

Decision

**Unfair pricing in respect of the supply of
phenytoin sodium capsules in the UK**

Case 50908

21 July 2022

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Confidential information in the original version of this Decision has been redacted from the published version on the public register. Redacted confidential information in the text of the published version of the Decision is denoted by [X]. Some numbers have been replaced by a range; these are shown in square brackets. The names of individuals mentioned in the original version of this Decision have been removed from the published version on the public register. Names have been replaced by [X] or a general descriptor of the individual's role.

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1. Introduction and Executive Summary

A. Addressees and summary

- 1.1 This Decision of the Competition and Markets Authority (the '**CMA**'),¹ including Annexes A to M (the '**Decision**'), is addressed to:
 - 1.1.1 Pfizer Limited² and Pfizer Inc³ (collectively, '**Pfizer**'); and
 - 1.1.2 Flynn Pharma Limited⁴ and Flynn Pharma (Holdings) Limited⁵ (collectively, '**Flynn**').
- 1.2 The CMA finds that from 24 September 2012 to 7 December 2016 (the '**Relevant Period**'):
 - 1.2.1 Pfizer Limited and Pfizer Inc formed part of the same undertaking; and
 - 1.2.2 Flynn Pharma Limited and Flynn Pharma (Holdings) Limited formed part of the same undertaking.
- 1.3 In this Decision, the CMA concludes that each of Pfizer and Flynn (each a '**Party**', together the '**Parties**') has infringed the prohibition imposed by section 18 (the '**Chapter II prohibition**') of the Competition Act 1998 (the '**Act**').⁶
- 1.4 The CMA finds that throughout the Relevant Period Pfizer abused its dominant position in the market for the manufacture of Pfizer-manufactured phenytoin sodium capsules ('**Capsules**') that are distributed in the United Kingdom ('**UK**') by charging Flynn unfairly high selling prices in respect of each of 25mg, 50mg, 100mg and 300mg strength Capsules (collectively, '**Pfizer's Prices**'), thereby infringing the Chapter II prohibition.
- 1.5 Throughout this Decision, the 25mg, 50mg, 100mg and 300mg strength Capsules sold by Pfizer to Flynn for distribution in the UK are collectively referred to as '**Pfizer's Products**'.
- 1.6 As Pfizer charges different prices and incurs different costs for each of Pfizer's Products, the CMA finds that Pfizer has engaged in four separate abuses of

¹ References to the CMA in this Decision should be read as referring to the Office of Fair Trading (the '**OFT**') where they concern matters prior to 1 April 2014 (the date on which the CMA formally came into existence, and it took over the OFT's functions under the Competition Act 1998).

² Registered in England and Wales, with company number 00526209.

³ Incorporated in the state of Delaware in the United States of America.

⁴ Registered in Ireland with company number 210742.

⁵ Registered in England and Wales, with company number 05875486.

⁶ This Decision is issued under section 31 of the Act and in accordance with rule 10(1) of The Competition Act 1998 (Competition and Market Authority's Rules) Order 2014 (the '**CMA Rules**'), SI 2014/458.

dominance. The CMA therefore finds four separate infringements in respect of Pfizer's conduct – one for each of Pfizer's Products.

- 1.7 The CMA collectively refers to the four separate abuses of dominance it finds in respect of Pfizer as **'Pfizer's Infringements'**.
- 1.8 The CMA finds that throughout the Relevant Period Flynn abused its dominant position in the market for the distribution of Capsules in the UK by charging its customers (wholesalers and pharmacies) unfairly high selling prices in respect of each of 25mg, 50mg, 100mg and 300mg strength Capsules (collectively, **'Flynn's Prices'**), thereby infringing the Chapter II prohibition.
- 1.9 Throughout this Decision, the four strengths of 25mg, 50mg, 100mg and 300mg Capsules sold by Flynn are collectively referred to as **'Flynn's Products'**.
- 1.10 As Flynn charges different prices and incurs different costs for each of Flynn's Products, the CMA finds that Flynn has engaged in four separate abuses of dominance. The CMA therefore finds four separate infringements in respect of Flynn's conduct – one for each of Flynn's Products.
- 1.11 The CMA collectively refers to the four separate abuses of dominance it finds in respect of Flynn as **'Flynn's Infringements'**.
- 1.12 The CMA collectively refers to Pfizer's Infringements and Flynn's Infringements as the **'Infringements'**.
- 1.13 The CMA has decided to impose a financial penalty under section 36 of the Act on Pfizer in respect of Pfizer's Infringements and on Flynn in respect of Flynn's Infringements.
- 1.14 A glossary of key terms and individuals is set out at Annex A.

