385/1866 days.

[2421] The Cinven Entities are liable for £1,927,170 for Focus Period 2 at the end of Step 3 / the start of Step 4 as no compliance discount has been applied to the Cinven Entities, but the Focus Entities and Mercury Pharma Group Limited are liable for £1,843,380.

[2422] 21 October 2015 to 31 July 2018.

[2423] The precise figure is 1015/1866 days.

Alliance

Specific deterrence

8.211 In considering at Step 4 whether any adjustments should be made to the penalty to be imposed on Alliance, the CMA has had regard to the need adequately to deter Alliance from breaching competition law in the future.

Relevant turnover

8.212 As set out in the CMA Penalties Guidance, the CMA may make '*more significant adjustments, both for general and specific deterrence […] where the relevant turnover did not accurately reflect the scale of an undertaking's involvement in the infringement or the likely harm to competition*' and refers, by way of example, to where an undertaking's turnover in the last business year before the infringement ended was '*unusually low*'.[2424]

8.213 The CMA does not consider Alliance's relevant turnover to accurately reflect the scale of its involvement in the Infringement or the likely harm to competition.[2425]

8.213.1 Firstly, Alliance's relevant turnover in its last business year of the Infringement (£976,000) is significantly less than its equivalent turnover during each of its preceding three full business years during the Infringement.[2426] Alliance's relevant turnover used at Step 1 of this penalty calculation is approximately half (53.8%) of its average turnover in the relevant market for the previous three years. Alliance's relevant turnover was therefore unusually low in its last business year of the Infringement.

8.213.2 Secondly, the scale of Alliance's involvement in the Infringement or the likely harm to competition is not adequately reflected in the revenues that it protected by entering into the Market Exclusion Agreement and preventing Lexon's market entry. As set out at paragraph 5.278 of this Decision, the payments made to Lexon as compensation were funded through the significant increase in market prices and profits that Alliance enabled by de-branding its Buccastem product and removing it from the price and profit constraints of the PPRS. Lexon was compensated for non-entry out of the profits earned from price increases that Alliance had enabled and that were to the detriment of the NHS. The turnover that Alliance earned from sales of Prochlorperazine POM does not therefore reflect these significant price increases that it enabled and that were used to fund the compensation payments made for Lexon's exclusion from the

[2424] CMA Penalties Guidance, paragraph 2.22.

[2425] CMA Penalties Guidance, paragraph 2.22.

[2426] In its business years ending 31 December 2014, 2015 and 2016, Alliance's turnover in the relevant market was respectively £1,813,437, £1,916,547 and £1,708,000. Section 26 response of Alliance, dated 14 May 2021, to the CMA Notice of 7 May 2021 (URN: PRO-C7211 and PRO-C7212).

market, such that the scale of Alliance's involvement in the Infringement and the likely harm to competition is not adequately reflected in its relevant turnover.

8.214 Alliance submitted that its lower relevant turnover in the financial year preceding the end of the Infringement is neither '*very low or zero*' (citing paragraph 2.22 of the CMA Penalties Guidance) nor '*out of the norm*' (citing the CAT's judgment in *FP McCann*)[2427] and therefore does not provide a '*valid basis*' for applying any increase at Step 4.

8.215 The CMA Penalties Guidance does not however limit adjustments at Step 4 to cases where an undertaking's turnover is very low or zero and the CMA notes that the CAT's comments in *FP McCann* were made in the context of departures from the CMA's '*usual approach*' to calculating relevant turnover at Step 1.

8.216 As set out in the CMA Penalties Guidance, the CMA may also make '*more significant adjustments, both for general and specific deterrence […] where the relevant turnover did not accurately reflect the scale of an undertaking's involvement in the infringement or the likely harm to competition*' and refers, by way of example, to where an undertaking's turnover in the last business year before the infringement ended was '*unusually low*'.[2428] In this case, in accordance with its Guidance, the CMA has found that Alliance's turnover in the last business year of the Infringement was unusually low.

Turnover outside the relevant market

8.217 Alliance achieved a significant proportion of its turnover outside the relevant market of Prochlorperazine POM.

8.218 Alliance's turnover in its last financial year of the Infringement (1 January 2017 to 31 December 2017) in the relevant market amounted to £976,000, as compared to its total worldwide turnover in that year of £101.6 million[2429] – meaning that over 99% of its turnover was achieved outside the relevant market.

Size and financial position

8.219 The Alliance corporate group is a significant, publicly listed undertaking. In its last full business year for the year ending 31 December 2020, Alliance reported revenue of £129.80 million, profit after tax of £8.03 million, and reported a net asset

[2427] Alliance RDPS, paragraph 8.12 (URN: PRO-C7461), citing CMA Penalties Guidance, paragraph 2.22 and *FP McCann Limited v CMA* [2020] CAT 28, paragraph 179 on whether and when the CMA might depart from its 'usual approach' to calculating relevant turnover at Step 1 of its penalty calculation: '*All one can usefully say is that the Penalty Guidance is to be applied in the normal case so that there must be something out of the norm to justify departing from it and using an average of the turnovers for the whole period of the infringement (or some other approach)*'.

[2428] CMA Penalties Guidance, paragraph 2.22.

[2429] Alliance Pharma plc statutory accounts for year ending 31 December 2018 restating results for year ending 31 December 2017.

position of £280.96 million.[2430] Over a three year average for the years ending 31 December 2018 to 2020, Alliance's reported revenue is £127.88 million, its profit after tax is £17.13 million and its net assets are £269.11 million.[2431]

8.220 The penalty to be imposed on Alliance at the end of Step 3 (£1,767,780) would represent:

8.220.1 1.38% of its worldwide turnover (averaged over the last three years);

8.220.2 10.32% of its profit after tax (averaged over the last three years); and

8.220.3 0.63% of its net assets and dividends (last year's net assets plus last three year's dividends).

8.221 The CMA also observes that Alliance's turnover has grown very significantly over the last five years from £48.34 million for the year ending 31 December 2016 to £129.80 million for the year ending 31 December 2020. Alliance's operating cashflow has also significantly increased over the last five years from £16.93 million for the year ending 31 December 2016 to £41.57 million for the year ending 31 December 2020, and for the five years ending 31 December 2016 to 2020, Alliance paid out dividends of on average £5.14 million per year, suggesting the financial strength of the business.[2432]

Relevant circumstances of the case

8.222 The CMA has taken account of the relevant circumstances of the case.[2433]

8.223 Alliance entered into a horizontal market exclusion agreement with Lexon that was implemented via two separate agreements with a common third party (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected.

8.224 Furthermore, by entering into the Market Exclusion Agreement, Alliance:

8.224.1 aimed to protect (and protected) its monopoly in the supply of Prochlorperazine POM in the UK until Morningside obtained its MA in April 2017; and

8.224.2 aimed to ensure (and ensured) it sustained its pre-existing monopoly earnings from the sale of the product by implementing a fixed price supply

[2430] Alliance Pharma plc statutory accounts for year ending 31 December 2020.

[2431] Alliance Pharma plc statutory accounts for years ending 31 December 2018-2020.

[2432] Alliance Pharma plc statutory accounts for years ending 31 December 2016-2020.

[2433] CMA Penalties Guidance, paragraph 2.21.

agreement with Focus which matched Alliance's previous price for its branded Prochlorperazine POM product, Buccastem.

8.225 The Market Exclusion Agreement envisaged and ensured that:

8.225.1 Lexon would (and did) not enter the market for the supply of Prochlorperazine POM, with no competition in that market until Morningside obtained its MA, insulating Alliance's profits (amounting to £5.3m[2434] between December 2013 and July 2018) from any competition until April 2017 and from competition from Lexon and Medreich throughout the Infringement Period;[2435] and

8.225.2 Focus would be (and was) able to implement a series of substantial price increases[2436] at a cost to the NHS (and ultimately the taxpayer), the significant profits from which Focus shared with Lexon (and Medreich) as compensation for not entering the market.[2437]

Increase for specific deterrence

8.226 The CMA considers that Alliance's penalty at the end of Step 3 should be increased significantly given:

8.226.1 Alliance's relevant turnover does not accurately reflect the scale of its involvement in the Infringement or the likely harm to competition;

8.226.2 the large majority of Alliance's turnover was achieved outside the relevant market;

8.226.3 the penalty at the end of Step 3 would be relatively modest in terms of Alliance's size and financial position; and

8.226.4 the relevant circumstances of the case, as described in paragraphs 8.223 to 8.225 above.

8.227 Alliance has submitted representation on how it considers the CMA should take account of any financial gain Alliance may have made from the Infringement, arguing that it made '*no incremental gains*' as a result of the Market Exclusion Agreement. The CMA does not accept Alliance's analysis, for the reasons set out in paragraphs H.104 to H.112.3 of Annex H of this Decision.

[2434] Including monopoly profits until Morningside obtained its MA in April 2017.

[2435] See Figure 5, paragraph 5.721.8.

[2436] See Figure 2.

[2437] See Figure 5, paragraph 5.721.8.

8.228 As a result, the CMA considers that a significant uplift for the purpose of specific deterrence is appropriate in this case, which would result in a penalty for Alliance of £7.9 million at the end of Step 4.[2438]

Proportionality assessment

8.229 The CMA considers that uplifting the penalty to £7.9 million will provide an effective yet proportionate deterrent for Alliance, having had regard to Alliance's size and financial position, the nature of the Infringement, Alliance's role in the Infringement and the impact of Alliance's infringing activity on competition.[2439]

8.230 A penalty of £7.9 million at the end of Step 4 would represent:

8.230.1 6.18% of Alliance's worldwide turnover (averaged over the last three years);

8.230.2 46.12% of its profit after tax (averaged over the last three years); and

8.230.3 2.65% of net assets and dividends (last year's net assets plus last three year's dividends).

8.231 As set out in paragraph 8.221 above, Alliance's turnover and operating cashflows have increased very significantly over the last five years and Alliance paid out substantial dividends over the same period.[2440]

8.232 Alliance entered into a market exclusion agreement, which is one of the most serious infringements of competition law. As the incumbent supplier of the product that was the subject of that agreement, Alliance was a critical part of the Market Exclusion Agreement, which:

8.232.1 comprised a horizontal market exclusion agreement between Alliance and Lexon that was implemented via two separate agreements with a common third party (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected, and

8.232.2 was structured to ensure that Alliance sustained its pre-existing monopoly earnings while the NHS paid for the price increases implemented to generate the profits to compensate Alliance's competitor for not entering the market.

[2438] Alliance has submitted that the penalty is higher than necessary to deter Alliance and referred to [✂]. See Alliance RDPS, 7 July 2021, paragraphs 1.5.2(g), 8.63-8.64 (URN: PRO-C7461) and Alliance Oral Hearing, 20 July 2021, page 26, lines 14-18 (URN: PRO-C7633).

[2439] CMA Penalties Guidance, paragraphs 2.23-2.24.

[2440] Alliance Pharma plc statutory accounts for years ending 31 December 2016-2020.

8.233 During the term of the Market Exclusion Agreement, there was no entry into the market for the supply of Prochlorperazine POM until Morningside gained its MA in April 2017 and competition thereafter was limited to supply from Morningside until the end of the Infringement Period.

8.234 Alliance has submitted in response to the Draft Penalty Statement that a proposed penalty of £7.9 million which would have amounted to 46.1% of Alliance's profit after tax (averaged over its last financial three years) was '*excessive*'.[2441]

8.235 The CMA disagrees and notes that, in *Almamet*, the EU General Court ruled that '*the fact that the fine imposed on an undertaking is considerably higher than its entire net profit in a financial year is not, in itself, sufficient for it to be concluded that the fine is disproportionate*' (emphasis added).[2442]

8.236 The penalty to be imposed on Alliance is significantly less than its entire net profit in a financial year and, as set out in paragraphs 8.229 to 8.233 of this Decision, is appropriate in the round given Alliance's size and financial position, the nature of the Infringement, Alliance's role in the Infringement and the impact of the Alliance's infringing activity on competition.

8.237 Alliance additionally submitted that the CMA should take account of [✂].[2443]

8.238 The CMA disagrees. [✂]. The CMA has not therefore [✂] in its assessment of Alliance's penalty against indicators of its size and financial position.

8.239 The CMA therefore does not consider a penalty of £7.9 million to be excessive or disproportionate.

Lexon

Specific deterrence

8.240 In considering at Step 4 whether any adjustments should be made to the penalty to be imposed on Lexon, the CMA has had regard to the need adequately to deter Lexon from breaching competition law in the future.

Financial benefit from the Infringement

8.241 Pursuant to the Market Exclusion Agreement, Lexon received significant profit share payments that were paid as compensation for its agreement not to commercialise the Prochlorperazine POM product it had jointly developed with Medreich.

[2441] Alliance RDPS, 7 July 2021, paragraph 8.62 (URN: PRO-C7461).

[2442] T-410/09 *Almamet v Commission*, EU:T:2012:676, paragraph 271.

[2443] Alliance DPS Oral Hearing, 20 July 2021, page 8, line 5 to page 9, line 6 (URN: PRO-C7633), [✂] (URN: PRO-C7605).

8.242 In entering into the Market Exclusion Agreement, Lexon obtained the certainty of profit share payments arising under the Market Exclusion Agreement (from Alliance, indirectly via Focus), whilst avoiding the vagaries of profits that might have resulted from market entry in competition with Alliance based on the product Lexon had developed with Medreich.[2444]

8.243 Based on the net profit share payments Lexon received from Focus after deducting the payments Lexon made to Medreich,[2445] Lexon obtained a financial benefit from the Infringement that amounted to:

8.243.1 £4,269,204.01 in the period from 7 June 2013 to 28 February 2018 ('Lexon Period 1'), for Lexon (UK) Limited; and

8.243.2 £689,950.78 in the period from 1 March 2018 to 31 July 2018 ('Lexon Period 2'), for Lexon (UK) Limited and Lexon UK Holdings Limited

(together £4,959,154.79).

8.244 The penalty at the end of Step 3 for Lexon (£2,903,200) is significantly less than the financial benefit that Lexon made from the Infringement during the Infringement Period.

8.245 Lexon has accepted that it is important from the perspective of deterrence to ensure that any penalty imposed on Lexon is no less than the financial benefit Lexon made from the Infringement,[2446] but noted that Lexon paid corporation tax on the net profit share payments Lexon received from Focus (after deducting the payments Lexon made to Medreich), thereby '*reducing the benefit to Lexon*'.[2447]

8.246 To the extent that Lexon has submitted that the CMA should have taken account of corporation tax paid by Lexon when calculating the financial benefit, the CMA rejects this submission. The EU General Court has rejected the suggestion that competition authorities should deduct expenses, including tax, from the amount of the value transfer as the '*purpose of a fine is not simply to remove the benefits that an undertaking has obtained through its anticompetitive conduct, but also […] to deter that undertaking and other undertakings from engaging in such conduct*'.[2448] The EU General Court held that if the basic amount of the fine imposed on a generic company were set at a lower level than that of the inducive benefit which it enjoyed as a result of a market exclusion infringement, it would not have such a deterrent effect as *'that company might find it preferable to conclude an agreement with an originator company allowing it, even where that agreement gave rise to a*

[2444] T-471/13 *Alpharma v Commission*, EU:T:2016:460, paragraph 432.

[2445] See Annex I, Prochlorperazine Profit Share Payments.

[2446] Lexon RDPS, 2 July 2021, paragraph 2.8 (URN: PRO-C7416).

[2447] Lexon RDPS, 2 July 2021, paragraph 2.8 (URN: PRO-C7416).

[2448] T-705/14 *Unichem Laboratories v Commission*, EU:T:2018:915, paragraphs 447 and 493-503. See also T-701/14 *Niche Generics v Commission*, EU:T:2018:921, paragraphs 365 and 411-421.

penalty, to retain a part of the inducive benefit resulting from the infringement, rather than to enter the market at risk.[2449] In this case, the CMA similarly considers that if Lexon's penalty was set below the financial benefit that it made from the Infringement the penalty would not have a deterrent effect.[2450]

Turnover outside the relevant market

8.247 Lexon achieved a significant proportion of its turnover outside the relevant market of Prochlorperazine POM.

8.248 Lexon's turnover in its last financial year of the Infringement (1 May 2017 to 30 April 2018) in the relevant market amounted to £1.76 million, as compared to its total worldwide turnover in that year of £258.02 million[2451] – meaning that over 99% of its turnover was achieved outside the relevant market.

Size and financial position

8.249 The Lexon corporate group is a significant undertaking. In its last full business year for the year ending 30 April 2021, Lexon reported revenue of £438.65 million (up from £381.34 million in 2020 and £301.08 million in 2019), profit after tax of £1.84 million, and reported a net asset position of £48.53 million.[2452] Over a three year average for the years ending 30 April 2019-2021, Lexon's worldwide turnover averaged £373.69 million, net profit after tax of £2.16 million, and net assets of £46.66 million.[2453]

8.250 The penalty to be imposed on Lexon at the end of Step 3 (£2,903,200), would represent:

8.250.1 0.78% of its worldwide turnover (averaged over the last three years);

8.250.2 134.45% of its profit after tax (averaged over the last three years); and

8.250.3 5.74% of its net assets and dividends (last year's net assets plus last three year's dividends).

[2449] T-705/14 *Unichem Laboratories v Commission*, EU:T:2018:915, paragraphs 497 and 501; See also T-701/14 *Niche Generics v Commission*, EU:T:2018:921, paragraphs 415 and 419.

[2450] See also the European Commission's written observations in *Tessenderlo Chemie NV v the Belgian State*, Case 5285, dated 8 March 2012, sj.e(2012)227414, paragraph 24: '*The Commission emphasises that the fines imposed under Regulation No 1/2003 serve a punitive and deterrent purpose and are thus not primarily intended to deprive the party which breached the competition rules of the advantages which it would have obtained from this infringement. […] If the scale of the advantage derived can be objectively established – in most cases it will be difficult to give a reliable estimate of this – the Commission can take this into account and ensure that the fine is at least higher than the amount of the gains improperly made. The advantage an undertaking has derived from an infringement may thus play a part in the calculation of the amount of a fine, in the sense that the fine will not have a deterrent effect if it is less than the advantage unlawfully obtained.*'.

[2451] Lexon UK Holdings Limited statutory accounts for year ending 30 April 2019 restating results for year ending 30 April 2018.

[2452] Lexon UK Holdings Limited statutory accounts for year ending 30 April 2021.

[2453] Lexon UK Holdings Limited statutory accounts for years ending 30 April 2021, 2020 and 2019.

Relevant circumstances of the case

8.251 The CMA has taken account of the relevant circumstances of the case.[2454]

8.252 Lexon entered into a horizontal market exclusion agreement with Alliance that was implemented via two separate agreements with a common third party (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected.

8.253 Furthermore, by entering into the Market Exclusion Agreement, Lexon agreed not to enter the market for the supply of Prochlorperazine POM with the product it had developed with Medreich in exchange for a share of the significant profits made by the sale, by Focus, of Alliance's Prochlorperazine POM.

8.254 The Market Exclusion Agreement envisaged and ensured that:

8.254.1 Lexon would (and did) not enter the market for the supply of Prochlorperazine POM, with no competition in that market until Morningside gained its MA in April 2017 and competition thereafter limited to supply from Morningside until the end of the Infringement Period.

8.254.2 Focus would be (and was) able to implement a series of substantial price increases,[2455] at a cost to the NHS (and ultimately the taxpayer), that would generate the substantial profits which Focus shared with Lexon (and Medreich) as compensation for not entering the market.[2456]

8.255 Lexon has submitted that the CMA's assessment is '*erroneous*' on the basis of Lexon's submission that it was unable to enter the market for the supply of Prochlorperazine POM until November 2017 and consequently '*no cost to the NHS was incurred*'.[2457]

8.256 The CMA disagrees.

8.256.1 As established in *Lundbeck*, the CMA should '*principally [take] into account evidence prior to or contemporaneous with the date on which the [agreement] at issue [was] concluded*', given that the parties '*decided to adopt a particular course of conduct*' and conclude the Market Exclusion Agreement '*solely on the basis of the information available to them at the time and their perception of the market at that time*'.[2458]

[2454] CMA Penalties Guidance, paragraph 2.21.

[2455] See Figure 2.

[2456] See Figure 5, paragraph 5.721.8

[2457] Lexon RDPS, paragraph 2.13.

[2458] T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraphs 138-139.

8.256.2 As set out in this Decision, the Market Exclusion Agreement aimed to ensure that Alliance, the incumbent in the market for the supply of Prochlorperazine POM would not face any competition from Lexon, the sole potential competitor in that market at the point Alliance and Lexon entered into the Market Exclusion Agreement. Lexon was the sole potential competitor in the market for the supply of Prochlorperazine POM at that time and remained a potential competitor throughout the duration of the Market Exclusion Agreement, irrespective of any (temporary and resolvable) manufacturing or regulatory issues that may have subsequently arisen and which were unknown at the point Alliance and Lexon entered into the Market Exclusion Agreement.

8.257 Moreover, and in any event, Lexon is wrong to assume that the timing of Lexon's entry would have been the same in the absence of the Market Exclusion Agreement. The conduct of Medreich and Lexon would inevitably have been very different and they would have had every incentive to commercialise their product as quickly as possible. For example, Lexon would have most likely have instructed Medreich to:

8.257.1 progress manufacturing Prochlorperazine POM earlier,[2459] rather than informing its development partner that the product was '*best left alone*'.[2460]

8.257.2 manufacture commercial volumes of Prochlorperazine POM, rather than limit supply to single batch to avoid the application of the Sunset Clause.

8.258 Equally, it is wholly unclear whether, absent the Market Exclusion Agreement, Alliance would have de-branded Prochlorperazine POM and enabled Focus' implementation of price increases.

8.259 By contrast, the Market Exclusion Agreement:

8.259.1 comprised Lexon's commitment not to enter the market for the supply of Prochlorperazine POM; and

8.259.2 was structured on the basis that there would be price increases of Prochlorperazine POM, the resulting profits from which would be shared with Lexon in exchange for non-entry.

[2459] By way of comparison, Medreich internally ordered prochlorperazine 5mg tablets on 21 March 2014 which were delivered to Lexon on 4 June 2015 (See paragraph 5.424).

[2460] Email [Lexon Director 1] to [Medreich Employee 1] entitled '*RE: Products*' 4 February 2014 (URN: PRO-E002750). See paragraph 5.422.

Increase for specific deterrence

8.260 Although the penalty after Step 3 represents a material proportion of Lexon's profits, the CMA considers that Lexon's penalty at the end of Step 3 should be increased significantly given:

8.260.1 Lexon realised significant financial benefits from the Infringement that materially exceed its penalty at the end of Step 3; for this reason alone, the CMA considers that Lexon's penalty should be increased significantly;

8.260.2 the large majority of Lexon's turnover was achieved outside the relevant market; and

8.260.3 the relevant circumstances of the case, as described in paragraphs 8.252 to 8.259 above.

8.261 As a result, the CMA considers that a significant uplift for the purpose of specific deterrence is appropriate in this case, which would result in a penalty for Lexon of £7.3 million at the end of Step 4, to be allocated as:

8.261.1 £6,706,220 for Lexon Period 1 (for which Lexon (UK) Limited is liable); and

8.261.2 £593,780 for Lexon Period 2 (for which Lexon (UK) Limited and Lexon UK Holdings Limited are jointly and severally liable)

(together £7.3 million).[2461]

Proportionality assessment

8.262 The CMA considers that uplifting the penalty to £7.3 million will provide an effective yet proportionate deterrent for Lexon, having had regard to Lexon's size and financial position, the nature of the Infringement, Lexon's role in the Infringement and the impact of Lexon's infringing activity on competition.[2462]

[2461] Citing the CMA's decision in *Paroxetine*, Lexon submitted that the '*lengthy period of investigation*', including a pause in the investigation, had entailed a '*substantially increased administrative burden*' for Lexon and the CMA should consequently '*not impose an uplift*'. The CMA rejects this submission. The CMA's investigation did not impose an administrative burden on the parties above and beyond that to be expected in the normal course of an investigation under the Act. The CMA paused its investigation between 7 April 2020 and 20 July 2020 to reallocate resources to ensure that the CMA was able to focus on urgent work during the Coronavirus COVID-19 pandemic. The pause was of relatively short duration and did not involve any additional procedural steps or additional requirements being made of the parties. Notwithstanding that the CMA is not bound by its previous decisions, Lexon's comparison with *Paroxetine* is inappropriate. In that decision, the CMA was '*mindful of the passage of time*' between the infringement period and the launch of its investigation – a period of more than seven years. Such a scenario does not apply to this investigation. See Lexon RDPS, 2 July 2021, paragraphs 2.14-2.17 (URN: PRO-C7416) and the CMA's decision in *Paroxetine* (CE-9531/11), paragraph 11.59.

[2462] CMA Penalties Guidance, paragraphs 2.23-2.24.

8.263 A penalty for Lexon of £7.3 million at the end of Step 4 represents:

8.263.1 1.95% of Lexon's worldwide turnover (averaged over the last three years);

8.263.2 338.07% of its profit after tax (averaged over the last three years);[2463] and

8.263.3 14.44% of its net assets and dividends (last year's net assets plus last three year's dividends).

8.264 Whilst the penalty to be imposed on Lexon at the end of Step 4 (£7.3 million) is relatively significant when compared to Lexon's profit after tax in its most recent financial year ending 30 April 2021, the CMA observes that:

8.264.1 as set out in paragraphs 8.241 to 8.246 above, any penalty imposed on Lexon in relation to the Infringement should exceed the financial benefit it obtained from the Infringement (£4,959,154.79) by a material amount in order to be a meaningful deterrent;

8.264.2 the CMA's guidance states that it may also consider indicators of size and financial position from the time of the Infringement;[2464] in this respect:[2465]

(a) Lexon's profit after tax was significantly higher during the period of the Infringement (i.e. £9.51 million for the year ending 30 April 2016, £6.51 million for the year ending 30 April 2017 and £6.92 million for the year ending 30 April 2018) than on average over the last three years; and

(b) during the four years ending 30 April 2016-2019, Lexon had sufficient resources to pay out approximately £2 million in cash dividends each year;

8.264.3 this penalty represents only 1.95% of Lexon's worldwide turnover (averaged over the last three years); furthermore, Lexon's turnover has remained high over the last three years: £301.08 million for the year ending 30 April 2019, £381.34 million for the year ending 30 April 2020 and £438.65 million for the year ending 30 April 2021;[2466]

[2463] The CMA's originally proposed penalty in the DPS of £7.9 million would have represented 205.18% of Lexon's profit after tax, averaged over the financial years ending 30 April 2018-2020. Although Lexon's average profit after tax has decreased from the financial years ending 30 April 2018-2020 to those ending 30 April 2019-2021, the CMA notes that Lexon's worldwide turnover remained high (£258.0 million in 2018, £301.1 million in 2019, £381.3 million in 2020 and £438.6 million in 2021) as has its operating cashflow (£11.5 million in 2018, £6.3 million in 2019, £8.7 million in 2020 and £16.3 million in 2021). For these reasons as well as those set out at paragraphs 8.264 and 8.265 to 8.268, the CMA does not consider the penalty to be imposed on Lexon to be excessive or disproportionate.

[2464] CMA Penalties Guidance, paragraph 2.20.

[2465] Based on Lexon (UK) Limited statutory accounts for years ending 30 April 2016 and 2017 and Lexon UK Holdings Limited statutory accounts for years ending 30 April 2019, 2020 and 2021.

[2466] Based on Lexon UK Holdings Limited statutory accounts for years ending 30 April 2019, 2020 and 2021.

8.264.4 this penalty represents 62.44% of Lexon's EBITDA for its last financial year, and 58.73% averaged over the last three years;[2467]

8.264.5 Lexon is also generating healthy cashflow from operations – £16.35 million for year ending 30 April 2021, up from £8.68 million for year ending 30 April 2020, and up from £6.30 million for year ending 30 April 2019;[2468] and

8.264.6 the '*fact that the fine imposed on an undertaking is considerably higher than its entire net profit in a financial year is not, in itself, sufficient for it to be concluded that the fine is disproportionate*'.[2469]

8.265 Lexon entered into a market exclusion agreement, which is one of the most serious infringements of competition law. As, with Medreich, the first potential competitor in the market for the supply of Prochlorperazine POM, Lexon was a critical part of the Market Exclusion Agreement:

8.265.1 which comprised a horizontal market exclusion agreement between Alliance and Lexon that was implemented via two separate agreements with a common third party (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected; and

8.265.2 during the term of which there was no entry into the market until Morningside gained its MA in April 2017. Competition thereafter was limited to supply from Morningside until the end of the Infringement Period.

8.266 In total, Lexon received £7,861,912.90 from Focus, of which it retained £4,959,154.79 after its payments to Medreich, in exchange for non-entry.

8.267 Lexon has submitted that the CMA should consider that:

8.267.1 Lexon is a '*high volume low margin business*', adding that it considers the CMA's originally proposed penalty of £7.9 million, which represented '*over two years*' of Lexon's net profit after tax, to be '*neither reasonable nor proportionate*' particularly given that Lexon's profits before tax are '*diminishing*';[2470]

[2467] Based on Lexon UK Holdings Limited statutory accounts for years ending 30 April 2019, 2020 and 2021.

[2468] Lexon UK Holdings Limited statutory accounts for years ending 30 April 2019, 2020 and 2021.

[2469] T-410/09 *Almamet v Commission*, EU:T:2012:676, paragraph 271 and the case-law cited therein.

[2470] Lexon RDPS, 2 July 2021, paragraphs 2.9-2.10 (URN: PRO-C7416).

8.267.2 Lexon's growth in group turnover has been produced by Healthnet Homecare Ltd, which is an entity in which Lexon holds 56% of the share capital but does not exercise management control;[2471] and

8.267.3 [✂].[2472]

8.268 The CMA rejects these submissions and observes that:

8.268.1 Although the CMA recognises that Lexon's penalty is relatively significant when compared to Lexon's profit after tax, the CMA considers that, for the reasons set out in paragraph 8.264 of this Decision, the increase in Lexon's penalty at Step 4 is neither disproportionate or excessive.

8.268.2 Healthnet Homecare Ltd's statutory accounts for the financial year ending April 2021 state that its '*ultimate parent and controlling party is Lexon UK Holdings Limited*'.[2473] In any event, even if the CMA were to exclude all of Healthnet Homecare Ltd's turnover from Lexon's group accounts, Lexon's turnover would remain high, with a penalty of £7.3 million representing only 3.03% of Lexon's remaining worldwide turnover (averaged over the last three years).[2474]

8.268.3 [✂]. Its published accounts for the financial year ending April 2021 show that its net cash generated from operating activities has been positive and that Lexon has a net increase in cash and cash equivalents, after its investing and financing activities.[2475]

8.269 The CMA therefore does not consider a penalty of £7.3 million to be excessive or disproportionate.

Medreich

Specific deterrence

8.270 In considering at Step 4 whether any adjustments should be made to the penalty to be imposed on Medreich, the CMA has had regard to the need adequately to deter Medreich from breaching competition law in the future.

[2471] Lexon RDPS, 2 July 2021, paragraph 2.10 (URN: PRO-C7416).

[2472] Lexon RDPS, 2 July 2021, paragraphs 2.11-2.12 (URN: PRO-C7416).

[2473] Healthnet Homecare Ltd statutory accounts for year ending 30 April 2021, page 17 and Healthnet Homecare (UK) Limited's statutory accounts for year ending 30 April 2021, page 26.

[2474] Based on Lexon UK Holdings Limited statutory accounts for years ending 30 April 2019, 2020 and 2021 and Healthnet Homecare (UK) Limited's statutory accounts for years ending to 30 April 2019, 2020 and 2021.

[2475] Lexon UK Holdings Limited full accounts made up to 30 April 2021, page 19.

Relevant turnover

8.271 Medreich's relevant turnover in its last business year of the Infringement (£1,221,398) is significantly higher than its equivalent turnover during each of its preceding three full business years during the Infringement.[2476] Medreich's relevant turnover used at Step 1 of this penalty calculation is therefore triple its average turnover in the relevant market for the previous three years. Medreich's relevant turnover was therefore unusually high in its last business year of the Infringement.

8.272 The significance of Medreich's higher relevant turnover is, however, outweighed by the other factors set out in paragraphs 8.273 to 8.283 below, which the CMA considers justify an uplift at Step 4 to ensure specific deterrence. In particular, Medreich's relevant turnover is entirely comprised of its profit share receipts from Lexon in the financial year ended 31 March 2017 and, as a result, represents pure profit, which is not subject to any costs of supplying product. Medreich's relevant turnover and starting point used at Step 1 as well as its penalty at the end of Step 3 are consequently significantly smaller than the financial benefit Medreich obtained during the entire duration of the Infringement (see further at paragraph 8.274 below).

Financial benefit from the Infringement

8.273 Pursuant to the Market Exclusion Agreement, Medreich received significant profit share payments that were paid as compensation for its participation in the agreement that Lexon reached with Alliance not to commercialise the product Lexon had jointly developed with Medreich. In participating in the Market Exclusion Agreement, Medreich obtained the certainty of profit share payments arising under the Market Exclusion Agreement (from Alliance, indirectly via Focus and Lexon), whilst avoiding the vagaries of profits that might have resulted from market entry in competition with Alliance based on the product it had developed with Lexon.[2477]

8.274 Based on the net profit share payments Medreich received from Lexon,[2478] Medreich obtained a financial benefit from the Infringement that amounted to:

8.274.1 £335,179.88 in the period from 5 February 2014 to 11 February 2015 ('Medreich Period 1'), for Medreich plc and Medreich Ltd;[2479] and

[2476] In its business years ending 31 March 2014, 2015 and 2016, Medreich's turnover in the relevant market was respectively £40,316, £335,180 and £846,429. Submission of Medreich dated 11 May 2021, in response to the CMA questions of 7 May 2021, question 1 (URN: PRO-C7206 and PRO-C7207).

[2477] T-471/13 *Alpharma v Commission*, EU:T:2016:460, paragraph 432.

[2478] Annex I, Prochlorperazine Profit Share Payments.

[2479] Note that this excludes the first profit share payment of £40,315.78 from January 2014 given that this pre-dates Medreich's participation in the Infringement from 5 February 2014.

8.274.2 £2,527,262.45 in the period from 12 February 2015 to 15 February 2018 ('Medreich Period 2'), for Medreich plc, Medreich Ltd, Meiji Seika Pharma Co and Meiji Holdings Co Ltd

(together £2,862,442.33).

8.275 The penalty at the end of Step 3 for Medreich (£1,713,010) is significantly less than the financial benefit that Medreich made from the Infringement during the Medreich Infringement Period.

Turnover outside the relevant market

8.276 Medreich achieved a significant proportion of its turnover outside the relevant market of Prochlorperazine POM.

8.277 Medreich's turnover in its last financial year of its participation in the Infringement (1 April 2016 to 31 March 2017) in the relevant market amounted to £1,221,398, as compared to Medreich plc's total worldwide turnover in that year of £36.97 million[2480] and Meiji Holdings Co Ltd's total worldwide turnover in the year ending 31 March 2017 of £8.79 billion[2481] – meaning that over 96% of Medreich plc's turnover and over 99% of Meiji Holdings Co Ltd's turnover was achieved outside the relevant market.

Size and financial position

8.278 As at the date of this Decision, the Medreich undertaking comprised Medreich plc, Medreich Ltd, Meiji Seika Pharma Co and Meiji Holdings Co Ltd.[2482]

8.279 Medreich is an extremely large, multi-national undertaking. In its last full business year for the year ending 31 March 2021, the Meiji Holdings Co Ltd corporate group reported revenue of £8.59 billion, profit after tax of £473.12 million, and reported a net asset position of £4.32 billion.[2483] Over a three year average for the years ending 31 March 2019 to 2021, Meiji Holdings Co Ltd's worldwide turnover averaged £8.76 billion, profit after tax of £461.75 million and net assets of £4.22 billion.[2484]

[2480] Based on Medreich plc's statutory accounts for year ending 31 March 2017 and conversion from US $ to £ at a Bank of England average spot rate of 1.306:1 for the year ending 31 March 2017.

[2481] Based on Meiji Holdings Co Limited's published annual report for year ending 31 March 2017 and conversation from JPY ¥ to £ at a Bank of England average spot rate of 141.370:1 for the year ending 31 March 2017.

[2482] CMA Penalties Guidance, paragraph 2.20.

[2483] Based on Meiji Holdings Co Limited's published annual report for year ending 31 March 2021. Revenue and profit after tax are converted from JPY ¥ to £ at a Bank of England 12 month average spot rate of 138.751:1, and net assets is converted at a Bank of England spot rate of 152.473:1 for the year ending 31 March 2021.

[2484] Based on Meiji Holdings Co Limited's published annual reports for the years ending 31 March 2019, 2020 and 2021 and conversation from JPY ¥ to £ at Bank of England 12 month average spot rates of 145.621:1, 138.171:1 and 138.751:1, and year end spot rates of 144:229:1, 133.866:1 and 152.473:1 respectively.

8.280 The cumulative penalty for Medreich Period 1 and Medreich Period 2 at the end of Step 3 (£1,713,010) would represent:

8.280.1 0.02% of its worldwide turnover (averaged over the last three years);

8.280.2 0.37% of its profit after tax (averaged over the last three years); and

8.280.3 0.04% of its net assets and dividends (last year's net assets plus last three year's dividends).

Relevant circumstances of the case

8.281 The CMA has taken account of the relevant circumstances of the case.[2485]

8.282 Medreich participated in a horizontal market exclusion agreement between Alliance and Lexon that was implemented via two separate agreements with a common third party (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected.

8.283 Furthermore, by participating in the Market Exclusion Agreement, Medreich received a share of the significant profits made by the sale, by Focus, of Alliance's Prochlorperazine POM as compensation for, with Lexon, not entering the market for the supply of Prochlorperazine POM with the product it had developed with Lexon.

8.284 The Market Exclusion Agreement envisaged and ensured:

8.284.1 Lexon would (and did) not enter the market for the supply of Prochlorperazine POM, with no competition in that market until Morningside gained its MA in April 2017 and competition thereafter limited to supply from Morningside until the end of the Infringement Period; and

8.284.2 Focus would be (and was) able to implement a series of substantial price increases[2486] at a cost to the NHS (and ultimately the taxpayer), the substantial profits from which Focus shared with Medreich (and Lexon) as compensation for its participation in Lexon's agreement with Alliance not to enter the market.[2487]

[2485] CMA Penalties Guidance, paragraph 2.21

[2486] See Figure 2.

[2487] See Figure 5, paragraph 5.721.8

Increase for specific deterrence

8.285 The CMA considers that Medreich's penalty at the end of Step 3 should be increased significantly given:

8.285.1 Medreich realised significant financial benefits from the Infringement that materially exceed its penalty at the end of Step 3; for this reason alone, the CMA considers that Medreich's penalty should be significantly increased;

8.285.2 the large majority of Medreich's turnover was achieved outside the relevant market;

8.285.3 the penalty at the end of Step 3 would be negligible as compared to the Medreich undertaking's size and financial position; the CMA must ensure that any penalty that Medreich is required to pay is not negligible in light of its financial capacity;[2488] and

8.285.4 the relevant circumstances of the case, as described in paragraphs 8.282 to 8.283 above.

8.286 Citing the CMA's Decision in *Pre-cast concrete drainage products*,[2489] Medreich has submitted that any uplift reflecting Meiji's size and financial position should be applied only to Medreich Period 2, which represents the period when Meiji owned Medreich plc.[2490]

8.287 The CMA disagrees. In *YKK*, the European Commission applied the deterrence multiplier not only to the part of the penalty for which the parent companies, YKK Holding and YKK Corp., were liable, but also to the part of the penalty for which their subsidiary YKK Stocko was solely liable (prior to its acquisition by the parent companies).[2491] The EU General Court and ultimately the EU Court of Justice upheld the Commission's approach.[2492]

8.288 The facts of YKK are, for Medreich, analogous to those in this Decision.[2493] By contrast, in *Pre-cast concrete drainage products*, the infringing entity was acquired by the ultimate parent company after the end of the infringement. The two entities were '*wholly unconnected […] at the time of the infringing conduct*' and the

[2488] See for example C-511/11 P *Versalis v Commission*, EU:C:2013:386, paragraph 102.

[2489] *Pre-cast concrete drainage products* (50299), 23 October 2019, footnote 1138.

[2490] Medreich RDPS, 7 July 2021, paragraphs 4.20-4.25 (URN: PRO-C7444).

[2491] Commission decision of 19 September 2007 in Case 39.168 *PO/Hard Haberdashery: Fasteners*, paragraph 538. See also C-408/12 P *YKK v Commission*, EU:C:2014:2153, paragraphs 74 and 78.

[2492] See C-408/12 P *YKK v Commission*, EU:C:2014:2153, paragraphs 86-87 and 91

[2493] YKK Stocko was acquired by YKK Holding (wholly owned by YKK Corp) part way through the infringement period. YKK Holding and YKK Corp were therefore only held liable for the part of penalty and YKK Stocko was held liable for the remainder. See C-408/12 P *YKK v Commission*, EU:C:2014:2153, paragraphs 9-10.

Decision was not addressed to the ultimate parent company.[2494] This was not the case in *YKK* and is not the case here for Medreich.