B. Executive Summary of the Infringements

I. Introduction

- 1.15 This Decision concerns the very high prices imposed by Pfizer and Flynn for the supply of Capsules to the NHS, following the imposition of very significant overnight price increases.
- 1.16 The high prices that the Parties imposed were the result of an agreement between them under which Capsules were de-branded and removed from the branded price regulatory regime (the Pharmaceutical Price Regulation Scheme (the **'PPRS'**)), so that they could significantly increase their prices and share the substantial profits generated between them.

- 1.17 Indeed, the Court of Appeal stated that the ‘stark reality’ of this conduct was that ‘literally overnight, Pfizer and Flynn increased their prices for [Capsules] by factors of between approximately 7 and 27, when they were in a dominant position in each of their markets’.⁷
- 1.18 Following the overnight price increases by the companies, the National Health Service’s (**‘NHS’**) spending on phenytoin sodium capsules rose from around £2 million a year in 2012 to about £50 million in 2013. Pfizer’s prices were between 780% and 1,600% higher than it had previously charged. Pfizer then supplied the drug to Flynn, which added its own margin and sold the drug to wholesalers and pharmacies at prices between 2,300% and 2,600% higher than those they had paid to Pfizer previously. The Parties maintained their increased prices for a period of over four years.
- 1.19 This remittal investigation follows appeals to the Competition Appeal Tribunal (**‘CAT’**) and Court of Appeal of the CMA’s decision of 7 December 2016 which had found that each of Pfizer and Flynn had abused their respective dominant positions by imposing unfairly high selling prices for Capsules in the UK in the period from 24 September 2012 to at least 7 December 2016 (the **‘2016 Infringement Decision’**). The CAT upheld the CMA’s findings on market definition and dominance and ordered that the issue of abuse and any consequential matters be remitted back to the CMA for reconsideration. Following the Court of Appeal’s judgment, the CMA decided to re-investigate the matters remitted by the CAT and opened its current investigation in June 2020.

II. Phenytoin sodium capsules

- 1.20 Phenytoin sodium is an anti-epileptic drug (**‘AED’**). It is available in the UK in a variety of forms, including as capsules and tablets. Prescriptions for these drugs are funded by the NHS, and ultimately the taxpayer. Capsules are available in four strengths: 25mg, 50mg, 100mg and 300mg. The 100mg capsule is by far the biggest selling capsule strength, accounting for over 70% of all phenytoin sodium capsules dispensed in the UK by volume.⁸
- 1.21 Phenytoin sodium is an old drug: originally synthesised in 1908 and first commercialised in 1938, it became the first widely available treatment for epilepsy. However, it has long been superseded as a ‘first-line’ AED by newer drugs with superior clinical characteristics.⁹ Phenytoin sodium capsules are now (and were during the Relevant Period) only considered as a treatment for epilepsy if first-line and second-line AEDs are ineffective or not tolerated by a patient, and are only

⁷ See *CMA v Flynn Pharma and Pfizer Inc. (‘Phenytoin CoA’)* [2020] EWCA Civ 339, paragraph 243.

⁸ Calculations are based on prescription cost analysis (**‘PCA’**) data for England, Northern Ireland, Scotland and Wales, see PAD00021, PAD00063-PAD00065, PAD00083-PAD00086, PAD00098-PAD00101, PAD00113-PAD00116, PAD00121.

⁹ National Institute for Health and Care Excellence (**‘NICE’**) guidance published in 2012 identifies three potential stages of AED prescribing in treating epilepsy. Phenytoin sodium capsules are a ‘third-line’ AED.

suitable for treating certain types of seizure. Consequently, phenytoin sodium capsules were only very rarely used as a treatment for new patients during the Relevant Period and the number of patients taking the product is declining.

- 1.22 There is a relatively small difference between the level of the drug that is necessary to achieve therapeutic efficacy and the level which, if exceeded, might result in adverse side effects. This feature of phenytoin sodium is referred to as its narrow therapeutic index ('**NTI**'). Given this as well as other limitations,¹⁰ clinical guidance recommends that patients stabilised on a particular manufacturer's phenytoin sodium capsule should be maintained on that product and should not be switched to another manufacturer's product. This recommendation is referred to in this Decision as '**Continuity of Supply**'.

III. The Parties' conduct

- 1.23 Capsules were sold by Pfizer under the brand name *Epanutin* until 23 September 2012. When the drug was acquired by Pfizer in 2000, it had already been off-patent for decades and, as a branded drug, its price was regulated in the UK under the PPRS.
- 1.24 In the course of 2012, Pfizer entered into commercial arrangements with Flynn relating to Capsules. Pursuant to the arrangements:
- 1.24.1 Flynn purchased Pfizer's Marketing Authorisations ('**MAs**') for *Epanutin* for £1;
 - 1.24.2 Pfizer continued to manufacture its Capsules but, instead of supplying these downstream to wholesalers and pharmacies in the UK, supplied to Flynn on an exclusive basis; and
 - 1.24.3 on 24 September 2012, Flynn de-branded *Epanutin*, removing it from the PPRS, after which Flynn began to sell its unbranded capsules to pharmacies and wholesalers (ie Pfizer's previous customers) under the name 'Phenytoin Sodium Flynn Hard Capsules'.
- 1.25 As demonstrated by Table 1.1 below, Pfizer's average selling prices ('**ASPs**') for Flynn for each capsule strength were between 783% and 1,603% higher than those it charged pharmacies and wholesalers before September 2012. Flynn's ASPs to pharmacies and wholesalers were between 2,366% and 2,682% higher than Pfizer had charged before September 2012.

¹⁰ Phenytoin sodium's pharmacokinetics (that is, how the drug moves through the body from its absorption to its eventual break-down and excretion) are non-linear.

Table 1.1: Pfizer and Flynn’s ASPs for Capsules and percentage changes relative to Pfizer’s pre-September 2012 ASPs for Capsules¹¹

	Pre-September 2012	Pfizer’s ASPs post-September 2012	Pfizer’s percentage change	Flynn’s ASPs post-September 2012	Flynn’s percentage change
25mg	£0.51	£4.50	783%	£14.19	2,682%
50mg	£0.52	£6.71	1,185%	£14.40	2,656%
100mg	£2.21	£37.56	1,603%	£54.40	2,366%
300mg	£2.20	£37.01	1,584%	£55.21	2,412%

- 1.26 The Capsules remained identical to *Epanutin* in all but product name. The only change in the supply chain brought about by the new arrangement was that, after 24 September 2012, Flynn was inserted and placed orders with Pfizer on a weekly basis.¹²
- 1.27 These price increases were not driven by changes in costs or any improvement, innovation, investment, or additional benefits for patients having been created.
- 1.28 Flynn took very little commercial risk and did not undertake any significant commercial activity in relation to the supply of Capsules. This was recognised in the CAT’s judgment: ‘the contractual indemnity [from Pfizer], together with the terms of the Exclusive Supply Agreement [with Pfizer], in the context of Continuity of Supply and the established user base and distribution arrangements, provided a very substantial degree of comfort to Flynn and meant it was taking very little business risk. Flynn’s involvement in these arrangements was not to provide risk-taking or significant commercial activity.’¹³ Contemporaneous evidence shows that a key reason for adding Flynn to the supply chain was to manage the anticipated reputational risk for Pfizer arising from significant overnight price increases.
- 1.29 There were many occasions where customers raised concerns which should have caused the Parties to reconsider their pricing approach. The Department of Health and Social Care (**‘DHSC’**) raised concerns with Flynn regarding its proposed pricing prior to the price increases being implemented. The DHSC also raised concerns with both Parties shortly after they imposed the price increases.¹⁴ Furthermore, a significant number of Clinical Commissioning Groups (**‘CCGs’**), which pay the cost of Capsules from their prescribing budgets, raised concerns with the Parties about the impact on the NHS.¹⁵ The nature and sheer number of

¹¹ See Tables 2.3 to 2.6.

¹² Pfizer continued to manufacture its capsules in Germany and deliver them directly to the same pre-wholesaler in the UK that it had used previously, [X] ([X]).

¹³ *Phenytoin* [2018] CAT 11, paragraph 346.

¹⁴ See Annex C which provides an overview of the Parties’ interactions with the DHSC and shows that the DHSC raised explicit concerns directly with the Parties regarding the sheer scale of their price increases.

¹⁵ See Annex B which shows that the Parties received a large number of reasoned complaints from CCGs explicitly and strongly contesting the scale of their price increases, highlighting the absence of any therapeutic justification and raising concerns about harm to CCG budgets and the impact on patient care.

complaints at the time reveal frustration that the scale of the price increases was 'completely unjustifiable' given 'the product is unchanged', there was not 'a justifiable increase in costs' and 'no additional health benefit for patients'. One complaint described how this appeared to be a 'clear case of abuse of a virtual monopoly position for purely commercial gains', noting that '[t]his change, if unchallenged will cause the NHS to pay an unnecessary and unwarranted, additional £41Million for no clinical benefit'.