8.289 As set out in paragraph 8.278 above, the Medreich undertaking comprises at the time of this Decision Medreich plc, Medreich Ltd, Meiji Seika Pharma Co and Meiji Holdings Co Ltd. It is therefore appropriate for the CMA to consider the size and overall resources of the Medreich undertaking comprising those entities when determining an appropriate increase to Medreich's penalty at Step 4 of the CMA's penalty calculation.

8.290 As a consequence, the fact that Meiji is not held jointly and severally liable for the infringement committed by Medreich plc in the period prior to 12 February 2015 has no bearing on the determination of the deterrence multiplier.[2495]

8.291 Medreich has also submitted that an increase for specific deterrence is not required as Medreich has admitted its involvement in the Infringement, brought its participation in the Infringement to an end and taken steps to ensure future compliance with competition law.[2496]

8.292 The CMA disagrees. As set out in paragraphs 1.41 to 1.43, Medreich continued to participate in the Market Exclusion Agreement until 15 February 2018. Medreich only admitted its involvement in the Infringement and ended its participation in the Market Exclusion Agreement after the CMA had opened its investigation – and less than seven months before the end of the Infringement on the part of the other parties.

8.293 Moreover, as set out in paragraphs 8.178 and 8.378 of this Decision, the CMA has reduced Medreich's penalty at Step 3 to take account of the steps Medreich has taken to ensure future compliance with competition law and has reduced Medreich's penalty at Step 6 of its penalty calculation given Medreich's leniency agreement with the CMA, which followed its admission of its involvement in the Infringement.

8.294 The CMA does not therefore consider it appropriate additionally to account for Medreich's admission and termination of its participation in the Infringement at Step 4.

[2494] *Pre-cast concrete drainage products* (50299), 23 October 2019, footnote 1138.

[2495] C-408/12 P *YKK v Commission*, EU:C:2014:2153, paragraphs 87 and 92.

[2496] Medreich RDPS, 7 July 2021, paragraphs 4.44-4.45 (URN: PRO-C7444), Medreich Oral Hearing, 21 July 2021, page 25 line 14 to page 26 line 20 (URN: PRO-7635).

8.295 As a result, the CMA considers that a significant uplift for the purpose of specific deterrence is appropriate in this case, which would result in a penalty for Medreich of £7.7 million at the end of Step 4, to be allocated as:

8.295.1 £1,945,924 for Medreich Period 1 (for which Medreich plc and Medreich Ltd are jointly and severally liable); and

8.295.2 £5,754,076 for Medreich Period 2 (for which Medreich plc, Medreich Ltd, Meiji Seika Pharma Co and Meiji Holdings Co Ltd are jointly and severally liable)

(together £7.7 million).

Proportionality assessment

8.296 The CMA considers that uplifting the penalty to £7.7 million will provide an effective yet proportionate deterrent for Medreich, having had regard to Medreich's size and financial position, the nature of the Infringement, Medreich's role in the Infringement and the impact of Medreich's infringing activity on competition.[2497]

8.297 A cumulative penalty for Medreich Period 1 and Medreich Period 2 of £7.7 million at the end of Step 4 represents:

8.297.1 0.09% of Medreich's worldwide turnover (averaged over the last three years);

8.297.2 1.67% of its profit after tax (averaged over the last three years); and

8.297.3 0.16% of its net assets and dividends (last year's net assets plus last three year's dividends).

8.298 Medreich participated in a market exclusion agreement, which is one of the most serious infringements of competition law. Medreich was, with Lexon, the first potential competitor in the market for the supply of Prochlorperazine POM. During the term of the Market Exclusion Agreement, there was no entry into the market until Morningside gained its MA in April 2017 and competition thereafter was limited to supply from Morningside until the end of the Infringement Period. Medreich participated in a horizontal market exclusion agreement between Alliance and Lexon that was implemented via two separate agreements with a common third party (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected. In total, Medreich received £2,862,442.33[2498] from Lexon in exchange for non-entry. As the parent exercising decisive influence within the

[2497] CMA Penalties Guidance, paragraphs 2.23-2.24.

[2498] Note this figure excludes the first profit share payment received from Lexon in January 2014. The total figure including that sum was £2,902,758.11.

Medreich undertaking, Meiji did not act to discontinue the anti-competitive conduct of its subsidiary, Medreich plc.

8.299 Medreich has submitted that its penalty at the end of Step 4 is '*disproportionate*' when assessed against the directly infringing entity within the Medreich undertaking, Medreich plc. Medreich has further claimed that the CMA's increase at Step 4 is '*driven by reference to financial metrics*' that are not related to Prochlorperazine POM or Medreich's activities in the UK (or the EU) as:[2499]

8.299.1 Medreich plc's parent company, Meiji Holdings Co Ltd, has no other entities operating in the UK; and

8.299.2 Medreich plc accounts for a '*very small proportion of the interest of Meiji*'.

8.300 The CMA rejects these submissions, which disregard the applicable legal framework and the need for specific deterrence.

8.300.1 As described in paragraph 7.56 of this Decision, the CMA has found that Meiji Holdings Co Ltd formed part of the Medreich undertaking from 12 February 2015 until the end of the Medreich Infringement Period.

8.300.2 As part of the Medreich undertaking during its period of ownership, Meiji Holdings Co Ltd committed an infringement of competition law and is held jointly and severally liable with the other entities forming part of that undertaking on that basis.[2500]

8.300.3 As a parent company exercising decisive influence, Meiji Holdings Co Ltd failed to ensure its subsidiary discontinued its involvement in the Infringement, despite being made aware of Medreich's participation in the infringing conduct.[2501]

8.301 Further, Medreich's submission in relation to Meiji's turnover outside of the UK is misplaced. The CMA Penalties Guidance provides that, *inter alia*, the penalty should be assessed by reference to an undertaking's total turnover to ensure that the penalty is sufficient to deter that specific undertaking.[2502] It is the undertaking, and not the local unit, that must be deterred. If only a fraction of that undertaking's turnover was considered (and non-UK turnover was ignored), then the penalty would not sufficiently deter.

[2499] Medreich RDPS, 7 July 2021, paragraphs 4.15-4.19, 4.26-4.29 (URN: PRO-C7444).

[2500] See C-50/12 P *Kendrion v Comission*, EU:C:2013:771, paragraphs 55-56.

[2501] See paragraph 5.677 of this Decision.

[2502] CMA Penalties Guidance, paragraph 2.20.

8.302 The CMA therefore continues to consider that it is appropriate to have regard to Meiji Holdings Co Ltd when assessing the proportionality of Medreich's penalty at the end of Step 4.

8.303 The CMA therefore does not consider a penalty of £7.7 million to be excessive or disproportionate.

Focus

8.304 At the date of this Decision, the legal entities liable for:

8.304.1 Focus Period 1 (the Focus Entities) and Focus Period 3 (the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities, together the Advanz Group) form the Focus undertaking as it currently exists.

8.304.2 Focus Period 2 (the Focus Entities, Mercury Pharma Group Limited and the Cinven Entities) do not all form part of the Focus undertaking as it currently exists, with

(a) the Focus Entities and Mercury Pharma Group Limited continuing to form part of the Focus undertaking as it current exists; and

(b) the Cinven Entities no longer forming part of the Focus undertaking.

8.305 As set out in paragraph 8.196 above, the CMA has therefore separately assessed for specific deterrence and proportionality at Step 4 the parts of the penalty for which:

8.305.1 the legal entities comprising the Focus undertaking at the date of this Decision, i.e. the Advanz Group, are liable, which includes Focus Period 1, Focus Period 2 and Focus Period 3; and

8.305.2 the legal entities no longer comprising the Focus undertaking, i.e. the Cinven Entities, are liable, which includes Focus Period 2 only.

The Advanz Group

Specific deterrence

8.306 In considering at Step 4 whether any adjustments should be made to the penalty to be imposed on Focus, the CMA has had regard to the need adequately to deter the Focus undertaking as it currently exists from breaching competition law in the future.

Turnover outside the relevant market

8.307 During its period of ownership, the Advanz Group achieved a significant proportion of its turnover outside the relevant market of Prochlorperazine POM.

8.308 Focus' turnover in its last financial year of the Infringement (1 January 2017 to 31 December 2017) in the relevant market amounted to £5.2 million,[2503] as compared to Advanz Pharma Corp.'s worldwide turnover in 2017 of $626.17 million (£485.8 million)[2504]– meaning that approximately 99% of its turnover was achieved outside the relevant market.[2505]

Size and financial position

8.309 As at the date of this Decision, the Focus undertaking comprised the Advanz Group.[2506]

8.310 The Focus undertaking, as it currently exists, is of considerable size. In its last full business year for the year ending 31 December 2020, Advanz Pharma Corp. reported worldwide turnover of $525.59 million (£409.42 million), Adjusted EBITDA of $232.56 million (£181.15 million), operating cashflow of $166.21 million (£129.48 million), and reported a net asset position of $7.59 million (£5.56 million).[2507] Over a three year average for the years ending 31 December 2018 to 2020, the equivalent figures were turnover of $523.63 million (£403.03 million), Adjusted EBITDA of $238.81 million (£183.76 million), operating cashflow of $165.34 million (£127.57 million) and net assets of $73.12 million (£57.13 million).[2508] Advanz Pharma Corp. has cash and cash equivalents of $160.19 million (£117.36 million)

[2503] Section 26 response of Advanz dated 21 December 2018, to the CMA Notice of 11 December 2018 (URN: PRO-C3150) as confirmed by the section 26 response of Advanz dated 21 May 2021, to the CMA Notice of 7 May 2021 (URN: PRO-C7232 – PRO-C7235).

[2504]Advanz Pharma Corp. published annual report 2017 and conversion from US $ to £ at a Bank of England average spot rate of 1.289:1 for the year ending 31 December 2017.

[2505] Regarding Focus Period 1, Focus Pharmaceuticals Limited's turnover from sales of Prochlorperazine POM in the last full year of Focus Period 1 of the Infringement (that is 1 October 2013 – 30 September 2014) in the relevant market amounted to £2.0 million (section 26 response of Advanz dated 21 December 2018, to the CMA Notice of 11 December 2018 (URN: PRO-C3150) compared to the worldwide turnover of Focus Pharmaceuticals Limited in 2014 of £38.4m (Focus Pharmaceuticals Limited published accounts year for ending 31 December 2014) - meaning that around 95% of its turnover was achieved outside the relevant market). Regarding Focus Period 2, Focus Pharmaceuticals Limited's turnover from sales of Prochlorperazine POM in the last financial year of Focus Period 2 of the Infringement (that is 1 January 2014 – 31 December 2014) in the relevant market amounted to £2.5 million (section 26 response of Advanz dated 21 December 2018, to the CMA Notice of 11 December 2018 (URN: PRO-C3150) as confirmed by the section 26 response of Advanz dated 21 May 2021, to the CMA Notice of 7 May 2021 (URN: PRO-C7232 – PRO-C7235)) compared to the worldwide turnover of Focus Pharmaceuticals Limited in 2014 of £38.4m (Focus Pharmaceuticals Limited published accounts year for ending 31 December 2014) and of Mercury Pharma Group Limited of £31.3m (Mercury Pharma Group Limited published accounts for year ending 31 December 2014) meaning that around 92-94% of its turnover was achieved outside the relevant market.

[2506] CMA Penalties Guidance, paragraph 2.20.

[2507] Advanz Pharma Corp.'s consolidated annual financial statements for the financial year ending 31 December 2020 (https://www.advanzpharma.com/media/uploads/ADVZ-Financials-Annual-with-Audit-opinion-2020-FINAL-17032021.pdf) and Advanz Pharma Corp.'s 2020 Annual Management's Discussion and Analysis (https://www.advanzpharma.com/media/uploads/Advanz-Pharma-Corp.-Limited-Management-Discussion-and-Analysis-17-March-2021.pdf). Turnover and Adjusted EBITDA are converted from US $ to £ at a Bank of England 12 month average spot rate of 1.284:1 for the year ending 31 December 2020, and net assets is converted from US $ to £ at a Bank of England spot rate of 1.365:1 for the year ending 31 December 2020. The CMA has referenced Advanz's own Adjusted EBITDA metric, as defined in Advanz's 2019 Annual Management's Discussion Analysis as a profit measure due to the exceptional items in the Advanz Pharma Group's recent income statements.

[2508] Advanz Pharma Corp. published consolidated financial statements 2018 and Advanz Pharma Corp annual information form 2019 and consolidated annual financial statements for the financial year ending 31 December 2020. Turnover and Adjusted EBITDA are converted from US $ to £ at a Bank of England 12 month average spot rate of 1.336:1, 1.278:1 and 1.284:1, and net assets is converted at a Bank of England spot rate of 1.274:1, 1.321:1 and 1.365:1 respectively.

for the year ending 31 December 2020, $261.14 million (£197.68 million) for the year ending 31 December 2019, and $224.44 million (£176.21 million) for the year ending 31 December 2018 and that shows that it has significant cash liquidity.

8.311 Advanz Pharma Corp. reported losses of £153.5 million and £58.3 million respectively in 2019 and 2020 but reported a very high profit after tax of £1.1 billion in 2018. In the CMA's view, in the case of the Advanz Group, limited weight should be placed on its profit after tax metric given the extent to which it is affected by non-operational costs (such as finance costs; non-cash costs such as amortisation charges that relate to the value of intangible assets acquired by the Advanz Pharma Corp.) and one-off and exceptional items (such as the $1.9 billion (£1.4 billion) gain on debt settlement when the company underwent a restructuring in 2018).[2509] These costs do not reflect the operational profitability of the business nor its underlying health and financial position. The CMA considers that more appropriate and relevant measures by which to assess profitability in this case are therefore the adjusted EBITDA profit and operating cashflow that the Advanz Pharma Corp. reports to its shareholders in its annual report. As a result, the CMA has used the adjusted EBITDA and operating cashflow metrics to analyse the Advanz Group's profitability rather than the profit after tax measure which is distorted by non-relevant costs and gains.

8.312 Equally, the CMA also considers that the book value of net assets reported in Advanz Pharma Corp.'s financial statements is not a reliable indicator of the enterprise value and financial position of the Advanz Group as they are directly related to the profit after tax metric described above. This is illustrated by Nordic Capital's 2021 acquisition price of $846 million (approximately £620 million) for the entire share capital of Advanz Pharma Corp.[2510]

8.313 The combined penalty to be imposed at the end of Step 3 on the Focus Entities for Focus Period 1 (£2,231,208), Mercury Pharma Group Limited and the Focus Entities for Focus Period 2 (£1,843,380) and the Advanz Entities, Mercury Pharma Group Limited and the Focus Entities for Focus Period 3 (£4,859,819) would together (£8,934,407) represent:[2511]

8.313.1 2.22% of Advanz Pharma Corp.'s worldwide turnover (averaged over the last three years);

[2509] ADVANZ PHARMA Corp., Annual Accounts 2018, page 7 (https://www.advanzpharma.com/media/uploads/Audited-accounts-of-ADVANZ-PHARMA-for-the-financial-year-ended-31-December-2018.PDF).

[2510] See Advanz Pharma press release, 1 June 2021, available at: https://www.advanzpharma.com/news/2021/nordic-capital-acquires-specialty-pharmaceutical-company-advanz-pharma-in-deal-worth-846-million.

[2511] Advanz Pharma Corp. published consolidated financial statements 2018 and Advanz Pharma Corp annual information form 2019 and consolidated annual financial statements for the financial year ending 31 December 2020. Turnover and Adjusted EBITDA are converted from US $ to £ at a Bank of England average spot rate of 1.336:1, 1.278:1 and 1.284:1, and net assets is converted at a Bank of England spot rate of 1.274:1, 1.321:1 and 1.364:1 respectively.

8.313.2 3.02% of Advanz Pharma Corp.'s profit after tax (averaged over the last three years);

8.313.3 4.86% of Advanz Pharma Corp.'s adjusted EBITDA (averaged over the last three years);

8.313.4 7.00% of Advanz Pharma Corp.'s operating cashflow (averaged over last three years); and

8.313.5 160.75% of Advanz Pharma Corp.'s net assets and dividends (last year's net assets plus last three year's dividends).

Relevant circumstances of the case

8.314 The CMA has taken account of the relevant circumstances of the case.[2512] These factors are relevant both to the Advanz Group and the Cinven Entities.

8.315 Focus participated in a horizontal market exclusion agreement between Alliance and Lexon that was implemented via two separate agreements with a common third party, Focus (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected.

8.316 Furthermore, by participating in the Market Exclusion Agreement, Focus:

8.316.1 would gain (and gained) a monopoly in the supply of (Alliance's) Prochlorperazine POM until Morningside obtained its MA in April 2017;

8.316.2 would be (and was) able to implement – and implemented – a series of substantial price increases[2513] at a cost to the NHS (and ultimately the taxpayer) in the knowledge that it would not face constraint from Lexon's entry into the market with Medreich's Prochlorperazine POM product; and

8.316.3 would retain (and retained) a share of the significant profits it consequently made on the sale of Alliance's Prochlorperazine POM as compensation for facilitating payments to Lexon in exchange for not to entering the market.

8.317 The Market Exclusion Agreement envisaged and ensured that Lexon would (and did) not enter the market for the supply of Prochlorperazine POM, with no competition in that market until Morningside gained its MA in April 2017 and

[2512] CMA Penalties Guidance, paragraph 2.21.

[2513] See Figure 2. Focus increased the price that it sold Prochlorperazine POM to mainline wholesalers from an average selling price of £8 per pack in December 2013 to a peak average selling price of nearly £35 per pack in June 2017, an increase of 335%. By the end of the Infringement Period, Focus' average selling price was just under £28 per pack, or 249% higher than its initial average selling price of £8.

competition thereafter limited to supply from Morningside until the end of the Infringement Period.

8.318 Advanz has submitted that the relevant circumstances of the case do not justify an increase in its penalty at Step 4 of the CMA's penalty calculation. In particular, Advanz has claimed that the CMA should not consider Focus' implementation of a series of substantial price increases to be a reason to increase its penalty, given that the CMA has not alleged or shown that Focus's prices for Prochlorperazine POM were excessive and unfair.[2514]

8.319 Although Advanz is correct that the CMA has not alleged an excessive pricing case contrary to Chapter II of the Act, the CMA considers it appropriate to take account of price increases that, on entering into the Market Exclusion Agreement,

8.319.1 could be implemented and sustained in the knowledge that competition from the Lexon/Medreich product had been deferred; and

8.319.2 were to be used to generate the profits that would be shared with Lexon as compensation for its agreement not to enter the market.

Increase for specific deterrence of the Advanz Group

8.320 The CMA considers that the penalty for which the Advanz Group is liable at the end of Step 3 should be increased given:

8.320.1 the large majority of the Advanz Group's turnover was achieved outside of the relevant market;

8.320.2 the penalty at the end of Step 3 would be relatively modest in terms of Focus' size and financial position at the time of this Decision; and

8.320.3 the relevant circumstances of the case, as described at paragraphs 8.314 to 8.317 above.

8.321 As a result, the CMA considers that an uplift for the purpose of specific deterrence is appropriate in this case, which would result in a penalty for the Advanz Group of £13.4 million at the end of Step 4 to be allocated as:

8.321.1 £3,346,409 for Focus Period 1 (for which the Focus Entities are jointly and severally liable);

[2514] Advanz RDPS, 7 July 2021, paragraph 6.57 (URN: PRO-C7481).

8.321.2 £2,764,737 for Focus Period 2 (for which the Focus Entities and Mercury Pharma Group Limited are jointly severally liable);[2515] and

8.321.3 £7,288,853 for Focus Period 3 (for which the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities are jointly and severally liable)

(together £13.4 million).[2516]

Proportionality assessment

8.322 The CMA considers that uplifting the penalty to £13.4 million will provide an effective yet proportionate deterrent for the Advanz Group, having had regard to the Advanz Group's size and financial position, the nature of the Infringement, Focus' role in the Infringement and the impact of Focus' infringing activity on competition.[2517]

8.323 As set out in paragraphs 8.311 to 8.312, the CMA does not consider the profit after tax or net asset metrics to provide an appropriate indicator of the Advanz Group's size and financial position. The CMA has therefore assessed the proportionality of the Advanz Group's penalty by reference to its adjusted EBITDA, operating cash flow in addition to other appropriate indicators.

8.324 The combined penalty of £13.4 million for Focus Period 1, Focus Period 2 and Focus Period 3 would represent approximately:

8.324.1 3.32% of Advanz Pharma Corp.'s worldwide turnover (averaged over the last three years);

[2515] Of which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable with the Cinven Entities for £1,843,380, i.e. the penalty for Focus Period 2 for which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable with the Cinven Entities after the application of a 5% discount for members of the Advanz Group at Step 3 and prior to any adjustments at Step 4 for either the Focus undertaking as it currently exists, i.e. the Advanz Group, or the Cinven Entities (see Table 8). As set out at paragraphs 8.304 to 8.305, the Cinven Entities' liability for Focus Period 2 is assessed separately at Step 4 (see paragraphs 8.330 to 8.360 below).

[2516] Advanz has submitted that an uplift for specific deterrence is unwarranted as, in its view, there is '*simply nothing to deter*'. Advanz relies on a number of factors, including (a) the fact that there are a number of recent decisions and were (at the time Advanz submitted its representations) ongoing investigations by the CMA and the Commission concerning market sharing and/or market exclusion agreements in the pharmaceutical sector; (b) that the Infringement ceased over three years ago and there has been no repetition of any such arrangement and (c) that the '*lengthy, burdensome, costly, disruptive and reputationally damaging nature*' of the Investigation undermines the need for deterrence. The CMA rejects these contentions: (a) The fact that there are, or have been, other investigations into similar market sharing and/or market exclusion arrangements in the EU and the UK does not mean that there is no need to deter the parties to this particular Infringement. To the contrary, the fact that this and other such conduct persists, despite it being well established that market-sharing is a serious infringement of competition law, is in fact reason to ensure that penalties are sufficient to deter the parties from further such conduct in future. (b) Advanz's claim that it had not engaged in similar conduct since the infringement ended cannot be verified. While a similar point was recently considered by the CAT in the context of the Step 4 assessment in *Paroxetine*, this was considered in conjunction with the novelty argument advanced by the parties in that case. (c) Investigations under the Act typically require the parties to engage with the CMA's procedures and to respond to the allegations against them. These obligations do not, however, negate the need for any specific deterrence uplifts at Step 4, as such uplifts could otherwise never be imposed. See Advanz RDPS, 7 July 2021, paragraphs 6.51-6.53 (URN: PRO-C7481) and *Paroxetine II* [2021] CAT 9, paragraph 182.

[2517] CMA Penalties Guidance, paragraphs 2.23-2.24

8.324.2 4.53% of Advanz Pharma Corp.'s profit after tax (averaged over the last three years);

8.324.3 7.29% of Advanz Pharma Corp.'s adjusted EBITDA (averaged over the last three years);

8.324.4 10.50% of Advanz Pharma Corp.'s operating cashflow; and

8.324.5 241.10% of Advanz Pharma Corp.'s net assets and dividends (last year's net assets plus last three year's dividends).

8.325 Focus participated in a market exclusion agreement, which is among the most serious infringements of competition law. As the mechanism by which Alliance paid Lexon (and Medreich) in exchange for non-entry, Focus was a critical part of the Market Exclusion Agreement, during the term of which there was no entry into the market until Morningside gained its MA in April 2017 and competition thereafter was limited to supply from Morningside until the end of the Infringement Period. Focus participated in a horizontal market exclusion agreement between Alliance and Lexon that was implemented via two separate agreements with a common third party, Focus (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected. As the parent exercising decisive influence within the Focus undertaking, the Advanz Entities did not act to discontinue the anti-competitive conduct of their subsidiary, Focus Pharmaceuticals Limited.

8.326 Notwithstanding the assessment above, the CMA notes that, following the adjustment made to the Focus Entities' penalty for Focus Period 1 at Step 5,[2518] the penalty imposed on the Advanz Group is £10,602,934 (that is £549,343 for Focus Period 1, £2,764,737 for Focus Period 2[2519] and £7,288,853 for Focus Period 3).

8.327 Advanz has submitted that the CMA's assessment significantly overstates its size and financial position for the purpose of calculating its fine and has argued that the CMA should have considered additional financial indicators in its Step 4 assessment including, for example, level of dividends or industry margins.[2520]

8.328 The CMA disagrees. Although Advanz Pharma Corp. did not pay out any dividends over its last three financial years, the CMA considers that the combined penalty of £13.4 million for Focus Period 1, Focus Period 2 and Focus Period 3 is proportionate and not excessive when assessed in the round against indicators of

[2518] The statutory cap for Focus Pharmaceuticals Limited for the year ending 31 December 2020 is £549,343. Focus Pharmaceuticals Limited's turnover from the year ending 31 December 2019 has significantly reduced because, as noted on page 3 of the published accounts for that year, '*[w]ith effect from 1 October 2018, the entire business has been transferred to its fellow subsidiary Advanz Pharma Generics (UK) Limited*'.

[2519] Of which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable with the Cinven Entities for £1,843,380 (see Table 8).

[2520] Advanz RDPS, 7 July 2021, 6.59-6.82 (URN: PRO-C7481).

the Advanz Group's size and financial position. Advanz Pharma Corp.'s underlying health and financial position is reflected in its adjusted EBITDA and cash liquidity. Wider industry margins are not informative regarding the financial performance of the Advanz Group and are not therefore relevant. At this step, the CMA has considered appropriate indicators for the Advanz Group's size and financial position in the round and concludes that the penalty is neither excessive nor disproportionate.

8.329 The CMA therefore does not consider a penalty of £13.4 million to be excessive or disproportionate.

The Cinven Entities

Specific deterrence

8.330 In considering at Step 4 whether any adjustments should be made to the penalty to be imposed on Focus, the CMA has had regard to the need adequately to deter the Cinven Entities from breaching competition law in the future.

Turnover outside the relevant market

8.331 During their period of ownership, the Cinven Entities achieved a significant proportion of their turnover outside the relevant market of Prochlorperazine POM.

8.332 Focus' turnover in the last full year of the Cinven Entities ownership period (1 October 2014 to 30 September 2015) in the relevant market amounted to £3.5 million[2521] as compared to the Cinven Entities' group (as it existed at the time) worldwide turnover in 2015 of [✂][2522] – meaning that well over [✂] of its turnover was achieved outside the relevant market.

8.333 Cinven has submitted that its turnover outside of the relevant market is '*meaningless*' and '*discriminatory*' as a '*private equity investor cannot be compared in this manner to undertakings who are directly active in the supply of goods and services*'.[2523]

[2521] Section 26 response of Advanz dated 21 December 2018, to the CMA Notice of 11 December 2018 (URN: PRO-C3149 and PRO-C3150).

[2522] Section 26 response of Cinven dated 14 May 2021, to the CMA Notice of 7 May 2021 (URN: PRO-C7214 and PRO-C7215).

[2523] Cinven RDPS, 7 July 2021, paragraphs 3.69-3.70 (URN: PRO-C7439). Cinven submitted that in the European Commission's decisions in *Power Cables* (which involved a private equity investor) and *Fentanyl*, other undertakings with substantial out-of-market turnover were subject to no, or much lower deterrence uplifts than Cinven in this case. Cinven's references to *Power Cables* and *Fentanyl* are misplaced. First, the CMA assesses penalties on a case-by-case basis and is not bound by previous decisional practice. Second, as the CAT observed in *Roland*, the European Commission has different practices and fining policies and does not apply the CMA Penalties Guidance. The CMA is not required by s.60A of the Competition Act to calculate the penalties it imposes in the same manner as penalties imposed by the Commission. That being so, '[*t*]*he CMA is entitled to take a UK specific view in the light of its own particular experience*'. See *Roland (UK) Ltd v CMA* [2021] CAT 8, paragraph 90.

8.334 The CMA disagrees. Given the scale of Cinven's business as compared to the turnover generated in the relevant market, it is appropriate for the CMA to consider whether to apply a significant upward adjustment to produce a penalty that has a real financial impact to ensure adequate deterrence.[2524] In this context, there is no reason to distinguish between private equity investors and other companies.

Size and financial position

8.335 As at the date of this Decision, the Cinven Entities no longer form part of the Focus undertaking. As set out at paragraphs 8.304 to 8.305 above, the CMA has therefore separately assessed the penalty to be imposed on the Cinven Entities for Focus Period 2 with regard to their size and financial position at the time the penalty would be imposed.[2525]

8.336 The Cinven Entities are of considerable size. Cinven has made more than 130 investments and has realised more than €37 billion.[2526] Turnover relevant to the Cinven Entities was [✂] in the financial year ended 31 December 2020.[2527] Operating profits totalling [✂] were generated in the same period.[2528]

8.337 The penalty to be imposed on the Cinven Entities at the end of Step 3 for Focus Period 2 (£1,927,170[2529]), would represent:[2530]

8.337.1 [✂] of the Cinven Entities' worldwide turnover (averaged over the last three years); and

8.337.2 [✂] of the Cinven Entities' profit after tax (average over last three years); and

8.337.3 [✂] of the Cinven Entities' net assets and dividends (last year's net assets plus last three year's dividends).

8.338 The CMA considers that for private equity firms, turnover is a more meaningful indicator of the entity's size and financial position than profit after tax, which may

[2524] *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 90.

[2525] CMA Penalties Guidance, paragraph 2.20.

[2526] See https://www.cinven.com/who-we-are/.

[2527] Section 26 response of Cinven dated 15 October 2021, to the CMA Notice of 23 September 2021, Annex 1 (URN: PRO-C7770, and PRO-C7771).

[2528] Section 26 response of Cinven dated 15 October 2021, to the CMA Notice of 23 September 2021, Annex 1 (URN: PRO-C7770, and PRO-C7771).

[2529] Of which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable with the Cinven Entities for £1,843,380 (see Table 8).

[2530] Section 26 response of Cinven dated 15 October 2021, to the CMA Notice of 23 September 2021, Annex 1 (URN: PRO-C7770, and PRO-C7771).

be impacted by non-relevant factors such as the choice of capital structure for firms in the portfolio and associated financing costs.[2531]

Relevant circumstances of the case

8.339 The CMA has taken account of the relevant circumstances of the case.[2532] These factors, which are set out in paragraphs 8.315 to 8.317 above, apply both to the Advanz Group and the Cinven Entities.

Increase for specific deterrence of the Cinven Entities

8.340 The CMA considers that the penalty for which the Cinven Entities are liable at the end of Step 3 should be significantly increased given:

8.340.1 the large majority of the Cinven Entities' turnover was achieved outside of the relevant market;

8.340.2 the penalty at the end of Step 3 would be negligible as compared to the Cinven Entities' size and financial position; the CMA must ensure that any penalty that the Cinven Entities are required to pay is not negligible in light of their financial capacity;[2533] and

8.340.3 the relevant circumstances of the case, as described at paragraphs 8.314 to 8.316 above.

8.341 Cinven has submitted that no uplift for specific deterrence is warranted given its role in relation to the Market Exclusion Agreement during its period of ownership.[2534]

8.341.1 Cinven has argued that it was '*not in a position to identify, never mind prevent, any alleged anti-competitive aspects*' of the Alliance-Focus Agreement and the Focus-Lexon Heads of Terms' as these contracts were entered into prior to its period of ownership and, on the CMA's case, in

[2531] Private equity firms seek to generate returns for their investors by increasing the gearing levels of companies within their portfolio in order to reduce the required level of equity investment in firms. This, in turn, results in higher finance costs which distorts their profit after tax. In general, private equity firms do not look to make returns via the payment of dividends but rather by the realisation of significant capital gains on disposal of the businesses in which they invest.

[2532] CMA Penalties Guidance, paragraph 2.21.

[2533] See for example C-511/11 P *Versalis v Commission*, EU:C:2013:386, paragraph 102.

[2534] Cinven RDPS, 7 July 2021, paragraphs 3.53-3.57 (URN: PRO-C7439). Cinven has further submitted that the CMA should reduce its penalty at Step 4 as, on Cinven's submission, the penalty at the end of Step 3 calculated based on Focus' relevant turnover does not take account of the '*undertaking's "real economic situation" during Focus Period 2*'. As set out at paragraphs 8.91 and 8.95 to 8.96 of this Decision, the CMA considers its approach to calculating Focus' relevant turnover at Step 1 of its penalty calculation to be appropriate and in line with the CMA Penalties Guidance. The CMA does not consider any adjustments need to be made at Step 4 having regard to Focus' relevant turnover. Even if the CMA were to take account of the fact that Focus' turnover in the relevant market was lower in its last business year prior to the end of Cinven's period of ownership, the CMA would still consider that an increase to £6.7 million is appropriate in light of the factors set out in paragraph 8.340 of this Decision.

such a way to '*hide their […] anticompetitive purpose*'.[2535] Cinven has also submitted that even if the CMA could show that the Implementing Agreements were designed to hide their anti-competitive purpose, there was no evidence Cinven was aware of, or ought to have been aware of this as, it submitted, would be '*required to establish the need to specifically deter [Cinven] from future infringements of competition law*'.[2536]

8.341.2 Cinven has further submitted that it had been informed at board meetings that '*competition law compliance was taken seriously*' by the AMCo Group, which included the Focus Entities, with '*audits […] and remedial action implemented*' across the group.[2537]

8.342 Cinven has argued that, in such circumstances, it is '*entirely unclear what conduct the CMA is seeking to deter*' as Cinven could not '*conceivably have acted any differently*' during its period of ownership and no longer holds the '*investments that resulted in the Fifth Cinven Fund having a brief indirect interest in Focus*'.[2538]

8.343 Cinven also contends that the CMA is wrong to apply a separate uplift in Step 4 specifically to Cinven, alleging that '*it is not open to the CMA to apply a higher fine on the Cinven Addressees than the directly infringing entities'* with whom they formed a single undertaking during its period of ownership.[2539] It argues that the CMA's approach '*clearly breaches*' the principle set out by the EU Court of Justice in *Areva,* in which it ruled that the '*total amount which the parent company may be required to pay cannot be greater than the amount which that [directly infringing] subsidiary must pay*'.[2540] According to Cinven, any penalty imposed on Focus for its period of ownership, including any increase for the purpose of specific deterrence, must be '*imposed on a joint and several basis*' on all entities that formed part of Focus undertaking during that period.[2541] Cinven has submitted that the EU Court of Justice's reasoning in *YKK* means that any uplift for the purpose of specific deterrence should be '*applied to Focus alone or the undertaking of which it now forms part*'.

8.344 Cinven also submitted[2542] that the CMA's *'approach to imposing a substantial uplift on [Cinven] based on what the CMA considers to be the wider undertaking which [Cinven] formed part of during [Cinven's ownership period]*' is inconsistent with the

[2535] Cinven RDPS, 7 July 2021, paragraph 3.55 (URN: PRO-C7439) and Cinven RLF, 30 November 2021, paragraphs 3.46-3.49 (URN: PRO-C7919), where Cinven further submitted that AMCo would also have been unable to identify and discontinue the anti-competitive conduct.

[2536] Cinven RDPS, 7 July 2021, paragraph 3.55(c) (URN: PRO-C7439).

[2537] Cinven RDPS, 7 July 2021, paragraph 3.56 (URN: PRO-C7439).

[2538] Cinven RDPS, 7 July 2021, paragraph 3.57 (URN: PRO-C7439).

[2539] Cinven RDPS, 7 July 2021, paragraphs 3.58-3.61 (URN: PRO-C7439).

[2540] Cinven RDPS, 7 July 2021, paragraph 3.59 (URN: PRO-C7439). See Case C-247/11 *Areva v Commission* EU:C:2014:257, paragraph 138.

[2541] Cinven RDPS, 7 July 2021, paragraph 3.59 (URN: PRO-C7439).

[2542] Cinven RLF, 30 November 2021, paragraph 3.48 footnote 49 (URN: PRO-C7919).

EU Court of Justice's recent judgment in *Sumal*'.[2543] Cinven submitted that, in light of that judgment, the CMA's approach of '*imposing a significant 'deterrence' uplift based on the out of market turnover of portfolio companies, the activities of which are in different economic fields with no connection to the subject matter of the investigation* [✂]*, is flawed*'.[2544]

8.345 Cinven's submissions are misconceived.

8.345.1 As set out at paragraph 7.16 of this Decision, it is not relevant for the question of liability whether a parent company (or private equity investor) was directly involved in the Infringement or even whether it was aware of the Infringement.

8.345.2 As part of the Focus undertaking during its period of ownership, Cinven committed an infringement of competition law and is held jointly and severally liable with the other entities forming part of that undertaking on that basis.[2545] This is true even if Cinven had been unaware of the Infringement.[2546]

8.345.3 Moreover, as a parent company exercising decisive influence within the Focus undertaking, Cinven failed to ensure its subsidiaries discontinued their anti-competitive conduct.

8.346 The same considerations must apply to the question of whether or not an uplift for specific deterrence is required.

8.346.1 As set out in the CMA Penalties Guidance and paragraph 8.193 above, the CMA considers at Step 4 whether an increase in penalty is necessary to ensure that the penalty imposed on the Focus undertaking – which included Cinven – will deter it from breaching competition law in the future.[2547] It is clearly appropriate for the CMA to make this assessment in relation to the Cinven Entities, which were part of the Focus undertaking during the time of the Infringement but no longer form part of the Focus

[2543] C-882/19 *Sumal, S.L. v Mercedes Benz Trucks España, S.L.*, EU:C:2021:800.

[2544] Cinven letter dated 16 December 2021, paragraphs 6-7 (URN: PRO-C7945).

[2545] See C-50/12 P *Kendrion,* EU:C:2013:771, paragraphs 55-56.

[2546] C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraph 102: '*what counts is not whether the parent company encouraged its subsidiary to commit an infringement …, or whether it was directly involved in the infringement committed by its subsidiary, but the fact that those two companies constitute a single economic unit and thus a single undertaking … which enables the Commission to impose a fine on the parent company*'. See also C-97/08 *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 59 and 77, and T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraph 367 and the case law cited.

[2547] CMA Penalties Guidance, paragraph 2.21.

undertaking at the date of this Decision.[2548] This approach is supported by precedent; it is consistent with:

(a) The EU Court of Justice's ruling in *Kendrion*, where a 10% ceiling was applied separately to a parent and its former subsidiary as they no longer formed part of the same undertaking at the date of Decision, meaning that a parent may pay a different penalty than its former subsidiary and a separate assessment is carried out for each of them;[2549]

(b) The EU Court of Justice's ruling in *Akzo*, where it held that '*factors specific to the parent company may justify assessing the parent company's liability and that of its subsidiary differently, even if the liability of the former is based exclusively on the unlawful conduct of the latter*';[2550] and

(c) The CAT's ruling in *Paroxetine*, where it held that the CMA must separately assess the proportionality of penalties to be imposed on parent and its subsidiary, where that subsidiary is no longer under the same ownership at the date of the Decision.[2551]

It logically follows that the same must be true when assessing at Step 4 whether the penalty to be imposed on an undertaking will deter it from breaching competition law in future, given its size and financial position at the time the penalty is imposed as well as any other relevant circumstances of the case.

8.346.2 Moreover, were this not the case, there would be an incentive for parent companies (including private equity investors) to close their eyes to any infringing conduct on the part of their subsidiaries during their period of ownership – including in, but by no means limited to, the course of any due diligence conducted during acquisition.

8.346.3 Neither the structure of the Market Exclusion Agreement nor AMCo's assurances that competition law compliance was taken seriously within the AMCo Group detract from Cinven's responsibilities as a parent

[2548] The CAT held in *Paroxetine* that, when assessing the proportionality of a penalty under Step 4, the CMA must separately assess that penalty for a parent and its subsidiary where that subsidiary is no longer under the same ownership. The logical successor of this view is that the CMA must also, when assessing whether a penalty will deter an undertaking from breaching competition law in the future, separately assess the penalty for that parent and its subsidiary where that subsidiary is no longer under the same ownership. The CMA therefore properly assessed whether, for each of Cinven and Advanz (current owner of the Focus Entities), the penalty reached at the end of Step 4 was both an adequate specific deterrent and proportionate. See *Paroxetine II* [2021] CAT 9, paragraph 196.

[2549] C-50/12 P *Kendrion v Commission*, EU:C:2013:771, paragraphs 55-58.

[2550] See C-516/15 P *Akzo Nobel NV v Commission*, EU:C:2017:314, paragraph 74 endorsing the opinion of AG Wahl in Case C-516/15 P *Akzo Nobel NV v Commission*, EU:C:2016:1004, paragraphs 58–59.

[2551] *Paroxetine II* [2021] CAT 9, paragraph 196.

company exercising decisive influence to ensure that its subsidiaries' conduct is compliant with competition law.

8.347 As regards Cinven's submission that it only held its investment in Focus for a relatively short period and no longer holds an interest in Focus, the CMA has taken account of the duration of Cinven's involvement in the Infringement via the apportionment of the penalty imposed on Focus by duration at Step 4 (see paragraphs 8.205 to 8.208 above).

8.348 The CMA also rejects Cinven's submission that the CMA cannot impose a higher fine on Cinven than the directly infringing entities.