IV. Competition in the supply of generic drugs

- 1.30 Through their conduct, Pfizer and Flynn exploited a loophole in the regulation of drug prices. The prices of generic drugs are generally unregulated in the UK. Whereas the profits made from branded drugs are often constrained by regulation, the assumption underlying the pricing of generic drugs in the UK is that, once patents have expired and competitors become free to enter with generic versions of a drug, competition would prevent suppliers from charging high prices for those drugs. This period is often referred to as the 'third stage' of the drug life cycle (following initial development of a drug, and its commercialisation under patent). By this point, the cost of the drug's development should long since have been recouped and any innovation rewarded. During the third phase of the drug life cycle, competition between suppliers will typically drive prices down and be expected to keep prices low.
- 1.31 Capsules lost patent protection many years ago and have long been in the third stage of the drug life cycle where competition is expected to keep prices low. The drug life cycle is not expected to work differently for essential medicines and the fact that Capsules may remain an essential medicine for stabilised patients does not indicate that they should be expensive.
- 1.32 Competition between generic suppliers is expected to be an effective means of securing value for money for the NHS. However, the assumption that market forces will ensure competitive prices for generic drugs only holds good where competition works. For some generic drugs, competition is impeded or delayed, or may not be sustainable. This may be because of market features such as barriers to entry or expansion, or where the market is too small to attract entry.
- 1.33 Capsules proved to be such a generic drug, with competition not working properly as a result of high barriers to entry and expansion as well as a relatively small market size. The evidence shows that the Parties were or should have been aware that these market features would allow them to impose sustainable and significant price increases. Indeed, the Parties were imposing such a significant level of price increase that Flynn noted in a presentation to Pfizer that 'even if' 50% of sales of

100mg capsules were lost to parallel imports, the 'upside' of the arrangements would still be in excess of £20 million.¹⁶

V. The consequences of the Parties' conduct

- 1.34 The hike in prices for Capsules resulted in a significant increase in the NHS annual expenditure on Capsules. Prior to September 2012, the NHS' annual expenditure on phenytoin sodium capsules was approximately £2 million. Despite the volumes purchased falling year-on-year, NHS spend on the drug rose to approximately £50 million in 2013, £42 million in 2014, £37 million in 2015 and £35 million in 2016. As Pfizer and Flynn were the dominant suppliers of phenytoin sodium capsules in the UK, the NHS had no choice but to pay the unfairly high prices for this vital medicine.
- 1.35 This increased expenditure diverted constrained NHS resources to the detriment of the NHS and patients, with CCGs raising concerns that it had negative effects on their ability to fund and provide patient care. Only a few weeks after the price increases, one group responsible for coordinating decision making on medicines for 12 CCGs, the Greater Manchester Medicines Management Group ('**GMMM**G'), wrote to the Parties, amongst others, describing the price increases as 'unethical, anticompetitive behaviour at the expense of patient care'.¹⁷

VI. Market definition and dominance

- 1.36 The CAT upheld the CMA's findings on market definition and dominance in its *Phenytoin* judgment.¹⁸ Accordingly this Decision does not include a detailed assessment of market definition and dominance.
- 1.37 Pfizer's ability to increase its prices for Capsules to between 783% and 1,601% higher than those it charged to pharmacies and wholesalers until September 2012 was made possible by its dominant position.¹⁹
- 1.38 Similarly, Flynn's ability to charge pharmacies and wholesalers (ie Pfizer's previous customers) prices for Capsules which were between 2,361% and 2,686% higher than Pfizer's pre-September 2012 prices (and significantly above the already inflated supply prices it paid to Pfizer from September 2012) was also made possible by its dominant position.²⁰
- 1.39 It is also clear that the Parties understood that they possessed substantial market power and that they chose to exploit it. For example, in a presentation Flynn gave

¹⁶ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27), page 11.

¹⁷ PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.527).

¹⁸ *Phenytoin* [2018] CAT 11, paragraphs 192-198 and paragraphs 251-253.

¹⁹ *Phenytoin* [2018] CAT 11, paragraphs 198 and 253.

²⁰ *Phenytoin* [2018] CAT 11, paragraphs 198 and 253.

to Pfizer in July 2010, Flynn highlighted that the Parties could lose 50% of the market to parallel imports and the increased prices they were planning to impose would still generate more than £20 million in additional profit.²¹ An internal Pfizer email regarding the arrangements with Flynn also stated that '[t]he incremental revenue will be approximately £20M / year – and as nothing else changes significantly, this goes straight through to the bottom line'.²²

VII. The CMA finds that Pfizer and Flynn charged excessive and unfair prices

1.40 The CMA finds that, throughout the Relevant Period:

1.40.1. Pfizer's Prices for each of Pfizer's Products were excessive and unfair; and

1.40.2. Flynn's Prices for each of Flynn's Products were excessive and unfair.

a. Excessive

1.41 The amounts by which Pfizer's Prices for each capsule strength exceeded costs plus a reasonable rate of return ('**Cost Plus**') are shown in Table 1.2. These excesses are presented in absolute terms and on a percentage basis. Table 1.2 shows that Pfizer made over £57 million in excess profit (that is pure profit on top of a reasonable rate of return) across Pfizer's Products during the Relevant Period.

Table 1.2: Pfizer's excesses on Pfizer's Products, September 2012 to December 2016

	Capsule strength				Total sales
	25mg	50mg	100mg	300mg	
Revenue	£2,406,053	£7,254,162	£37,094,139	£24,532,890	£71,287,245
Cost Plus	£1,935,870	£3,792,624	£4,834,151	£3,259,203	£13,821,849
Excess (revenue)	£470,184	£3,461,538	£32,259,988	£21,273,687	£57,465,397
Excess (per pack)	£0.88	£3.20	£32.67	£32.10	N/A
Excess (%)	24%	91%	667%	653%	416%

Source: CMA analysis in Section 5 (Excessive).

1.42 The amounts by which Flynn's Prices for each capsule strength exceeded Cost Plus are shown in Table 1.3. These excesses are presented in absolute terms and on a percentage basis. Table 1.3 shows that Flynn made approximately £36 million

²¹ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27), page 11.

²² PHT00350, Email of 1 December 2011 from [Pfizer Employee 2] Pfizer to [Pfizer Employee] Pfizer (CMA document reference 00141.209). See also PHT00213, Email of 7 June 2011 from [Pfizer Director 1] to [Pfizer President 2] and [Pfizer Employee 6], (CMA document reference 00141.136): '[t]here is a significant commercial upside for EPUK - approx £25m per annum in revenues, practically all of which goes straight through to IBT [income before taxes]': PHT00213, Email of 7 June 2011 from [Pfizer Director 1] to [Pfizer President 2] and [Pfizer Employee 6], (CMA document reference 00141.136). See further PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 81, lines 4 to 6.

in excess profit (that is pure profit on top of a reasonable rate of return) during the Relevant Period.

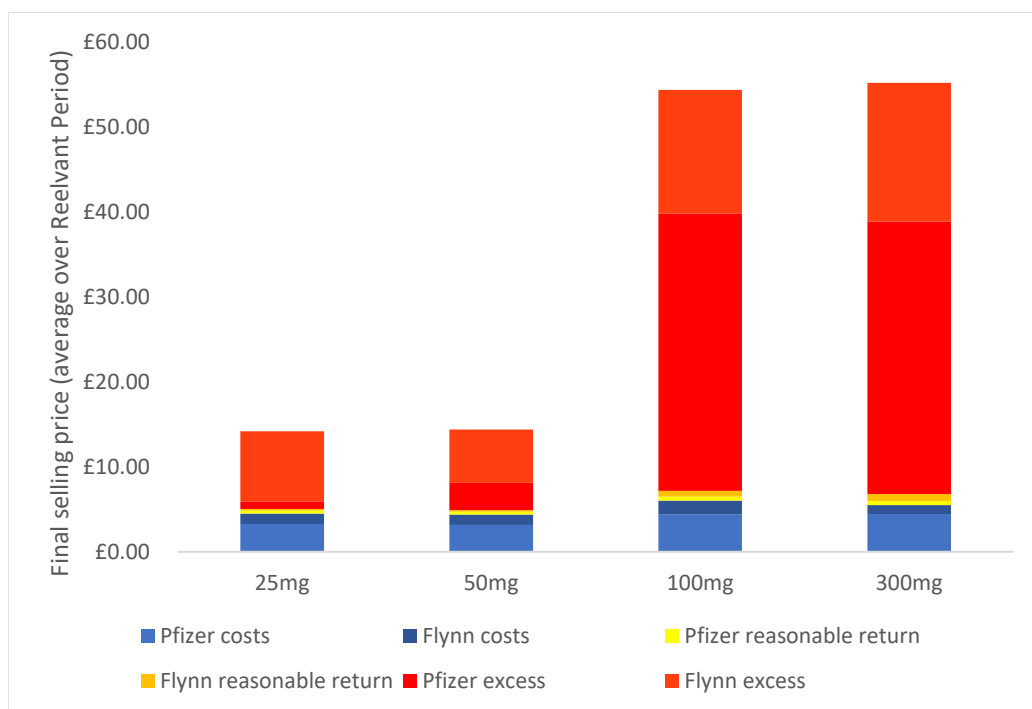
Table 1.3: Flynn's excesses on Flynn's Products, September 2012 to December 2016

	Capsule strength				Total
	25mg	50mg	100mg	300mg	
Revenue	£7,499,989	£15,317,886	£52,700,832	£35,881,444	£111,400,152
Cost Plus	£3,132,759	£8,643,336	£38,602,169	£25,286,634	£75,664,898
Excess (revenue)	£4,367,230	£6,674,550	£14,098,664	£10,594,810	£35,735,253
Excess (per pack)	£8.26	£6.27	£14.55	£16.30	N/A
Excess (%)	139%	77%	37%	42%	47%

Source: CMA analysis in Section 5 (Excessive).