8.348.1 The EU Court of Justice's judgement in *Areva* does not address the question of how to assess whether a penalty will achieve specific deterrence and/or is proportionate when imposed jointly and severally on several entities which formed part of a single undertaking at the time of the infringement but are no longer part of this same undertaking at the time of the infringement decision.[2552] *YKK* is more instructive in this context. As established in YKK and set out at paragraph 8.287 above, the CMA must take '*account […] of the size and overall resources of those undertakings at the time when the contested decision is adopted*' in order to '*impose a fine of an amount capable of deterring the undertakings concerned from infringing, in the future*'.[2553]

8.348.2 Further, as cited at paragraph 8.346.1 above, there is established authority that:

(a) a former parent company may be fined more than its former subsidiary;[2554]

(b) there may be circumstances specific to the subsidiary or to the parent company that may justify the imposition of penalties of different amounts;[2555] and

[2552] While the facts were not dissimilar, the legal context which formed the backdrop of the EU Court of Justice's statement in *Areva* was quite different from this case. Like this case, Areva involved a subsidiary which had committed a competition law infringement and was controlled by successive parent companies (Areva and Alstom) over the course of the infringement period. The European Commission (upheld by the EU General Court) had incorporated the amount of the fine for which Areva and the directly infringing subsidiary were jointly and severally liable in the fine for which Alstom (the subsequent parent company) and the directly infringing subsidiary were jointly and severally liable. In practice, this flawed approach meant that Alstom was effectively jointly and severally liable for the fine imposed on Areva, despite Areva and Alstom never having been part of the same undertaking as they owned the directly infringing subsidiary at different times. It also led to the sum of the fines imposed on both parent companies being larger than the fine for which the directly infringing subsidiary itself was liable. The EU Court of Justice's statement was made against this specific background to support its conclusion that the Commission and the EU General Court's interpretation of the concept of joint and several liability had been incorrect.

[2553] C-408/12 P *YKK v Commission*, EU:C:2014:153, paragraphs 86 and 91.

[2554] C-50/12 P *Kendrion v Commission*, EU:C:2013:771, paragraphs 55-58.

[2555] See C-516/15 P *Akzo Nobel NV v Commission*, EU:C:2017:314, paragraph 74 endorsing the opinion of AG Wahl in Case C-516/15 P *Akzo Nobel NV v Commission*, EU:C:2016:1004, paragraphs 58–59.

(c) the CMA must separately assess the proportionality of penalties to be imposed on a parent and its subsidiary, where that subsidiary is no longer under the same ownership at the date of the Decision.[2556] The logical successor of this view is that, where the same circumstances occur, the CMA must also separately assess the penalty for that parent and its subsidiary for the purpose of specific deterrence.

8.349 Consequently, the CMA considers that the proportionality and specific deterrence assessment in this case needs to be carried out in relation to the economic entities in the states in which they exist at the time of this Decision. In Cinven's case, this means that a separate proportionality and specific deterrence assessment needs to be carried out based on its specific financial situation and other circumstances, and not just in relation to '*Focus alone or the undertaking of which it now forms part.'*

8.350 The CMA also rejects Cinven's submissions regarding the *Sumal* case.[2557] *Sumal* concerned the circumstances in which a victim of an anti-competitive practice by an undertaking may bring an action for damages not only against a parent company which has been punished by the Commission for that practice in a decision, but also against a subsidiary of that company which is not referred to in that decision. The facts of this case are very different. Firstly, this case does not concern a damages action and the CMA's Decision would not preclude or limit the bringing of any action for damages. Secondly, this Decision *is* addressed to the Cinven Entities, who have been held jointly and severally liable for the Infringement. Thirdly, Cinven's submissions concern a different issue, which is whether the CMA can have regard to the *'out of market turnover'* of Cinven portfolio companies when assessing whether the penalty for the Cinven Entities should be increased for specific deterrence. The CMA notes that under Step 4 of the CMA Penalties Guidance the CMA will consider appropriate indicators (including total turnover) of the undertaking's size and financial position at the time the penalty is being imposed and that the CMA Penalties Guidance also specifically provides for an increase for specific deterrence in situations where an undertaking has a significant proportion of its turnover outside the relevant market.[2558] The CMA considers it appropriate to have regard to the size and financial position of the Cinven Entities as they currently exist[2559] (including such portfolio companies) when assessing the appropriate uplift for specific deterrence.[2560]

[2556] *Paroxetine II* [2021] CAT 9, paragraph 196.

[2557] Which post-dates IP completion day (as defined as 31 December 2020 at 11.00 p.m. in section 39 of the European Union (Withdrawal Agreement) Act 2020).

[2558] CMA Penalties Guidance, paragraphs 2.20 and 2.21.

[2559] See CMA Penalties Guidance, paragraphs 2.20-2.21.

[2560] See further paragraphs 8.356 to 8.358 below, including [✂].

8.351 As a result, the CMA considers that an uplift for the purpose of specific deterrence is appropriate in this case, which would result in a penalty for the Cinven Entities for Focus Period 2 of £6.7 million[2561].

Proportionality assessment

8.352 The CMA considers that uplifting the penalty to £6.7 million will provide an effective yet proportionate deterrent for the Cinven Entities, having had regard to the Cinven Entities' size and financial position, the nature of the Infringement, Focus' role in the Infringement and the impact of Focus' infringing activity on competition.[2562]

8.353 A penalty of £6.7 million at the end of Step 4 represents:

8.353.1 [✂] of the Cinven Entities' worldwide turnover (averaged over the last three years); and

8.353.2 [✂] of the Cinven Entities' profit after tax (averaged over the last three years); and

8.353.3 [✂] of the Cinven Entities' net assets and dividends (last year's net assets plus last three year's dividends).

8.354 This is not disproportionate or excessive by reference to the Cinven Entities' worldwide turnover, operational profit or net assets. [✂]. For the reasons set out at paragraph 8.338 above, the CMA considers that for private equity firms, turnover is a more meaningful indicator of the entity's size and financial position than profit after tax.

8.355 Focus participated in a market exclusion agreement, which is among the most serious infringements of competition law. As the mechanism by which Alliance paid Lexon (and Medreich) in exchange for non-entry, Focus was a critical part of the Market Exclusion Agreement, under which all competition was excluded from the market until Morningside gained its MA in April 2017 and competition thereafter was limited to supply from Morningside until the end of the Infringement Period. Focus participated in a horizontal market exclusion agreement between Alliance and Lexon that was implemented via two separate agreements with a common third party, Focus (the Implementing Agreements), avoiding the need for direct payments from one competitor to the other and reducing the likelihood of the Infringement being detected. As the parent exercising decisive influence within the Focus undertaking, the Cinven Entities did not act to discontinue the anti-competitive conduct of its subsidiary, Focus Pharmaceuticals Limited.

[2561] Of which the Focus Entities and Mercury Pharma Group Limited would be jointly and severally liable with the Cinven Entities for £1,843,380, i.e. the penalty for Focus Period 2 for which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable with the Cinven Entities prior to any adjustments at Step 4 for either the Focus undertaking as it currently exists, i.e. the Advanz Group, or the Cinven Entities (see Table 8).

[2562] CMA Penalties Guidance, paragraphs 2.23-2.24.

8.356 Cinven has submitted that the CMA has had regard to the wrong financial indicators in relation to the Cinven Entities.[2563]

8.356.1 According to Cinven, the CMA has erred in taking account of the financial indicators (in particular turnover and net assets) of its portfolio companies in assessing the need for a deterrence uplift and whether the proposed penalty is excessive and disproportionate. Cinven argues that when assessing Cinven's size and financial position, the CMA should only have regard to the fees they received from the relevant funds and from portfolio companies.[2564]

8.356.2 Cinven has also submitted that the CMA has erred in having regard to total proceeds realised by the Cinven Funds. [✂].[2565]

8.357 The CMA rejects these arguments. As explained in paragraphs 7.85 to 7.275 of this Decision, notwithstanding the complex structures of the core Cinven private equity group and the Fifth Cinven Fund, the Cinven Entities acted as one in relation to their investment in the Focus Entities. The Cinven Entities' submission that the CMA has '*failed to have proper regard to the structure of the Cinven Funds*'[2566] is a continuation of their submission that none of the Cinven Entities should in fact be liable for the Infringement (and that the CMA should instead impose a penalty on 'the Fund'). As explained in that section, this submission focuses on corporate technicalities and ignores the economic reality, which is that the Cinven Entities exercised decisive influence over the Focus Companies during their ownership period.

8.358 This is illustrated by the Cinven Entities' acknowledgement that '*one or more of the Cinven [Entities] have decisive influence for the purposes of the EU Merger Regulation*'[2567] over (and therefore form an undertaking with) the portfolio companies whose financial information is included in the figures submitted to the CMA. Although the Cinven Entities expressly stated that this did not amount to an admission of decisive influence for the purposes of attributing liability, as explained in paragraph 7.234 of this Decision, the concept of decisive influence in merger control is related to the question of decisive influence for attribution of liability. This was, for example, recognised by the parties in *Toshiba*.[2568] It would make little sense for the Cinven Entities to accept that these portfolio companies' turnover should be consolidated in their merger notifications – the purpose of which is to allow the European Commission to gauge the size of the parties to a concentration

[2563] Cinven RDPS, 7 July 2021, paragraphs 3.73-3.86 (URN: PRO-C7439).

[2564] Cinven RDPS, 7 July 2021, paragraphs 3.76ff. (URN: PRO-C7439).

[2565] Cinven RDPS, 7 July 2021, paragraph 3.82 (URN: PRO-C7439).

[2566] Cinven RDPS, 7 July 2021, paragraph 3.75 (URN: PRO-C7439).

[2567] Cinven RDPS, 7 July 2021, paragraph 3.74 (URN: PRO-C7439).

[2568] C-623/15P *Toshiba v Commission*, EU:C:2017:21, paragraph 67. See also the EU General Court's judgment in the same case, T-104/13, EU:T:2015:610, paragraphs 107-111: the EU Jurisdictional Notice's '*relevance to the present case is not disputed by the parties*'.

and the likely impact on the market – but excluded when it comes to assessing their size and financial ability to bear a penalty for an antitrust infringement.

8.359 [✂].[2569] [✂].

8.360 The CMA therefore does not consider a penalty of £6.7 million to be excessive or disproportionate.

Calculation at the end of Step 4

8.361 Taking a step back and assessing the penalties for each of the undertakings in the round, the CMA concludes that they are appropriate in the light of all the relevant factors and circumstances, including 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 undertaking's infringing activity on competition.

8.362 At the end of Step 4, the penalty for the Infringement to be imposed on each undertaking is set out in Table 9.

Table 9: Calculation at the end of Step 4

Undertaking	Legal entities liable jointly and severally	Penalty after Step 4
Alliance	Alliance Pharmaceuticals Limited Alliance Pharma plc	£7,900,0000
Lexon	**Lexon Period 1** Lexon (UK) Limited	£6,706,220
	Lexon Period 2 Lexon (UK) Limited Lexon UK Holdings Limited	£593,780
Medreich	**Medreich Period 1** Medreich plc Medreich Ltd	£1,945,924
	Medreich Period 2 Medreich plc Medreich Ltd Meiji Seika Pharma Co Meiji Holdings Co Ltd	£5,754,076
Focus	**Focus Period 1** Focus Entities	£3,346,409

[2569] [✂].

Undertaking	Legal entities liable jointly and severally	Penalty after Step 4
	Focus Period 2 Focus Entities Mercury Pharma Group Limited Cinven Entities	Focus Entities, Mercury Pharma Group Limited – £2,764,737[2570] Cinven Entities - £6,700,000[2571]
	Focus Period 3 Focus Entities Mercury Pharma Group Limited Advanz Entities	£7,288,853

Step 5 – Adjustment to prevent maximum penalty from being exceeded and to avoid double jeopardy

Adjustments to prevent maximum penalty from being exceeded (statutory cap)

8.363 The final amount of the penalty calculated according to the method set out above may not in any event exceed 10% of the worldwide turnover of the undertaking in its last business year.[2572] Any adjustments necessary to comply with this statutory cap are set out below.

Adjustments to avoid double jeopardy

8.364 In addition, the CMA must, when setting the amount of a penalty for a particular agreement or conduct, take into account any penalty or fine that has been imposed by the European Commission or by a court or other body in another Member state in respect of the same agreement or conduct.[2573] No adjustments to the level of the penalty for which any of the Parties is liable at the end of Step 4 are required in order to avoid double jeopardy.

[2570] Of which the Cinven Entities are jointly and severally liable for £1,843,380.

[2571] Of which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable for £1,843,380.

[2572] Section 36(8) of the Act, the 2000 Turnover Order, as amended and the CMA Penalties Guidance, paragraph 2.25. The applicable turnover of an undertaking is limited to the amounts derived by the undertaking from the sale of products and the provision of services falling within the undertaking's ordinary activities after deduction of sales rebates, value added tax and other taxes directly related to turnover (2000 Turnover Order, Schedule, paragraph 3). The business year based on which worldwide turnover is determined will be the one preceding the date on which the decision of the CMA is taken or, if figures are not available for that business year, the one immediately preceding it. If necessary, the penalty will be adjusted to ensure that it does not exceed this maximum.

[2573] CMA Penalties Guidance, paragraph 2.28.

Principles applicable to the calculation of the statutory cap at Step 5

8.365 The statutory cap in relation to the Alliance undertaking is straightforward as there have been no changes in ownership during the Infringement Period.

8.366 With respect to the penalty to be imposed on each of the Lexon and Medreich undertakings, there have been changes to the corporate group during the Infringement Period and the Medreich Infringement Period respectively. For this reason, the statutory cap is calculated by reference to two different periods. For the first period, the statutory cap is calculated at 10% of the worldwide turnover of the legal entities constituting the undertaking at that time and not the worldwide turnover of the entities subsequently constituting the undertaking. The statutory cap is then calculated at 10% of the worldwide turnover of the entities subsequently constituting the undertaking to confirm that the aggregate penalty for the two periods does not exceed this statutory cap.

8.367 With respect to the penalty to be imposed on the Focus undertaking:

8.367.1 as regards the portion of the penalty attributable to Focus Period 1, the total amount for which the Focus Entities can be held jointly and severally liable is capped at 10% of their worldwide turnover and not Advanz Pharma Corp.'s worldwide turnover;

8.367.2 with respect to the portion of the penalty attributable to Focus Period 2, the total amount for which the Focus Entities and Mercury Pharma Group Limited can be held jointly and severally liable is capped at 10% of their combined worldwide turnover, and not Advanz Pharma Corp.'s worldwide turnover. The Cinven Entities, as former parent entities, would not benefit from any reductions made on the basis of the statutory cap applicable to the Focus Entities and Mercury Pharma Group Limited in relation to the penalty for Focus Period 2;[2574] and

8.367.3 with respect to Focus Period 3, the worldwide turnover of the undertaking of which the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities together form part is relevant for the application of the statutory cap at Step 5. The CMA has also considered whether the aggregate fine imposed on the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities for Focus Period 1, Focus Period 2 and Focus Period 3 exceeds that statutory cap.

Alliance

8.368 The penalty to be imposed on the Alliance undertaking does not exceed 10% of the worldwide turnover of Alliance Pharma plc in the financial year ended 31

[2574] C-50/12 P *Kendrion v Commission*, EU:C:2013:771, paragraph 57.

December 2020[2575] and so the liability of Alliance Pharmaceuticals Limited and Alliance Pharma plc for the penalty remains unadjusted.

Lexon

8.369 The penalty to be imposed on the Lexon undertaking comprises:

8.369.1 a penalty of £6,706,220 for Lexon Period 1, for which Lexon (UK) Limited is liable; this does not exceed 10% of the worldwide turnover of Lexon (UK) Limited[2576] in the financial year ended 30 April 2021 and so its liability for the penalty for this period remains unadjusted; and

8.369.2 a penalty of £593,780 for Lexon Period 2, for which Lexon (UK) Limited and Lexon UK Holdings Limited are jointly and severally liable; the total penalty to be imposed on the Lexon undertaking (of £7.3 million), in respect of Lexon Period 1 and Lexon Period 2 does not exceed 10% of the worldwide turnover of Lexon UK Holdings Limited in the financial year ended 30 April 2021[2577] and so the liability of Lexon (UK) Limited and Lexon UK Holdings Limited for the penalty remains unadjusted.

Medreich

8.370 The penalty to be imposed on the Medreich undertaking comprises:

8.370.1 a penalty of £1,945,924 for Medreich Period 1, for which Medreich plc and Medreich Ltd are jointly and severally liable; this does not exceed 10% of the worldwide turnover of Medreich plc in the financial year ended 31 March 2021[2578] and so the liability of Medreich plc and Medreich Ltd for the penalty remains unadjusted; and

8.370.2 a penalty of £5,754,076 for Medreich Period 2, for which Medreich plc, Medreich Ltd, Meiji Seika Pharma Co, and Meiji Holdings Co Ltd are jointly and severally liable; the total penalty to be imposed on the Medreich undertaking (of £7.7 million), in respect of Medreich Period 1 and Medreich Period 2 does not exceed 10% of the worldwide turnover of Meiji Holdings Co Ltd for the financial year ended 31 March 2021,[2579] and so the liability of Medreich plc, Medreich Ltd, Meiji Seika Pharma Co and Meiji Holdings Co Ltd for the penalty remains unadjusted.

[2575] Alliance Pharma plc statutory accounts for year ending 31 December 2020.

[2576] Lexon (UK) Limited statutory accounts for year ending 30 April 2021.

[2577] Lexon UK Holdings Limited statutory accounts for year ending 30 April 2021.

[2578] Medreich plc published accounts for year ending 31 March 2021.

[2579] Based on Meiji Holdings Co Limited's published annual report for year ending 31 March 2021 and conversion from JPY ¥ to £ at a Bank of England spot rate of 152.473:1.

Focus

Focus Period 1 – the Focus Entities

8.371 Absent the statutory cap, the Focus Entities would be jointly and severally liable for £3,346,409 for Focus Period 1.

8.372 However, on the basis of the most recently available financial statements of Focus Pharmaceuticals Limited,[2580] the maximum penalty the CMA could impose on these entities for Focus Period 1 is £549,343. Since the penalty in respect of Focus Period 1 exceeds this amount, their liability to pay such penalty must be adjusted to £549,343.

Focus Period 2 – the Focus Entities, Mercury Pharma Group Limited and the Cinven Entities

8.373 The penalty to be imposed in respect of Focus Period 2 as regards the Focus Entities and Mercury Pharma Group Limited is £2,764,737[2581]; the penalty to be imposed in respect of Focus Period 2 as regards the Cinven Entities is £6,700,000.[2582]

8.374 The penalty as regards the Focus Entities and Mercury Pharma Group does not exceed 10% of the worldwide turnover of Mercury Pharma Group Limited in the year ending 31 December 2020,[2583] and the penalty as regards the Cinven Entities does not exceed 10% of the worldwide turnover of the Cinven Entities in the financial year ending 31 December 2020.[2584] The liability for each of the Focus Entities, Mercury Pharma Group Limited and the Cinven Entities in respect of their respective penalties for Focus Period 2 therefore remains unadjusted.

Focus Period 3 – the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities

8.375 The penalty of £7,288,853 to be imposed for Focus Period 3 for which the Focus Entities, Mercury Pharma Group Limited and the Advanz Entities are jointly and severally liable does not exceed 10% of the worldwide turnover of Advanz Pharma Corp. in the year ending 31 December 2020, so their liability for the penalty for

[2580] Financial statements for the year ending 31 December 2020 for Focus Pharmaceuticals Limited, publicly available from Companies House. Focus Pharmaceuticals Limited's turnover from the year ending 31 December 2019 has significantly reduced because, as noted on page 3 of the published accounts for that year, '*[w]ith effect from 1 October 2018, the entire business has been transferred to its fellow subsidiary Advanz Pharma Generics (UK) Limited*'.

[2581] Of which the Cinven Entities are jointly and severally liable for £1,843,380.

[2582] Of which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable for £1,843,380.

[2583] Financial statements for the year ending 31 December 2020 for Mercury Pharma Group Limited, publicly available from Companies House.

[2584] Section 26 response of Cinven dated 15 October 2021, to the CMA Notice of 23 September 2021, Annex 1 (URN: PRO-C7770, and PRO-C7771).

Focus Period 3 remains unadjusted.[2585] In addition, the total, aggregate penalty to be imposed on the Advanz Group in respect of Focus Period 1 (as adjusted to reflect the statutory cap of the Focus Entities), Focus Period 2 and Focus Period 3 (in total, £10,602,934) does not exceed that maximum.

Calculation at the end of Step 5

8.376 At the end of Step 5, the penalty for the Infringement to be imposed on each undertaking is set out in Table 10.

Table 10: Calculation at the end of Step 5

Undertaking	Legal entities liable jointly and severally	Adjustment at Step 5	Penalty after Step 5
Alliance	Alliance Pharmaceuticals Limited Alliance Pharma plc	N/A	£7,900,000
Lexon	**Lexon Period 1** Lexon (UK) Limited	N/A	£6,706,220
	Lexon Period 2 Lexon (UK) Limited Lexon UK Holdings Limited		£593,780
Medreich	**Medreich Period 1** Medreich plc Medreich Ltd	N/A	£1,945,924
	Medreich Period 2 Medreich plc Medreich Ltd Meiji Seika Pharma Co Meiji Holdings Co Ltd		£5,754,076
Focus	**Focus Period 1** Focus Entities	Application of statutory cap	£549,343

[2585] Advanz Pharma Corp.'s consolidated annual financial statements for the financial year ending 31 December 2020 and Advanz Pharma Corp.'s 2020 Annual Management's Discussion and Analysis, dated March 17, 2021. Available at: https://www.advanzpharma.com/news/2021/advanz-pharma-corp-limited-announces-fourth-quarter-and-2020-results. Turnover is converted from US $ to £ at a Bank of England average spot rate of 1.284:1 for the year ending 31 December 2020.

Undertaking	Legal entities liable jointly and severally	Adjustment at Step 5	Penalty after Step 5
	Focus Period 2 Focus Entities Mercury Pharma Group Limited Cinven Entities	N/A	Focus Entities, Mercury Pharma Group Limited – £2,764,737[2586] Cinven Entities - £6,700,000[2587]
	Focus Period 3 Focus Entities Mercury Pharma Group Limited Advanz Entities	N/A	£7,288,853

Step 6 – Application of reductions for leniency and settlement

8.377 The CMA will reduce an undertaking's penalty at Step 6 where the undertaking has a leniency agreement with the CMA, provided that the undertaking meets the conditions of the leniency agreement, [2588] and/or agrees to settle with the CMA. [2589]

Medreich

8.378 As set out in paragraph 1.42, Medreich applied to the CMA for leniency on 24 April 2018 and was granted a provisional Type B leniency marker under the CMA's leniency policy. Medreich admitted its involvement in the Infringement and subsequently signed a Leniency Agreement with the CMA (dated 21 May 2019).[2590] Provided Medreich continues to co-operate and comply with the conditions of the CMA's leniency regime, as set out in the Leniency Agreement, Medreich will benefit from a leniency discount of 40%.

[✂]

8.379 [✂].[2591]

8.380 [✂].[2592]

[2586] Of which the Cinven Entities are jointly and severally liable for £1,843,380.

[2587] Of which the Focus Entities and Mercury Pharma Group Limited are jointly and severally liable for £1,843,380.

[2588] CMA Penalties Guidance, paragraph 2.29.

[2589] CMA Penalties Guidance, paragraph 2.30.

[2590] See Leniency agreement between the CMA and Medreich as signed 21 May 2019 (URN: PRO-C6682).

[2591] [✂].

[2592] [✂].

8.381 [✂].[2593] [✂][2594] [✂].[2595] [✂].[2596]

8.382 [✂].

Other parties

8.383 No settlement agreement was reached with any undertaking and therefore no adjustments are required in this respect.

Calculation at the end of Step 6

8.384 At the end of Step 6, the penalty for the Infringement to be imposed on each undertaking is set out in Table 11.

Table 11: Calculation at the end of Step 6

Undertaking	Legal entities liable jointly and severally	Adjustment at Step 6	Penalty after Step 6
Alliance	Alliance Pharmaceuticals Limited Alliance Pharma plc	n/a	£7,900,000
Lexon	**Lexon Period 1** Lexon (UK) Limited	n/a	£6,706,220
	Lexon Period 2 Lexon (UK) Limited Lexon UK Holdings Limited		£593,780
Medreich	**Medreich Period 1** Medreich plc Medreich Ltd	Application of leniency discount	£1,167,554
	Medreich Period 2 Medreich plc Medreich Ltd Meiji Seika Pharma Co Meiji Holdings Co Ltd		£3,452,446
Focus	**Focus Period 1** Focus Entities	n/a	£549,343

[2593] [✂].
[2594] [✂].
[2595] [✂].
[2596] [✂].

Undertaking	Legal entities liable jointly and severally	Adjustment at Step 6	Penalty after Step 6
	Focus Period 2 Focus Entities Mercury Pharma Group Limited Cinven Entities	n/a	Focus Entities, Mercury Pharma Group Limited – £2,764,737[2597] Cinven Entities – £6,700,000[2598]
	Focus Period 3 Focus Entities Mercury Pharma Group Limited Advanz Entities	n/a	£7,288,853

Payment of penalty

8.385 The CMA requires the legal entities to which this Decision is addressed to pay the penalty applicable to it:

8.385.1 Alliance: Alliance Pharmaceuticals Limited and Alliance Pharma plc are jointly and severally liable for £7,900,000.

8.385.2 Lexon:

(a) Lexon (UK) Limited is liable for £6,706,220; and

(b) Lexon (UK) Limited and Lexon UK Holdings Limited are jointly and severally liable for a further £593,780.

8.385.3 Medreich:

(a) Medreich plc and Medreich Ltd are jointly and severally liable for £1,167,554; and

(b) Medreich plc, Medreich Ltd, Meiji Seika Pharma Co. and Meiji Holdings Co. Ltd are jointly and severally liable for a further £3,452,446;

8.385.4 Focus:

(a) Focus Pharmaceuticals Limited and Focus Pharma Holdings Limited are jointly and severally liable for £549,343;

[2597] Of which the Cinven Entities are jointly and severally liable for £1,843,380.

[2598] Of which the Focus Entities and the Mercury Pharma Group Limited are jointly and severally liable for £1,843,380.

(b) Focus Pharmaceuticals Limited, Focus Pharma Holdings Limited, Mercury Pharma Group Limited, Cinven Capital Management (V) General Partner Limited, Cinven (Luxco 1) S.à.r.l.[2599] and Cinven Partners LLP are jointly and severally liable for a further £1,843,380;

(c) Focus Pharmaceuticals Limited, Focus Pharma Holdings Limited and Mercury Pharma Group Limited are jointly and severally liable for a further £921,357;

(d) Cinven Capital Management (V) General Partner Limited, Cinven (Luxco 1) S.à.r.l.[2600] and Cinven Partners LLP are jointly and severally liable for a further £4,856,620;

(e) Focus Pharmaceuticals Limited, Focus Pharma Holdings Limited, Mercury Pharma Group Limited, Concordia Investment Holdings (UK) Limited, Concordia Investments (Jersey) Limited and Advanz Pharma Corp. Limited are jointly and severally liable for a further £7,288,853.

8.386 The penalties will become due to the CMA in their entirety on 4 April 2022[2601] and must be paid to the CMA by close of banking business on that date.[2602]

3 February 2022

Stephen Blake, Senior Legal Director, Cartels and Consumer Protection, for and on behalf of the Competition and Markets Authority

Anne Fletcher, CMA Panel Member, for and on behalf of the Competition and Markets Authority

Paul Muysert, 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

[2599] Formerly Cinven (Luxco 1) S.A.

[2600] Formerly Cinven (Luxco 1) S.A.

[2601] The next working day two calendar months from the expected date of receipt of the Decision.

[2602] Details on how to pay the penalty are set out in the letter accompanying this Decision.

Annex A: Parties' representations on legal framework for participation in an infringement

A.1 As set out at paragraph 5.147 of this Decision, the parties made extensive representations on the use of the conditions set out at paragraph 5.128 in this case to establish that Focus and Medreich[2603] participated in and are thus liable for the Market Exclusion Agreement. Having carefully considered these representations, the CMA finds them to be without foundation, for the reasons set out below.

Misapplication of the concept of 'single and continuous infringement'

A.2 Advanz and Cinven submitted that the CMA has misapplied the concept of *'single and continuous infringement'* as its use is restricted to *'complex cartels of long duration'*[2604] and the present case is distinct from the cases in which the concept has been applied previously.[2605] Advanz and Cinven each cited a number of cases in which the concept of single and continuous infringement was applied to a complex cartel case in support of their submissions.[2606]

A.3 The CMA rejects these submissions. The CMA has not misapplied the concept of 'single and continuous infringement' as the CMA does not find that the Market Exclusion Agreement constitutes a single and continuous infringement. Rather, the CMA finds that Alliance and Lexon entered into the Market Exclusion Agreement and that Focus and Medreich participated in the Market Exclusion Agreement because the conditions set out at paragraph 5.128 are fulfilled.

A.4 While those conditions were first recognised by the EU Courts in *Anic*,[2607] which concerned a long-running complex cartel, their application has not been limited to that context (see, for example, the *ICAP* and *VM Remonts* cases referenced at paragraph 5.129 above). Further, there is no basis to suggest that legal concepts should be restricted to situations that are factually similar to the cases in which they were first applied. For this reason, the CMA rejects Advanz's and Cinven's representations on the applicability of the conditions to the present case.

A.5 Even if (which the CMA does not accept) this case did concern a single and continuous infringement, it would still be incorrect to argue that the conditions could only be applied to a complex cartel of long duration, as they have been applied to

[2603] While Cinven is held liable in this Decision for Focus' participation in the Market Exclusion Agreement it has also challenged the use of the same legal framework to assess whether Medreich participated in the Market Exclusion Agreement. See Cinven RSO, 15 August 2019, paragraphs 1.10, 3.1, 3.9-3.16 (URN: PRO-C5132).

[2604] Advanz RSO, 1 August 2019, paragraph 3.28 (URN: PRO-C5111).

[2605] Advanz RSO, 1 August 2019, paragraphs 3.28 - 3.34 (URN: PRO-C5111); Advanz RLF, 22 April 2021, paragraph 2.17 (URN: PRO-C7112); and Cinven RSO, 15 August 2019, paragraphs 3.3-3.8 and 3.15 (URN: PRO-C5132).

[2606] Advanz RSO, 1 August 2019, paragraph 3.29, footnote 119 (URN: PRO-C5111); Cinven RSO, 15 August 2019, paragraphs 3.3-3.7 (URN: PRO-C5132).

[2607] C-49/92 P *Commission v Anic Partecipazioni SpA,* EU:C:1999:356.

single and continuous infringements involving: a limited number of participants,[2608] only one jurisdiction,[2609] only one product,[2610] and infringements with a duration of shorter than one year.[2611]

No finding of 'facilitation' in relation to Focus

A.6 Advanz submitted that the CMA is not permitted to apply the conditions set out at paragraph 5.128 or to rely on cases concerning so-called 'facilitators' because these cases set out the test for *'facilitation'* whereas *'(i) the CMA does not say that Focus was a facilitator, and (ii) the CMA does not make out a case that Focus was a facilitator.'*[2612] Advanz noted in particular references to '***facilitation***' in the judgment of the EU General Court in *Icap,*[2613] a case relied on by the CMA.[2614] Advanz also submitted that in not using the term 'facilitator' in respect of Focus, the CMA failed to clearly state its case against Focus.[2615]

A.7 This argument is unpersuasive. For the conditions set out at paragraph 5.128 to apply, it is not necessary for an undertaking to be categorised as a facilitator – and the absence of a reference to the term 'facilitator' does not have any bearing on the legal principles to be applied. The relevant question is whether Focus participated in the infringement – and that question is answered through the application of the conditions set out at paragraph 5.128 above.

A.8 Further, the fact that the conditions set out at paragraph 5.128 have been applied to find an undertaking who facilitated an infringement was liable for the entire infringement does not mean that their application is limited to that scenario.

A.9 In *VM Remonts*, the EU Court of Justice does not refer at all to earlier 'facilitation' cases (or the term 'facilitation') when applying the conditions set out at paragraph

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[2608] See, for example, Commission decision of 4 February 2015 in Case AT.39861 – *Yen Interest Rate Derivatives (Icap)*, paragraphs 206-217 in which each infringement concerned three participants; upheld on appeal (with the exception of the UBS/RBS 2008 infringement) in T-180/15 *Icap plc and Others v Commission*, EU:T:2017:795.

[2609] See, for example, T-29/05 *Deltafina v Commission*, EU:T:2010:355, paragraphs 57-61.

[2610] See, for example, Commission decision of 8 February 2017 in Case AT.40018 *Car Battery Recycling*, paragraphs 3 and 202-219.

[2611] See, Commission decision of 4 December 2013 in Case AT.39861 – *Yen Interest Rate Derivatives*, paragraphs 74-75 and 138 where the infringements found by the Commission ranged in duration from just over one month (the UBS/JBM 2007 infringement and the Citi/UBS 2010 infringement), to less than eleven months (the UBS/DB 2008-09 infringement); Commission Decision of 29 September 2020 in Case AT.40299-*Closure Systems*, paragraphs 2, 59-60, 74, and 76, where the first infringement found by the Commission lasted for seven months; CMA decision in case 50507.2 *Nortriptyline (information exchange)*, CMA decision of 4 March 2020, paragraphs 1.11, 5.158 to 5.171, where the CMA found that the Relevant Period 1 infringement (which formed part of a single repeated infringement) lasted for only 1 month and 22 days.

[2612] Advanz RSO, 1 August 2019, paragraphs 3.13-3.14; 3.52-3.54 (URN: PRO-C5111); Advanz RLF, 22 April 2021, paragraphs 2.36, 2.48 (URN: PRO-C7112). See also Advanz RDPS, 7 July 2021, paragraph 5.24 (URN: PRO-C7481).

[2613] T-180/15 *Icap and Others v Commission*, ECLI:EU:T:2017:795.

[2614] Advanz RSO, 1 August 2019, paragraph 3.53 (URN: PRO-C5111). Advanz also submitted that the CMA has overlooked the test articulated by the EU General Court at paragraph 208 of the *Icap* judgment when assessing the duration of the infringements which it ruled that ICAP had intentionally participated in (Advanz RSO, 1 August 2019 paragraph 3.54 (URN: PRO-C5111)). However, this is not the case (see for example Statement of Objections paragraph 4.90).

[2615] Advanz RSO, 1 August 2019, paragraphs 3.144, 3.53-3.54 (URN: PRO-C5111).

5.128 above, referencing only the *Anic*[2616] case as authority for the application of the conditions. This demonstrates that:

A.9.1 using the term 'facilitation' is unnecessary to apply the conditions at paragraph 5.128 above;[2617] and

A.9.2 there is no difference in how the conditions apply in 'facilitation' or non-'facilitation' cases.

A.10 The CMA set out these conditions in the SO,[2618] including expressly referencing and relying on cases including *Icap,*[2619] *Deltafina*[2620] and *AC Treuhand II*[2621]*.* The Addressees would have been aware that the CMA considered the legal tests in those cases to be applicable to the present case. The CMA also set out in the Statement of Objections the proposed application of these conditions to Focus (and Medreich)[2622]. The CMA therefore provided sufficient clarity to Focus (and Medreich) as to the legal test it proposed to apply.

No separate infringement

A.11 Cinven and Advanz both submitted that the CMA ignored an essential legal condition in applying the conditions set out at paragraph 5.128. Specifically, they submitted that the CMA must first show that an undertaking has *'committed [a separate] infringement of Article 101(1)/Chapter I'*[2623] or that the CMA must *'first prove that the undertaking concerned participated in at least one infringement of Article 101/Chapter I, which infringement is itself part of a series of anticompetitive agreements'*[2624] before it can assess whether the conditions at paragraph 5.128 can be applied.[2625] Advanz also referred to the CMA's closure on administrative

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[2616] C-542/14 *VM Remonts and Others,* EU:C:2016:578, paragraph 29 citing C-49/92 *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraph 87.

[2617] Indeed in *AC Treuhand I,* the first case in which a finding of liability by a 'facilitator' for an infringement was upheld by the EU Courts, there is no specific finding by the EU General Court that the appellant was a 'facilitator'. Rather, the EU General Court applied the conditions set out at paragraph 5.128 to find that the appellant, who had facilitated the infringement was liable for the cartel as a whole. See T-99/04 *AC Treuhand v Commission* EU:T:2008:256, paragraphs 130 to 136 and 150 to 157.

[2618] See Statement of Objections paragraphs 4.90 to 4.103.

[2619] T-180/15 *Icap and Others v Commission*, ECLI:EU:T:2017:795, paragraph 180. See SO, paragraphs 4.90 (footnote 466), 4.92 (footnote 468) 4.96 (footnote 476), 4.97 (and footnote 478), 4.101 (footnote 482), and 4.182 (footnote 578).

[2620] T-29/05 *Deltafina v Commission*, ECLI:EU:T:2010:355. See SO, paragraphs 4.96 (footnote 476) 4.98 (footnote 479, 4.99 (footnote 480).

[2621] T-27/10 *AC Treuhand v Commission*, EU:T:2014:59 and C-194/14 *AC-Treuhand v Commission*, ECLI:EU:C:2015:717. See SO, paragraph 4.90 (footnote 466), 4.92 (footnote 468), 4.94 (footnotes 472 and 473), 4.182 (footnote 578).

[2622] In relation to Focus, see Statement of Objections paragraphs 4.182-4.189 and 4.229-4.230. In relation to Medreich, See Statement of Objections paragraphs 4.190-4.230.

[2623] Cinven RSO, 15 August 2019, paragraph 3.16 (URN: PRO-C5132). See also Cinven RSO, 15 August 2019, paragraphs 3.9 to 3.12, 3.14, 3.17, 3.19-3.21 (URN: PRO-C5132).

[2624] Advanz RSO, 1 August 2019, paragraph 3.42 (URN: PRO-C5111). See also Advanz RSO, 1 August 2019, paragraphs 3.19 and 3.43-3.46 (URN: PRO-C5111).

[2625] Cinven also submitted that the implications for parties found to have participated in a SCI (including being served with a single fine (as opposed to separate fines for different infringements)) relate to the nature and extent of an

priorities grounds of its investigation into whether the Alliance-Focus Agreement[2626] and the Focus-Lexon-Medreich Agreement[2627] were in themselves infringements of Chapter I. Advanz submitted that, as a result, *'there is nothing to attach Focus to the alleged [Market Exclusion] Agreement, and the CMA's case as regards Focus falls away in its entirety'*.[2628]

A.12 These submissions are not well-founded. The cases cited by the Parties in support of these submissions are all cases where the conditions are being used to legally characterise various agreements, concerted practices or decisions by associations of undertakings as a single agreement or infringement.[2629] This is not the relevant application of the conditions in the present case. As noted above, the CMA is applying the conditions in this case to show that Focus and Medreich are liable for the Market Exclusion Agreement as a result of their participation in it. The EU Courts have expressly approved the use of the conditions for this purpose and in so doing have not required that the undertaking concerned was party to a separate infringing agreement, concerted practice or decision to the one it is alleged to have participated in.

A.13 In its *Icap* decision, the European Commission (as noted by the EU General Court on appeal)[2630] *'did not find the existence of separate infringements between Icap and UBS, then Icap and Citi'*[2631] when finding that Icap was liable in respect of the infringements committed by the banks concerned. Instead, the European Commission's approach was to decide Icap's liability on the basis of its participation in the anticompetitive conduct found by the European Commission.[2632] In view of the European Commission's reasoning, it was necessary for the EU General Court to ascertain whether Icap's participation satisfied the conditions set out at paragraph 5.128 above.[2633] On the facts, with the exception of one infringement, the EU General Court upheld the European Commission's findings

infringement already found rather than liability for the infringement. Cinven therefore submits that the CMA has a *'duty to evidence an infringement prior to and separate from its ability to proceed with the case as a SCI'*. Cinven RSO, 15 August 2019, paragraph 3.14 (URN: PRO-C5132). However, Cinven's submissions ignore the fact that for a single fine to be imposed on an undertaking for an infringement, the undertaking must have already been found to have been liable for that infringement. As regards Focus, the CMA has established Focus' liability in accordance with the conditions set out at paragraph 5.128 above.

[2626] As defined in the Deprioritisation decision of 22 January 2021 (see paragraph 2.39 above).

[2627] As defined in the Deprioritisation decision of 22 January 2021 (see paragraph 2.39 above).

[2628] Advanz RLF, 22 April 2021, paragraphs 2.7, 2.11, 2.13-2.14; 2.28-2.32, 2.63 (URN: PRO-C7112).

[2629] In any event, in that context, while some European Court authority suggests that each of the relevant agreements, concerted practices or decisions must themselves infringe Article 101/Chapter I (See T-380/10 *Wabco Europe and Others* v *European Commission* EU:T:2013:449, paragraph 92 as cited by Advanz at RSO, 1 August 2019 (URN: PRO-C5111), paragraph 3.36), other European Court authority suggests that this position is not settled and that *'even if none of the different elements of evidence of the infringement in question constitutes, considered separately, an agreement or concerted practice prohibited by Article 101 TFEU, this does not prevent those elements, considered together, from constituting such an agreement or practice in view of the fact that they gave substantive shape to the common wish to restrict competition.'* (C-407/08 P *Knauf Gips v Commission* EU:C:2010:389, paragraphs 45 and 47-48).

[2630] T-180/15 *Icap and Others v Commission* EU:T:2017:795.

[2631] T-180/15 *Icap and Others v Commission* EU:T:2017:795, paragraph 105.

[2632] T-180/15 *Icap and Others v Commission* EU:T:2017:795, paragraph 105.