- 1.43 The CMA finds that each of the above excesses are material. These excesses have been sustained for over four years and are in most cases significantly greater than the percentage excesses found to have been excessive in other cases.
- 1.44 It is important to note that Flynn's percentage excesses are suppressed by the high supply prices it agreed to pay to Pfizer. Flynn's Cost Plus is significantly higher than Pfizer's Cost Plus as a consequence of the Parties' arrangement. This has the effect that significant excess profits earned by Flynn are associated with much lower computed percentage excesses than those observed for Pfizer. The full extent of Flynn's excesses is shown by its absolute excesses, which materially exceeded Cost Plus for each capsule strength.
- 1.45 Figure 1.1 below shows the final prices charged to wholesalers and pharmacies during the Relevant Period broken down into (i) the Parties' costs of supply; (ii) a reasonable rate of return for each Party; and (iii) the excesses earned across each capsule strength. This shows that the Parties' excesses formed the significant majority of the final prices charged to wholesalers and pharmacies.

Figure 1.1: Breakdown of final prices charged (per pack) to wholesalers and pharmacies during the Relevant Period



Notes:

CMA analysis in Section 5 (Excessive) explains that Flynn’s costs comprise: (i) the supply prices it agreed to pay to Pfizer; (ii) storage and distribution fees; and (iii) an apportionment of common costs. Figure 1.1 shows the supply prices that Flynn paid to Pfizer during the Relevant Period broken down as Pfizer’s costs, reasonable return and excesses. Flynn’s costs as presented in Figure 1.1 are calculated as those costs incurred by Flynn in addition to the prices it paid to Pfizer.

During the Relevant Period, the Parties’ total excesses formed: 64% of the final price for 25mg capsules; 66% of the final price for 50mg capsules; 87% of the final price for 100mg capsules; and 88% of the final price for 300mg capsules.

b. Unfair

i. Unfair in itself

1.46 The CMA finds that Pfizer’s Prices and Flynn’s Prices for Capsules were not only excessive but were also unfair in themselves during the Relevant Period.

1.47 In coming to this conclusion, the CMA has had regard to the following factors, among others:²³

1.47.1. Pursuant to the arrangements entered into in 2012, the Parties implemented significant price increases which resulted in very high prices (relative to costs) and went well beyond any level that might have been required to ensure the drug was commercially viable or sustainable.

1.47.2. The selective nature of the price increases, whereby it was only in the UK that Pfizer entered into arrangements of the type agreed with Flynn and

²³ See section 6.B.

significantly increased its prices well above the level charged by Pfizer for the identical product in other European jurisdictions (Capsules supplied in EU Member States were all manufactured by Pfizer in the same German facility as the Capsules supplied to Flynn in the UK).

- 1.47.3. The Parties' prices reflected their substantial market power. Features of the relevant markets, including the absence of effective competitive constraints and very high barriers to entry, meant that those markets were incapable of functioning in a manner likely to produce a reasonable relationship of price to economic value. The Parties were aware of their market power and exploited this to impose significant price increases overnight which they maintained for over four years. In doing so, the Parties wilfully ignored customer concerns.
- 1.47.4. An assessment of the features of the products does not provide any justification or legitimate reason for the price increases or the resulting very high prices.
- 1.47.5. The Parties' prices had a significant and adverse effect on the end customer, the NHS, and on patient welfare.

ii. *Unfair when compared to competing products*

- 1.48 In the light of the CMA's conclusion that the Parties' prices during the Relevant Period were unfair in themselves, the CMA is not required to demonstrate that they were also unfair when compared to competing products.²⁴
- 1.49 However, the Parties have argued that the £30 Drug Tariff price²⁵ of phenytoin sodium tablets ('**Tablets**') and the prices of certain other AEDs demonstrate that their prices were fair by comparison. For the purposes of assessing the Parties' arguments, the CMA has gathered and carefully evaluated evidence relating to the following potential comparators:
 - 1.49.1. the £30 Drug Tariff price of Tablets;
 - 1.49.2. upstream ASPs of Tablet suppliers; and
 - 1.49.3. the prices of other AEDs.

²⁴ C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255; *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 259.

²⁵ The Drug Tariff is the primary mechanism for determining how dispensers are reimbursed for generic drugs. It is produced monthly by NHS Prescription Services and governs the price that is reimbursed to pharmacies for fulfilling NHS prescriptions, subject to any price concessions agreed between the DHSC and the Pharmaceutical Services Negotiating Committee (the '**Drug Tariff price**' or reimbursement price). See section 2.C.II.d.

- 1.50 For the reasons summarised below, the CMA has found that these are not meaningful comparators for the purposes of assessing the fairness of the Parties' prices for Capsules during the Relevant Period.