[2633] T-180/15 *Icap and Others v Commission* EU:T:2017:795, paragraph 106.

that Icap was liable in relation to the infringements found by the European Commission.[2634] In its assessment, the EU General Court only considered the three conditions set out at paragraph 5.128 above and did not consider the existence of any separate infringement to which Icap was a party.[2635]

A.14 Similarly, in *VM Remonts*[2636] the EU Court of Justice found that an undertaking could, in principle, be held liable for a concerted practice on account of the acts of an independent provider without any suggestion that it was party to an infringing agreement itself. When the EU Court of Justice set out the relevant legal test, it only referred to the three conditions set out at paragraph 5.128: *'an undertaking may, in principle, be held liable for a concerted practice on account of the acts of an independent service provider supplying it with services… if …that undertaking was aware of the anti-competitive objectives pursued by its competitors and the service provider and intended to contribute to them by its own conduct, or … that undertaking could reasonably have foreseen the anti-competitive acts of its competitors and the service provider and was prepared to accept the risk which they entailed.'*[2637]

A.15 Advanz also submitted that the CMA's description of Focus as a 'vehicle' or 'mechanism' via which Alliance and Lexon effected the alleged value transfer to Lexon/Medreich does not mean that Focus participated, knowingly and intentionally, in at least one infringement of Chapter I.[2638]

A.16 The CMA agrees that the mere description of Focus as a 'vehicle' or 'mechanism' would not be sufficient to establish that Focus participated in and was liable for the Market Exclusion Agreement. However that is not the approach the CMA has followed in this case. The CMA has applied the conditions set out at paragraph 5.128 above to assess whether Focus (and Medreich) participated in and were liable for the Market Exclusion Agreement (see paragraphs 5.629 to 5.688).

Focus is not a competitor of Alliance, Lexon or Medreich

A.17 Advanz submitted that it was the CMA's case that Focus was a "competitor" of Alliance and Lexon and Medreich and that the CMA must show *'that Focus was a competitor within the context of the alleged [Market Exclusion] Agreement'* before demonstrating that Focus *'shared the [Market Exclusion] Agreement/Common Objective, and [...] that Focus intentionally contributed to it'*.[2639]

[2634] T-180/15 *Icap and Others v Commission,* EU:T:2017:795, paragraphs 122-182.

[2635] T-180/15 *Icap and Others v Commission,* EU:T:2017:795, paragraphs 100 and 107.

[2636] C-542/14 *VM Remonts and Others,* EU:C:2016:578.

[2637] C-542/14 *VM Remonts and Others,* EU:C:2016:578, paragraph 33.

[2638] Advanz RSO, 1 August 2019, paragraph 3.46 (URN: PRO-C5111); Advanz RLF, 22 April 2021, paragraph 2.34 (URN: PRO-C7112).

[2639] Advanz RSO, 1 August 2019, paragraph 3.88 (URN: PRO-C5111).

A.18 The CMA has not submitted that Focus was a competitor to Alliance, Lexon and Medreich in the context of the Market Exclusion Agreement. Rather, as noted above, it is the CMA's case that the conditions at paragraph 5.128 above are fulfilled in respect of Focus (and Medreich).

A.19 It is not a necessary precondition for the application of the conditions at paragraph 5.128 above for Focus to be a competitor to Alliance, Lexon or Medreich (or for Medreich to be a competitor to Alliance, Lexon or Focus). It is settled case-law that undertakings which are not active on the relevant market affected by a restriction of competition may be found to have participated in the relevant infringement where the conditions at paragraph 5.128 are met.[2640]

Shared objective

A.20 Advanz appeared to submit that, in addition to the conditions set out at paragraph 5.128 above, the CMA must also demonstrate that Focus *'shared'* the same alleged anti-competitive common objective as Alliance, Lexon and Medreich[2641] (or that it could reasonably have foreseen it and was prepared to take the risk).[2642]

A.21 As noted above, Focus' participation in the Market Exclusion Agreement is demonstrated by the fulfilment of the three conditions set out at paragraph 5.128 of this Decision. Specifically, it is Focus's intentional contribution – through its own conduct – to the common objective (see paragraphs 5.649 to 5.654) (and its state of awareness – see paragraphs 5.635 to 5.648) that renders it liable for the infringement as a whole. This is consistent with the case-law set out at paragraph 5.129 above and no additional requirement needs to be fulfilled to demonstrate Focus' participation in the Market Exclusion Agreement.

A.22 In this case, the CMA identifies a common objective (ie the implementation of the Market Exclusion Agreement (see paragraphs 5.631 to 5.634 of this Decision) and demonstrates that Focus had the requisite awareness of and has intentionally contributed to that common objective (see paragraphs 5.635 to 5.654 of this Decision). As the EU General Court held in *JFE Engineering*[2643] *'the fact that different undertakings have played different roles in the pursuit of a common objective does not mean that there was no identity of anti-competitive object.'*[2644].

A.23 As regards Advanz's submission that the CMA must demonstrate that Focus shared the same anti-competitive objective as Medreich, the CMA has

[2640] See for example, T-29/05 *Deltafina SpA v Commission* EU:T:2010:355, paragraphs 45 to 49; Case T-99/04 *AC-Treuhand v Commission* EU:T:2008:256; paragraphs 122, 127, 150.

[2641] Advanz RSO, 1 August 2019, paragraphs 3.15, 3.40, 3.48 to 3.55 (URN: PRO-C5111); Advanz RLF, 22 April 2021, paragraphs 2.26, 2.39-2.40, 2.48 (URN: PRO-C7112); Advanz RDPS, 7 July 2021, paragraphs 5.25-5.26 (URN: PRO-C7481).

[2642] Advanz RSO, 1 August 2019, paragraph 3.15 (URN: PRO-C5111).

[2643] Joined Cases T-67/00, T-68/00, T-71/00 and T-78/00 *JFE Engineering v Commission* EU:T:2004:221.

[2644] Joined Cases T-67/00, T-68/00, T-71/00 and T-78/00 *JFE Engineering v Commission* EU:T:2004:221, paragraph 370.

demonstrated that both Focus and Medreich had the requisite awareness of, and intentionally contributed to, the same objectives as Alliance and Lexon (see paragraphs 5.629 to 5.688).

A.24 The CMA has also considered carefully the evidence that Focus submits casts doubt on Focus pursuing the same objective as Alliance, Lexon and Medreich. Therefore, contrary to a submission from Advanz, the CMA has not 'assumed' a common objective.

Requirement to show agreement, joint intention or concurrence of wills

A.25 Lexon submitted that it was necessary for the CMA to prove that Lexon *'agreed with the three other parties'* not to enter *'the Prochlorperazine market'* in order for the CMA to prove the Market Exclusion Agreement.[2645] Alliance submitted that the CMA was required to provide evidence that Alliance, Focus, Lexon and Medreich *'each jointly intended to conduct themselves to pursue the objectives which are alleged in the SO.'*[2646]

A.26 Advanz also submitted that Chapter I CA98 does not apply unless *'there exists a concurrence of wills between the parties concerned'* [2647] and Focus shared *'one and the same **joint intention** as the other parties to conduct itself on the market in a specific anti-competitive way'* (emphasis in original).[2648]

A.27 To the extent that Lexon, Alliance and Advanz are seeking to assert in these submissions that fulfilment of the three conditions set out at paragraph 5.128 above would be insufficient to establish Focus and Medreich's participation in the Market Exclusion Agreement, the CMA considers that this is mistaken for the reasons set out at paragraphs 5.127 to 5.146 and A.20 to A.23 above.[2649]

Threshold to establish awareness

A.28 Advanz made representations regarding the test to establish that an undertaking has the requisite awareness to have participated in and be liable for an infringement. The CMA does not consider that these representations alter the test to be applied.

[2645] Lexon RSO, 31 July 2019, paragraph 5 (URN: PRO-C5091).

[2646] Alliance RSO, 1 August 2019, paragraph 2.1 (URN: PRO-C5096).

[2647] Advanz RSO, 1 August 2019 paragraph 3.39 (URN: PRO-C5111); Advanz RLF, 22 April 2021 paragraph 2.25 (URN: PRO-C7112).

[2648] Advanz RLF, paragraph 2.19 (URN: PRO-C7112).

[2649] To the extent that Lexon and Alliance are submitting that the CMA has not applied the correct legal framework to establish Lexon and Alliance's liability for the Infringement, this is also mistaken. The CMA has, in accordance with established precedent, found at paragraph 5.628 (based on the evidence set out in Chapter 5) and paragraphs 5.726 to 5.727 above that Lexon and Alliance entered into the Market Exclusion Agreement which had the object of restricting competition in the market for the supply of Prochlorperazine POM in the UK.

A.29 First, Advanz submitted that the EU Courts have annulled a number of European Commission decisions on the basis that the Commission failed to prove to the requisite standard the awareness of a participant in an infringement.[2650] However, the mere fact that the EU Courts have annulled a number of decisions of the European Commission is not of particular relevance to this case. Each of the decisions cited by Advanz turned on its particular facts and the court's assessment of the evidence which had been adduced by the Commission to support its finding of awareness.

A.30 Secondly, Advanz appeared to cast doubt on the inclusion of 'reasonable foreseeability' as part of the test for awareness[2651] based on statements by the Court of Appeal in *Argos & Littlewood*.[2652] However, the statements by the Court of Appeal in *Argos & Littlewoods* were expressed in the specific context of so-called 'ABC information exchange' (and in any event were *obiter* in that context).[2653] It is well-established in numerous European Court judgments[2654] that reasonable foreseeability is part of the test for awareness. Indeed, a number of the European Court judgments cited by Advanz in its submissions on awareness specifically refer to reasonable foreseeability as part of that test.[2655] The Court of Appeal in its judgment in *Balmoral Tanks* has also referred to reasonable foreseeability as part of the test for awareness.[2656]

A.31 Thirdly, while Advanz's submissions sometimes use terminology that suggest a different standard[2657] applies to establish awareness, Advanz itself accepts that reasonable foreseeability forms part of the legal test.[2658] In any event, the CMA has found at paragraphs 5.635 to 5.648 that Focus was aware, or could reasonably

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[2650] Advanz RSO, 1 August 2019, paragraphs 3.41, 3.60-3.80 (URN: PRO-C5111).

[2651] Advanz RSO, 1 August 2019, paragraph 3.59 (URN: PRO-C5111).

[2652] *Argos Limited and Littlewoods Limited, JJB Sports plc v Office of Fair Trading* [2006] EWCA Civ 1318, paragraph 91.

[2653] *Argos Limited and Littlewoods Limited, JJB Sports plc v Office of Fair Trading* [2006] EWCA Civ 1318, paragraph 91 *'That being so, we do not need to decide, in the context of the Football Shirts appeal , whether Mr Lasok's criticism of paragraph 659 of the Tribunal's judgment, referred to at paragraph [32] above, is justified . But it does seem to us that the Tribunal may have gone too far, in that paragraph, insofar as it suggests that if one retailer (A) privately discloses to a supplier (B) its future pricing intentions "in circumstances where it is reasonably foreseeable that B might make use of that information to influence market conditions" and B then passes that pricing information on to a competing retailer (C) then A, B and C are all to be regarded as parties to a concerted practice having as its object or effect the prevention, restriction or distortion of competition. The Tribunal may have gone too far if it intended that suggestion to extend to cases in which A did not, in fact, foresee that B would make use of the pricing information to influence market conditions or in which C did not, in fact, appreciate that the information was being passed to him with A's concurrence. This is not such a case on the facts.'*

[2654] See, for example, T-204/08 *Team Relocations v Commission*, EU:T:2011:286, paragraph 37; T-180/15 *Icap and Others v Commission* EU:T:2017:795, paragraph 100; and C-194/14 *AC-Treuhand v Commission* EU:C:2015:717, paragraph 30.

[2655] See, for example, Case C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission v Fresh Del Monte Produce*, EU:C:2015:416 paragraphs 158-159 cited in Advanz RSO at paragraph 3.57; Case T-208/06 *Quinn Barlo and Others v Commission*, EU:T:2011:701, paragraph 150 cited in Advanz RSO, 1 August 2019, paragraph 3.61 (URN: PRO-C5111). and Case T-180/15 *Icap and Others v Commission,* EU:T:2017:795, paragraphs 119-120 cited in Advanz RSO, 1 August 2019, paragraph 3.66 (URN: PRO-C5111).

[2656] *Balmoral Tanks Limited and Balmoral Group Holdings Limited v CMA*, [2019] EWCA Civ 162, paragraph 20.

[2657] See, for example, Advanz RSO, 1 August 2019 paragraphs 3.40, 3.58 (URN: PRO-C5111), where Advanz submits that the CMA should show that Focus *'knew or must have known'* when it participated in the Market Exclusion Agreement that in doing so it was joining in the overall cartel.

[2658] Advanz RSO, 1 August 2019, paragraph 3.56 (URN: PRO-C5111).

have foreseen it and was willing to take the risk, that Alliance and Lexon had entered into the Market Exclusion Agreement and of the conduct engaged in by Alliance, Lexon and Medreich in pursuit of the common objective.

A.32 Fourthly, Advanz appeared to submit that where an undertaking participates in some but not all of the anti-competitive conduct forming part of an infringement, in order to demonstrate that the undertaking has the requisite awareness, it is necessary to show that the various elements of the infringement are *'intrinsically linked'*, citing the EU General Court judgment in *Buchmann*.[2659] However, the EU General Court in *Buchmann* is not establishing an additional criterion that needs to be met in order to establish awareness and is merely rejecting a claim of the European Commission that two elements of the infringement (collusion on market shares and collusion on prices and downtime) were *'intrinsically linked'*.[2660]

Subject matter of awareness

A.33 Advanz submitted that it was not sufficient for the CMA to show that Focus had the requisite awareness in relation to the unlawful conduct planned or put into effect by Alliance and Lexon, and that it was also necessary for the CMA to show that Focus had the requisite levels of awareness in relation to unlawful conduct planned or put into effect by Medreich.[2661] The CMA does not accept that this is a necessary criterion. It is not necessary for each undertaking to be aware of the full detail of all the participants' activities in order to establish the necessary awareness, so long as each *'could not have been unaware of the general scope and the essential characteristics of the cartel as a whole'*.[2662]

A.34 As such, to establish that an undertaking participated in an infringement through application of the conditions at paragraph 5.128 above, it is not necessary to show that that undertaking was aware of the unlawful conduct of another undertaking which also participated in that infringement through application of those same conditions.

A.35 Nevertheless, in this case, the CMA has shown at paragraphs 5.637 to 5.648 that Focus was aware, or could reasonably have foreseen it and was willing to take the risk, of the unlawful conduct of Medreich in pursuit of the Market Exclusion Agreement (and indeed that Medreich was aware, or could reasonably have foreseen it and was willing to take the risk, of the unlawful conduct of Focus in pursuit of the Market Exclusion Agreement (see paragraphs 5.657 to 5.677).

[2659] Advanz RSO, 1 August 2019, paragraph 3.77 (URN: PRO-C5111).

[2660] T-295/94 *Buchmann v Commission*; EU:T:1998:88, paragraph 119.

[2661] Advanz RSO, 1 August 2019, paragraph 3.40 (URN: PRO-C5111); Advanz RLF, 22 April 2021, paragraphs 2.25-2.26 (URN: PRO-C7112).

[2662] T-259/02 to T-264/02 and T-271/02 *Raiffeisen Zentralbank Osterreich* v *Commission*, EU:T:2006:396, paragraph 193.

Annex B: Parties' representations on Events leading to the agreements

Creo Pharma

B.1 As stated above in paragraph 5.164, in early 2013, Alliance had also been exploring the option of launching its own generic Prochlorperazine POM (i.e. Option 1) and using Creo Pharma (a company described by Alliance as, like Focus, a 'specialty generics company'[2663]) to distribute that product.

B.2 Creo Pharma told the CMA that it had first discussed the potential distribution of Prochlorperazine POM (as well as a number of other products) with Alliance at a meeting on 28 February 2013.[2664]

B.3 While the CMA acknowledges that Creo Pharma has told the CMA that 'very little discussion' relating to Prochlorperazine POM took place after its inclusion in the original product list discussed on 28 February 2013,[2665] it is evident that [Alliance Employee 1] was actively considering Creo Pharma as an option for the distribution of a de-branded Prochlorperazine POM product. This is evidenced by the following documents which post-date the original inclusion in the product list:

B.3.1 An email from [Alliance Employee 1] to [Creo Pharma employee] on 9 April 2013 to discuss Lexon's entry into the market stating:

'I would also like to pick your brains regarding options for prochlorperazine now that Lexon are coming with a generic for both the 50 pack and the 8 pack in the 3mg. Is there a good time to talk?'[2666]

B.3.2 A further email from [Alliance Employee 1] to [Creo Pharma employee] on 8 May 2013 to inform him that '[l]ooks like we are going to launch prochlorperazine as a generic so there is potential to add this into the mix in a few months.'[2667]

B.3.3 Internal Alliance meeting notes from 13 May 2013 which record that, in relation to Prochlorperazine POM, [Alliance Employee 1] was

[2663] Section 26 response of Alliance, part 2, dated 16 November 2017, to CMA Notice dated 16 October 2017, paragraph 12 (URN: PRO-C0367). Alliance subsequently commented that this reference did not mean that Creo Pharma was an equally valid alternative to Focus in the case of distributing Prochlorperazine POM given the *'wide range of generics intermediaries'*, some of whom would be more suited to commodity generics (Alliance RLF, 29 April 2021, paragraphs 2.9-2.11 (URN: PRO-C7118)). In this respect, the CMA's finding is not that all distributors are identical – but more that Alliance considered it initially appropriate to place Focus and Creo Pharma into the same category as 'speciality generics companies'.

[2664] Section 26 response of Creo Pharma dated 17 October 2018, to CMA Notice of 4 October 2018, question 2(a) (URN: PRO-C2624).

[2665] Section 26 response of Creo Pharma dated 17 October 2018, to CMA Notice of 4 October 2018, question 2(d) (URN: PRO-C2624).

[2666] Email [Alliance Employee 1] to [Creo Pharma employee] entitled '*Meeting 22nd*' 9 April 2013 (URN: PRO-E000991).

[2667] Email [Alliance Employee 1] to [Creo Pharma employee] entitled *'Indapamide'* 8 May 2013 (URN: PRO-E000995).

'[p]rogressing launch of generic Prochlorperazine to combat the anticipated launch of competitor product by Lexon Prochlorperazine 3mg will potentially be marketed/traded through Creo Pharma'.[2668]

B.3.4 An email from [Alliance Employee 1] to colleagues at Alliance on 23 May 2013 stating that he was 'reviewing a contract regarding supply of a number of our generic portfolio to a specialist company (Creo)… The first product is … (others are expected to follow – … – prochlorperazine as and when)…'.[2669]

B.4 However, consistent with an agreement having been discussed at the Second Meeting between Alliance and Lexon, three days after [Alliance Director 2]'s email of 7 June 2013, an internal Alliance document on 10 June 2013 records, for the first time in 2013, the option of Alliance supplying Prochlorperazine POM through Focus rather than Creo Pharma. [Alliance Employee 2] emailed colleagues at Alliance to inform them that:

'We have a project ongoing to plan to react to the threat of a generic Prochlorperazine 3mg buccal entrant into the UK market. One of the options we are reviewing would be to cease manufacturing the branded 50s pack and drive all sales to a generic pack produced by Alliance but sold by another partner eg Focus.'[2670]

B.5 The CMA acknowledges that Alliance had previously discussed with Focus the possibility of Focus distributing Buccastem on behalf of Alliance during negotiations for a distribution agreement in 2011.[2671] However, the CMA has seen no evidence that Alliance seriously considered this approach at that time, nor is there any evidence that Alliance had any discussions with Focus regarding distributing the Prochlorperazine POM product in early 2013.

B.6 Alliance told the CMA that:

'*Creo were a contact of [Alliance Employee 1]'s and, by a coincidence of timing [Alliance Employee 1] was discussing with Creo at the time the events under discussion in 2013 a wholesale distribution relationship for one or two commodity genericised products.'*[2672]

B.7 Similarly, [Alliance Director 2] told the CMA that:

[2668] Community and Consumer Products Report, dated 13 May 2013, page 5 (URN: PRO-E001008).

[2669] Email [Alliance Employee 1] to various recipients at Alliance entitled '*Supply of stock to third party distributor'* 23 May 2013 (URN: PRO-E001005).

[2670] Email [Alliance Employee 2] to [Alliance employee] and others at Alliance entitled '*Buccastem*' 10 June 2013 (URN: PRO-E001010).

[2671] Email [Focus Director 2] to [Alliance employee] entitled *'Meeting Follow-up'* 20 June 2011 (URN: PRO-E001466).

[2672] Alliance RSO, paragraph 4.45 (URN: PRO-C5096).

'The fact that there is no record of this choice of Focus is explained by the fact that there was no need to record it. It would have been an easy choice to make. As I have explained above, the reality of our business environment is dynamic. We take governance processes seriously and address all commercial issues carefully, but we do not write down a decision or record a conversation unless there is a particular need to do so.'[2673]

B.8 In its representations, Alliance claimed that Creo was '*never seriously considered*' for the Prochlorperazine POM product in the first place.[2674] Alliance submitted that, among other things:

B.8.1 Alliance had a long-standing distribution agreement arrangement with Focus in respect of aspirin E/C and Alliance and Focus had previously discussed Focus distributing Prochlorperazine POM;[2675]

B.8.2 Prochlorperazine was 'barely discussed' with Creo, and then only tentatively;[2676] and

B.8.3 Focus was the party with whom Alliance had a relationship and Focus was well-known to, and trusted by, Alliance.[2677]

B.9 [Alliance Director 2] provided witness evidence that [Alliance Employee 1] was in parallel arranging for Creo to distribute [✂] generic products that had been subject to generic competition for some years. [Alliance Director 2] considered that the Alliance management team would not have regarded Creo as a serious candidate to distribute Prochlorperazine POM, having regard to the fact that Creo was a small company selling [✂] generic products, fulfilling orders and operating as a wholesaler. On that basis, if [Alliance Employee 1] had suggested using Creo to distribute Prochlorperazine POM, [Alliance Director 2] states he would have pointed out that they were not an appropriate choice to distribute a significant, newly de-branded product like prochlorperazine.[2678]

B.10 The CMA has considered the submissions of Alliance and [Alliance Director 2] as set out above in respect of Creo, but observes that:

B.10.1 the contemporaneous documentary evidence as set out in paragraph B.3 does suggest that Creo was considered a candidate to distribute Prochlorperazine POM: indeed at the time [Alliance Employee 1] described it as a 'specialist company'; the CMA places greater weight on

[2673] Witness Statement of [Alliance Director 2], paragraph 4.3, page 12 (URN: PRO-C5098)

[2674] Alliance RSO, paragraph 4.51 (URN: PRO-C5096); Alliance RLF, 29 April 2021, paragraph 1.5 and paragraphs 2.1 – 2.11 (URN: PRO-C7118).

[2675] Alliance RSO, paragraph 4.51(a) (URN: PRO-C5096).

[2676] Alliance RSO, paragraph 4.51(b) (URN: PRO-C5096).

[2677] Alliance RSO, paragraph 4.51(e) (URN: PRO-C5096).

[2678] Witness Statement of [Alliance Director 2], paragraph 4.5, page 13 (URN: PRO-C5098).

these contemporaneous documents as compared to the subsequent representations of [Alliance Director 2] and Alliance;

B.10.2 Alliance's distribution agreement arrangement in respect of Aspirin 300mg E/C was for a *'very small product'*, and yet Focus was used for this, therefore undermining any suggested distinction that Creo would be used for small products and Focus for large;[2679]

B.10.3 an email dated 29 April 2013 in respect of the de-branding of Alliance's Atarax product suggests that Alliance would contemplate supplying the recently de-branded product through Creo Pharma;[2680] and

B.10.4 Alliance had not previously supplied product to Focus in circumstances where Focus did not hold a marketing authorisation for a competing product, or where Focus was used to supply its product in competition with another supplier. The only product for which Alliance and Focus had entered into a supply agreement was Aspirin E/C 300mg, and pursuant to that agreement Focus had committed not to supply its own product and instead supply the Alliance product (see paragraph 5.284). That arrangement saw the competing Focus product exit from the market and Focus purchase all of its volume requirements from Alliance. In return, Focus obtained the benefit of the increased price charged for Alliance's de-branded generic product.

B.11 Given the consideration that was evidently given to the appointment of Creo, it is significant that Alliance took no steps to at the very least compare the terms on which Focus and Creo Pharma could have offered to supply Alliance's Prochlorperazine POM to the market.

B.12 This failure is consistent with the CMA's conclusion that [Alliance Employee 1] and [Lexon Director 1] met on 12 April 2013 and in May or June 2013 and proceeded to reach an agreement which involved the supply by Alliance of Prochlorperazine POM to Focus as part of a wider arrangement (namely, the Market Exclusion Agreement) in which Lexon was compensated for not competing with Alliance.

[2679] Interview [Focus Director 1], 2 October 2018, page 31, line 9 (URN: PRO-C3294).

[2680] Email [Alliance Employee 1] to [Alliance Director 2], cc [Alliance Director 1] and [Alliance Director 3] (all Alliance) entitled *'RE: Generic Atarax'* 29 April 2013 (URN: PRO-E004766). The CMA does not find persuasive Alliance's submission that [Alliance Director 2] was only suggesting that Atarax be raised with Creo, and that this does not suggest he considered Creo would be suitable to act as a distributor (Alliance RLF, 29 April 2021, paragraphs 2.7-2.8 (URN: PRO-C7118)); further, the fact that [Alliance Director 2]'s suggestion was not pursued and did not come to fruition does not mean that no inference can be drawn from his email: the evidence is relevant in so far as it clearly shows that [Alliance Director 2] did, at least at the time, and contrary to Alliance's representations and his own witness evidence, regard Creo as capable of managing the distribution of a newly de-branded product.

Annex C: Parties' representations on the Implementing Agreements

Alliance's representations on the CMA's comparative analysis of the margins afforded to Focus

C.1 Alliance criticise the CMA's comparison of the margins afforded to other distributors that have been used by Alliance to supply its products to wholesalers and pharmacies (see paragraph 5.283, Figure 3), on the basis that they are [✂] products for which generic competition already existed, and concern only four products.[2681] However, such issues do not undermine the significance of the comparison performed by the CMA.

C.1.1 The fact that the relevant products were [✂] does not undermine this comparison as, other things being equal, [✂] products would be expected to attract a higher percentage discount on the sales made to ensure that the distributors receive a sufficient pounds and pence margin to cover their costs. However, notwithstanding this point, the implied percentage margin being afforded to Focus was far in excess of the other distributors relevant to Figure 3.

C.1.2 Alliance's claim that the comparison is inappropriate given that other drugs faced competition is at odds with its own representations. Alliance claims that it forecasted generic competition to emerge almost immediately following the commencement of the Alliance-Focus Agreement (see paragraph 5.391) and also that the very purpose of that agreement was to enable it to compete effectively in a multi-source environment. It is entirely valid, therefore, for the CMA to contrast the margins earned by Focus on the sale of Prochlorperazine POM with those earned on other products that attracted generic competition. That comparison provides further confirmation that the relevant margins are inconsistent with those observed in situations where a distributor was appointed to better enable Alliance to compete with other suppliers, but consistent with the existence of the Market Exclusion Agreement and an intention to provide Focus with the means to compensate Lexon for its agreement not to enter the market.

C.1.3 Finally, it is noted that, on any basis, the margins afforded by Alliance to those entities involved in the distribution of its prescription medicines are far lower than the huge margins afforded to Focus in relation to the supply of Prochlorperazine POM.[2682] Whether one considers the margins afforded

[2681] Alliance RSO, paragraphs 3.25(d)(iv)-(v) and 5.14 (URN: PRO-C5096).

[2682] The only other circumstance in which such significant levels of margins have been paid to a distributor being the agreements concerning Aspirin 300mg, as discussed in paragraph 5.284.

to distributors/drugs that did not face generic competition, those that did face generic competition such as the products supplied by Creo, or the margins afforded to wholesalers by Alliance, it is only the agreement that involved a competing supplier committing not to supply its product that involved profit margins that are in any sense comparable with those observed in the Alliance-Focus Agreement.

C.2 Alliance also submitted that it is wrong to draw an analogy with the commercial arrangement reached between Alliance and Focus in relation to the Aspirin Agreement, because (i) [Focus Director 1][2683] stated that Focus had been no longer able to make the product and (ii) [Alliance Director 1][2684] has stated that it was a low profit product that may have otherwise been discontinued by Alliance.[2685] However in this respect:

C.2.1 Regarding point (i), the CMA observes that Alliance is not claiming to have been aware of this point at the time of the conclusion of the Aspirin Agreement, such that this factor cannot be relevant to Alliance's willingness to have conceded such a large margin to Focus. Indeed, there is no mention of it in Alliance's contemporaneous documents, and its own witnesses have not suggested that it played any role in Alliance's decision to permit Focus to retain such a significant margin on the supply of its product. Further, and for completeness, it is noted also that [Focus Director 1]'s claim is itself inconsistent with the evidence that Focus was (and Alliance understood Focus was) already distributing its unbranded product at the time.[2686]

C.2.2 As regards point (ii), the CMA understands Alliance's submission to be that, because it may have otherwise exited the market, this explains its willingness to offer a higher margin to Focus to supply only the Alliance product and not to supply its own product. The CMA observes therefore that, even if it were accepted that this was the basis on which the Aspirin Agreement was entered into, it would not be inconsistent with the CMA's findings that such substantial margins have been observed only where another MA holder has agreed not to supply its product, as it would imply that this was a factor in the margin afforded to Focus.

[2683] [Focus Director 1] stated that *'… though we could originally … manufacture from it, … as all the regulations tightened up, we … couldn't. And to … rework the licence actually wasn't feasible, so … we would've actually discontinued'* (Interview [Focus Director 1], 2 October 2018, page 33, lines 5 to 8 (URN: PRO-C3294)).

[2684] [Alliance Director 1] stated in his witness statement that '*APL chose to debrand its branded aspirin product (Nu-Seals) because the income generated by Nu-Seals made continuing sales of the branded product commercially non-viable within the constraints of PPRS pricing (which, of course, only applied to branded products). There was a risk that we may have discontinued the Nu-Seals brand*' ([Alliance Director 1] Witness Statement of 29 July 2019, paragraph 5.2 (URN: PRO-C5097)).

[2685] Alliance RSO, 1 August 2019, paragraphs 5.30 to 5.32 (URN: PRO-C5096).

[2686] The Alliance strategy meeting presentation of 29/30 June 2011 shows on slide 49 that Focus was supplying generic Aspirin E/C 300mg at that point (Alliance presentation entitled '*Strategy Meeting EPBU [Alliance employee]*' 29/30 June 2011, slide 49 (URN: PRO-E000932)).

C.2.3 Finally, and for completeness, it is observed that the contemporaneous documents (see paragraph 3.70) refer to the increases in profits that could be secured by supplying Focus with its product rather than supplying its product in competition with Focus, and do not refer to Alliance having otherwise decided to withdraw its product.

C.3 Alliance submitted that the adoption of a fixed price for the distribution of Prochlorperazine POM by Focus was consistent with its expectation that prices would fall after an initial period, and that a central benefit of the fixed price that it adopted was that it transferred the risk of price/margin volatility to Focus.[2687] The CMA observes though that, while the adoption of a fixed price denied Alliance a share of any price increases, it did not insulate it from the risks of increased competition. As [Alliance Employee 1] and [Alliance Director 2] observed, in the hypothetical scenario in which prices had decreased due to the onset of competition, Focus would have needed to renegotiate the supply price and Alliance would have done so.[2688]

C.4 Alliance stated that if it had been comfortable in the knowledge that it had eliminated the only prospective entrant, capping its share of future anti-competitive profits would have been a non-sensical decision as compared to demanding a share of the profit margins.[2689] The CMA observes that the arrangement adopted by Alliance and Focus ensured that Focus had sufficient scope to inflate the price and make substantial payments to Lexon during the course of the agreement, while ensuring that Alliance was able to preserve the profits it had earned as the monopoly supplier of the product. Such an approach was a highly effective means of sharing in the monopoly profits earned from the supply of the Alliance product, and ensured that Alliance, and Lexon/Medreich, earned significant profits. While it is possible that Alliance could have achieved a similar result by agreeing to retain a particular share of the Focus net profits, whilst allowing Focus a sufficient margin to be able to compensate Lexon, its decision not to do so does not undermine the CMA's findings regarding the basis upon which Alliance agreed to cap its own price at the same time as it de-branded its product.

Advanz's representations on the existence of an exclusivity obligation on Focus in the Alliance-Focus Agreement

C.5 In its representations on the Statement of Objections, Advanz submitted that Alliance and Focus did not specifically negotiate and agree the exclusivity obligation on Focus, they did not intend to be bound by it and they did not consider themselves bound by it, as evidenced by the fact that Focus actively sought to

[2687] Alliance RLF, 29 April 2021, paragraph 2.18 (URN: PRO-C7118).

[2688] Interview [Alliance Employee 1], 4 October 2018, part 1, page 63, lines 21-24 (URN: PRO-C2909) and Interview [Alliance Director 2], 5 October 2018, page 53, lines 17-23 (URN: PRO-C2941).

[2689] Alliance RLF, 29 April 2021, paragraph 2.18 (URN: PRO-C7118).

source Prochlorperazine POM from Lexon notwithstanding the exclusivity clause.[2690] Advanz provided a number of explanations for its view that the exclusivity obligation on Focus had not been agreed between Alliance and Focus, but the CMA finds that none of these is compelling. Specifically:[2691]

C.5.1 Advanz observes that the exclusivity obligation was part of the existing agreement relating to Aspirin 300mg E/C and that it is not clear that Focus intended to abide by it in relation to Prochlorperazine POM.[2692] However, in addition to the plain reading of the clause itself, Focus did in fact abide by the restriction, save for the one batch of Lexon product required to be sold for the purpose of the Sunset Clause. Further, although Alliance and Focus specifically agreed a number of amendments to the existing agreement when they signed the addendum dated 22 August 2013, these amendments did not include any change to the exclusivity obligation.[2693]

C.5.2 The CMA does not accept Advanz's submission that the agreement of the exclusivity obligation on Focus was illogical and inconsistent with the Market Exclusion Agreement given that Lexon had already agreed with Alliance not to bring its Prochlorperazine POM product to market. To the contrary, the CMA finds that the Alliance-Focus Agreement was complementary to the Market Exclusion Agreement in ensuring that the Lexon product would not be commercialised: the Alliance-Focus Agreement implemented the Market Exclusion Agreement as agreed in principle between Alliance and Lexon.

C.5.3 Advanz submitted that the evidence of [Alliance Employee 1] shows that Alliance did not consider that the exclusivity obligation on Focus reflected Alliance's and Focus's joint intention.[2694] The CMA does not accept this. The fact that [Alliance Employee 1] said that adding Prochlorperazine POM to the existing agreement was the '*easiest thing to do*' and that he did not spend a long time considering the legal terms[2695] does not detract from the fact that the agreement did contain the clause, and that was not amended by Alliance and Focus (see sub-paragraph C.5.1 above); further,

[2690] Advanz RSO, paragraph 5.4.5 and paragraphs 5.110-5.111 (URN: PRO-C5111).

[2691] The CMA rejects Advanz's submission that Focus actively sought to source Prochlorperazine POM from Lexon notwithstanding the exclusivity clause (Advanz RSO, paragraph 5.110.3 (URN: PRO-C5111)): see paragraphs 5.598 to 5.602, 5.605 to 5.608 and 5.612 to 5.615, inclinding in particular 5.614.3).

[2692] During the course of the Market Exclusion Agreement, Focus received only one batch of Lexon product and sold it into the market from August 2018 (Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, question 2(c) and 2(f) (URN: PRO-C3149) and Annex (URN: PRO-C3150)).

[2693] Section 26 response of Alliance, part two, dated 16 November 2017, to CMA Notice dated 2 October 2017, Appendix 2, Alliance-Focus Agreement (URN: PRO-C0369).

[2694] Advanz RSO, paragraph 5.110.6 (URN: PRO-C5111).

[2695] Interview [Alliance Employee 1], part 2, page 34, line 2 and page 37 lines 3 to 11 (URN: PRO-C2910).

[Alliance Employee 1] also confirmed that it was reasonable to expect Focus not to sell other products.[2696]

C.5.4 The CMA does not accept Advanz's submission that it is relevant that Alliance did not seek to enforce the exclusivity clause when Focus purchased product from Lexon in March 2018.[2697] The CMA finds that Alliance and Lexon agreed pursuant to the Market Exclusion Agreement that Lexon would produce one batch of product to avoid the application of the Sunset Clause (see paragraphs 5.194 and 5.270). It was therefore not in Alliance's interest to enforce the clause at this time. Nor does the CMA accept Advanz's submission that it is relevant that Alliance did not seek to enforce the exclusivity clause when, Advanz claims, Focus' successor took steps to bring its own product to market pursuant to the Primegen MA: this is because the CMA has found that AMCo in fact decided to use the Primegen licence as leverage with Lexon rather than manufacturing and supplying its own product onto the market (see paragraphs 5.490 to 5.507) such that there would have been no need for Alliance to enforce the exclusivity clause against Focus.[2698]

C.5.5 Advanz submitted that an internal Alliance forecast email showed that Alliance did not consider the exclusivity clause to be binding on Focus.[2699] However, the fact that [Alliance Employee 1] contemplated Focus not '*tak[ing] [Alliance Prochloperazine POM] for whatever reason*' does not show that Alliance contemplated (let alone endorsed) Focus selling product from another competing supplier.

C.5.6 The CMA finds that Advanz's submission[2700] that the existence of the exclusivity clause is impossible to reconcile with the CMA's claim that the Market Exclusion Agreement between Alliance and Lexon envisaged that Lexon and Medreich would supply Prochlorperazine POM to Focus to avoid the application of the Sunset Clause is without substance. Whilst sale by Focus of this one Lexon batch would have been a technical, albeit non-material breach,[2701] it was foreseen as part of the Market Exclusion

[2696] Interview [Alliance Employee 1], part 2, page 37 lines 10 to 11 (URN: PRO-C2910). The CMA also rejects Advanz's submission that the comments made by [Alliance Employee 1] and [Alliance Director 2] about the potential re-negotiability of the Alliance-Focus Agreement mean that exclusivity had not been agreed (Advanz RSO, paragraph 5.110.6(a) (URN: PRO-C5111). The Alliance comments about re-negotiability referred to duration or pricing of the agreement, rather than exclusivity, and are not informative, in any event, of whether exclusivity had previously been agreed.

[2697] Advanz RSO, paragraph 5.110.6 (URN: PRO-C5111).

[2698] Advanz RSO, paragraph 5.110.6 (URN: PRO-C5111). This also answers Advanz's claim that the evidence around the Primegen development shows that neither Focus nor its successors intended to respect or considered themselves bound by the exclusivity clause (Advanz RSO, paragraph 5.110.4 (URN: PRO-C5111)).

[2699] Advanz RSO, paragraph 5.110.6(d) (URN: PRO-C5111) citing email [Alliance Employee 1] to [Alliance employee] entitled '*RE: Focus Aspirin & Prochloperazine Forecast – March 2014*' 19 March 2014 (URN: PRO-E001113).

[2700] Advanz RSO, paragraph 5.110.7 (URN: PRO-C5111).

[2701] Lexon delivered to Focus a batch of [✂] packs in March 2018, as compared to 185,034 packs dispensed in 2017 and 164,510 in 2018 (see paragraph 4.223 and Table 1).

Agreement (see paragraph 5.194 above) and was therefore permitted by Alliance.

C.6 On the basis of the above, the CMA finds that the Alliance-Focus Agreement contained a contractual prohibition on Focus supplying any other source of Prochlorperazine POM other than that sourced from Alliance. This is consistent with the terms of the Market Exclusion Agreement, namely that Lexon would not enter the market with the product it had developed with Medreich other than as regards the one batch required to avoid the application of the Sunset Clause.

Annex D: Parties' representations on subsequent conduct – Lexon

[Lexon Director 1]'s claims about the relative profitability of launching the Medreich product, rather than receiving profit share from Focus pursuant to the Market Exclusion Agreement, are not borne out

D.1 [Lexon Director 1] provided modelling in his witness statement to support his claim that, in June 2013, it would have been '*unquestionably in Lexon's best interests to proceed with the launch of the Medreich Prochlorperazine POM product as soon as possible*', rather than to be party to the Market Exclusion Agreement.[2702]

D.2 [Lexon Director 1]'s modelling assumed that Lexon, as the first generic entrant, would gain a 60% share of the market and would make a monthly profit of £[✂] (to be split with Medreich) based on Focus selling the product to the market at £5.65 and based on a Medreich cost price of £[✂].[2703] [Lexon Director 1] contrasted this with Lexon's monthly profit share receipts for the period Q1 2014 from Focus of £38,593.70,[2704] with the suggestion that Lexon would therefore have made some £[✂] more per month had it been able to launch the Medreich product.[2705]

D.3 The CMA has considered [Lexon Director 1]'s representations in his witness statement. For the reasons set out below, the CMA finds that the factors set out by [Lexon Director 1] cannot credibly have justified any belief on his part in either June 2013 (that is, the date on which Lexon entered into the Market Exclusion Agreement) or February 2014 (that is, the date on which he informed Medreich that Prochlorperazine POM was '*best left alone as we make far much [sic] more as it is*'[2706]) that it would have been more profitable for him to launch the Medreich product than to share Focus' monopoly profits on the sale of the Alliance product.