£30 Drug Tariff price of Tablets

- 1.51 The Parties benchmarked their prices for Capsules by reference to the prevailing Drug Tariff price of Tablets of £30 (for 28x 100mg Tablets). The Parties submit that this was an appropriate benchmark because the £30 price level was implemented following discussions between DHSC and Teva UK Limited ('**Teva**') - the historical monopoly supplier of Tablets - and therefore represented the price that the DHSC was willing to pay for Tablets. The Parties submit that they therefore relied upon this figure, in good faith, as a reference price for increasing their own prices for Capsules.
- 1.52 However, the following evidence supports the conclusion that the £30 Drug Tariff price of Tablets was not a meaningful benchmark and did not justify the Parties significant price increases:²⁶
- 1.53 The £30 Drug Tariff price was not a like-for-like comparison with the Parties' prices, which were at a different level of the supply chain. The £30 Drug Tariff price was significantly higher than actual supply prices charged at the equivalent level of the supply chain to Flynn during the Relevant Period. This makes any comparison against Flynn's Prices (and even more so against Pfizer's Prices) inconsistent.
- 1.54 The £30 Drug Tariff price was not a price reflective of any degree of competition and remained highly inflated by Teva's exercise of its market power and significant price increases between 2005 and 2007.²⁷ Whilst the £30 Drug Tariff price reflected a reduction compared to the Drug Tariff price the DHSC had paid in the previous quarter, this remained almost eight times higher than the Drug Tariff price of £3.87 at the beginning of scheme M and almost 18 times higher than the Drug Tariff price of £1.70 in March 2005.
- 1.55 The evidence clearly demonstrates that the DHSC and CCGs did not consider £30 to be the value of Capsules, or Tablets, and were not willing to pay this price during the Relevant Period.
- 1.56 The Parties' contention that £30 reflected what the DHSC accepted as the value of Tablets and was willing to pay (and that, consequently, they relied in good faith upon this as a benchmark price), is simply not sustainable.

²⁶ See further section 6.C.II.d.

²⁷ A Teva internal document from 2007 reported that 'Phenytoin (epilepsy) is the star in our generic portfolio and as we are the only supplier in the market we have been able to maintain high prices. We estimate to make an additional margin of £19.6m vs the initial WP. Sales are estimated to have gone up from an initial estimate of £5.8m to £25.4m by the year end' (emphasis added). See PRE00496, Teva internal presentation, Staff Briefing Q2 2007, page 19.

- 1.57 First, it ignores the context described above surrounding the Drug Tariff price being fixed at £30. Following the DHSC's discussions with Teva, the DHSC was still paying a price significantly higher than it had done prior to Teva's very significant Tablet price increases in the period between 2005 and 2007.
- 1.58 Second, it ignores the financial impact of the Parties' pricing decisions. The Tablets market is significantly smaller than the Capsules market, meaning that a high drug tariff price for Tablets would have a much lower impact on CCG budgets than the same drug tariff price for Capsules. This point was made explicitly by the DHSC to Flynn when contesting the Parties' use of the £30 Drug Tariff price in 2012. The DHSC saw the larger market for Capsules as an important reason why Tablets were not an appropriate benchmark.²⁸ Reflecting this concern, during the Relevant Period, the DHSC spent around £41.1 million on Tablets compared to around £177.5 million on Capsules.²⁹ [Former Teva Director], Teva's [X] and its representative, in discussions with the DHSC in respect of Tablets pricing, confirmed that the DHSC's focus would have been on 'overall cost' rather than the specific price.³⁰
- 1.59 Third, the Parties' reliance on the Tablets Drug Tariff price was based solely upon an inference as to the DHSC's views on the £30 Drug Tariff price following the meeting between DHSC and Teva. However, this inference needs to be balanced against the substantial volume of evidence which shows that the Parties knew that the DHSC (and many CCGs and other stakeholders) objected to their prices and did not consider that the benchmarking against the Tablets Drug Tariff price was justified and that these reservations were communicated unambiguously to the Parties.
- 1.60 Please see Annex C for a comprehensive analysis of the Parties' contacts with the DHSC.³¹ In summary:
- 1.60.1. The evidence demonstrates that, prior to the Parties' price increases, the DHSC had rejected requests from both Pfizer and Flynn to increase the price of Capsules within the PPRS by reference to the Drug Tariff price of Tablets.

²⁸ See further Annex C.

²⁹ For 100mg capsules: for 2012, a weighted average has been calculated using the Drug Tariff prices of 66p and £67.50; for 2013, the prevailing Drug Tariff price of £67.50 per pack has been used; for 2014, a weighted average has been calculated using the Drug Tariff prices of £54 and £67.50; and between 2015 and 2016, the prevailing Drug Tariff price of £54 per pack has been used. The same methodology has been used for the other strengths.

³⁰ PAD00030, [Former Teva Director] Cross Examination, day 5, page 37, lines 14-16.

³¹ The evidence regarding complaints received about the Parties' prices is set out in Annex B.