D.3.1 First, [Lexon Director 1]'s calculations do not properly account for the price rises that would have been expected to take place (and indeed, did take place) under the Market Exclusion Agreement in the absence of competition. [Lexon Director 1]'s analysis refers to the profit share payment of £115,781.11 that Lexon received in respect of sales made by Focus in the first quarter of 2014, equivalent to £38,593.70 per month.[2707] Yet, as [Lexon Director 1] acknowledges,[2708] the de-branding of the

[2702] [Lexon Director 1] Witness Statement of 31 July 2019, paragraphs 59-63 (URN: PRO-C5092).

[2703] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 62(b) (URN: PRO-C5092).

[2704] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 64, citing the figure of £115,781.11 for Q1 2014 (URN: PRO-C5092). See Annex I:.

[2705] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 64 (URN: PRO-C5092).

[2706] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*RE: Products*' 4 February 2014 (URN: PRO-E002750).

[2707] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 64 (URN: PRO-C5092).

[2708] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 62(a)(ii) (URN: PRO-C5092).

Alliance product allowed Focus to raise prices. The Market Exclusion Agreement meant that these price rises would be unconstrained by any competition from Lexon/Medreich, such that the assessment of the analysis [Lexon Director 1] would have undertaken in June 2013 (that he seeks to replicate in his witness statement) would inevitably have considered the increased profits that Lexon/Medreich would earn in later periods as prices rose. The following points are relevant in this respect.

D.3.2 Elsewhere in his witness statement, [Lexon Director 1] stated that, upon learning of Alliance's intention to de-brand he 'knew this would result in Alliance/Focus increasing the price for its Product **substantially** since many other manufacturers had taken similar action in relation to other medicines in recent years' (emphasis added).[2709]

D.3.3 [Lexon Director 1] stated that he would have expected any price increase to be limited to the then pro rata price of the OTC product, namely £22.88 for the 50 pack.[2710] However, even at this price level (which was in fact subsequently exceeded by Focus, see Figure 2), Lexon's monthly profits under the Market Exclusion Agreement (and the 25/75% split originally reflected in the Focus-Lexon Heads of Terms) would have been £258,450[2711] – many multiples more than [Lexon Director 1]'s modelled profit of £[✂] based on sales of the Medreich product (see paragraph D.2 above).[2712]

D.3.4 More generally, [Lexon Director 1] has entirely disregarded the evidence relating to the increased payments that he stated he would have foreseen (based on his pricing expectations described above) and that he went on to receive in the years after the Q1 2014 period on which he has focussed his analysis. As early as Q3 2014, Lexon's quarterly profit share receipts had already increased to £202,329 (£67,443 per month) and by Q4 2015 they had reached £633,011 (£211,003 per month), which far exceed the

[2709] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 72 (URN: PRO-C5092).

[2710] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 62(a)(ii) (URN: PRO-C5092).

[2711] Based on a Focus sale price of £22.88, a supply price to Alliance of £5.65 (as per the Alliance-Focus Agreement (URN: PRO-C0369)), 20,000 packs per month (as per [Lexon Director 1]'s assumptions in his Witness Statement of 31 July 2019, paragraph 62(b) (URN: PRO-C5092)), and Lexon receiving 75% profit share from Focus (as per the Focus-Lexon Heads of Terms (URN: PRO-E000429)).

[2712] If the sale price had risen to £11.20, as [Focus Director 1] had anticipated in his email of 18 July 2013 (Email [Focus Director 1] to [Focus Director 2] entitled '*Prochlorperazine 3mg Tabs*' 18 July 2013 (URN: PRO-E001478)), this would have equated to a Lexon monthly profit of £83,250 (based on, other than sales price, the same assumptions as in footnote 2711), significantly more than [Lexon Director 1]'s modelled profit of £[✂]. For completeness, in his 18 July 2013 email, [Focus Director 1] had modelled Focus' monthly profit as £34,845 (for a 25% share), meaning Lexon's profit (for a 75% share) would be £104,535. The difference in the two profit figures is explained by the use of a different supply price and monthly sales volume: on 18 July 2013 [Focus Director 1] had assumed a supply price of £5.68 rather than £5.65 and a monthly volume figure of 25,250 rather than 20,000.

profits from launching the Medreich product that [Lexon Director 1]'s modelling predicts.[2713]

D.3.5 Whilst [Lexon Director 1] stated that he would have expected price increases to take place over a period of between two to three years,[2714] it is clear that only a small increase in price would mean that Lexon's profits from the Market Exclusion Agreement would exceed the monthly figure of £[✂] [Lexon Director 1] says he would have modelled as regards the launch of the Medreich product. Based on [Lexon Director 1]'s assumptions set out in his witness statement,[2715] Lexon's profits under the Market Exclusion Agreement would have exceeded this level when the Focus price rose above £[✂][2716] – and this was achieved by Focus in [✂] 2014,[2717] with the result that Lexon's actual profits for the quarter period Q3 2014 exceeded [Lexon Director 1]'s modelled level at £202,329, equivalent to a monthly profit of £67,443.

D.3.6 Second, [Lexon Director 1]'s modelling of the scenario in which Lexon entered with sales of the Medreich product does in any case include an unrealistic assumption as regards the sales price. [Lexon Director 1]'s modelling in his witness statement prepared for the purposes of this investigation assumed, under conditions of competition (that is, Lexon/Medreich selling through Focus and competing with the Alliance product), a Focus sales price for the Medreich product of £5.65.[2718] However:

(a) this price level is unrealistically optimistic, as it does not take account of any price *decrease* likely resulting from competition between the Alliance and Lexon/Medreich product;[2719] and

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[2713] See Annex I:.

[2714] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 62(a)(ii) (URN: PRO-C5092).

[2715] That is, a supply price to Alliance of £5.65, 20,000 packs per month, and Lexon receiving 75% profit share from Focus ([Lexon Director 1] Witness Statement of 31 July 2019, paragraph 62(b) (URN: PRO-C5092)).

[2716] At a Focus sales price of £[✂], a supply price to Alliance of £5.65, 20,000 packs per month, and Lexon receiving 75% profit share from Focus, Lexon would have made £[✂] per month, above the £[✂] figure quoted by [Lexon Director 1] in his witness statement.

[2717] Based on Section 26 response of Advanz dated 21 December 2018, to CMA Notice of 11 December 2018, Question 1 and Annex 1 (URN: PRO-C3149 and URN: PRO-C3150).

[2718] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 62(b) (URN: PRO-C5092).

[2719] In his witness statement, [Lexon Director 1] stated in respect of the calculation under which he launched the Medreich product that '*Assuming I had knowledge of the Focus/Alliance plan to debrand Buccastem, the profit calculation was likely to be higher as Focus/Alliance increased their prices*' ([Lexon Director 1] Witness Statement of 31 July 2019, paragraph 62(b)(i) (URN: PRO-C5092)). He later makes the same point in paragraph 64: '*This is £[✂] less than Lexon would have made under the second option set out in paragraph 61(b) above without taking account of the price increases which took place following Focus/Alliance decision to debrand Buccastem in December 2013.*' In both cases, [Lexon Director 1] ignores the fact that the price increases implemented by Focus in respect of the de-branded Alliance product would not have been expected had the Lexon/Medreich product entered in competition with Alliance. Lexon further commented that '*[Lexon Director 1] would have assumed that by debranding the price of Prochlorperazine was bound to increase. Accordingly, the assumption that the price would remain at £5.65 notwithstanding the presence of competition from Alliance was a conservative assumption*' (Lexon submission dated 10 December 2019, in response

(b) by way of evidence of the above, when [Lexon Director 1] had in fact modelled the launch of the Prochlorperazine POM tablets for his own purposes in 2012, he had assumed a competitive sales price of £2.95 as compared to a cost price of £[✂] (based on a scenario of two MA holders, including Medreich).[2720]

D.3.7 Third, [Lexon Director 1]'s modelling of the scenario in which Lexon entered with sales of the Medreich product includes an unrealistic assumption as regards the market share that Lexon would achieve. [Lexon Director 1] assumed in his witness statement modelling that Lexon would gain a 60% market share (despite offering no discount) on the basis that 40% of the market was made up of branded prescriptions, leaving 60% of the market available to Lexon as the first generic supplier to market.[2721] However:

(a) it does not follow from the fact that 40% of prescriptions were branded that Lexon would take the entirety of the remaining 60% of the market: in addition to being guaranteed the 40% of branded sales (if Alliance retained its branded product), Alliance would have been able to compete with Lexon for the 'open' prescriptions for generic Prochlorperazine POM (with either a branded or an unbranded product) given that an 'open' generic prescription can be fulfilled by a branded or generic product (see paragraph 5.361); and

(b) by way of evidence of the above, when [Lexon Director 1] actually had modelled the launch of the Prochlorperazine POM tablets for his own purposes in 2012, he had in fact assumed that Lexon/Medreich would achieve a 35% market share;[2722] this share level appears more realistic given that there is no reason why Lexon would have assumed in 2013 that Alliance would not contest those sales or would have

to CMA questions of 26 November 2019, question 5 (URN: PRO-C5477)). However, there is no basis to conclude that price competition between the Alliance and Lexon/Medreich products would not have brought the price to a level below £5.65 (consistent with [Lexon Director 1]'s own modelling from 2012: see paragraph D.3.8 and note 2720).

[2720] Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine and Bisoprolol*' 31 May 2012 (URN: PRO-E002538), and attached Excel spreadsheet entitled '*lexon medreich generics new line forcasts.xlsx*' by [Lexon Director 1] dated 31 May 2012 (URN: PRO-E002539).

[2721] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 60(e) (URN: PRO-C5092). [Lexon Director 1]'s reference to comments made by [Alliance Employee 1] in his interview do not appear relevant in this context given that [Lexon Director 1] was providing evidence on what *he* would have understood to be the position in June 2013 ([Lexon Director 1] witness statement paragraph 62(b), footnote 30 (URN: PRO-C5092)).

[2722] Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine and Bisoprolol*' 31 May 2012 (URN: PRO-E002538) and attached Excel spreadsheet entitled '*lexon Medreich generics new line forcasts.xlsx*' by [Lexon Director 1] dated 31 May 2012 (URN: PRO-E002539). In earlier email correspondence with Medreich in January 2012, [Lexon Director 1] had stated in respect of Lexon/Medreich's anticipated entry in the supply of Prochlorperazine POM, *'I would anticipate gaining 40% of the market as if we went for more price erosion would make it less profitable*' (Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine Maleate*' 20 January 2012 (URN: PRO-E002509)).

believed that Lexon would obtain the entirety of the 'open' prescriptions.

D.3.8 Fourth, [Lexon Director 1]'s own contemporaneous modelling in 2012 envisaged an actual total estimated profit per month of £[✂] for Prochlorperazine POM (based on monthly market size of 12,917 packs);[2723] this would therefore subsequently have equated to a monthly profit of £[✂] for Lexon (given its 75% share under the Focus-Lexon Heads of Terms). To the extent that [Lexon Director 1]'s own 2012 modelling (that is, a £2.95 sale price, 35% market share and £[✂] cost) is adjusted for the increase in market size from 2012 to 2013 (from 12,917 packs to 20,000 packs per month), this would still have resulted in a total profit per month for the Lexon/Medreich product of only £[✂] (equivalent to a Lexon 75% profit share of £[✂]). These figures are significantly below even the initial profit share figures actually received by Lexon from Focus in Q1 2014 (equating to £38,593.70 per month) under the Market Exclusion Agreement, as quoted by [Lexon Director 1] in his witness statement.[2724]

D.4 Given the points set out above, whilst [Lexon Director 1] quotes Lexon's initial actual profit share receipts of £115,781.11 from Focus for Q1 2014 in his witness statement (equivalent to £38,593.70 per month)[2725] and submits that this is less than the £[✂] per month profit he models in his witness statement based on an entry scenario with the Medreich product, this comparison is misleading given that:

D.4.1 [Lexon Director 1]'s witness statement modelling, prepared for the purpose of this investigation, includes flawed assumptions (as set out in paragraph D.3 above) regarding both the price and market share levels that could have been achieved on launching the Medreich product; and

D.4.2 when modelling the profitability of the Market Exclusion Agreement, [Lexon Director 1] failed to account of the price increases that he foresaw and their impact on the profit share payments that Lexon would receive from Focus; in practice (see paragraph D.3.1) the profit share payments Lexon received very quickly exceeded the profits that [Lexon Director 1] suggests could have been realised from launching the Medreich product.

[2723] Email [Lexon Director 1] to [Medreich Director 2] cc [Medreich Employee 1] entitled '*RE: Prochlorperazine and Bisoprolol*' 31 May 2012 (URN: PRO-E002538) and attached Excel spreadsheet entitled '*lexon Medreich generics new line forcasts.xlsx*' by [Lexon Director 1] dated 31 May 2012 (URN: PRO-E002539).

[2724] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 64 (URN: PRO-C5092).

[2725] [Lexon Director 1] Witness Statement of 31 July 2019, paragraph 64 (URN: PRO-C5092).

Annex E: Parties' representations on subsequent conduct – Focus

Alliance's lack of involvement in the profit share re-negotiations between Focus and Lexon does not undermine the existence of the Market Exclusion Agreement

E.1 The CMA has considered representations made by Advanz,[2726] Cinven[2727] and Alliance[2728] that the lack of any involvement by Alliance in relation to the profit share renegotiations between Focus and Lexon (whether the first renegotiation concluded in November 2014 and/or the second renegotiation concluded in February 2016) undermine the CMA's conclusion relating to the existence of a Market Exclusion Agreement between Alliance and Lexon under which value would be transferred from Alliance to Lexon through Focus in return for Lexon not entering the market with the Prochlorperazine POM product it had developed with Medreich.

E.2 Advanz submits that, in respect of the November 2014 profit share renegotiation, '*it is implausible that Focus would have had the freedom to negotiate it down, either at all or without conferring with Alliance. The CMA does not […] explain why […] Alliance had no direct or indirect control over the amounts that were being paid to Lexon and why there is no evidence of any communications between Focus and Alliance or between Lexon and Alliance in respect of the same'*.[2729] Cinven stated that '*on the CMA's case, the apportionment of the profit share in the [Focus-Lexon] Heads of Terms was an Alliance-Lexon matter, since this was the mechanism by which Alliance obtained Lexon's agreement not to enter*'.[2730]

E.3 Advanz made the same submission in respect of the second (Primegen) profit share renegotiation, also noting that there was no evidence that AMCo/Focus or Lexon had informed Alliance of the Primegen development or (subsequently) that the competitive threat that this could have posed to the Market Exclusion Agreement had been neutralised by means of the second profit share renegotiation.[2731] Advanz submitted that if the second profit share renegotiation

[2726] See Advanz RSO, 1 August 2019, paragraph 3.212 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraph 4.121 (URN: PRO-C7112).

[2727] See Cinven RSO, 15 August 2019, paragraph 4.58 and paragraphs 4.171-4.173 (URN: PRO-C5132) and Cinven RLF, 22 April 2021, paragraphs 1.9(c), 1.9(d) and 2.57 (URN: PRO-C7107).

[2728] Alliance RLF, 30 November 2021, paragraph 3.13(b) and paragraph 5.15 (URN: PRO-C7914), stating that there was no indication that Alliance was involved in, or briefed about, the subject matter of the 2014 Correspondence (including the November 2014 profit share amendment) and that Focus (and AMCo) did not use the Primegen product as leverage over Alliance to secure better supply terms despite, on the CMA's case, Alliance being an integral party to the Market Exclusion Agreement.

[2729] Advanz RSO, 1 August 2019, paragraph 3.212 (URN: PRO-C5111).

[2730] Cinven submission dated 10 December 2019 in response to the CMA's follow-up questions of 26 November 2019 to Cinven Oral Hearing, paragraph 1.18 (URN: PRO-C5479).

[2731] Advanz RLF, 22 April 2021, paragraph 4.119.1-4.119.2 (URN: PRO-C7112).

had had anything to do with the Market Exclusion Agreement, Alliance would have known about it, participated in it, and taken steps to neutralise any risk of competitive threat from Focus in order that the Market Exclusion Agreement remained intact.[2732] Advanz[2733] submitted that, in fact, AMCo was unable to secure better commercial terms from Alliance, as shown by the fact that just a few months earlier in 2015 Alliance had raised its supply price from £5.65 to £6.10 from April 2015 – a fact which, Cinven[2734] noted, was not apparently queried by [Focus Director 1]'s colleagues.

E.4 The CMA does not accept Advanz's, Cinven's and Alliance's submissions in this respect, and finds that the lack of Alliance's involvement in the two sets of profit share renegotiations between Focus and Lexon does not undermine the existence of the Market Exclusion Agreement, based on the reasoning set out below.

E.5 The CMA has found (see paragraph 5.270 above) that, pursuant to the Focus 22 June 2013 email,[2735] [Lexon Director 1]'s agreement with Alliance of the margin that Alliance retained, and that Focus could earn, reflected a common understanding between Alliance and Lexon that the terms on which Alliance supplied Focus would impact upon the remuneration that Lexon would in turn receive. Further, pursuant to the [Alliance Director 1] notebook entry and its reference to Lexon using '*Focus to distribute*',[2736] the CMA has inferred that there was a common understanding between Alliance and Lexon that Focus would serve as the vehicle for Lexon to be paid (see paragraph 5.270 above).

E.6 The CMA has not found, nor has it needed to find for the purpose of establishing the Market Exclusion Agreement, that Alliance was aware of, or agreed to, the precise terms of the profit-sharing agreement reached by Focus and Lexon (see paragraph 5.272); it is sufficient that Alliance knew that profit on the sales of its product would be shared with Lexon as compensation for Lexon not entering the market with the product it had developed with Medreich (see paragraph 5.271). Whilst [Focus Director 1]'s email to [Focus Director 2] of 22 June 2013[2737] refers to the '*25/75 % profit share in Lexon favour (as it is his licence)*', this is in a separate paragraph to that starting '*[Focus Director 2] In case [Alliance Employee 1] rings you , [sic] the agreement [Lexon Director 1] made […]*'. It is therefore not clear on the face of the note whether the agreement between [Alliance Employee 1] and [Lexon Director 1] extended to the level of the profit share split between Focus and

[2732] Advanz RLF, 22 April 2021, paragraph 4.122 (URN: PRO-C7112).

[2733] Advanz RLF, 22 April 2021, paragraph 4.119.3 (URN: PRO-C7112), and see paragraph 3.175.

[2734] Cinven RSO, 15 August 2019, paragraph 4.173 (URN: PRO-C5132).

[2735] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

[2736] [Alliance Director 1] Notebook entry CXH005 page 36 (URN: PRO-E003980).

[2737] Email [Focus Director 1] to [Focus Director 2] entitled '*Fwd: Prochlorperazine IMS*' 22 June 2013 (URN: PRO-E001476).

Lexon, or whether the 25% / 75% split had been separately agreed between Focus and Lexon.

E.7 Given the above, the CMA does not consider it probative, or indeed surprising, that it does not have evidence that Alliance was involved in the subsequent profit share renegotiations between Focus and Lexon. This is because, provided that Lexon was compensated for and therefore refrained from entering the market such that Alliance's sales volumes and its prior price were protected (consistent with the terms of [Focus Director 1]'s 22 June 2013 email), the precise commercial terms agreed between Focus and Lexon, including the level of the profit share split, was not a matter that would directly concern or impact Alliance (in contrast to the level of the Alliance to Focus supply price, which would impact on the profits payable to Lexon – see paragraph 5.271 above). As a result, there was no need or reason for Alliance to have been involved, either originally or subsequently, in setting or indeed adjusting the level of the profit share split between Focus and Lexon.

E.8 With respect to the second profit share renegotiation, specifically, the CMA does not accept Advanz's submission[2738] that the evidence relied on the CMA for the purpose of establishing the Market Exclusion Agreement, and Focus' awareness of it, is undermined by an absence of evidence that AMCo/Focus or Lexon had informed Alliance of the Primegen development or (subsequently) that the competitive threat that this could have posed to the Market Exclusion Agreement had been neutralised by means of the second profit share renegotiation. In fact, the CMA has found that Alliance was aware of the Primegen development (see paragraph 5.399). But, in any event, given the evidence and analysis set out above, it is not necessary for the CMA to show that Focus or Lexon had communicated to Alliance the fact of the second profit share renegotiation or the consequences of it.

E.9 The CMA does not consider that the absence of evidence showing that AMCo/Focus sought to renegotiate the price for the supply of product from Alliance to Focus is inconsistent with the existence of the Market Exclusion Agreement:

E.9.1 the potential for AMCo/Focus to seek to renegotiate the supply price between Alliance and Focus as a response to AMCo acquiring the Primegen licence development is implicit within [Focus Director 1]'s statement in his email to [Focus Director 2] in June 2015: '*[sic] If they push* ***alliance*** *[sic] or lexon/Medreich [sic] too much it will end up being a car crash for all'* (emphasis added);[2739] and

E.9.2 the CMA is not aware of evidence that AMCo/Focus chose to approach Alliance, and has not concluded as to why it might be that AMCo/Focus

[2738] Advanz RLF, 22 April 2021, paragraph 4.119.1-4.119.2 (URN: PRO-C7112).

[2739] Email [Focus Director 1] to [Focus Director 2] entitled '*Re: Prochlorperazine Buccal 3mg*' 15 June 2015 (URN: PRO-E001616).

did not seek to re-negotiate the level of price it was paying for Alliance's product as a result of its acquisition of Primegen; however, the absence of evidence of any such negotiation is not, given the evidence and analysis set out above, inconsistent with the existence of the Market Exclusion Agreement between Alliance and Lexon.[2740]

E.10 On the basis of the above, the CMA does not consider it relevant that, as Advanz submitted,[2741] the supply price between Alliance and Focus had been agreed to be raised from £5.65 to £6.10; it is notable in addition that this amendment was agreed between Alliance and Focus in January 2015 (see paragraph 3.175) and was therefore unconnected to the Primegen second profit share renegotiation which took place from June 2015.

Morningside's lack of involvement does not undermine the existence of the Market Exclusion Agreement

E.11 Cinven submitted that the CMA's assessment of the Market Exclusion Agreement was deficient in that it did not include any evidence of the Parties attempting to include Morningside within the agreement. Cinven submitted that, on the CMA's case, all the Parties would have been incentivised to add Morningside to the arrangement, since its entry had the potential to cause the price of Prochlorperazine POM to fall dramatically, which would have substantially eroded their profits. Cinven noted that previous 'pay for delay' cases suggest that it is normal for subsequent potential entrants to be scoped into such agreements at a later date, and the level of the profits earned prior to the grant of Morningside's MA in 2017 were such that these could have been used to pay off Morningside.[2742]

E.12 Cinven cited evidence on the file which it submits suggests that the Parties did not seek to extend the Market Exclusion Agreement to Morningside.[2743]

E.13 The CMA rejects Cinven's submission that, in effect, the fact that Morningside was not brought into the Market Exclusion Agreement is evidence against the existence of the Market Exclusion Agreement in and of itself. The CMA's case does not rest on demonstrating why Morningside was not brought into the Market Exclusion Agreement. There are many potential reasons for this, not the least of which is that

[2740] The CMA considers that, to the extent that AMCo/Focus did not approach Alliance, this could, for example, reflect a commercial decision on the part of AMCo/Focus that it considered it appropriate to leverage the licence vis-à-vis Lexon rather than vis-à-vis Alliance: this was potentially on the basis that (i) Focus had already been very successful in raising prices between the start of 2014 and June 2015 (to the benefit of Focus and Lexon/Medreich, but not to Alliance) and/or (ii) Alliance might have resisted any attempt by AMCo/Focus to renegotiate the transfer price on the basis that this would have led to a more uneven distribution of profits of each party under the Market Exclusion Agreement (see in this respect Figure 5). It could also, or alternatively, have reflected a common understanding amongst the Parties that, whilst Alliance would preserve the profits it had been making on sales of Buccastem POM prior to de-branding, the profits above that were to be split between the other Parties, and therefore when both AMCo and Lexon/Medreich each had a licence, it was natural that these profits be split 50 / 50.

[2741] Advanz RLF, 22 April 2021, paragraph 4.119.3 (URN: PRO-C7112).

[2742] Cinven RSO, 15 August 2019, paragraph 4.175 (URN: PRO-C5132).

[2743] Cinven RSO, 15 August 2019, paragraph 4.176 (URN: PRO-C5132).

the Market Exclusion Agreement had been implemented through two bilateral contracts, and to seek to extend any such structure to Morningside, some several years after the Market Exclusion Agreement had been put into place, might have been commercially complicated and raised the potential for regulatory discovery. However, it is not necessary or relevant for the CMA to conclude on this point.

Annex F: Parties' representations on the alternative explanations for the 2014 Correspondence

F.1 The CMA has set out in paragraphs 5.582 to 5.620 of the Decision its reasoning as to why the Parties' explanations for the three sets of correspondence on 14 April 2014,[2744] 2 and 3 September 2014[2745] and 4 November 2014[2746] between [Focus Director 1] and [Lexon Director 1] (together the '**2014 Correspondence**') are inconsistent with the wider evidence base.

F.2 The CMA finds that there are several other plausible explanations of the 2014 Correspondence which are not inconsistent with the wider evidence base. These explanations are consistent with Focus and Lexon not expecting Lexon to supply commercial volumes of the Lexon product to Focus; they are also consistent with Focus not being misled by Lexon in this regard.

F.3 The CMA has set out these plausible explanations in summary form in the Decision (paragraphs 5.602, 5.608 and 5.616). It sets out in detail in this annex its reasoning as to why these explanations are plausible given the surrounding evidence, context and conduct, the Parties' representations on these other plausible explanations and its analysis of those representations.

The 14 April 2014 exchange

F.4 For the reasons set out in the Decision, the CMA has rejected the Parties' submission that the exchange of 14 April 2014 provides evidence of Lexon intending to supply, and Focus intending to purchase, commercial volumes of Prochlorperazine POM (see paragraphs 5.598 to 5.602).

F.5 The CMA considers that there are other potential explanations of the 14 April 2014 email exchange that do not involve an expectation on the part of either Lexon or Focus of the supply of commercial volumes of Lexon's Prochlorperazine POM product by Lexon to Focus. The CMA highlights, in particular, the following three points which are to some extent overlapping.

F.6 First, the CMA considers that the exchange can plausibly be explained on the basis that Focus and Lexon were contemplating and discussing the provision of the

[2744] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794) and email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795) and email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

[2745] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811) and email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812) and email [Lexon Director 1] to [Focus Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003813).

[2746] Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832) and email [Lexon Director 1] to [Focus Director 1] entitled '*RE: Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

single batch of Prochlorperazine POM necessary to avoid the application of the Sunset Clause (see paragraphs 5.194 and 5.270). By way of evidential support for this explanation, the CMA notes as follows.

F.6.1 On 4 February 2014, [Lexon Director 1] had asked Medreich to provide him with details of the batch size for the single batch he had agreed to supply every three years so that he could *'plan*'.[2747] Any such planning would have needed to involve Focus, given the fact that even the minimum batch size of product would involve production and supply of a number of packs of product and given Focus' role in drifting that batch, potentially obtained from Lexon in multiple chunks, into the stock of Alliance product.

F.6.2 [Lexon Director 1]'s apologies '*for the confusion*'[2748] in his email of 14 April 2014 may therefore be explained by his concern that a failure to provide clarity regarding the potential timing of the single batch of product would inconvenience [Focus Director 1], including as regards the forecasts that he should provide to Alliance and any plans he could make (or was making) to drift that batch of product into sales of the Alliance stock.[2749]

F.6.3 This explanation would be consistent with the content of [Focus Director 1]'s email responses. [Focus Director 1]'s demonstrable lack of concern about the delay ('*I totally understand the issues involved*'),[2750] the fact that he did not make any inquiry about the timetable for delivery of product, but that he would continue to make payments to Lexon for nothing in return, is consistent with the fact that obtaining that single batch would have been unlikely to be a commercial priority for Focus; albeit that, given that Focus may have needed to plan in order to be able to drift that batch of product into sales of the Alliance stock, it may still have been of some inconvenience, and hence would have explained why [Lexon Director 1] felt the need to apologise '*for the confusion*'.

F.7 Advanz and Cinven submitted that this explanation could not explain the 14 April 2014 exchange given its timing: they stated it is not plausible that Lexon (or Focus[2751]) would be concerned about an expiry of the three year Sunset Clause

[2747] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*Products*' 4 February 2014 (URN: PRO-E002750).

[2748] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794).

[2749] As [Lexon Director 1] described it in his email to [Medreich Employee 1] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

[2750] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795). The CMA rejects Cinven's submission that [Focus Director 1] cannot have been unconcerned about the delay given the fact that [Lexon Director 1] and [Focus Director 1] went on to discuss amending the profit share (Cinven, RLF 30 November 2021, paragraph 3.34 footnote 36 (URN: PRO-C7919)). It is only [Focus Director 1] that refers to the profit share, and his statement is that he is content for it to continue, which is not consistent with him being concerned or frustrated about the delay.

[2751] Advanz's representations in Advanz RLF, 30 November 2021, paragraphs 1.6.1(d) and 2.31 (URN: PRO-C7917) were based on Focus being concerned about expiry of the Sunset Clause, but the CMA's posited explanation was based

just three months after grant of the licence, particularly given that extensions to the Sunset Clause could be (and were) obtained.[2752] Cinven submitted that it was not plausible that Lexon would have felt pressured to reach an agreement with Focus on granular issues such as the timetable of the delivery of such a batch at such an early stage.[2753]

F.8 However, these objections do not take account of the fact that the evidence shows clearly that, as early as February 2014, [Lexon Director 1] was interested in understanding the batch size from Medreich so he could '*plan*' (see paragraph F.6); on this basis, it is indeed plausible that [Lexon Director 1] could have discussed the timing of provision of that batch with Focus by April 2014, and hence have been apologising for an amendment to any such timetable. Further, subsequent evidence during 2014 and 2015 shows that Lexon and Medreich were contemplating production of a single batch, and communicated batch size information to Focus, and the CMA infers from this that they considered that production of the single batch might take some time to arrange and should not be left unduly late:

F.8.1 following a subsequent enquiry about batch sizes and costs by [Lexon Director 1] on 22 August 2014,[2754] [Medreich Director 2] stated internally that there was '*maybe a possibility of doing a batch of Prochloroperazine [sic] 3mg'* (emphasis added) of [✂] tablets on 27 August 2014;[2755]

F.8.2 [Lexon Director 1] provided batch size information to [Focus Director 1] on 2 September 2014;[2756] and

on the inconvenience caused to Focus by amendments to the timing for the provision of such a batch, rather than Focus being directly concerned about obtaining the single batch; the CMA accepts that production of the single batch would have been of greatest concern for Lexon. Advanz's representation (paragraphs 1.6.1(e), 2.31.4 and 2.36) that Focus should not have been concerned about production of a single batch given that Focus would no longer be beholden to Lexon for a share in the profits made on the sale of Alliance's product does not, therefore, undermine this explanation for the April 2014 exchange.

[2752] Advanz RLF, 30 November 2021, paragraphs 1.6.1, 2.31 and 2.36 (URN: PRO-C7917), Cinven RSO, 15 August 2019, paragraph 4.108 (URN: PRO-C5132) and Cinven RLF, 30 November 2021, paragraphs 1.11, 3.31 and 3.32 (URN: PRO-C7919). The Parties also cited evidence as originally set out in the Statement of Objections showing that [Lexon Director 1] had stated in interview that the Sunset Clause took effect after five years (Interview [Lexon Director 1], 10 September 2018, Part 1 CD4, page 26, lines 27 (URN: PRO-C3189)); however the evidence from 2014 indicates that [Lexon Director 1] did understand the relevant sunset clause provision to be three years rather than five years at the time given that his correspondence with Medreich on 4 February 2014 referred to the (correct) understanding of three years for the sunset clause (email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750)).

[2753] Cinven RLF, 30 November 2021, paragraph 3.32 (URN: PRO-C7919).

[2754] Email [Lexon Director 1] to [Medreich Director 2] entitled '*[No subject]*' 22 August 2014 (URN: PRO-E000434).

[2755] Email [Medreich Director 2] to [Medreich employee], cc [Medreich employee] entitled '*FW: Prochloroperazine [sic] 3mg*' 27 August 2014 (URN: PRO-E002867).

[2756] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811).

F.8.3 when [Lexon Director 1] ordered product on 23 June 2015, Medreich was clear that this was the *'1 batch required in order to keep the license [sic] active'*.[2757]

F.9 Cinven submitted that there was no reference in the 2014 Correspondence to Focus being concerned about Lexon's failure to provide a timetable.[2758] In this respect, the wording of [Focus Director 1]'s response email of 14 April 2014 itself may suggest that Focus was interested in the timetable: '*we can revisit in June when you have more information*'; furthermore, [Focus Director 1] himself asked about '*the lead time*' in his email of 3 September 2014,[2759] suggesting that he was – in 2014 – interested in the timing of the delivery.

F.10 Cinven submitted that the single batch explanation fails to explain why [Focus Director 1] referred in his response to the profit share clause, which it says would be consistent with Lexon's failure to supply commercial volumes of product; when coupled with the fact that Focus had stated in its 28 January 2014[2760] and 24 March 2014[2761] sales meeting minutes that [Focus Director 1] should discuss the profit share agreement with Lexon, that [Lexon Director 1] offered his '*sincere apologies*' for the delay in his email of 4 April 2014 and that Focus and Lexon did in November 2014 amend the profit share split, Cinven submits that the April 2014 exchange must have been a discussion about Lexon's delay in supplying commercial volumes of product, and that the CMA's single batch explanation is not plausible.[2762] However, the CMA finds that:

F.10.1 it is implausible that the January 2014 and March 2014 Focus sales meeting minutes reflect a frustration on Focus' part at the lack of Lexon product given that the Medreich MA had only recently been granted (on 9 January 2014) – and to the extent that these references relate to obtaining product from Lexon, there is no reason for this to be referring to commercial volumes of product rather than the single batch contemplated pursuant to the Market Exclusion Agreement;

F.10.2 [Lexon Director 1]'s apology in his 14 April 2014 email must be read in the context of the evidence showing that he was not seeking product from Medreich at this point (see paragraph 5.600);

[2757] Email [Medreich employee] to various Medreich colleagues entitled '*Exco minutes*' 29 June 2015 (URN: PRO-E002984) attaching '*Minutes of the Meeting of the Executive Committee of Medreich Plc Held on 14th June 2015 at 10:30am in the Board Room of Medreich PIC Offices*' 29 June 2015 (URN: PRO-E002985). [Lexon Director 1]'s comments on the significance of this document are addressed in paragraph 5.463.

[2758] Cinven RLF, 30 November 2021, paragraph 3.33 (URN: PRO-C7919).

[2759] Email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812).

[2760] *Minutes of a Focus Sales Meeting*, 28 January 2014, page 5 (URN: PRO-E003779).

[2761] *Minutes of a Focus Sales Meeting*, 24 March 2014, page 4 (URN: PRO-E003785).

[2762] Cinven RLF, 30 November 2021, paragraph 3.34 (URN: PRO-C7919).

F.10.3 [Focus Director 1]'s response is not consistent with him being highly troubled or vexed by the delay (see paragraph F.6.3);

F.10.4 based on the wording of the April 2014 exchange, [Focus Director 1] did not seek to amend the profit share in April 2014, and when an amendment was agreed in November 2014, it was motivated by the extent of Focus' price increases rather than reflecting Lexon's failure to deliver product: see paragraph 5.551); and

F.10.5 based on the above, and the fact that [Focus Director 1] may have confirmed his willingness to continue to pay profit share on the basis that he understood Lexon would be supplying the single batch in due course, the fact that [Focus Director 1]'s second email refers to the profit share clause does not provide a sound basis for concluding that the April 2014 exchange related to Lexon's failure to supply commercial volumes of product.

F.11 Second, as an extension of the first point set out above, it may be that Lexon was particularly keen to give the impression (to Focus, and potentially indirectly to Alliance) that it was pressing ahead as fast as possible with the single batch, and could produce more product should the Market Exclusion Agreement be terminated. The reason for that is that the transfer of profits from Alliance to Lexon was premised on the notion that, without such transfer, Lexon would enter the market. Lexon may therefore have been motivated to avoid the possibility of Focus seeking a greater proportion of the profit share, or Alliance seeking to increase its selling price to Focus (with the effect of decreasing the profit share payments to Lexon/Medreich) and/or of either party terminating the Market Exclusion Agreement. This would provide a further explanation for the timing of Focus and Lexon's discussion of the single batch.

F.12 The CMA considers this additional explanation is plausible based on the following:

F.12.1 The need for Lexon and Medreich to demonstrate such leverage had been raised by Medreich with Lexon in February in [Medreich Employee 1]'s email to [Lexon Director 1] of 4 February 2014: '*I think we should also get ready to do the 3 mg POM as well, even if only so that Alliance cannot try to increase the Purchase price going forward*'.[2763]

F.12.2 Medreich had more recently followed up with a further question regarding the reasonableness of what it perceived as Alliance's supply price increases: '*I have been asked for a detailed analysis of how the COGS has increased now to £5.47 against a cost last quarter of £4.85. This is a product that should cost some [✂], so we feel that Alliance are making still*

[2763] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled '*Products*' 4 February 2014 (URN: PRO-E002744).

the lion's share at £1m a year profit, and we are getting about £220k each. Is there anything that can be used to help me corroborate the increase in the COGS from Focus perhaps. Could we see please the supplier invoices? I do not want to be difficult as it is a clever arrangement, but I am cutting a bit of a sorry figure with the management here, as I cannot explain how suddenly the supplier is going for this 13% cost increase'.[2764]

F.12.3 This interpretation would explain [Lexon Director 1]'s comment that '*the API comes from a third party and [✂]*[2765] the suggestion being that this delay was not attributable to Medreich or reflective of an inability to supply on Medreich's part and that, once this issue was remedied, Medreich would soon thereafter be in a position to obtain the contemplated single batch of stock (and, by implication, more product if Lexon was not adequately compensated for not launching its product).

F.12.4 This explanation would be consistent with [Focus Director 1]'s demonstrable lack of concern about the delay ('*I totally understand the issues involved*'[2766]) and with his subsequent confirmation that he remained content to pay profit share to Lexon (in the absence of product from Lexon) pursuant to the provisions of the Focus-Lexon Heads of Terms.[2767]

F.13 Cinven submitted that this interpretation was itself at odds with the Market Exclusion Agreement which required Lexon to stay off the market, consistent with [Lexon Director 1]'s email of 4 February 2014 to Medreich that '*3mg POM is best left alone*'.[2768] However, Lexon/Medreich's willingness to stay off the market was itself contingent on receipt of profit share payments as compensation for not doing so – and in turn, Alliance and Focus' willingness to compensate Lexon/Medreich would depend on the implicit threat that, in the absence of such compensation, Lexon/Medreich could, and would, enter the market. As such, this potential explanation for the April 2014 exchange is entirely consistent with the Market Exclusion Agreement.

F.14 Advanz submitted that there was nothing in [Lexon Director 1]'s email to support the CMA's interpretation in this respect.[2769] Cinven also challenged the plausibility

[2764] Email [Medreich Employee 1] to [Lexon Director 1] entitled '*FW: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002803).

[2765] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794).

[2766] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795).

[2767] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

[2768] Cinven RLF, 30 November 2021, paragraph 3.37 (URN: PRO-C7919) citing email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750). [Lexon Director 1]'s comments on the significance of this document are addressed in paragraphs 5.426 to 5.432.

[2769] Advanz RLF, 30 November 2021, paragraph 2.33 (URN: PRO-C7917). Advanz also submitted that this interpretation was undermined by the existence of the September and November 2014 correspondence in which [Focus Director 1]

of this explanation based on the wording of [Lexon Director 1]'s email, in which he offered '*sincere apologies*' and said '*there is nothing short term I can do to address the problem*', which Cinven said was inconsistent with Lexon being able to enter imminently.[2770] Alliance stated that the April 2014 exchange involved [Lexon Director 1] conveying an indefinite production delay, such that Alliance submitted it was not coherent that this email would serve the aim of demonstrating to Alliance that Lexon were credibly or imminently able to supply commercial volumes of Prochlorperazine POM to Focus.[2771]

F.15 The CMA finds that these submissions place insufficient emphasis on [Lexon Director 1]'s reference to the issue not being something he could address in the '*short term'* and was a consequence merely of the API supplier [✂]. As noted above (see paragraph F.12.3), the implication from this was that any delay would not be attributable to Medreich and its ability to manufacture the drug and once corrected, Medreich would soon thereafter be in a position to produce the contemplated single batch of stock (and, by implication, more product if Lexon was not adequately compensated for not launching its product).

F.16 Alliance also submitted that the April 2014 exchange could not have been created for the purpose of Focus passing on information to Alliance given that there was no explicit or implicit suggestion in the documents that passing on such information to Alliance was the underlying intention of the parties involved, and there was no subsequent communication from Focus to Alliance conveying this information.[2772] These submissions are not persuasive:

F.16.1 for [Lexon Director 1]'s email to be a credible means of demonstrating Lexon/Medreich's ability to supply product, it would not be expected that it would itself suggest that the information within it should be passed to Alliance; but it does not follow that [Lexon Director 1] did not have Alliance's position in mind when writing his original email; and

F.16.2 as regards Alliance's statement that there was no subsequent communication from Focus to Alliance conveying this information, that again does not undermine a potential explanation in which [Lexon Director

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referred to his '*requirements*' and enquires about lead times (Advanz RLF, 30 November 2021, paragraph 2.37 (URN: PRO-C7917)): however, the CMA rejects this and addresses the interpretation of [Focus Director 1]'s subsequent correspondence (including his reference to his '*requirements*') below.

[2770] Cinven RLF, 30 November 2021, paragraph 3.38 (URN: PRO-C7919).

[2771] Alliance RLF, 30 November 2021, paragraph 5.9 (URN: PRO-C7914).

[2772] Alliance RLF, 30 November 2021, paragraph 5.9 (URN: PRO-C7914). Alliance also submitted in relation to the 2014 Correspondence as a whole that there was no indication that Alliance was involved in, or briefed about, the subject matter of the discussions between Focus and Lexon (Alliance RLF, 30 November 2021, paragraph 5.15 (URN: PRO-C7914)). However, the CMA does not consider that this representation is instructive or relevant: as set out in paragraph 5.272, the CMA does not find that Alliance was aware of, or agreed to, the precise terms of the profit-sharing agreement reached by Focus and Lexon; similarly, the production and sale of the single batch of Lexon/Medreich product necessary to avoid the application of the sunset clause was – albeit agreed to by Alliance (see paragraph 5.270) – a matter for Lexon/Medreich and Focus; as such, there was no requirement based on any of the interpretations considered by the CMA for Alliance actually to be involved in or briefed about the subject matter of the 2014 Correspondence.

1] contemplated the possibility of such a communication – if it were necessary;

F.16.3 further, it is not clear from Alliance's submission how it can be clear that no such communication was ever made other than in writing (for example orally between [Focus Director 1] and [Alliance Employee 1]).

F.17 Third, the contents of the 14 April 2014 exchange may have been influenced by the authors' caution regarding what they put into writing. In particular:

F.17.1 At a minimum, the Parties may have been wary of stating in writing that their intention was to produce and sell only a single batch of Medreich Prochlorperazine POM, as they appreciated that an express statement to that effect would have provided direct evidence of the (unlawful) Market Exclusion Agreement. Thus, even when communicating about the single batch, the Parties may have had good reason not to mention that fact explicitly.

F.17.2 More generally, it is also possible that the Parties went further, by deliberately creating a written record meant to give the impression that they were intending to supply and receive commercial volumes.

F.18 The CMA notes as follows.

F.18.1 [Lexon Director 1] and [Focus Director 1] had various potential motivations for caution regarding the written record, including the possibility of scrutiny of the payments in the following scenarios:

(a) in the event that this Lexon income stream was the subject of any corporate or audit scrutiny in the future;

(b) during the anticipated sale of Focus: Focus was up for sale at this point[2773] and such a sale would likely have involved (and indeed, did involve) due diligence being carried out by the buyer's representatives over Focus' contracts and accounts; and/or

(c) to limit the risks of Competition Act enforcement action.

F.18.2 Such an interpretation would be consistent with the CMA's finding that [Lexon Director 1] and [Focus Director 1] had originally decided to enter into the Focus-Lexon Heads of Terms by 1 August 2013 in a form which omitted from the document the intention that the profit share payments would be made to Lexon as compensation for the agreement it had made with Alliance not to enter the market (see paragraph 5.302).

[2773] As stated by Advanz in its RSO, 1 August 2019, paragraphs 3.171 and 3.227 (URN: PRO-C5111).

F.18.3 Such an interpretation would explain [Lexon Director 1] electing to write a relatively formal email containing repeated '*sincere apologies*'[2774] to [Focus Director 1] for the non-provision of product so soon after the grant of the Medreich licence on 9 January 2014, and [Focus Director 1] in turn responding in comparably formal style, on the same day that they had an in-person meeting.[2775]

F.18.4 This interpretation would also explain why [Lexon Director 1] emphasised in his email his inability to resolve the problem himself ('*as I am sure you can guess there is nothing short term I can do to address the problem*')[2776] and why [Focus Director 1] went to the trouble not only to reply initially confirming that the lack of product was not problematic,[2777] but also to send a second email to record in writing the fact that [Focus Director 1] was content to '*continue with the current agreement as signed in the heads of agreement*' – that is, to emphasise the contractual basis for Focus to continue to pay profit share to Lexon despite the absence of product.[2778]

F.19 Advanz submitted in respect of this interpretation that the CMA had not identified nor proved the existence of a pattern of behaviour on the part of Focus that involved engaging in sham communications with the aim of keeping hidden from lawyers conducting due diligence for the purpose of a sale and purchase of Focus and from competition authorities that Focus was engaged in the Market Exclusion Agreement and had not shown a '*concurrence of wills*' with Lexon to engage in sham correspondence for that purpose.[2779] Cinven made similar representations, stating that the CMA had not investigated as a separate allegation that the officers and employees of Focus and Lexon conspired to create a false record of events.[2780]

F.20 The CMA rejects these representations. The CMA's approach does not depend on establishing a pattern of behaviour, and it has set out the basis on which it considers this interpretation of the exchange to be plausible. Furthermore, the CMA *has* put to the Parties that [Focus Director 1] and [Lexon Director 1] may have been motivated by caution regarding the written record, up to and including the

[2774] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794).

[2775] Email [Focus Director 1] to [Focus Director 2] entitled '*Lexon meeting*' 9 April 2014 (URN: PRO-E003793): that email referred to a forthcoming meeting between [Focus Director 1] and [Lexon Director 1] 'on Monday'; the Monday after the email was sent would have been Monday 14 April 2014. The Parties have not stated in any of their representations that that meeting scheduled for Monday 14 April 2014 did not in fact take place.

[2776] Email [Lexon Director 1] to [Focus Director 1] entitled '*Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003794).

[2777] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003795).

[2778] Email [Focus Director 1] to [Lexon Director 1] entitled '*Re: Prochlorperazine 3mg*' 14 April 2014 (URN: PRO-E003796).

[2779] Advanz RLF, 30 November 2021, paragraphs 1.6.2, 2.34 and 2.38 (URN: PRO-C7917).

[2780] Cinven RLF, 30 November 2021, paragraph 3.25 (URN: PRO-C7919).

possibility that they deliberately created a misleading record[2781] – meaning that the Parties have been able to comment on, and produce any evidence relating to, this proposed explanation.

F.21 Cinven also questioned any reliance on the '*relatively formal*' tone of the emails given that such formality would be expected given that Lexon was apologising for being behind schedule. In any event, Cinven submitted that the April 2014 exchange was not overly formal or indeed inconsistent with other emails exchanged between [Lexon Director 1] and [Focus Director 1]; Cinven also queried whether the CMA should assume that '*sham emails are generally written 'relatively formally'*.[2782]

F.22 In relation to Cinven's specific comments on the language of the emails, the CMA has not made a finding, as Cinven suggests, that '*sham emails are generally written relatively formally*'. However, the CMA considers that the relatively formal language used in the 14 April 2014 exchange would be consistent with the emails having been written with a view to wider scrutiny, in particular given the apparently unnecessary nature of the correspondence, noting that:

F.22.1 [Focus Director 1] and [Lexon Director 1] had a meeting on the same day, a point that neither Advanz nor Cinven addressed in their representations; and

F.22.2 the 14 April 2014 exchange did not involve any amendment to the status quo, for example there was no amendment to the profit share terms that it would have been necessary to record such a change in writing.

The 2 and 3 September 2014 exchange

F.23 For the reasons set out in the Decision, the CMA has rejected the Parties' submission that the exchange of 2 and 3 September 2014 provides evidence of Lexon intending to supply, and Focus intending to purchase, commercial volumes of Prochlorperazine POM (see paragraphs 5.605 to 5.608).

F.24 The CMA finds that there are other potential explanations for [Lexon Director 1]'s email to Focus of 2 September 2014 and [Focus Director 1]'s response of 3 September 2014 that do not involve an expectation on the part of either Lexon or Focus of the supply of commercial volumes of Lexon's Prochlorperazine POM product by Lexon to Focus. The CMA highlights, in particular, the following two points which are to some extent overlapping.

[2781] The CMA put these points in a letter of facts issued to the Parties on 12 November 2021, to which Advanz and Cinven both responded on 30 November 2021.

[2782] Cinven RLF, 30 November 2021, paragraph 3.40 including footnote 46 (URN: PRO-C7919).

F.25 First, it is plausible that Focus and Lexon were contemplating and discussing the provision of the single batch of Prochlorperazine POM necessary to avoid the application of the Sunset Clause (see paragraphs 5.194 and 5.270). Against a backdrop in which [Medreich Director 2] had recently stated within Medreich on 27 August 2014 that there was *'maybe a possibility of doing a batch of Prochloroperazine [sic] 3mg'* of [✂] tablets but noting that *'we do need small batch sizes',* the CMA considers this explanation is plausible based on the following points.

F.25.1 [Lexon Director 1]'s original email[2783] forwarding batch size information to [Focus Director 1] can plausibly be explained on the basis that [Focus Director 1] would need to know this information prior to Lexon supplying the single batch of Prochlorperazine POM needed to avoid the Medreich MA Sunset Clause (see paragraphs 5.194 and 5.270).

F.25.2 [Focus Director 1]'s email response[2784] can plausibly be explained on the basis that, in referring to his '*requirements*', [Focus Director 1] was referring to the time(s) at which he wished to take delivery of a single batch of product (said by Medreich at the time to comprise [✂] tablets (i.e. [✂] packs), but subsequently confirmed to comprise [✂] tablets, that is [✂] packs: see paragraph 3.233), which may or may not have been delivered in a single delivery.

F.26 Advanz submitted that if this explanation were correct, there would not have been any need for Focus to refer to its future '*requirements*' or to enquire about lead times.[2785] However, as noted above (see paragraph F.25) it is not clear that in referring to '*requirements*' and in enquiring about the lead time, [Focus Director 1] was necessarily referring to the provision of multiple batches, rather than the timing of (potentially multiple deliveries) within one batch. Cinven submitted that this interpretation of the word '*requirements*' strains the use of language to an impermissible degree, but did not provide further reasoning in this respect.[2786]

F.27 Second, as an extension of the first point set out above, it may be that Lexon was keen to give the impression (to Focus, and potentially indirectly to Alliance) that it was pressing ahead as fast as possible with the single batch, and that it could provide more product should the Market Exclusion Agreement be terminated.[2787]

[2783] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811).

[2784] Email [Focus Director 1] to [Lexon Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003812).

[2785] Advanz RLF, 30 November 2021, paragraph 2.47 (URN: PRO-C7917).

[2786] Cinven RLF, 30 November 2021, paragraph 3.34 footnote 39 (URN: PRO-C7919).

[2787] Lexon's potential motivations in this respect and the relevant documentary context are set out in paragraph F.12 above.

F.28 The CMA notes:

F.28.1 This may explain [Lexon Director 1]'s forwarding on the batch size information to Focus:[2788] the provision of batch size information may have given the impression that Lexon would soon be able to manufacture the single batch of product (and more product, should the Market Exclusion Agreement be terminated).

F.28.2 This may also explain [Lexon Director 1]'s reference to the lead times being 20 weeks for the first batch and then *"12 weeks thereafter"*.

F.29 Advanz and Cinven submitted that had Lexon engaged in the exchange to demonstrate its ability to supply, and had Focus understood that to be the case, there would not have been any need for Focus to refer to its '*requirements*' or to enquire about the lead time.[2789] The CMA does not accept these submissions, on the basis that it considers [Focus Director 1]'s response is consistent with this explanation as well as with him referencing his '*requirements*' and '*the lead time*' as regards the delivery timetable for the planned single batch of product (see paragraph F.25).

F.30 Alliance submitted (in relation to both the September 2014 and November 2014 correspondence) that there was no evidence that the purpose of the emails was for such information to be passed on to Alliance, and that there is no evidence that Alliance was at the time challenging or querying Focus (or indeed Lexon) on the credibility of Lexon's ability to launch its own generic product, or that Alliance was threatening to bring the arrangements to an end or increase its supply price to Focus if such information was not proffered by Focus.[2790] In this respect:

F.30.1 the CMA does not accept Alliance's representation that there was no contemporaneous evidence suggesting that the purpose of the email could have been for such information to be passed to Alliance: for the CMA's analysis in this respect, see paragraph F.16 above; and

F.30.2 the CMA does not accept the inference Alliance seeks to draw from its other points: the fact that Alliance may not have been actively challenging or querying Focus or that the information may not actually have been passed on by Focus to Alliance (if correct) does not undermine the suggestion that [Lexon Director 1] may have been motivated by the *possibility* of such developments (see further paragraph F.16 above).

[2788] Email [Lexon Director 1] to [Focus Director 1] entitled '*FW: Prochloroperazine 30mg [sic] – 50's*' 2 September 2014 (URN: PRO-E003811).

[2789] Advanz RLF, 30 November 2021, paragraph 2.47 (URN: PRO-C7917) and Cinven RLF, 30 November 2021, paragraph 3.38 (URN: PRO-C7919).

[2790] Alliance RLF, 30 November 2021, paragraph 5.13 (URN: PRO-C7914).

F.31 In relation to [Lexon Director 1]'s email response of 3 September 2014 commenting on lead times,[2791] the CMA makes three points.

F.32 First, the CMA notes that the email was a short email sent as a quick response from [Lexon Director 1]'s iPhone. In his interview, [Lexon Director 1] explained that the reference to 12 weeks was because '*on a line like that if there's profit we'd airfreight it … [which was] more reliable than by boat*'.[2792] The reference to 12 weeks may therefore have simply been a stock response, rather than evidence of what was in fact intended in relation to Prochlorperazine POM.

F.33 Cinven submitted that the 'stock response' explanation was implausible on the CMA's own case given the CMA's finding that Focus and Lexon exhibited a high degree of caution regarding what they put into writing,[2793] meaning that it was implausible that [Lexon Director 1] would have replied with a stock or standardised response. However, the CMA does not find this submission persuasive. The fact that [Focus Director 1] and [Lexon Director 1] may have been cautious not to put inculpatory information into writing does not mean that [Lexon Director 1] could not, in other circumstances, have provided a quick response, containing wholly non-inculpatory information, from his iPhone.

F.34 Second, it is possible that the reference to future lead times being 12 weeks was to the lead times relevant to the future production of a single batch of Prochlorperazine POM product every three years needed to avoid the Medreich MA Sunset Clause (see paragraphs 5.194 and 5.270). This would be consistent with the wording of [Lexon Director 1]'s earlier response to [Medreich Employee 1] of 4 February 2014: '*make a batch every 3 years and drift it into the Alliance stock*'.[2794]

F.35 Cinven submitted that it is not clear why [Lexon Director 1] would be providing information in respect of multiple batches in 2014 given that the subsequent batch would not be an issue until 2020 at the earliest, when such information would clearly be outdated.[2795] However, whilst it might be the case that [Lexon Director 1] did not *need* to provide such information to Focus in 2014, that is not the relevant question: rather, the CMA considers it is plausible – in particular given that [Lexon Director 1] was clearly mindful in February 2014 of the need for a batch to be made every three years – that [Lexon Director 1] provided this information to Focus when replying (from his iPhone) to [Focus Director 1]'s question on the lead time.

[2791] Email [Lexon Director 1] to [Focus Director 1] entitled '*RE: Prochloroperazine 30mg [sic] – 50's*' 3 September 2014 (URN: PRO-E003813).

[2792] Interview [Lexon Director 1], 10 September 2018, CD 4/5, page 10, lines 5 to 8 (URN: PRO-C3189).

[2793] Cinven RLF, 30 November 2021, paragraph 3.34 (URN: PRO-C7919).

[2794] Email [Lexon Director 1] to [Medreich Employee 1] cc [Medreich Director 2] entitled '*Re*: *Products*' 4 February 2014 (URN: PRO-E002750).

[2795] Cinven RLF, 30 November 2021, paragraph 3.34 (URN: PRO-C7919).

F.36 Third, it is possible that [Lexon Director 1] was contemplating a scenario in which multiple batches were in fact ordered given Focus' impending sale. Depending on the approach taken to Focus' existing Prochlorperazine POM commercial arrangement by any new owners of the Focus business following its sale, [Lexon Director 1] may have been providing for a possible (albeit ultimately unrealised) situation in which Focus' new owners chose to end its participation in the Market Exclusion Agreement and sought instead to obtain commercial volumes of product from Lexon.

F.37 Cinven submitted that this ran contrary to the other interpretations, namely that Focus and Lexon were not contemplating commercial volumes in the September 2014 exchange (and the 2014 Correspondence more widely).[2796] However, the CMA does not consider this objection to be well-founded. This explanation is based specifically on a potential scenario, relevant as the sale of Focus to a new owner approached, in which Lexon may have contemplated the situation in which the Market Exclusion Agreement no longer continued: to seek to undermine its plausibility on the basis that it was inconsistent with other plausible explanations (that are premised on the Market Exclusion Agreement continuing) is therefore without foundation.

The 4 November 2014 exchange

F.38 For the reasons set out in the Decision, the CMA has rejected the Parties' submission that the exchange of 4 November 2014 provides evidence of Lexon intending to supply, and/or of Focus intending to purchase, commercial volumes of Prochlorperazine POM (see paragraphs 5.612 to 5.616) – including rejecting the submission that Focus was being misled by Lexon as to Lexon's strategy of refraining from commercialising the product.

F.39 The CMA finds that there are at least two alternative plausible explanations for the 4 November 2014 email exchange that do not involve an expectation on the part of either Lexon or Focus of the supply of commercial volumes of Lexon's Prochlorperazine POM product by Lexon to Focus – that is, including that do not include a scenario in which Focus expected to order commercial volumes of Prochlorperazine POM but was being misled by Lexon as to its progress and order status.

F.40 First, it is plausible that, although Focus and Lexon intended that Lexon would supply to Focus only the single batch of Prochlorperazine POM necessary to avoid the application of the Sunset Clause, Lexon additionally wished to demonstrate to Focus (and thereby, potentially, indirectly to Alliance, with whom Focus were in contact) its imminent ability to make the single batch (and more product, should the

[2796] Cinven RLF, 30 November 2021, paragraph 3.43 (URN: PRO-C7919).

Market Exclusion Agreement be terminated). The CMA considers this explanation is plausible based on the following points.

F.40.1 [Lexon Director 1] might have had an incentive to mislead [Focus Director 1] by informing him that he had ordered a batch of product from Medreich,[2797] thereby suggesting that Lexon was closer to production of Prochlorperazine POM than was actually the case (given that no order or written instruction was placed by Lexon on Medreich until 23 June 2015).[2798] Lexon's potential motivations in this respect and the relevant documentary context are set out in paragraph F.12 above.

F.40.2 [Focus Director 1] records neutrally that [Lexon Director 1] had placed an order for stock and expected it to arrive in '*early 2015*':[2799] this is consistent with the email relating to a single batch, rather than commercial volumes of product: had Focus actually been seeking commercial volumes, [Focus Director 1] would presumably have expected [Lexon Director 1] to have placed an order with Medreich significantly prior to this and to be more urgently seeking to obtain product from Medreich.

F.41 Cinven submitted that this explanation was inconsistent with the wording of the 4 November 2014 emails on the basis that, given that the Market Exclusion Agreement envisaged Lexon staying off the market, it is not clear why [Lexon Director 1] would have felt required to claim he had placed an order; indeed, Cinven stated that Lexon's placing of an order would have risked being seen by Focus and Alliance as being contrary to the Market Exclusion Agreement.[2800] The CMA does not find this representation to undermine the credibility of the explanation: it was accepted and expected that Lexon/Medreich would produce and sell through Focus a single batch of product necessary for the avoidance of the application of the Sunset Clause (see paragraphs 5.194 and 5.270); as such, Focus (and Alliance, had it been informed as such by Focus) would not have seen the submission of an order by Lexon as being contrary to the Market Exclusion Agreement provided the order was for a single batch of product (which was the case for the order placed by Lexon on 23 June 2015).

F.42 Advanz criticised the plausibility of this explanation on the basis of the timing of the exchange being in advance of the expiry of the Sunset Clause and on the basis that it was implausible that [Focus Director 1] and [Lexon Director 1] would meet in person to discuss the manufacture and supply of a single batch needed by 9

[2797] For this reason, the CMA rejects Advanz's claim that the CMA has not engaged with the issue why Lexon might have misled Focus as to the placing of an order with Medreich if Focus were a knowing participant in the Market Exclusion Agreement (Advanz RLF, 30 November 2021, paragraphs 2.11 and 2.54 (URN: PRO-C7917)).

[2798] Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, response to question 2.1 (URN: PRO-C3856): see paragraphs 5.434 and 5.435.

[2799] Email [Focus Director 1] to [Lexon Director 1] entitled '*Prochlorperazine 3mg tabs*' 4 November 2014 (URN: PRO-E003832).

[2800] Cinven RLF, 30 November 2021, paragraph 3.38(d) (URN: PRO-C7919).

January 2017.[2801] For the reasons set in paragraph F.8, the CMA rejects this submission.

F.43 Second, it is possible that the contents of the 4 November 2014 emails were influenced by Focus and Lexon's caution regarding what they put into writing. In particular, they may each have recognised the value of having a written record which would if necessary support the contention that they expected Lexon to provide commercial volumes. The CMA considers this explanation is plausible based on the following points.

F.43.1 [Focus Director 1]'s and [Lexon Director 1]'s potential motivations for the creation and continuance of such a record are set out in paragraph F.18 above.[2802] With reference to this email correspondence, specifically, Focus had only very recently been sold to AMCo at this point, and the sale and purchase agreement between AMCo and the Focus vendors incorporated a warranty regarding compliance with competition law.[2803] [Focus Director 1] may therefore have seen benefits in creating a written record that, depending on the approach to Focus' existing Prochlorperazine POM commercial arrangement taken by any new owners of the business following its sale, could explain why payments were being made by Focus to Lexon in return for no product.

F.43.2 This would explain [Focus Director 1] choosing to send a relatively formal email response to [Lexon Director 1] the day after [Focus Director 1] and [Lexon Director 1] had an in-person meeting, as recorded in [Focus Director 1]'s email of 4 November 2014 itself.

F.43.3 Whether [Focus Director 1] knew that no order had been placed by Lexon, or was being misled by [Lexon Director 1] on this point, this interpretation would explain why [Focus Director 1] recorded that Lexon had placed an order for product with Medreich, which was not in fact the case (given that no order was placed by Lexon on Medreich until 23 June 2015).[2804] In either scenario, [Focus Director 1] would have had an interest in creating a written record that Lexon was seeking the manufacture of product from Medreich, which would explain why [Lexon Director 1] confirmed [Focus Director 1]'s recorded understanding on this point in his email response.

[2801] Advanz RLF, 30 November 2021, paragraph 1.6.1 and 2.56 (URN: PRO-C7917).

[2802] As noted in paragraph F.18.2 above, such an interpretation would be consistent with the CMA's finding that [Lexon Director 1] and [Focus Director 1] had originally decided to enter into the Focus-Lexon Heads of Terms by 1 August 2013 in a form which omitted from the document the intention that the profit share payments would be made to Lexon as compensation for the agreement it had made with Alliance not to enter the market (see paragraph 5.302).

[2803] Agreement for the sale and purchase of Focus Pharmaceuticals executed 29 September 2014 Schedule 5, Article 17 (URN: PRO-E003826).

[2804] Medreich submission dated 21 March 2019, in response to the CMA questions of 15 March 2019, response to question 2.1 (URN: PRO-C3856). See paragraphs 5.434 and 5.435.

F.44 Advanz made similar representations[2805] as regards the plausibility of this explanation for the 4 November 2014 exchange as it had done for the 14 April 2014 exchange (see paragraph F.19 above) to which the CMA's analysis as set out in paragraph F.20 applies here also.

F.45 Cinven submitted that this explanation for the November 2014 exchange was undermined by Lexon agreeing to a renegotiation of the profit share against its commercial interests.[2806] However, the CMA rejects this submission: the fact that Lexon agreed to amend the profit share in recognition of Focus' success in raising prices (see paragraph 5.551) does not mean that Focus and Lexon could not at the same time have seen the value in recording, incorrectly, that Lexon had placed an order for stock at that point in time.

The Parties' representations on the CMA's approach to assessing the 2014 Correspondence

F.46 The Parties made a number of representations regarding the CMA's assessment of the 2014 Correspondence, and its finding that there are a number of plausible explanations for the exchanges that do not involve an expectation on the part of Lexon or Focus of the supply by Lexon to Focus of commercial volumes of Prochlorperazine POM product.[2807]

F.47 Advanz submitted that:

F.47.1 the explanations set out by the CMA cannot all be equally plausible and Cinven submitted that the CMA has not indicated which of the alternative explanations are its '*primary case*';[2808]

F.47.2 it was not open to the CMA to rely on plausible explanations to reach an infringement finding and that the explanations advanced by the CMA did not constitute '*precise and consistent evidence to give grounds for a firm conviction that the alleged infringement took place*';[2809]

[2805] Advanz RLF, 30 November 2021, paragraph 2.56 (URN: PRO-C7917).

[2806] Cinven RLF, 30 November 2021, paragraph 3.29 (URN: PRO-C7919).

[2807] Lexon stated that it did not accept or admit that any of the interpretations put forward by the CMA to explain the 2014 Correspondence were either credible, based on the facts of the case, or consistent or inconsistent with the CMA's proposed findings as regards the Market Exclusion Agreement (Lexon RLF, 25 November 2021, paragraph 2 (URN: PRO-C7901)).

[2808] Advanz RLF, 30 November 2021, paragraph 1.5 (URN: PRO-C7917). Cinven RLF, 30 November 2021, paragraph 3.15 (URN: PRO-C7919).

[2809] Advanz RLF, 30 November 2021, paragraphs 1.7, 2.48 and 2.59 (URN: PRO-C7917). Cinven also submitted that the CMA is only entitled to infer matters where its inference is the only plausible explanation of the evidence (Cinven RLF, 30 November 2021, paragraph 3.20 footnote 27 URN: PRO-C7919)).

F.47.3 because the CMA advanced a number of interpretations for each exchange, it follows that such interpretations '*by their nature…cannot be anything but speculative and implausible*';[2810] and

F.47.4 the CMA is required to have put the plausible explanations set out above to the authors of the 2014 Correspondence through further witness interviews.[2811]

F.48 Cinven submitted that the plausibility of individual explanations is undermined as, in their submission, the individual explanations were in some instances inconsistent with each other.[2812] Cinven also submitted that the CMA has assumed that an infringement occurred and then sought to interpret any potentially inconsistent evidence in a manner that is consistent with that assumed position.[2813]

F.49 The CMA rejects these submissions, for the reasons set out below:

F.49.1 The CMA has not identified a large number of freestanding explanations. Rather, as explained, the CMA considers that there are several overlapping explanations consistent with the intent to supply one batch to avoid the operation of the Sunset Clause.

F.49.2 The CMA has not settled on one single view of the Parties' exact motivations behind every expression in the 2014 Correspondence because it does not need to. The CMA does not rely on the 2014 Correspondence to establish the existence of the Market Exclusion Agreement (or Focus' participation in it). The CMA's point is, rather, that the 2014 Correspondence can be explained in various ways and that, when the evidence is viewed in the round, it does not undermine the existence of the Market Exclusion Agreement or Focus' participation in it.

F.49.3 Advanz is wrong to claim that the CMA is obliged to have put the plausible explanations identified above to the authors of the 2014 Correspondence through further witness interviews. The 2014 Correspondence was discussed in the witness interviews carried out with [Lexon Director 1] and [Focus Director 1] (as set out in the extracts in paragraphs 5.594, 5.603 and 5.609) and the CMA's assessment has taken account of their explanations. The CMA's case was then put to the Parties through a letter of facts.[2814]

F.49.4 The CMA's finding that each of the individual explanations is plausible is not undermined by the Parties' claim that, in some instances, the

[2810] Advanz RLF, 30 November 2021, paragraphs 2.46 and 2.57 (URN: PRO-C7917).
[2811] Cinven RLF, 30 November 2021, paragraph 3.24 (URN: PRO-C7919).
[2812] Cinven RLF, 30 November 2021, paragraphs 2.7 and 3.41 (URN: PRO-C7919).
[2813] Cinven RLF, 30 November 2021, paragraphs 1.10, 3.16, 3.21 to 3.23 (URN: PRO-C7919).
[2814] Letter of Facts 12 November 2021 and annexes (URN: PRO-C7829 to URN: PRO-C7863).

individual explanations would themselves be mutually inconsistent. In the main, the CMA's finding is that there are several key themes that may plausibly explain the 2014 Correspondence (which are not inconsistent with the existence of the Market Exclusion Agreement); however, the CMA does not find that all of the potential explanations are complementary and cumulative in application, and in some instances they are put forward as alternatives.

F.49.5 The CMA rejects Cinven's submission that the CMA has assumed that an infringement occurred and then sought to interpret any potentially inconsistent evidence in a manner that is consistent with that assumed position. Rather, the CMA has considered the evidence in the round. That has necessarily involved (a) asking whether there are plausible interpretations of the 2014 Correspondence which are consistent with the finding of a Market Exclusion Agreement and Focus' participation in it, and then (b) standing back and assessing the evidence in the round to decide whether there was a Market Exclusion Agreement and whether Focus participated in it.

Annex G: Parties' representations on Focus Participation

The Parties' representations that the evidence provided by the leniency applicant, Medreich, does not implicate Focus

G.1 The CMA has considered representations made by Advanz[2815] that the leniency applicant in this case, Medreich, '*offers no evidence against Focus*'. Specifically, Advanz stated that:

G.1.1 Medreich does not implicate Focus and makes no allegations regarding Focus's awareness of or participation in the Market Exclusion Agreement; and

G.1.2 the Medreich witnesses do not provide evidence of Focus knowing of and intentionally contributing to the common objective.

G.2 Advanz submitted that the EU General Court in its Icap and Soliver judgments, 'was careful to emphasise that the leniency applicant or whistleblower in each case had not stated that ICAP and Soliver (respectively) were aware of the cartel'[2816] and that it was 'of material significance' that the leniency applicant in this case did not implicate Focus with knowledge of the Market Exclusion Agreement or with an intention to participate in it.[2817]

G.3 More generally, Advanz submitted that Medreich's leniency evidence consists of repeated statements that it did not have visibility (or knowledge) as regards the Infringement and, even in relation to the sharing of the profit between Lexon and Medreich that Lexon obtained from the Focus-Lexon Heads of Terms, the Medreich employees and former employees do not accept responsibility for any illegal activities,[2818] for example citing [Medreich Director 2]'s interview transcript[2819] and [Medreich Employee 1]'s comment in his interview that '*… as far as I know, nobody in Medreich had any clue that there was anything distorting the market, or anything in the form of a cartel-type behaviour.*'[2820]

G.4 Cinven submitted that Medreich had informed the CMA that its understanding of the Focus-Lexon Heads of Terms was based on speculation, and as such its

[2815] See Advanz RSO, 1 August 2019, paragraphs 3.128 – 3.131 (URN: PRO-C5111). See also Advanz RSO, 1 August 2019, paragraphs 3.23 and 3.24 (URN: PRO-C5111) and Advanz RLF, 22 April 2021, paragraph 2.59 (URN: PRO-C7112).

[2816] Advanz RSO, 1 August 2019, paragraph 3.74 (URN: PRO-C5111).

[2817] Advanz RSO, 1 August 2019, paragraphs 3.23, 3.24 and 3.130 (URN: PRO-C5111). See also Advanz RLF, 22 April 2021, paragraph 2.59 (URN: PRO-C7112).

[2818] See Advanz RSO, 1 August 2019, paragraph 3.131 (URN: PRO-C5111).

[2819] Interview [Medreich Director 2], 2 July 2018, page 109, lines 7-10 (URN: PRO-C3684).

[2820] Interview [Medreich Employee 1], 12 July 2018, page 145, lines 21-23 (URN: PRO-C3666).

claims are at best hearsay.[2821] In particular, Cinven quoted extracts from [Medreich Employee 1]'s interview in which [Medreich Employee 1] said that his understanding was formed by looking at the events '*with hindsight*' and that he '*can only speculate*' on what occurred, since '*[w]e never discussed it*'.[2822]

G.5 Cinven added that none of the Medreich emails cited in the SO, nor any of the transcripts of the interviews with current or former Medreich employees, suggest that Focus was aware or ought to have been aware of any alleged Market Exclusion Agreement between Alliance and Lexon.[2823]

G.6 The CMA has considered Advanz and Cinven's representations in this respect, but it does not consider that they undermine the CMA's conclusion that Focus was aware of the conduct of Alliance and Lexon in pursuit of the common objective or that it could reasonably have foreseen it and that it was prepared to take the risk, and intended to contribute by its own conduct to, the common objective, for the following reasons.

G.6.1 The CMA's finding that Focus was aware of the conduct of Alliance and Lexon in pursuit of the common objective or that it could reasonably have foreseen it and that it was prepared to take the risk and intended to contribute by its own conduct to the common objective does not depend solely, or principally, on evidence originating from Medreich or provided by Medreich in its capacity as leniency applicant; this conclusion has been reached based on the evidence as set out in paragraphs 5.635 to 5.645 of this decision.

G.6.2 It is not necessary for the above finding to rest on any evidence originating from Medreich or provided by it in its capacity as leniency applicant. Leniency evidence does not have any particular legal significance when a competition authority is assessing whether an undertaking has participated in an infringement. Indeed, in the *Icap* and *Soliver* judgments cited by Advanz, the EU General Court does not apply any hierarchy of evidence when considering the settlement,[2824] whistle-blower and leniency[2825]

[2821] Cinven RSO, 15 August 2019, paragraph 4.142 (URN: PRO-C5132).

[2822] Cinven RSO, 15 August 2019, paragraph 4.142 (URN: PRO-C5132), citing Interview [Medreich Employee 1], 12 July 2018, pages 73 and page 116 (URN: PRO-C3666).

[2823] Cinven RSO, 15 August 2019, paragraph 4.143 (URN: PRO-C5132).

[2824] See Case T-180/15 *Icap and Others v Commission*, EU:T:2017:795, paragraphs 126-128 and 136-145. For example, at paragraph 126, the Court notes that the European Commission's '*contested decision mentions only two items of evidence that might be capable of proving that Icap knew of RBS's participation in the UBS/RBS 2007 infringement, namely (i) the conversation of 14 August 2007 and (ii) UBS's statements in its application for settlement. […]*'.Having found at paragraph 127 that the settlement statements did not show the requisite awareness, the EU General Court proceeded to find at paragraph 128 that '*[i]t follows that the only item of evidence capable of showing that Icap knew of the role played by RBS in the UBS/RBS 2007 infringement is to be found in a passage of the conversation of 14 August 2017 […]*'.

[2825] T-68/09 *Soliver NV* v *Commission*, EU:T:2014:867, paragraphs 82-98. As regards the whistleblower evidence in particular, see paragraph 84 and as regards the leniency evidence in particular see paragraphs 93 to 94. While Advanz also refers to paragraph 98 of this judgment, here the EU General Court merely finds that references by the Commission

evidence. Rather the EU General Court assesses such evidence in the same way as, and on an equal footing to, the other evidence before the Court.

G.6.3 Notwithstanding the above, the leniency agreement signed by Medreich does include, as part of the description of the cartel activity, Focus' participation in the Market Exclusion Agreement. Medreich signed a leniency agreement that described the Market Exclusion Agreement as:

'A market sharing arrangement by way of a pay-for-delay agreement relating to Prochlorperazine 3mg buccal tablets prescription-only medicine ('Prochlorperazine POM') between Alliance Pharmaceuticals Limited ('Alliance') and Lexon (UK) Limited ('Lexon') in which Focus Pharmaceuticals Limited ('Focus'), and subsequently the Applicant, participated and were therefore each a party to that agreement.'[2826]

G.6.4 The CMA has not alleged or found that there was direct contact relating to the Market Exclusion Agreement between Focus and Medreich. Medreich's understanding of the Market Exclusion Agreement was based on the information provided to it by Lexon. As a result, it is not possible to place any exculpatory weight on the fact that Medreich's understanding of Focus' participation in the Market Exclusion Agreement was based on information obtained from Lexon.

G.6.5 In any event, the documentary evidence is clear that Medreich was aware of Focus' role in the Market Exclusion Agreement, as evident from, in particular:

(a) [Medreich Employee 1]'s email of 4 February 2014 showing knowledge of the '*Focus deal … on the 3mg POM licence*'.[2827]

(b) [Medreich Employee 1]'s spreadsheet of 28 March 2014 showing his understanding that Alliance supplied Focus at a fixed price and Focus took 25% of the profit of the sales of the Alliance product: '*Focus take 25%*' and '*We split 75% of the profit with Lexon'*.[2828]

(c) [Medreich Director 1]'s email of 7 April 2014 in which he questioned whether Focus should accept the increase in the price paid to Alliance

to leniency statement extracts at the court hearing did not cast doubt on the Court's view that the evidence did not show the applicant was aware, or should have been aware, of the general scope and essential characteristics of the cartel at issue.

[2826] Leniency agreement between the CMA and Medreich as signed 21 May 2019, paragraph 3 (URN: PRO-C6682).

[2827] Email [Medreich Employee 1] to [Lexon Director 1] cc [Medreich Director 2] entitled *'Products'* 4 February 2014 (URN: PRO-E002744); see further paragraph 5.665.

[2828] Email [Medreich Employee 1] to [Medreich Director 1] and [Medreich employee] cc [Medreich employee] and [Medreich Director 2] entitled '*RE: Prochlorperazine 3 mg x 50 Focus*' 28 March 2014 (URN: PRO-E002787) attaching Excel spreadsheet entitled *'Prochlorperazine 2014 budget.xlsx'* 28 March 2014 (URN: PRO-E002788); see further paragraph 5.673.

for Prochlorperazine POM (from £4.85 from the initial batch to £5.65 going forward) stating '*… Focus cant [sic] accept such price increases on costs which in any case are inflated many folds…. The magnitudes will multiply once we throw additional products in to similar arrangements.*'[2829]

G.6.6 The explanation provided by [Lexon Director 1] to [Medreich Director 2] and [Medreich Director 1] in 2016 relating to the need to accommodate Primegen, as recorded in [Lexon Director 1]'s email of 8 July 2016: '*…there is a new player and we need to accommodate that as per conversation with [Medreich Director 2] and [Medreich Director 1]*'.[2830]

G.6.7 The CMA considers that [Medreich Employee 1]'s comments, as quoted by Advanz and Cinven (see paragraphs G.3 and G.4 above) related predominantly to the legality of the arrangements and that it is clear from the contemporaneous evidence (see paragraph 5.669) and from other parts of [Medreich Employee 1]'s interview (see for example paragraphs 5.661 and 5.668) that Medreich was aware (or could reasonably have foreseen and was prepared to take the risk) of the common objective and the conduct of Focus in pursuit of the common objective.

G.6.8 In so far as the Advanz representations refer to the evidence provided by [Medreich Director 2] in his interview (see paragraph G.3 above), the CMA considers that the witness interview evidence provided by [Medreich Director 2] should be treated with caution. On 23 October 2020, the CMA wrote to [Medreich Director 2] informing him that the CMA was withdrawing his immunity from a competition disqualification order with effect from the date of that letter.[2831] The CMA's reasoning for that decision was set out in full in that letter, including that the CMA found that [Medreich Director 2] had not been complete and truthful in his interview in relation to the evidence he had provided at interview in respect of, amongst other things, his email of 21 July 2017[2832] (see paragraph 5.578).

[2829] Email [Medreich Director 1] to [Medreich Employee 1] and [Medreich employee] cc [Medreich Director 2] and [Medreich employee] entitled '*RE: Prochlorperazine 3mg share profit Jan 2014 – March 2014*' 7 April 2014 (URN: PRO-E002798).

[2830] Email [Lexon Director 1] to [Lexon employee] cc [Medreich Director 2] and [Medreich employee] and [Lexon employee] entitled '*Re: Prochlorperazine Profit Share Reconciliation Q2 2016*' 8 July 2016 (URN: PRO-E003130) see further paragraph 5.676.

[2831] CMA Letter sent to [Medreich Director 2], 23 October 2020, paragraphs 61 to 72 (URN: PRO-C6362).

[2832] Email [Medreich Director 2] to [Meiji employee] entitled '*Re: Prochlorperazine --- profit sharing*' 21 July 2017 (URN: PRO-E003351).

The Parties' representations that it is necessary for the CMA to show that Focus attended meetings

G.7 Cinven submitted that in precedent cases, parties have been found not to have had the requisite levels of awareness for participation in an infringement based on their absence from cartel meetings. Cinven notes that the CMA has not alleged that Focus was present at any meetings between Alliance and Lexon at which the CMA claims that the anti-competitive objective was agreed.[2833] Cinven also submitted that it is necessary for the CMA to prove through primary evidence that Focus attended meetings at which anti-competitive discussions and agreements took place, and thereby intended to contribute to a Market Exclusion Agreement.[2834]

G.8 Contrary to Cinven's submissions, it is not necessary to prove that Focus attended meetings at which anti-competitive discussions and agreements took place to demonstrate that Focus had the requisite awareness or to demonstrate that Focus intentionally contributed by its own conduct to the common objective.

G.9 While the EU Courts have found that to prove to the requisite legal standard that an undertaking participated a cartel 'it is **sufficient** for the Commission to show that the undertaking concerned attended meetings at which anticompetitive agreements were concluded, without manifesting its opposition to such meetings' (emphasis added)[2835] such attendance has not been found to be a **necessary** condition. The EU General Court has held that the fact that an undertaking did not attend a cartel meeting is not decisive if the functioning of the cartel shows that its members did not need to participate in meetings to be aware of or involved in the agreements.[2836]

G.10 In *Soliver*, cited by Cinven[2837] while the EU General Court found that the applicant had not participated in any cartel meetings it did not find that attendance at such meetings was a precondition to finding the requisite awareness of an infringement, or an intentional contribution to the common objective. The EU General Court also did not find that absence of attendance at meetings disposed of the case. Rather, the EU General Court went on to assess whether, based on the other evidence relied on by the European Commission, the applicant's participation in the relevant infringement had been established.[2838]

[2833] Cinven RSO, 15 August 2019, paragraphs 3.29 to 3.30 (URN: PRO-C5132). Advanz also submitted that the CMA had not alleged that Focus attended the meetings between Alliance and Lexon (Advanz RSO, 1 August 2019, paragraph 3.115 (URN: PRO-C5111)).

[2834] Cinven RSO, 15 August 2019, paragraph 3.25 (URN: PRO-C5132).

[2835] Case T-99/04 *AC Treuhand v Commission*, EU:T:2008:256, paragraph 130; T-29/05 *Deltafina SpA v Commission*, EU:T:2010:355, paragraph 59. See also Case C-194/14 P *AC Treuhand AG v Commission,* EU:C:2015:717, paragraph 31.

[2836] Case T-204/08 *Team Relocations v Commission*, EU:T:2011:286, paragraph 51.

[2837] Cinven RSO, 15 August 2019, paragraph 3.29 (URN: PRO-C5132), citing T-68/09 *Soliver NV v Commission* EU:T:2014:867, paragraph 66.

[2838] Case T-68/09 *Soliver NV v Commission*, EU:T:2014:867, paragraphs 67-105.

Annex H: Parties' representations on penalties

H.1 The CMA addresses in this Annex the Parties' representations on penalties which have not already been discussed in Chapter 8 of this Decision.

Intention and negligence

H.2 As set out at paragraphs 8.23 and 8.70 of the Decision, the Parties have submitted a number of representations on the CMA's proposed conclusion that they committed the Infringement intentionally or, at the very least, negligently, including as to the test to be applied.

The Parties' representations on the applicable legal test

H.3 Advanz submitted that the correct legal test for intent and negligence in this case is whether Focus was aware that its conduct is 'probably' or 'clearly' unlawful, based on the criteria set out by the CAT in *Cardiff Bus* and *Sainsbury's/MasterCard*.[2839]

H.4 The CMA rejects this argument. As recently confirmed by the CAT in its *Paroxetine*[2840] judgment, the relevant legal test for intent and negligence in competition law infringement proceedings under the Act remains that set out in *Napp, Argos, Ping, Schenker* and others, and applied by the CMA in this Decision.

H.5 The CAT's judgments in *Cardiff Bus* and *Sainsbury's/MasterCard* neither modified nor glossed the well-established test for the assessment of intentional or negligent conduct.[2841] Rather, the judgments considered the issues of intent and/or negligence on the specific facts of those cases. They did so by reference to particular criteria, namely whether the infringing conduct was '*probably or clearly unlawful*' which the CAT considered to be suitable for the purpose of determining an award of exemplary damages (in the case of *Cardiff Bus*) and the illegality or '*ex turpi causa*' defence (in the case of *Sainsbury's/MasterCard*).[2842] Those criteria are neither necessary nor appropriate for determining the question of intent and/or negligence in the present case, which can be established by the evidence set out and referred to in paragraphs 8.22 to 8.69 of this Decision.

[2839] Advanz RDPS, 7 July 2021, paragraphs 2.9-2.10, 4.5-4.9, 5.6 (URN: PRO-C7481).

[2840] *Paroxetine II* [2021] CAT 9, paragraphs 114-117, by reference to *Napp* [2002] CAT 1, paragraphs 456 and 457, *Schenker*, C-681/11, EU:C:2013:404, paragraph 38 and *Ping* [2020] EWCA Civ 13, paragraph 117.

[2841] *Cardiff Bus* [2012] CAT 19, paragraph 489ff; *Sainsbury's/Mastercard* [2016] CAT 11, paragraph 322ff.

[2842] See *Cardiff Bus* [2012] CAT 19, paragraph 468, which refers to the need to establish a '*guilty knowledge*' and a '*motive'* of making a profit; see also *Sainsbury's/MasterCard* [2016] CAT 11, paragraph 406, which refers to the establishment of a turpitudinous '*state of mind*'. The scale of awareness of clear or probable lawfulness or clear or probable unlawfulness makes sense when deciding whether an act is turpitudinous but does not apply to the CMA's jurisdiction to impose fines. For example, the CAT's observations at paragraphs 320 to 327 of *Sainsbury's/MasterCard* drew upon its earlier observations in relation to exemplary damages in *Cardiff Bus* [2012] CAT 19. The CAT was not applying or seeking to modify the established test for intention or negligence under s.36(3) of the Act (which does not require knowledge that conduct is unlawful under Chapter I: *Napp* [2002] CAT 1 at paragraph 456).

H.6 None of the recent CAT or Court of Appeal judgments dealing with liability/fines for competition law infringements under the Act (as opposed to damages actions) since the *Cardiff Bus* and *Sainsbury's/MasterCard* judgments mention or apply the *Cardiff Bus / Sainsbury's/MasterCard* criteria either – see, eg *Ping*,[2843] *Royal Mail*,[2844] and *Paroxetine*.[2845]

H.7 Taking a different view would in any event risk violating section 60A of the Act, which requires the UK authorities and courts to act (so far as is compatible with the provisions of the Act) with a view to securing that there is no inconsistency between the principles that they apply, and the decision that they reach, and the principles laid down by the TFEU and the EU Court before IP completion day, and any relevant decision made by that Court before IP completion day,[2846] so far as applicable immediately before IP completion day in determining any corresponding question arising in EU law (subject to certain exceptions).[2847] The CMA is not aware of any EU precedents (either European Commission decisions or judgments of the EU Court of Justice or the EU General Court) which have established or applied a test for negligence or intent which mirrors or is similar to that set out in *Cardiff Bus / Sainsbury's/MasterCard*.[2848]

The Parties' representations on legal certainty, novelty and complexity

H.8 Advanz submitted that a lack of awareness would negate a finding of intention or negligence where it is unclear whether the conduct in question was unlawful, including because the case pursued by the competition authority is novel/there is

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[2843] See *Ping* [2020] EWCA Civ 13, paragraph 117, which refers explicitly to the test set out in *Argos Limited and Littlewoods Ltd v Office of Fair Trading* [2005] CAT 13, paragraph 221 according to which: '*An infringement is committed negligently if the undertaking ought to have known that its conduct would result in a restriction of competition*.' The same paragraph also refers to the statement in *Schenker* that '*Ignorance or mistake of law does not prevent a finding of intentional infringement: see Case C-681/11 Bundeswettbewerbsbehörde v Schenker & Co AG EU:C:2013:204, para 38*'.

[2844] See *Royal Mail* [2019] CAT 27, paragraphs 782ff: '*What matters is not whether Royal Mail was aware of any specific legal characterisation of its conduct but whether it was aware of its anti-competitive nature. This is shown very clearly in the Tribunal's judgments in the Argos and Littlewoods and Napp cases, referred to in paragraphs 766 and 767 above. Moreover, as the General Court stated in Case T-472/13 Lundbeck EU:T:2016:449 (at paragraph 762):*

"[…] with regard to whether an offence was committed intentionally or negligently and is therefore liable to be penalised by the imposition of a fine in accordance with the first subparagraph of Article 23(2) of Regulation No 1/2003, it is settled case-law that that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty (see judgment in Schenker & Co. and Others, cited in paragraph 748 above, EU:C:2013:404, paragraph 37 and the case-law cited)."'

[2845] *Paroxetine II* [2021] CAT 9, paragraphs 114-117. (The potential relevance of the legal test applied in *Cardiff Bus* and *Sainsbury's/MasterCard* to assess intention or negligent conduct was not discussed in the CAT's judgment despite having been raised by one of the parties (Merck)).

[2846] IP completion day is defined as 31 December 2020 at 11.00 p.m. in section 39 of the European Union (Withdrawal Agreement) Act 2020.

[2847] This also applies with regard to the CMA's powers to impose penalties. As the CAT pointed out in *Napp,* the slightly different structure under sections 36 and 38 of the Act, as compared to Article 15(2) of Council Regulation no.17, now replicated in very similar form in Article 23(2) and (3) of Council Regulation 1/2003, did not constitute a relevant difference between the provisions concerned for the purposes of section 60 of the Act, the predecessor provision of section 60A of the Act. See *Napp* [2002] CAT 1, paragraphs 453-455.

[2848] Advanz submitted that the test on intentional or negligent conduct set out in *Cardiff Bus* and *Sainsbury's/MasterCard* is in line with the case-law of the EU Courts on penalties and is '*confirmed by a consistent body of case-law and decisional practice finding no jurisdiction to fine an undertaking which was not aware, or could not have been aware, that the conduct in question was unlawful*'; Advanz RDPS, 7 July 2021, paragraph 4.9 (URN: PRO-C7481). The CMA disagrees and also notes that Advanz has not cited any cases in support of this contention.

no legal precedent, or because the assessment of the lawfulness of the conduct involves complex questions of law and economics. Advanz cited *Compagnie Générale Maritime* and *Atlantic Containers* in support of its submissions.[2849]

H.9 An assessment of novelty excusing a fine is very dependent on the particular facts and circumstances of the case.[2850] The *Compagnie Générale Maritime* and *Atlantic Containers* cases are based on specific facts: *Atlantic Containers* was an abuse of dominance case, both cases concerned the maritime transport sector and in both judgments, the EU General Court made clear that the '*complex questions of both an economic and a legal nature*' arose due to the close links between the relevant arrangements with maritime transport '*which is the subject of a wholly specific and exceptional set of rules*'.[2851] Such considerations do not arise in this case.

H.10 The CAT's assessment of these cases in *Paroxetine* (in the context of novelty excusing a fine) illustrates the extent to which the facts of these cases are far removed from the present case and do not provide precedent or justification for not imposing penalties for the breach of Chapter I in the present case.

H.10.1 As regards *Compagnie Générale Maritime*, the CAT noted that '*the Court of First Instance found that although the parties were aware of the anti-competitive character of their liner conference arrangement, it involved long-standing and public price-fixing which dated back to a period before the Commission had itself defined its position on the application of the competition rules to maritime transport. The Commission's own conduct had led the shipping companies to believe that their agreement was not unlawful. And by a decision adopted shortly beforehand, the Commission had imposed no penalty on the parties to another liner conference. See the judgment at paras 481-487*'.[2852]

H.10.2 As regards *Atlantic Containers*, the CAT noted that '*there, fines had been imposed by the Commission on parties to the Trans-Atlantic Conference Agreement ("TACA") pursuant to the then regulation governing international maritime transport (Reg 4056/86) and, in part, the then regulation governing inland transport (Reg 1017/68), on the basis that certain provisions of the TACA concerning service contracts were contrary*

[2849] Advanz RDPS, 7 July 2021, paragraphs 4.11-4.15 (URN: PRO-C7481).

[2850] *Paroxetine II* [2021] CAT 9, paragraph 140.

[2851] T-86/*95 Compagnie Générale Maritime*, EU:T:2002:50, paragraph 484. T-191/98 and T-212/98 to T-214/98 *Atlantic Containers,* EU:T:2003:245, paragraph 1615. In *Atlantic Containers* the EU General Court also observed that the Commission's decision was the first decision which directly assessed whether practices adopted by shipping conferences accorded with competition law rules (paragraph 1611).

[2852] *Paroxetine II* [2021] CAT, paragraph 140(1). See also the judgment of the Court of Appeal in *Ping*, where the Court of Appeal (in its assessment of intention or negligence) rejected the appellant's arguments that the situation in *Compagnie Générale Maritime* was similar to that of the appellant. It observed that in *Compagnie Générale Maritime*, the EU General Court noted that the infringement found by the Commission dated back to a period before the Commission had itself defined its views on the application of the rules to maritime transport, and the Commission had by its conduct led the applicants to believe that their agreement was not unlawful. Those factors were not present in *Ping* and are also not present in this case. *Ping* [2020] EWCA Civ 13, paragraph 122.

to Art 86. On appeal, the Court of First Instance held that since the TACA had been notified to the Commission for exemption, it was entitled to immunity from fines under Reg 4056/86. Although it had since been established that immunity did not similarly apply to a fine under Reg 1017/68, that accounted for only c. 5% of the fines imposed and the Court set aside the fines under that provision for several reasons, including the fact that the TACA had been notified voluntarily to the Commission and the applicants had thus on their own initiative revealed the position to the Commission; there was uncertainty at the time when TACA was notified whether notification granted immunity under Reg 1017/68 as well as under Reg 4056/86; the legal treatment of the practices of shipping conferences on service contracts was "not at all straightforward"; and conduct notified for individual exemption under Art 85(3) [now Art 101(3)] had not previously been subject to a fine for infringement of Art 86 [now Art 102]: judgment at paras 1597-1634'.[2853]

H.11 Advanz submitted that this case law indicates that a fine will be imposed only if unlawfulness would have been clear to the relevant undertaking,[2854] and that there was no basis on which the CMA could fine Focus because the CMA did not explain that the alleged unlawfulness would have been clear to Focus, or put forward other decisions in which a fine was imposed in similar circumstances to the alleged role played by Focus.[2855] The CMA rejects these arguments.

H.12 As recently confirmed by the CAT in *Paroxetine*, '*the question is not whether the Appellant should have known that the agreements were against the law but that they had an anticompetitive nature*'.[2856] The CMA is therefore not required to explain that the alleged unlawfulness '*would have been clear*' to Focus. It is also not necessary for the CMA to put forward other decisions where a fine was imposed in similar circumstances to the alleged role played by Focus, as a lack of legal precedent does not preclude a finding that an infringement was committed intentionally or negligently.[2857]

H.13 In any event (and in contrast to the case-law cited by Advanz) there is no '*genuine uncertainty*' in relation to market sharing/market exclusion agreements, and there is no novelty or complexity in relation to the CMA's case of the type seen in the cases cited by Advanz. All of the principles applied by the CMA are found in previous case-law and the CMA's case does not involve '*complex questions of both an economic and a legal nature*'. Indeed, in its *Lundbeck* judgment, the EU

[2853] *Paroxetine II* [2021] CAT, paragraph 140(7).

[2854] Advanz RDPS, 7 July 2021, paragraph 4.16 (URN: PRO-C7481).

[2855] Advanz RDPS, 7 July 2021, paragraph 4.17 (URN: PRO-C7481).

[2856] *Paroxetine II* [2021] CAT 9, paragraph 125.

[2857] *Paroxetine II* [2021] CAT 9, paragraph 125. '*Nor does the fact that at the time there was no legal precedent holding that an agreement of this nature infringed competition law preclude a finding that the infringement was committed intentionally or negligently: cp Case C-457/10 P AstraZeneca EU:C:2012:770 at para 164*'.

Court of Justice dismissed the appellant's argument around the novelty of the penalties in those pay-for-delay cases.[2858]

H.14 The CMA therefore rejects Advanz's submissions with regard to legal certainty, novelty and legal and economic complexity.

The Parties' representations on excusable error

H.15 Advanz submitted that no fine can be imposed where its imposition frustrates a legitimate expectation that the conduct complained of was lawful and/or that it would not be punished, including as a result of an excusable error on the part of the relevant undertaking. Advanz submitted that its arguments in respect of intention and negligence equally support a finding of 'excusable error' which precludes the imposition of a fine, or justifies the imposition of only a nominal fine.[2859]

H.16 The CMA rejects this submission. The case-law cited by Advanz makes clear that the concept of excusable error is applicable only in exceptional circumstances. In *CMB and Christof v Commission*, the EU General Court found that '*the concept of excusable error, which arises directly out of a concern that the principles of legal certainty and the protection of legitimate expectations should be upheld can, according to settled case-law, concern only exceptional circumstances in which, in particular, the conduct of the institution concerned has been, either alone or to a decisive extent, such as to give rise to a pardonable confusion in the mind of a party acting in good faith and exercising all the diligence required of a normally experienced person*'. No such exceptional circumstances giving rise to '*pardonable confusion*' arise on the facts of this case.

H.17 Advanz failed to explain the basis on which its arguments in respect of intention and negligence '*equally*' supported a finding of '*excusable error*'. Further, the CMA has addressed at paragraphs H.8 to H.14 above Advanz's arguments regarding legal certainty. The CMA therefore rejects Advanz's submissions that excusable error precludes the imposition of a fine, or justifies the imposition of only a nominal fine in relation to Focus.

The Parties' representations on the burden of proof

H.18 Advanz submitted that the burden of proof on the CMA is '*to adduce precise and consistent evidence to support the firm conviction that Focus participated in the alleged infringement intentionally or negligently*' and that the CMA has failed to do this.[2860]

[2858] C-591/16 P *Lundbeck v Commission*, EU:C:2021:243, paragraphs 166-168. See also *Paroxetine II* [2021] CAT 9, paragraph 142 which refers to the EU General Court judgments in the *Lundbeck* cases.

[2859] Advanz RDPS, 7 July 2021, paragraphs 2.16, 5.71 (URN: PRO-C7481).

[2860] Advanz RDPS, 7 July 2021, paragraph 5.5 (URN: PRO-C7481).

H.19 As set out at paragraphs 5.1 and paragraphs 5.17 to 5.22 of this Decision the burden of proving an infringement of the Chapter I prohibition is on the CMA and the standard of proof is on the balance of probabilities.[2861] Based on the evidence set out and referred to in paragraphs 5.630 to 5.654 and paragraph 5.688 of this Decision, the CMA has demonstrated to the requisite legal standard that Focus participated in the Market Exclusion Agreement, infringing the Chapter I prohibition. On making such a decision, under section 36(3) of the Act, the CMA may require Focus to pay a penalty if it is satisfied the undertaking participated in the Infringement intentionally or negligently. The legal test for intention or negligence is summarised in paragraphs 8.14 to 8.21 of the Decision and based on the evidence and for the reasons set out in paragraphs 8.65 to 8.69 of this Decision, the CMA is satisfied that Focus participated in the Infringement intentionally or at the very least negligently.

Parties' representations on the CMA's application of the legal test for intent/negligence

Alliance

H.20 Alliance submitted that its conduct was neither intentional nor negligent and therefore that the condition for imposition of a penalty in section 36(3) of the Act is not satisfied. Alliance submitted that '*[a]t most, the factual evidence put forward by the CMA may suggest that Alliance was unwittingly drawn into the [Focus-Lexon-Medreich] Agreement (as defined in the SO)*'.[2862]

H.21 Alliance submitted that the CMA has inferred Alliance's entry into, and awareness of, the Market Exclusion Agreement based on inferences drawn principally from two documents and '*speculative suppositions*' concerning what may have been said or agreed at meetings and that when properly construed the relevant documents relied on by the CMA are consistent with Alliance being unaware of the arrangements entered into by Focus, Lexon and Medreich.[2863]

H.22 Alliance further submitted that there is no evidence that Alliance was aware of the Lexon-Focus distribution agreement (and the associated profit share), let alone a willing participant in it. Alliance submitted that as the arrangements which gave rise to the Focus-Lexon-Medreich agreement were '*effectively agreed and put into place "behind Alliance's back"'* there is no basis upon which to suggest that Alliance 'ought' to have known about or reasonably foreseen any anti-competitive

[2861] *Napp* [2002] CAT 1, paragraph 109; *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraphs 197-204; *North Midland Construction v OFT* [2011] CAT 14, paragraphs 15-16 and *AH Willis and Sons Limited v OFT* [2011] CAT 13, paragraphs 45-47, both citing *Re H (Minors)* [1996] AC 563, paragraph 586; see also *Re D (Northern Ireland)* [2008] 1 WLR 1499, paragraph 28; and *Re B* [2009] 1 AC 11, paragraph 13.

[2862] Alliance RDPS, 7 July 2021, paragraph 2.2 (URN: PRO-C7461). Alliance also submitted that the evidence does not demonstrate this, but proceeds in its DPS response on the basis, *quod non*, that it does.

[2863] Alliance RDPS, 7 July 2021, paragraph 2.3 (URN: PRO-C7461).

conduct by Lexon, Focus and Medreich which may have followed.[2864] Alliance also submitted that the mere parallelism of Alliance's decision to appoint Focus as its exclusive distributor and any later '*opportunistic*' agreement struck between Focus, Lexon and Medreich does not provide a sufficient basis for establishing Alliance's '*awareness*' of any anti-competitive conduct agreed upon by those parties.[2865]

H.23 The CMA rejects these arguments.

H.24 The CMA's finding that Alliance entered into the Market Exclusion Agreement (and the CMA's finding that Alliance entered into the Market Exclusion Agreement intentionally, or at the very least, negligently) is based on a significant volume of evidence including the existence of communications and meetings between Alliance and Lexon, clear documentary evidence about what had been agreed between Alliance and Lexon, the subsequent conduct of Alliance as demonstrated through its decision to debrand, the terms of the Alliance-Focus Agreement and its internal forecasting and documentary evidence, all assessed within the relevant economic and legal context.

H.25 The CMA has considered at Chapter 5 of this Decision the explanations provided by Alliance for the documents referred to by Alliance, namely the 11 June 2013 notebook entry and the 22 June 2013 email, and does not consider them to be persuasive. Rather, the CMA considers that the plain reading of these documents is consistent with a finding that Alliance cannot have been unaware or ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature.[2866]

H.26 The CMA has found at paragraphs 8.22 to 8.39 based on the evidence in this Decision (including, but not limited to, the evidence discussed at paragraph H.25 above), that Alliance cannot have been unaware or ought to have known that: (i) Lexon and Medreich, working together, were its potential competitors; (ii) it was, indirectly through Focus, transferring value to Lexon; and (iii) those value transfers were in return for Lexon not entering the market with the product it had jointly developed with Medreich. The CMA has therefore found that Alliance cannot have been unaware or ought to have known that its conduct in participating in the Market Exclusion Agreement was anti-competitive in nature.

H.27 In any event, to the extent that the CMA partially relies on some inferences, this would not preclude a finding of intent or negligence. As noted at paragraph 8.20, an undertaking's intention can be confirmed by internal documents or, in the absence of any evidence to the contrary, the fact that certain consequences are

[2864] Alliance RDPS, 7 July 2021, paragraph 2.4, see also paragraph 6.5 (URN: PRO-C7461).

[2865] Alliance RDPS, 7 July 2021, paragraph 2.5 (URN: PRO-C7461).

[2866] The CMA has also found (see paragraphs 8.136 to 8.141) that Alliance's director [Alliance Director 1] was aware of and approved the Market Exclusion Agreement and that Alliance's director [Alliance Director 2] was aware of, as well as involved in the implementation of, the Market Exclusion Agreement.

plainly foreseeable is an element from which the requisite intention may be inferred.[2867]

Cinven

H.28 Cinven submitted that any conduct or intention established by the CMA on the part of other Addressees is not evidence as to the conduct and intention of Focus and therefore that evidence of Alliance and Lexon's conduct and intentions cannot be used to implicate Focus.[2868]

H.29 However, as set out at paragraphs 8.65 to 8.69 and paragraphs 5.635 to 5.654 above, the CMA has supported its finding that Focus committed the Infringement intentionally or at least negligently with evidence of Focus' conduct and intentions, including based on internal documentary evidence of Focus.[2869]

H.30 Cinven also submitted that the CMA's approach of only considering whether Focus (and not Cinven) participated in the Market Exclusion Agreement intentionally, or at the very least, negligently was inconsistent with the CMA's approach elsewhere in its draft penalty statement as regards Focus and Cinven. In particular, Cinven submitted that it was not permissible for the CMA to impose a fine '*specifically and singularly*' on the Cinven Entities at Step 4 of the penalty calculation without first considering whether the Cinven Entities intentionally or negligently contributed to the alleged Market Exclusion Agreement.[2870]

H.31 The CMA rejects this argument. Since Cinven formed part of the Focus undertaking during its ownership period of Focus, there is no requirement for the CMA to establish intent or negligence separately for Cinven.[2871] As set out at paragraphs 8.65 to 8.69 above, the CMA has shown that the Focus undertaking participated in the Market Exclusion Agreement intentionally, or at the very least, negligently.

H.32 At Step 4 of the penalty calculation, the CMA has concluded that the penalty for Cinven corresponding to its period of ownership should be increased to ensure effective deterrence, having regard in particular to the proportion of turnover achieved by the Cinven Entities outside the relevant market of Prochlorperazine POM and the Cinven Entities' size and financial position. In accordance with its penalties guidance, the CMA considers whether any adjustments should be made at Step 4 of the penalty calculation based on appropriate indicators of the

[2867] *Napp* [2002] CAT 1, paragraph 456.

[2868] Cinven RDPS, 7 July 2021, paragraph 2.4 (URN: PRO-C7439).

[2869] Cinven also repeated a number of representations which it had made regarding Focus' participation in the [Market Exclusion] Agreement and submitted that they also precluded a finding of intention and negligence. See Cinven RDPS, 7 July 2021, paragraphs 2.2, 2.3. 4.145 (URN: PRO-C7439). These representations have been addressed by the CMA as part of that assessment.

[2870] Cinven RDPS, 7 July 2021, paragraph 2.5 (URN: PRO-C7439). See also paragraphs 3.38 and 3.49-3.50.

[2871] See section 36(3) of the Act, which states that the undertaking (in this case the undertaking referred to as Focus in its changing forms/compositions throughout the Infringement Period) must have acted intentionally or negligently.

undertaking's size and financial position at the time the penalty is being imposed.[2872] As the Cinven Entities and the Focus Entities are no longer part of the same undertaking at the time the penalty is being imposed, it is appropriate to apply this increase for specific deterrence to the Cinven Entities only.[2873]

Advanz

H.33 Advanz submitted that the CMA committed a fundamental error of law by (i) failing to discharge its duty under section 36 of the Act to establish, for fining purposes, that Focus participated in the Infringement intentionally or negligently and (ii) failing to explain the precise legal test to establish that the Infringement was committed intentionally or negligently and then apply that test to the facts of this case.[2874] Advanz submitted that the CMA committed an error of assessment in that the CMA did not explain in the DPS what evidence it relied on to support a finding of intentional infringement for fining purposes[2875] and that the CMA did not provide any evidence or analysis to support its conclusion.[2876] Advanz also submitted that the CMA committed a procedural error by not putting Focus in a position where it was able to properly exercise its rights of defence on the issue of intention or negligence.[2877]

H.34 The CMA rejects these arguments. The CMA has discharged its duty under section 36 of the Act to establish, for the purposes of imposing a penalty, that Focus participated in the Infringement intentionally or negligently (see paragraphs 8.65 to 8.69 above).[2878] The basis on which the CMA proposed to make that finding was set out in provisional form in the DPS.[2879] Advanz was given an opportunity to make written and oral representations in response to the DPS within a reasonable deadline, and availed itself of that opportunity.

[2872] CMA Penalties Guidance, paragraph 2.20.

[2873] See also paragraphs H.91 to H.97.

[2874] Advanz RDPS, 7 July 2021, paragraph 5.4.1 (URN: PRO-C7481).

[2875] Advanz RDPS, 7 July 2021, paragraph 5.4.2 (URN: PRO-C7481).

[2876] Advanz RDPS, 7 July 2021, paragraphs 2.12-2.14, 4.4, 5.3 (URN: PRO-C7481).

[2877] Advanz RDPS, 7 July 2021, paragraph 5.4.3, see also paragraph 5.20 (URN: PRO-C7481).

[2878] Advanz also repeated, in the context of its submissions on intention and negligence, a number of its written and oral representations that there is no basis for a finding of an infringement in this case as regards Focus. Advanz also submitted that even if there was an infringement (which it did not accept) there was no intention or negligence on the part of Focus and therefore the CMA has no jurisdiction to impose a fine on Focus. (Advanz RDPS, 7 July 2021, paragraphs 5.13 to 5.69 (URN: PRO-C7481)). The CMA has demonstrated at Chapter 5 of this Decision that Focus participated in, and is therefore liable for, in the Infringement in this case and has addressed in detail at Chapter 5 of this Decision Advanz's representations that there is no basis for a finding of infringement in relation to Focus. Advanz's representations on intention and negligence which repeat these representations do not undermine the CMA's conclusion that Focus participated in the Market Exclusion Agreement intentionally, or at the very least negligently.

[2879] See paragraphs 3.1-3.13 Advanz DPS. Contrary to a representation from Advanz, the fact that the CMA cross-referred to evidence set out in the Statement of Objections and the February 2021 Letter of Facts to support its provisional finding does not undermine this conclusion.

Step 2 – Duration

Alliance

H.35 As set out in paragraph 5.729 of this Decision, the CMA has found that Alliance participated in the Infringement from at least 7 June 2013 until 31 July 2018 (5 years, 1 month and 25 days). The CMA has therefore applied a duration multiplier of 5.25 years.

H.36 Alliance submitted that the *'alleged OA period should not commence before the date of the Alliance-Focus agreement, reducing the relevant duration'.*[2880] In particular, Alliance submitted that the email[2881] on which the CMA makes the *'inference'* that the Infringement commenced *'does not suggest that the position is settled, as further "direction" is required'*.[2882] Alliance submitted that *'further analysis and internal considerations needed to be completed prior to any decision being made is also confirmed by* [[Alliance Director 2]'s witness statement of 29 June 2019]' and that this is *'consistent with Alliance internal documents, which demonstrate that Alliance was still evaluating how to address the threat of generic competition well after 6 June'* 2013.[2883]

H.37 The CMA rejects this submission. As set out in paragraph 5.729, the CMA finds that the agreement between Alliance and Lexon was most likely entered into by 7 June 2013 and at the latest by 22 June 2013[2884] as recorded in [Focus Director 1]'s email to [Focus Director 2]. The fact that the agreement in principle reached between Alliance and Lexon by 7 June 2013 required further steps in terms of its practical implementation, including any analysis or internal considerations within Alliance and the conclusion of the Alliance-Focus Agreement, does not detract from the fact that an agreement in principle had at this point been reached between Alliance and Lexon. This is consistent with the CAT's view in *Football Shirts* that the duration of an infringement runs *'from the date of making the agreement, not the date when it was put into effect'* and that *'it is from the date of making the agreement, at the latest, that the parties are aware of each others' future intentions, and can plan their commercial policies accordingly.*'[2885]

Advanz

H.38 As set out in paragraph 5.730 of this Decision, the CMA has found that Focus participated in the Infringement from at least 22 June 2013 until 31 July 2018 (5

[2880] Alliance RDPS, 7 July 2021, paragraph 1.5(c) (URN: PRO-C7461).

[2881] Email [Alliance Director 2] to [Alliance Director 1] and [Alliance Director 3] cc [Alliance Employee 1] entitled '*CCG switch and Buccastem defence*' 7 June 2013 (URN: PRO-E001009).

[2882] Alliance RDPS, 7 July 2021, paragraph 5.4 (URN: PRO-C7461).

[2883] Alliance RDPS, 7 July 2021, paragraph 5.4 (URN: PRO-C7461).

[2884] Even if the CMA were to take the period 22 June 2013 until 31 July 2018 (5 years, 1 month, 10 days) this would have no impact on the duration multiplier.

[2885] *Football Shirts* [2005] CAT 22, paragraph 184.

years, 1 month and 10 days). The CMA has therefore applied a duration multiplier of 5.25 years.

H.39 Advanz submitted that the CMA had not shown *'to the requisite standard that Focus's participation in the alleged [Market Exclusion] Agreement persisted unbroken for the entirety of the period of the Alleged Infringement'* and *'ought to have applied a significantly lower duration coefficient in step 2'.*[2886]

H.40 The CMA rejects Advanz's representation and, as set out in paragraphs 5.728-5.730, the CMA finds that most likely by 7 June 2013, and by 22 June 2013 at the latest, Alliance and Lexon had agreed that they would enter into a form of pay for delay agreement, and Focus then participated in that agreement from at least 22 June 2013. The CMA therefore finds that the Market Exclusion Agreement commenced by 7 June 2013 and persisted until 31 July 2018 (see paragraph 5.729) during which time Focus participated from 22 June 2013 onwards on a continuous basis, not least because Focus made regular profit share payments to Lexon despite the absence of product from Lexon/Medreich (see paragraph 5.643.2).

Cinven

H.41 As set out in paragraph 5.730 of this Decision, the CMA has found that Focus participated in the Infringement from at least 22 June 2013 until 31 July 2018 (5 years, 1 month and 10 days). The CMA has therefore applied a duration multiplier of 5.25 years.

H.42 Cinven submitted that the CMA had not explained why it considers it appropriate to apply a duration multiplier for the full duration of the Infringement noting that the CMA's ability to adjust the starting point to take into account the duration is discretionary.[2887] The CMA observes that there is no reason in this case to depart from the CMA's usual practice of applying a duration multiplier for the full duration of the Infringement. [2888]

H.43 Cinven also submitted that the CMA *'must consider the specific duration of the infringement alleged against the Cinven Addressees'*. As set out in paragraph 8.95, the CMA has found that that the Focus undertaking's involvement in the Infringement was that of a single undertaking throughout the three Focus periods, the configuration of which changed over time as successive parent companies joined and left it. The CMA has, as set out in Table 8 above, only held Cinven liable for its ownership period. The CMA has therefore taken duration into consideration.

[2886] Advanz RDPS, 7 July 2021, paragraph 6.30 (URN: PRO-C7481).

[2887] Cinven RDPS, 7 July 2021, paragraph 3.24 (URN: PRO-C7439).

[2888] In *FP McCann* the CAT held that the CMA's use of a duration multiplier equalling the full duration of the infringement was *'plainly the exercise of its judgement'*. *FP McCann Limited v CMA,* [2020] CAT 28, paragraph 190.

H.44 Cinven further argued that *'any multiplier for the Alleged Infringement should be less than its full duration, since, […] for nine months during Focus Period 2, neither Lexon nor Medreich were able to enter the market'* and accordingly the Market Exclusion Agreement had *'no effect on Lexon-Medreich's independent entry for most of Focus Period 2'*.[2889]

H.45 The CMA Penalties Guidance makes clear that the duration multiplier at Step 2 relates to the duration of the *infringement*. The CMA has found that the Market Exclusion Agreement restricted competition by object in the period 7 June 2013 to 31 July 2018, and has determined Focus' duration multiplier according to its period of involvement as set out in H.41 above. It is not necessary to undertake a separate effects analysis.

Step 3 – Aggravating and mitigating factors

Mitigating factor: Co-operation

H.46 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 CMA Penalties Guidance makes clear that, for these purposes, respecting CMA time limits specified or otherwise agreed will be a necessary but not sufficient criterion to merit a reduction at Step 3 ie cooperation over and above this will be expected.[2890]

Alliance

H.47 Alliance has submitted that the CMA should consider its cooperation with the CMA's investigation a mitigating factor, specifically citing its cooperation:[2891]

H.47.1 in addressing issues related to its ability to participate in the CMA's investigation;[2892] and

H.47.2 in reacting to an inadvertent disclosure of confidential information.[2893]

H.48 The CMA concludes that Alliance did not provide cooperation which enabled the CMA's investigation to be concluded more effectively and/or speedily.[2894]

H.48.1 Alliance's communication with the CMA in relation to its ability to participate in the investigation did not go beyond providing information requested by the CMA having taken steps that would be reasonably

[2889] Cinven RDPS, 7 July 2021, paragraph 3.25 (URN: PRO-C7439).
[2890] CMA Penalties Guidance, paragraph 2.19.
[2891] Alliance RDPS, 7 July 2021, paragraphs 1.5.1(e), 7.1 and 8.6.3 (URN: PRO-C7461).
[2892] Alliance RDPS, 7 July 2021, paragraphs 7.2-7.5 (URN: PRO-C7461).
[2893] Alliance RDPS, 7 July 2021, paragraphs 7.6-7.9 (URN: PRO-C7461).
[2894] See CMA Penalties Guidance, paragraph 2.19.

expected in the circumstances. Such cooperation would be reasonably expected in these particular circumstances and, in any event, did not enable the enforcement process to be concluded more effectively and/or speedily.

H.48.2 The fact that Alliance reacted to an inadvertent disclosure of confidential information does not go beyond the conduct the CMA would expect in these particular circumstances and did not, in any event, enable the CMA's investigation to be concluded more effectively and/or speedily.

Cinven

H.49 Cinven has submitted that the CMA should consider its cooperation with the CMA a mitigating factor, specifically citing:[2895]

H.49.1 its agreement to a streamlined access-to-file procedure, which included placing categories of documents into a confidentiality ring and applying redactions to information in documents that related to drugs other than Prochlorperazine; and

H.49.2 its voluntary decision to inform the CMA of an inadvertent disclosure of confidential information to them by the CMA with a letter of facts.

H.50 Cinven further submitted that it had respected all of the deadlines set or otherwise agreed with the CMA for the production of information in response to section 26 notices and representations on the SO, letter of facts and the DPS.

H.51 The CMA concludes that Cinven's conduct during the investigation was not sufficient to warrant a discount at Step 3:[2896]

H.51.1 The 'streamlined access to file procedure' which Cinven and the other Parties agreed to involved only relatively minor concessions relating to:

(a) the disclosure of certain (more peripheral) third party information, much of it from wholesalers, into a confidentiality ring; and

(b) the agreed redaction of information relating to other drugs that was outside of the scope of the investigation.

H.51.2 The time and resource savings resulting from these features were ultimately relatively limited. The access to file process was otherwise not limited in any way, in that it involved the disclosure to Cinven and the other

[2895] Cinven RDPS, 7 July 2021, paragraphs 3.41-3.44 (URN: PRO-C7439).

[2896] See CMA Penalties Guidance, paragraph 2.19.

case parties of the significant number of documents on the CMA case file, not just those cited in the SO.

H.51.3 The fact that Cinven's legal advisers alerted the CMA to the inadvertent disclosure of information to their client does not go beyond the conduct the CMA would expect in these particular circumstances and did not, in any event, enable the CMA's investigation to be concluded more effectively and/or speedily.

H.51.4 As set out at paragraph H.46 above, respecting deadlines, responding to information requests and providing written and oral representations is not sufficient to merit a discount at Step 3.

Mitigating factor: Inadvertent disclosure of confidential information

Cinven

H.52 Cinven has submitted that the CMA's '*mishandling of confidential information during the SO and Letter of Fact access to file processes*' should be '*reflected in the level of any penalty*' as:[2897]

H.52.1 Cinven had '*voluntarily and transparently*' notified the CMA of the inadvertent disclosure; and

H.52.2 the steps taken following the inadvertent disclosure had increased Cinven's costs.

H.53 The CMA does not consider that it is appropriate to take account of the inadvertent disclosure of certain confidential information to the Parties during the course of the investigation as a mitigating factor at Step 3 and observes that the steps taken by Cinven did not go beyond what the CMA would normally expect in such circumstances.

Mitigating factor: Role in the infringement

Focus

H.54 Advanz has submitted that the fact that Focus was not the leader or instigator of the Infringement makes it less culpable and ought to be recognised as a mitigating factor meriting a discount. It argues that the need for a lower fine follows from the CMA's conclusion that Alliance and Lexon were the architects of the Market Exclusion Agreement and '*used Focus as a "mechanism" for the arrangement*'.[2898] Similarly, Cinven submits that Focus's culpability in the setup of the Infringement

[2897] Cinven RDPS, 7 July 2021, paragraphs 3.45-3.47 (URN: PRO-C7439). Following the inadvertent disclosure of confidential information, Cinven had to delete various documents and has said it needed to subsequently re-review re-disclosed documents. Cinven has submitted that both the deletion and re-review of documents increased their costs.

[2898] Advanz RDPS, 7 July 2021, paragraph 6.48 (URN: PRO-C7481).

was not in any way comparable to that of the other parties and that this should be taken into account as a mitigating factor.[2899]

H.55 The CMA disagrees.

H.55.1 First, and as set out in paragraphs 5.649 to 5.654 of this Decision, Focus was not simply 'used' as a mechanism for the Market Exclusion Agreement, but played an essential role in implementing the arrangement by entering into the Implementing Agreements and continuing to share the profits from its sale of Alliance's Prochlorperazine POM with Lexon throughout the duration of the Infringement.

H.55.2 Second, the scenario outlined in the CMA Penalties Guidance as meriting a discount based on role of the undertaking is one where an '*undertaking is acting under severe duress or pressure'*.[2900] Focus, by contrast, entered into the Market Exclusion Agreement voluntarily and willingly and, indeed, greatly benefited from the arrangement.

H.55.3 Third, the EU General Court has, in any event, established that, as a matter of principle, '*a participant in an infringement cannot allege a mitigating circumstance deriving from the conduct of other participants in the infringement*'[2901] and therefore that a competition authority is not '*required to acknowledge a mitigating circumstance relating to [an] applicant's alleged secondary role*'.[2902]

H.56 Cinven has further submitted that the CMA must recognise Cinven's '*lack of involvement*' in the Infringement as an important mitigating factor and '*apply a commensurately substantial reduction in their fine*', particularly given that:[2903]

H.56.1 Cinven's period of ownership was '*short and post-dated the instigation*' of the Market Exclusion Agreement; and

H.56.2 '*unsurprisingly*' due diligence conducted when AMCo acquired Focus did not '*uncover*' the Market Exclusion Agreement as, on the CMA's case, its manner of implementation reduced the '*likelihood*' of detection.

H.57 The CMA disagrees. The short duration of Cinven's involvement in the Infringement is already taken into account in the apportionment of the penalty at

[2899] Cinven RDPS, 7 July 2021, paragraphs 3.34ff (URN: PRO-C7439).

[2900] CMA Penalties Guidance, paragraph 2.19.

[2901] T-30/10 *Reagens v Commission*, EU:T:2014:253, paragraphs 284-285. See also T-444/14 *Furukawa Electric v Commission*, EU:T:2018:454, paragraph 174.

[2902] T-30/10 *Reagens v Commission*, EU:T:2014:253 paragraph 286. See also T-444/14 *Furukawa Electric v Commission*, EU:T:2018:454, paragraph 174.

[2903] Cinven RDPS, 7 July 2021, paragraph 3.38 (URN: PRO-C7439). It argues that due diligence was carried out by Clifford Chance, Deloitte and Pharmacloud when AMCo acquired Focus.

the start of Step 4 (see **Table 8**) and does not justify any additional reduction in the fine at Step 3.

H.58 As set out in paragraphs 8.345 and 8.346 of this Decision as part of the Focus undertaking during its period of ownership, Cinven committed an infringement of competition law and is held jointly and severally liable with the other entities forming part of that undertaking on that basis, whether or not it was directly involved[2904] or was unaware of the Infringement.[2905] The lack of direct involvement in the infringement on the part of the parent company is not therefore a mitigating factor.

Mitigating factor: Negligence

Advanz

H.59 Advanz has argued that the CMA should apply a significant reduction to the level of any fine as Focus' '*conduct was far from intentional*'.[2906]

H.60 As a matter of principle, the CMA does not consider conduct that is not 'intentional' to be a mitigating factor. Rather, infringements which are committed intentionally rather than negligently are an aggravating factor in the CMA Penalties Guidance.[2907] In any event, the CMA has concluded that Focus committed the Infringement intentionally, or at the very least negligently (see paragraphs 8.65 to 8.69 of this Decision). No reduction of Focus' fine is therefore warranted.

Mitigating factor: Excusable error

Advanz

H.61 Advanz has also submitted (as a mitigating factor) that where the undertaking's uncertainty as to the unlawful nature of the conduct negated intent and negligence or gave rise to an excusable error on its part, any fine imposed should at most be nominal.[2908]

H.62 The CMA disagrees that such arguments are relevant as regards the assessment of Focus' fine. As set out at paragraphs H.8 to H.14 above, there was no uncertainty at the time of the Infringement that an agreement aimed at preventing or delaying a competing supplier from entering the market is anti-competitive in

[2904] See C-50/12 P *Kendrion*, EU:C:2013:771, paragraphs 55-56.

[2905] 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 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 59 and 77, and T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraph 367 and the case law cited.

[2906] Advanz RDPS, 7 July 2021, paragraphs 6.43ff (URN: PRO-C7481).

[2907] CMA Penalties Guidance, paragraph 2.18.

[2908] Advanz RDPS, 7 July 2021, paragraphs 6.46-6.47 (URN: PRO-C7481).

nature. There was also no scope for any excusable error on the Parties' part on this point (see paragraphs H.15 to H.17 above).[2909]

Mitigating factor: Claimed benefits to the NHS

Lexon

H.63 Lexon has submitted that the CMA should consider its purported attempts to secure supply of a competing Prochlorperazine POM product as well as its '*valuable contribution*' to the NHS by supplying pharmaceutical products as mitigating factors at Step 3 of the CMA's penalty calculation.[2910]

H.64 As set out in Chapter 5 of this Decision, the CMA has found that Lexon entered into an agreement with Alliance not to enter into the market for the supply of Prochlorperazine POM in exchange for a share in the profits generated from the sale of Alliance's Prochlorperazine POM by Focus. As described in paragraphs 5.434 to 5.441 of this Decision, the CMA has found that Lexon did not attempt to secure supply of a competing Prochlorperazine POM product for the duration of the Market Exclusion Agreement with the intention of entering the market with commercial volumes of product: its attempts to secure supply were limited to the one batch required to be produced in order to avoid the application of the Sunset Clause. The CMA therefore rejects Lexon's submission in this regard.

H.65 Lexon's role, more generally, as a supplier of pharmaceutical products is not relevant to the CMA's assessment at Step 3 of its penalty calculation. The CMA therefore rejects Lexon's submission.

Step 4 – Adjustment to ensure specific deterrence and proportionality

Parties' representations on the CMA's approach to Step 4

H.66 The Parties have made various representations relating to how the CMA has approached its assessment at Step 4 of its penalty calculation. These include:

H.66.1 Alliance, Cinven and Medreich have submitted that the CMA has not adequately quantified how each of the factors set out at Step 4 of the CMA's penalty calculation result in the increase applied at Step 4,

[2909] The circumstances in this case are very different to the ones in those cases cited by Advanz in support of its assertion that no fine, or a nominal fine, should be imposed. In *A.P. Møller*, the European Commission considered as a mitigating factor when imposing a fine for breach of the notification requirement and the standstill obligation under the Merger Regulation the fact that, at the time of the infringements, the European Commission had not yet taken any decision under Article 14 of the Merger Regulation (Commission decision of 10 February 1999 in Case No IV/M.969 *A.P. Møller*, paragraph 21). Similarly, in *Akzo,* one of the factors taken into account by the EU Court of Justice when reducing Akzo's fine was the fact that '*abuses of this kind come within a field of law in which the rules of competition had never been determined precisely*' (C-62/86 *AKZO v Commission*, EU:C:1991:286, paragraph 163). As set out at paragraph H.13 above, similar considerations do not apply in relation to market sharing / market exclusion agreements or pay-for-delay cases. Therefore, these cases do not support Advanz's assertion that no fine or a nominal fine is appropriate in this case.

[2910] Lexon RDPS, 2 July 2021, paragraph 2.7 (URN: PRO-C7416).

resulting in a '*disconnect*'[2911] between the CMA's penalty calculation at Steps 3 and 4 and a lack of clarity on how the CMA has reached the penalties to be imposed at the end of Step 4.[2912]

H.66.2 Alliance, Advanz, Cinven and Medreich have also made representations that select one factor relevant to the CMA's assessment at Step 4 of its penalties calculation and have presented arguments on why that particular aspect of the CMA's assessment is discriminatory or disproportionate when compared with the penalties imposed on other Parties to the Infringement.

H.67 These submissions mistakenly regard the CMA's assessment at Step 4 as the continuation of a purely quantitative assessment against fixed and separate parameters. At Step 4 of its penalty calculation, the CMA assesses whether the penalties to be imposed on the parties to the Infringement should be increased for the purpose of specific deterrence and are '*appropriate in the round*'.[2913] Various factors, not necessarily equally applicable across parties, are pertinent to this assessment.

H.68 As the CAT established in *Napp*,

> *'while the turnover in the products affected by the infringement may be an indicative starting point for the assessment of the penalty, the sum imposed must be such as to constitute a serious and effective deterrent, both to the undertaking concerned and to other undertakings tempted to engage in similar conduct'.*[2914]

H.69 In assessing what sum would constitute such a serious and effective deterrence, it is, as set out in *Eden Brown*,

> *'important not to lose sight of the need for the penalty properly to reflect […] the culpability of the undertaking in terms of the seriousness, and hence the scale and effect of the infringement'.*[2915]

H.70 Equally, the CAT noted that,

> *'it will often be just and proportionate to impose a higher penalty on a larger undertaking than a smaller undertaking involved in the same infringement, not only because the impact on the market is likely to have been greater but*

[2911] Alliance RDPS, 7 July 2021, paragraph 3.2 (URN: PRO-C7461). See also Medreich RDPS, 7 July 2021, paragraph 4.3 (URN: PRO-C7444).

[2912] Alliance RDPS, 7 July 2021, paragraph 3.2 (URN: PRO-C7461); Medreich RDPS, 7 July 2021, paragraphs 4.5-4.10 (URN: PRO-C7444); Cinven RDPS, 7 July 2021, paragraphs 3.66-3.68 (URN: PRO-C7439).

[2913] CMA Penalties Guidance, paragraphs 2.21-2.22 and 2.24.

[2914] *Napp* [2002] CAT 1, paragraph 502, quoted with approval by the Court of Appeal in *Argos Ltd v Office of Fair Trading* [2006] EWCA Civ 1318, paragraph 162.

[2915] *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 99.

because a higher financial penalty is required in order to achieve the required deterrent effect, in particular on senior management'.[2916]

H.71 Moreover, the CAT noted that '*where only a small part of an undertaking's total business is carried out in the relevant market*', the penalty may require a '*significant upward adjustment to produce a penalty that has a real financial impact on the undertaking in the context of its business*' and ensure '*adequate deterrence*'.[2917]

H.72 '*In short*', the CAT concluded, '*determination of the penalty requires a refined consideration and assessment of all the relevant circumstances*', which '*should take into account the various circumstances of the individual undertaking instead of imposing a mechanistic and artificially narrow formula*'.[2918] Or, as expressed by the CAT in *Football Shirts*, the CMA's approach to its penalty calculation cannot be '*as if the [CMA] is merely making a series of mechanical calculations according to a predetermined mathematical formula*', but involves '*a number of subjective and interrelated areas of judgment which necessarily play a part in fixing the final penalty*'.[2919]

H.73 In light of the above, the CMA disagrees with the Parties' arguments regarding Step 4, which are discussed at paragraphs H.74 to H.103 below.

The CMA's approach to Step 4: Parties' representations on their penalties compared with other Parties to the Infringement

H.74 Alliance, Medreich and Advanz have submitted that their penalties are disproportionate when compared with the other Parties to the Infringement.

H.74.1 Alliance has submitted that other Parties are '*vastly larger in size*' than Alliance.[2920]

H.74.2 Medreich has submitted that [✂].[2921]

H.74.3 Advanz has submitted that it has [✂] than the other Parties and, specifically, is '*not of considerable size relative to Cinven*'.[2922]

H.75 Alliance, Medreich and Advanz's submissions would, if accepted, reduce the CMA's Step 4 assessment to a basic comparison of discrete financial indicators. Such an assessment would fail to consider other factors relevant to the CMA's

[2916] *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 98.
[2917] *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 90.
[2918] *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraphs 99-100.
[2919] *Football Shirts* [2005] CAT 22, paragraph 105.
[2920] Alliance RDPS, 7 July 2021, paragraphs 1.5.2 (f), 8.8(g), 8.54-8.58 (URN: PRO-C7461).
[2921] Medreich RDPS, 7 July 2021, paragraphs 4.42-4.43 (URN: PRO-C7444).
[2922] Advanz RDPS, 7 July 2021, paragraphs 6.72-6.78 (URN: PRO-C7481).

consideration in the round of whether the penalty is not disproportionate or excessive, including the nature of the infringement, the undertaking's role in the infringement and the impact of the undertaking's infringing activity on competition, as well as the undertaking's size and financial position. The CMA also does not accept Advanz's submission that it [✂] than the other Parties (see paragraph 8.310). The CMA concludes that, when assessed in the round the increased penalties at Step 4 for Alliance, Medreich and Advanz are appropriate and proportionate.

The CMA's approach to Step 4: Parties' representations on the level of the increase applied to their penalties at Step 4

H.76 Alliance and Medreich have also submitted that the level of increase the CMA has applied to their penalties at Step 4 is, respectively, '*excessive in itself*'[2923] and '*significantly higher*' than those applied to both the other Parties to this Infringement and in other recent decisions of the CMA in the pharmaceutical sector.[2924]

H.77 The CMA disagrees. Simple comparisons between the level of increase within and between cases will inevitably fail to capture the various factors that contribute to the CMA's assessment at Step 4. This is particularly relevant in in this case, given that:

H.77.1 the undertakings generated turnover in different ways, meaning that the basis for the CMA's penalty calculation for each undertaking leading to their respective penalties at the end of Step 3 is different (see, for example, paragraphs 8.79 and 8.85; and

H.77.2 the various factors pertinent to the CMA's assessment at Step 4 are not necessarily equally applicable across the parties to the Infringement.

H.78 The CMA considers the penalties to be imposed on Alliance and Medreich appropriate and proportionate when assessed in the round against all relevant factors.

The CMA's approach to Step 4: Parties' representations on their role in the Infringement

H.79 Advanz has submitted that its penalty is disproportionately higher than other parties to the Infringement, despite what it describes as Focus' '*significantly more limited role*' as the '*mechanism*' by which Alliance transferred payments to Lexon.[2925]

[2923] Alliance RDPS, 7 July 2021, paragraph 1.5.2(a) (URN: PRO-C7461).

[2924] Medreich RDPS, 7 July 2021, paragraphs 4.11-4.12, 4.30-4.31 (URN: PRO-C7444).

H.80 Cinven has similarly submitted that the level of increase the CMA has applied to its penalty at Step 4 is greater than the level applied to Lexon, which it described as an instigator of the Infringement as well as on the Focus Entities and Advanz.[2926]

H.81 Medreich also submitted that its penalty is disproportionately higher than that imposed on Lexon and Alliance, who it described as instigators of the infringement and submitted that their involvement contrasted with Medreich's more '*passive role*'.[2927]

H.82 The CMA does not accept these submissions for the reasons set out below.

H.83 Advanz's submission significantly understates Focus' role in the Infringement. Focus effected the transfer of value from Alliance to Lexon in exchange for Lexon's non-entry and was the counterparty to both Implementing Agreements (see further at paragraphs 5.649 to 5.654). Advanz's submission also disregards the fact that Focus greatly benefitted from its participation in the Infringement even after making significant profit share payments to Lexon over many years.

H.84 Cinven, on the other hand, has overstated the significance of Lexon's role compared with Focus' role (see further at paragraph H.55 above) and, more significantly, disregards the other factors relevant to the CMA's assessment of an appropriate increase to ensure that Cinven is specifically deterred from future breaches of competition law. In addition to the relevant circumstances of the case, those factors include Cinven's turnover outside of the relevant market and its size and financial position (see further at paragraphs 8.331 to 8.340 above).

H.85 Similarly, Medreich's submission understates Medreich's role in agreeing not to commercialise its product and to accept payments in compensation and the extent to which Medreich was aware of and intentionally contributed to the Infringement (see further at paragraphs 5.680 to 5.686) as well as disregards the Medreich undertaking's greater size compared with Alliance and Lexon.

The CMA's approach to Step 4: Alliance and Medreich's representations on the lack of quantitative analysis at Step 4

H.86 Alliance has submitted that its lower relevant turnover in the last financial year only amounts to a sixth of the increase initially proposed by the CMA in the DPS and therefore does not '*justify*' the level of increase to its penalty at Step 4 of the CMA's penalty calculation.[2928]

H.87 Alliance is correct that its lower relevant turnover in its last financial year before the end of the Infringement only partially accounts for the increase in its penalty at

[2926] Cinven RDPS, 7 July 2021, paragraph 3.72 (URN: PRO-C7439).

[2927] Medreich RDPS, 7 July 2021, paragraphs 4.39-4.40 (URN: PRO-C7444).

[2928] Alliance RDPS, 7 July 2021, paragraph 8.13 (URN: PRO-C7461).

Step 4. However, as set out at paragraph 8.226 of this Decision, Alliance's lower relevant turnover is not the sole factor supporting an uplift at Step 4 of the CMA's penalty calculation and, as set out at paragraphs 8.229 to 8.239 of this Decision, the CMA considers that the uplift remains appropriate and proportionate when considered in combination with the other factors relevant to its assessment at Step 4.

H.88 Medreich has submitted that the '*only factor*' that could '*plausibly be relevant to any uplift*' at Step 4 of the CMA's penalty calculation would be the '*financial benefit to Medreich*' as there is '*no other quantitative analysis*' of '*how the other factors*' result in the penalty for Medreich at the end of Step 4 of the CMA's penalty calculation.[2929]

H.89 The CMA disagrees. Contrary to Medreich's submission, financial benefit is not the only factor relevant to the CMA's analysis at Step 4 of its penalty calculation. That the benefit gained by Medreich can be easily quantified does not provide a reason to disregard other factors (see further at paragraph 8.285 of this Decision) which also support a significant uplift to Medreich's penalty at Step 4.

H.90 Moreover, as set out in paragraphs H.67 to H.72 above and as summarised by the CAT in *Football Shirts*, the CMA's approach to its penalty calculation cannot be '*as if the [CMA] is merely making a series of mechanical calculations according to a predetermined mathematical formula*', but involves '*a number of subjective and interrelated areas of judgment which necessarily play a part in fixing the final penalty*'.[2930]

The CMA's approach to Step 4: Cinven's representations on the CMA's separate assessment for the Cinven Entities at Step 4

H.91 Cinven has submitted that the CMA has made a '*fundamental error*' in its approach to calculating Cinven's penalty, by '*cherry-picking*' at which steps of the penalty calculation it has assessed the penalty by reference to the Focus undertaking and at which steps it has assessed the penalty by reference to the Cinven Entities. Cinven argues that the CMA must calculate its penalty at each and every step of the calculation either by reference to the Focus undertaking or by reference to the Cinven Entities and their period of ownership, which would alternatively entail:[2931]

H.91.1 assessing the penalty to be imposed on the Focus undertaking at Step 4 by reference to the Focus Entities only or by reference to those entities that comprise the Focus undertaking at the time of the Decision; or

[2929] Medreich RDPS, 7 July 2021, paragraphs 4.10 and 4.24 (URN: PRO-C7444).

[2930] *Football Shirts* [2005] CAT 22, paragraph 105.

[2931] Cinven RDPS, 7 July 2021, paragraph 3.3 (URN: PRO-C7439). See also paragraphs 1.8, 1.11, 1.13, 2.5, 3.4, 3.5, 3.49, 3.61 and 3.86.

H.91.2 assessing the starting point at Step 1, duration at Step 2 and aggravating and mitigating circumstances at Step 3 as well as the threshold test for intention and negligence by reference to the particular conduct of the Cinven Entities.

H.92 Cinven has argued that that the CMA's approach is both '*internally inconsistent*' and '*breaches the principle that a penalty must be specific to the alleged offence and offender*' as the CMA has increased the penalty imposed on the Cinven Entities at Step 4, while disregarding evidence that Cinven submits would reduce its penalty at other steps of the calculation.[2932]

H.93 Cinven's submissions are misconceived. The CMA has not '*cherry-picked*' the steps of the CMA Penalties Guidance applied to the Focus undertaking as opposed to the Cinven Entities. The CMA has properly applied Steps 1 to 3 of the CMA Penalties Guidance to the infringement committed by the Focus undertaking.[2933] The CMA has considered the need for any adjustments for specific deterrence or proportionality at Step 4, having regard to the size and financial position of each of the companies at the time of the decision. When the former subsidiary is no longer under the same ownership, it is important that this assessment is carried out separately for each. That is what the CMA has done for the entities that currently comprise the Focus undertaking and the Cinven Entities, since they do not comprise the same undertaking at the date of the decision.

H.94 Where a parent company is jointly and severally liable for the anti-competitive behaviour of its wholly-owned subsidiary, but the companies do not constitute the same undertaking at the date of the decision, it is appropriate to distinguish between them and to assess the need for specific deterrence for each company separately. This is appropriate because it helps to ensure that the penalty imposed on the Cinven Entities is sufficient in order to deter it from breaching competition law in the future and is not disproportionate, having regard to their size and financial position at the date of the decision.

H.95 The CMA's assessment of the penalty imposed on the Cinven Entities under Step 4 is also appropriate because it takes into account the principle that a penalty needs to be specific to the offender and the offence[2934] and:

H.95.1 where an infringing entity has been owned by successive parents during the relevant infringement period, apportions the penalty at the start of Step

[2932] Cinven RDPS, 7 July 2021, paragraph 3.61 (URN: PRO-C7439).

[2933] Whether the aggravating or mitigating factor has been applied to the Focus undertaking or to the Cinven Entities necessarily depends on the factor under consideration. For example, the CMA has assessed the Focus undertaking's role in the Infringement by reference to the Focus undertaking (see paragraphs H.54-H.55 above), but has assessed Cinven's compliance activities separately to the compliance activities of those entities comprising the Focus undertaking given that Cinven either no longer forms part of the same undertaking (ie the Focus Entities and Mercury Pharma Group Limited) or has never formed part of the same undertaking (ie the Advanz Entities) (see paragraphs 8.182 to 8.190 of this Decision) to reflect the corporate scope of those compliance activities at the date of this Decision.

[2934] C-247/11 P *Areva and Others v Commission*, EU:C:2014:257, paragraphs 127 and 131.

4 for which those parents are jointly and severally liable with the infringing entity by the duration of their ownership period; and

H.95.2 where the legal entities that were part of an undertaking at the time of the Infringement no longer form part of the same undertaking today, separately considers at Step 4 the penalties imposed on:

(a) the undertaking as it exists at the date of this Decision; and

(b) those legal entities that no longer form part of the undertaking at the date of this Decision.

H.96 The CMA's approach is also supported by precedent. It is consistent with the judgments of the EU Court of Justice in *Kendrion*[2935] (which applied the 10% ceiling to a parent and its former subsidiary separately because they no longer constituted an undertaking at the date of the decision) and *Akzo*[2936] (which held that factors specific to the subsidiary or to the parent company may justify the imposition of penalties of different amounts) as well as of the CAT in *Paroxetine*[2937] (which took the same approach in relation to the assessment of proportionality at Step 4).

H.97 Finally, and in any event, the CMA observes that, by whatever method the penalty is calculated throughout Steps 1 to 3, Step 4 is the stage at which the CMA takes a step back and asks itself '*whether in all the circumstances a penalty at the proposed level is necessary and proportionate in order both to punish the particular undertaking for the specific infringement and to deter it and other companies from further breaches of that kind*'.[2938] This is precisely what the CMA has done in the present case.

The CMA's approach to Step 4: Cinven's representations on the increase of its penalty given its size and financial position

H.98 Cinven has submitted that the CMA's approach does not '*appear to reflect a true desire to deter undertakings from future engagement in anticompetitive behaviour*' but rather to '*penalise those thought to have the deepest pockets*'.[2939]

[2935] C-50/12 P *Kendrion v Commission*, EU:C:2013:771, paragraph 57: '*where two separate legal persons, such as a parent company and its subsidiary, no longer constitute an undertaking within the meaning of Article [101 TFEU] on the date on which a decision imposing a fine on them for breach of the competition rules is adopted, each of them is entitled to have the 10% ceiling applied individually to itself*'.

[2936] See C-516/15 P *Akzo Nobel NV v Commission*, EU:C:2017:314, paragraph 74 endorsing the opinion of AG Wahl in Case C-516/15 P *Akzo Nobel NV v Commission*, EU:C:2016:1004, paragraphs 58–59.

[2937] *Paroxetine II* [2021] CAT 9, paragraph 196: '*When the former subsidiary is no longer under the same ownership, it is particularly important that this assessment [of the proportionality of the penalty under Step 4] is carried out separately for each*'.

[2938] *Kier Group and Others v OFT* [2011] CAT 3, paragraph 166.

[2939] Cinven RDPS, 7 July 2021, paragraph 3.72 (URN: PRO-C7439).

H.99 The CMA rejects Cinven's claim.

H.99.1 The CMA has not simply or mechanistically imposed the largest penalties on the largest parties to the Infringement. [✂].[2940]

H.99.2 Cinven's size and financial position is, however, relevant to the CMA's assessment of whether Cinven's penalty should be adjusted to ensure the penalty imposed will deter Cinven from breaching competition law in the future.[2941] As set out in paragraphs 8.330 to 8.351 of this Decision, the CMA has increased the penalty to be imposed on Cinven at Step 4 given its size and financial position alongside other relevant factors considered in the round.

The CMA's approach to Step 4: Alliance's representations on the penalty compared with previous decisions

H.100 Alliance has further submitted that its penalty at the end of Step 4 is '*out of line*' with the level of penalties previously imposed by the CMA on undertakings of a '*similar size and financial position*'.[2942]

H.101 The CMA is not bound by its previous decisions, and the penalties imposed in previous cases do not provide any kind of maximum level of penalty that the CMA can impose in this case. The CMA's assessment of the need to adjust a penalty is made on a case-by-case basis for each individual infringing undertaking. The CMA therefore does not consider it appropriate to draw comparisons between the penalty imposed on Alliance and penalties imposed in previous infringement decisions.[2943]

H.102 In any case, the CMA observes that Alliance's analysis has focussed solely on the metric that it considers to be favourable to it (penalty as a proportion of worldwide turnover). Such an approach is an insufficient basis upon which to compare penalties across cases: the CMA's assessment at Step 4 considers, in the round,

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[2940] See paragraph 8.353 (for Cinven) compared with paragraphs 8.324 (for Advanz), 8.297 (for Medeich), 8.263 (for Lexon) and 8.230 (for Alliance).

[2941] CMA Penalties Guidance, paragraph 2.21.

[2942] Alliance RDPS, 7 July 2021, paragraphs 8.8(d), 8.59-8.62 (URN: PRO-C7461) and Appendix 2 of Alliance RDPS (URN: PRO-C7463).

[2943] The EU Courts have held that a competition authority's practice in previous decisions '*does not itself serve as a legal framework for the fines imposed in competition matters'* (See, for example, C-439/11 P *Ziegler v Commission*, EU:C:2013:513, paragraphs 132-134) and that undertakings can have no legitimate expectation that the Commission will not exceed the level of fines imposed in other cases (See, for example C-447/11 P *Caffaro v Commission*, EU:C:2013:797, paragraph 34, T-109/02 *Bolloré v Commission*, EU:T:2007:115 paragraph 377). The EU General Court has also found that '*[t]he Commission cannot be compelled to set fines which display perfect coherence with those imposed in other cases'*. (T-155/06 *Tomra Systems and Others v Commission,* EU:T:2010:370, paragraph 314). The EU Courts have also confirmed - in the context of undertakings involved in the same infringement - that a competition authority is not required, when determining the amount of fines, to ensure that the final amounts of the fines reflect any distinction in terms of their overall turnover. (C-101/15 *Pilkington Group and Others v Commission*, EU:C:2016:631, paragraphs 63-66). In the same context, the CAT has emphasised the importance of looking at the parameters included by a competition authority in its calculation rather than '*simply looking at the outcome of the fining process*'. See *Balmoral v CMA* [2017] CAT 23 paragraphs 167-169 and *G F Tomlinson v OFT* [2011] CAT 7, paragraphs 149-158.

appropriate indicators of an undertaking's size and financial position, as well as other factors relevant to its assessment in that case at Step 4.

H.103 As set out in paragraphs 8.229 to 8.239 of this Decision, the CMA has concluded that the penalty to be imposed on Alliance is appropriate and proportionate in the particular circumstances of this investigation and after considering the penalty in the round.

Parties' representations on financial gain

Alliance

H.104 Alliance has incorrectly asserted that, in observing that Alliance's involvement participation in the Infringement enabled it to insulate its profits of £5.3 million, the CMA has taken account of financial benefit obtained by Alliance from the Infringement in its penalty calculation.[2944] Similarly, Alliance has mistakenly claimed that, in observing that Alliance's involvement in the Infringement enabled Focus to implement a series of price increases for Prochlorperazine POM, the CMA has taken account of the financial benefit obtained by other parties from the Infringement when calculating Alliance's penalty.[2945]

H.105 Having made this incorrect assertion, Alliance has submitted further representations in relation to how it considers the CMA should take account of any financial gain it may have made from the Infringement.

H.106 Alliance has submitted that, on a '*plain reading*' of the CMA Penalties Guidance, the '*application of an uplift should be linked to the "economic and financial benefit from the infringement"*'[2946] and, accordingly, that the CMA should, when assessing any uplift at Step 4, consider the '*benefit gained by Alliance compared to the situation which would have prevailed had the infringement not occurred*'.[2947]

H.107 Alliance has argued that it made '*no incremental gains*' as a result of the Market Exclusion Agreement[2948] as, absent the Market Exclusion Agreement:

H.107.1 it would have acted in the same way; in the face of generic competition, Alliance has submitted that it would have de-branded Buccastem POM and entered into an exclusive, fixed supply price distribution agreement with Focus to distribute Prochlorperazine POM;[2949] and

[2944] Alliance RDPS, 7 July 2021, paragraphs 1.5.2(d), 3.4-3.8, 8.7, 8.8(b), 8.14-17 (URN: PRO-C7461).
[2945] Alliance RDPS, 7 July 2021, paragraphs 1.5.2(e), 8.7, 8.8(c), 8.52-8.53 (URN: PRO-C7461).
[2946] Alliance RDPS, 7 July 2021, paragraph 8.19-20 (URN: PRO-C7461) (emphasis added by Alliance).
[2947] Alliance RDPS, 7 July 2021, paragraph 8.19 (URN: PRO-C7461).
[2948] Alliance RDPS, 7 July 2021, paragraph 9.29 (URN: PRO-C7461).
[2949] Alliance RDPS, 7 July 2021, paragraph 8.28 (URN: PRO-C7461).

H.107.2 Focus and Lexon would also have acted in the same way; Alliance has submitted that Focus and Lexon would have entered into the Focus-Lexon Heads of Terms as they had the *'ability and incentive'* to enter into such agreement.[2950]

H.108 Alliance has additionally submitted that, when considering any gain that Alliance made from the Infringement, the CMA should take into account the regulatory and manufacturing issues associated with Medreich's Prochlorperazine POM licence. Alliance has argued that, absent the Market Exclusion Agreement, these issues would have been likely to occur and, accordingly, '*any "extra profits"' that would conceivably have been gained by Alliance*' as a result of the Infringement should be based on a '*considerably more limited duration of time*' than the period the CMA has used to calculate Alliance's gross profits sustained during the Infringement.[2951]

H.109 As set out in paragraphs 8.211 to 8.228 of this Decision, the CMA has adjusted the penalty at Step 4 of its penalty calculation:

H.109.1 in part to take account of Alliance's role in the infringement and the impact of Alliance's infringing activity (see paragraphs 8.222 to 8.225); and

H.109.2 in part because Alliance's relevant turnover does not accurately reflect the scale of Alliance's involvement in the Infringement or the likely harm to competition (see paragraphs 8.212 to 8.216).[2952]

H.110 It is in this context that the CMA has referred to the profits that Alliance insulated from competition by entering into the Market Exclusion Agreement as well as the price increases enabled by Alliance's de-branding of Buccastem POM and implemented by Focus to generate the profits used to compensate Lexon for non-entry, as well as Focus and Medreich.

H.111 The CMA has not sought to quantify the financial benefit made by Alliance from the infringement given the inherent challenge of identifying the appropriate counterfactual. A consideration of the financial benefit Alliance may have made from the Infringement has not therefore formed part of the CMA's penalty calculation for Alliance (including the extent of any uplift to be applied at Step 4). The CMA's assessment at Step 4 is based on other factors, which are relevant to circumstances of this case as well as the particular circumstances of Alliance and its unlawful conduct (see paragraph 8.226 of this Decision).

[2950] Alliance RDPS, 7 July 2021, paragraph 8.29 (URN: PRO-C7461).

[2951] Alliance RDPS, 7 July 2021, paragraphs 8.50-8.51 (URN: PRO-C7461).

[2952] CMA Penalties Guidance, paragraph 2.22.

H.112 In any event, and consistent with its findings as set out in paragraphs 5.285 to 5.294, the CMA considers there are a number of significant flaws in Alliance's submission in relation to gains it made from the Infringement. For example:

H.112.1 The evidence does not support Alliance's contention that, absent the Market Exclusion Agreement, it would have de-branded Buccastem POM and at the same time adopted the same fixed supply price agreement with Focus. As set out in paragraph 5.283 of this Decision, Alliance has referred the CMA to a number of distribution and wholesaler agreements for the UK supply of prescription medicines that, with the exception only of its agreements with Focus, have adopted percentage discounts and provided the appointed distributor with margins that are significantly lower. The sole exception concerned Alliance's Aspirin Agreement and related to an agreement in which the only other MA holder committed not supply its product on to the market. Such an agreement would have no relevance to the counterfactual contemplated by Alliance (because it does not contemplate the supply of its Prochlorperazine POM product to the only other MA holder for the product).

H.112.2 There is no documentary evidence to support its claim that the Focus-Lexon Heads of Terms would have existed absent the Market Exclusion Agreement. As set out at paragraphs 5.278 to 5.284, the CMA finds that that agreement was implemented pursuant to the Market Exclusion Agreement.

H.112.3 The date on which Lexon and Medreich would have otherwise entered the market is unknown. Plainly, Lexon and Medreich's incentive to quickly bring their Prochlorperazine POM to market would have been greatly enhanced in 2014 had there been no agreement for Lexon/Medreich not to supply commercial volumes of Prochlorperazine POM in exchange for a share in the profits made on the sale of Alliance's Prochlorperazine POM.[2953] Similarly, the priority that would have been afforded to resolving manufacturing challenges could be expected to have been greater under that scenario as compared to one in which Lexon and Medreich received payments on the basis of inaction. Accordingly, it is unduly simplistic to assume that the Medreich product would otherwise have followed the same timeline as the single batch of product that was produced to satisfy the Sunset Clause.

Cinven

H.113 Cinven has submitted that there is no basis for the CMA to impose a penalty on Cinven that significantly exceeds any potential financial gain. Cinven observes that,

[2953] By way of comparison, Medreich internally ordered prochlorperazine 5mg tablets on 21 March 2014 which were delivered to Lexon on 4 June 2015 (See paragraph 5.446.3).

even on the '*most conservative set of assumptions*', the '*maximum hypothetical financial gain*' Focus made from the Infringement during its period of ownership would be £750,000.[2954]

H.114 Cinven has further submitted that the CMA's uplift at Step 4 is discriminatory when compared to the other Parties to the investigation as the penalty for Lexon and Medreich exceeds the financial benefit they made from the Infringement by approximately 60% and 175% respectively compared with what Cinven has calculated would be almost 800% for Cinven.[2955]

H.115 Contrary to Cinven's submission, the CMA Penalties Guidance does not solely link an adjustment for specific deterrence at Step 4 of the CMA's penalty calculation to an undertaking's economic or financial benefit from the infringement.[2956]

H.116 As with Alliance (see further at paragraph H.111 above), the CMA has not sought to quantify Focus' economic or financial benefit from the Infringement given the inherent challenge in identifying the appropriate counterfactual. A consideration of the financial benefit Focus may have made from the Infringement has not therefore formed part of the CMA's penalty calculation for Cinven (including the extent of any uplift to be applied at Step 4). The CMA's assessment at Step 4 is based on other factors, which are relevant to the circumstances of this case as well as the particular circumstances of the Cinven Entities as well as Focus and its unlawful conduct (see paragraph 8.340 of this Decision). In light of this approach, even if the maximum financial benefit Cinven would have gained from the Infringement was £750,000, the CMA still considers an increase to £6.7 million to be appropriate and proportionate in light of those factors set out in paragraphs 8.340 to 8.351 and paragraphs 8.352 to 8.360 of this Decision.

H.117 Cinven's submission that the CMA has disproportionately increased its penalty when compared with Focus' financial gain during its period of ownership not only seeks inappropriately to benchmark Focus' penalty against those conjectural gains (see paragraph H.115 above) but also disregards the other factors relevant to the CMA's assessment of the appropriate level of penalty specifically to deter Cinven (see paragraphs 8.340 to 8.351 of this Decision).

[2954] Cinven RDPS, 7 July 2021, paragraphs 3.62-3.63 (URN: PRO-C7439). Cinven has calculated this figure on the CMA's profit calculations for Q4 2014 to Q3 2015 plus the proportion of the figure for Q4 2015 that fell within its period of ownership, commenting that this is '*likely to be a material overestimate of Focus' profit from the sale of Prochlorperazine POM*' as it does not '*take any account of Focus' cost of sales in estimating Focus' profits, and may also exclude VAT*'.

[2955] Cinven RDPS, 7 July 2021, paragraphs 3.62-3.64 (URN: PRO-C7439).

[2956] CMA Penalties Guidance, paragraphs 2.21-2.22.

Annex I: Prochlorperazine Profit Share Payments Table

Period covered	Date Focus to Lexon	Relevant URNs Focus to Lexon	Date Lexon to Medreich	Relevant URNs Lexon to Medreich	Overall Prochlorperazine Profit for period	Amount paid Focus to Lexon (before VAT)	Proportion of profit owed to Lexon	Amount paid Lexon to Medreich (before VAT)	Proportion of Lexon profit paid to Medreich	Profit retained by Lexon (before VAT)
Q4 2013	03-Jan-14	PRO-E000346 PRO-E000347	08-Jan-14	PRO-E002690 PRO-E002691	107,508.75	80,631.56	75%	40,315.78	50%	40,315.78
Q1 2014	07-Apr-14	PRO-E003789 PRO-E003790	07-Apr-14	PRO-E002793 PRO-E002794	154,374.81	115,781.11	75%	57,889.43	50%	57,891.68
Q2 2014	02-Jul-14	PRO-E003805 PRO-E003806	02-Jul-14	PRO-E002836 PRO-E002837	158,633.73	118,975.30	75%	59,487.65	50%	59,487.65
Q3 2014	07-Oct-14	PRO-E003820 PRO-E003821	07-Oct-14	PRO-E002879 PRO-E002880	269,773.00	202,329.75	75%	101,164.87	50%	101,164.88
Q4 2014	07-Jan-15	PRO-E003848 PRO-E003849	08-Jan-15	PRO-E000487 PRO-E000488	311,034.49	233,275.87	75%	116,637.93	50%	116,637.94
Q1 2015	15-Apr-15	PRO-E003869 PRO-E003870	15-Apr-15	PRO-E002956 PRO-E002957	479,605.04	320,725.58	January: 75% February, March: 75% to £10.50 50% above £10.50	160,362.79	50%	160,362.79
Q2 2015	02-Jul-15	PRO-E003880 PRO-E003881	03-Jul-15	PRO-E000534 PRO-E000535	567,427.50	363,911.87	75% to £10.50 50% above £10.50	181,955.93	50%	181,955.94
Q3 2015	07-Oct-15	PRO-E003890 PRO-E003891	08-Oct-15	PRO-E003014 PRO-E003015	585,250.51	375,209.66	75% to £10.50 50% above £10.50	187,604.83	50%	187,604.83
Q4 2015	08-Jan-16	PRO-E003894 PRO-E003895	11-Jan-16	PRO-E003049 PRO-E003050	1,084,535.26	633,011.31	75% to £10.50 50% above £10.50	316,505.66	50%	316,505.65
Q1 2016	06-Apr-16	PRO-E000584 PRO-E000585	13-Apr-16	PRO-E003079 PRO-E003080	1,077,610.95	628,779.18	75% to £10.50 50% above £10.50	314,389.59	50%	314,389.59
Q2 2016	07-Jul-16	PRO-E000703 PRO-E000704	12-Jul-16	PRO-E003135 PRO-E003136	1,220,200.15	610,100.07	50%	203,366.69	33.33%	406,733.38
Q3 2016	06-Oct-16	PRO-E000705 PRO-E000706	07-Oct-16	PRO-E003178 PRO-E003179	1,387,842.40	693,921.20	50%	231,307.07	33.33%	462,614.13
Q4 2016	06-Jan-17	PRO-E000707 PRO-E000708	09-Jan-17	PRO-E003232 PRO-E003233	1,387,424.25	693,712.13	50%	231,237.38	33.33%	462,474.75
Q1 2017	05-Apr-17	PRO-E000713 PRO-E000714	06/04/2017	PRO-E003275 PRO-E003276	1,446,581.58	723,290.79	50%	241,096.93	33.33%	482,193.86
Q2 2017	06-Jul-17	PRO-E000709 PRO-E000710	11-Jul-17	PRO-E003335 PRO-E003336	968,824.63	484,412.31	50%	161,470.77	33.33%	322,941.54
Q3 2017	06-Oct-17	PRO-E000711 PRO-E000712	09-Oct-17	PRO-E003408 PRO-E003409	1,017,128.08	508,564.04	50%	169,521.35	33.33%	339,042.69
Q4 2017	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	770,660.77	385,330.39	50%	128,443.46	33.33%	256,886.93
Q1 2018	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	734,246.38	367,123.19	50%	0.00	0	367,123.19
Q2 2018	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	481,091.80	240,545.90	50%	0.00	0	240,545.90
Jul-18	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	Unknown	Lexon s26 response PRO-C2977 and Advanz s26 response PRO-C3150	164,563.38	82,281.69	50%	0.00	0	82,281.69
** Note: profits are on Focus sales of Alliance Prochlorperazine POM until 31 July 2018; Focus' sales of Prochlorperazine POM sourced from Lexon start from August 2018 (see Advanz s26 response PRO-C3150)*										
*** Although not reflected in the profit share reconciliation statements (which continue to calculate COGs from Alliance at £5.65) Focus actually paid Alliance £6.10 from April 2015*										
Total to 31 July 2018					**14,374,317.46**	**7,861,912.90**		**2,902,758.11**		**4,959,154.79**