- 1.60.2. At a meeting with Flynn in July 2012, the DHSC ‘expressed the difficulties in agreeing to a launch price that was significantly higher than [the prevailing price of] Epanutin’.³²
- 1.60.3. In October 2012, the Parties received the letter from the GMMMG (a major purchaser of Capsules) which included a strong and reasoned critique of the Parties’ strategy and pricing from the customer’s perspective. The letter concluded that the Parties’ price increases amounted to a ‘cynical increase in costs’ and were an ‘abuse of a virtual monopoly position for purely commercial gains’ (a point which it reiterated on five occasions).
- 1.60.4. At a meeting with Flynn in November 2012, the DHSC told Flynn that it ‘had never confirmed that it was content with the price of the tablets’, that Flynn ‘should not [...] assume that the DH and NHS are happy with the price of the tablets’; that by using Tablets as a benchmark ‘the much larger market share of the capsules made the total cost very difficult for them, more visible and hitting hard NHS pockets’; and that the ‘DHSC were struggling and trying to understand the justification’.
- 1.60.5. At a meeting with Pfizer in January 2013 the DHSC sought comment on the price increases but was told by Pfizer that it could not comment on Flynn’s prices. Both Flynn and Pfizer also refused to provide costs information to the DHSC which it had requested so that it could understand the justification for the price increases.
- 1.60.6. Following the Parties’ price increases (in addition to the letter from the GMMMG described above), the Parties received a large number of reasoned complaints from CCGs explicitly and strongly contesting the scale of their price increases, highlighting the absence of any therapeutic justification and raising concerns about harm to CCG budgets and the impact on patient care.
- 1.60.7. Finally, the CMA opened an investigation into the Parties’ prices in May 2013. The CMA issued a Statement of Objections in August 2015 which made clear that it was the DHSC that had brought the Parties’ prices to the attention of the CMA.
- 1.61 However, despite this evidence showing that the DHSC and other key stakeholders did not accept the scale of the price increases, and the availability of a more reasonable course of action (by reducing their prices and engaging constructively

³² PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health’s response of 15 August 2013 to the OFT’s s.26 Notice information request of 26 June 2013 (CMA document reference 00367.9), page 1, paragraph 5.

with DHSC³³), the Parties continued to impose their high prices and did not engage constructively or sufficiently with the DHSC to resolve what Flynn noted were 'legitimate concerns' regarding the prices it was imposing.³⁴

- 1.62 Flynn informed the DHSC that the prices that it had imposed were necessary to ensure 'the continued commercially viable supply'³⁵ and that Flynn 'might have to discontinue the product if [it] didn't make sufficient margin'.³⁶ However, this explanation was somewhat disingenuous and concealed the fact that Flynn (and Pfizer) were making very substantial margins on their Capsules sales. Indeed, as the CAT itself found in its *Phenytoin* judgment, Flynn set its selling Prices 'well above [Pfizer's supply price] and could have reduced its prices and still made a material profit'.³⁷ Similarly, the CMA has established in this Decision that Pfizer's prices went well beyond the level that would have been necessary to ensure that it remained financially viable for them to continue to produce Capsules.
- 1.63 The evidence shows that the DHSC approached its discussions with the Parties in good faith and with the aim of understanding the reasons for the price increases proposed. The DHSC had accepted, based on Flynn's submissions, that a price increase might be justified and sought to get an understanding of the issue by reference to the Parties' costs of supply. However, following direct requests by the DHSC, both Pfizer and Flynn refused to provide their costs information to the DHSC. Instead, they continued to impose their high prices.
- 1.64 The Parties did not re-engage in discussions with the DHSC after the OFT opened its investigation in May 2013, or at any stage of the subsequent the OFT and CMA investigation. This further undermines the force of the Parties' argument that the Tablets Drug Tariff price was an appropriate benchmark. Given the obvious discrepancy between the Parties' understanding of the DHSC's views on Tablets and the position the DHSC took in practice, in seeking to rely on this benchmark in 'good faith', the Parties would have been expected to have contacted the DHSC to seek its views (and potentially its support) in making this representation.
- 1.65 Instead, despite the significant body of evidence that showed DHSC objected to the use of the Tablets Drug Tariff price as a price benchmark, the Parties continued to impose their very high prices, believing it was reasonable, instead, to rely upon an inference drawn from what happened to the Tablets Drug Tariff price following

³³ This possibility had been raised by the GMMM in its letter to the Parties on 10 October 2012. The letter from the GMMM set out that '[t]he only credible alternative is that the companies must make a case for a **modest** price increase, but this must stand up to economical and clinical justification'. See further Annex C.

³⁴ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 6: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18).

³⁵ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18).

³⁶ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

³⁷ *Phenytoin* [2018] CAT 11, paragraph 456.

the meeting between Teva and DHSC in October 2007. Neither Party attended that meeting and no formal announcement was made as to its outcome which they could have relied upon. Further, [Pfizer Director 1] of Pfizer confirmed that Pfizer did not speak to anyone from Teva or the DHSC about what happened at the meeting and that Pfizer relied purely on an inference relating to the outcome of the meeting between Teva and DHSC.³⁸

- 1.66 Given the scale of the evidence showing both Pfizer and Flynn were made aware of the DHSC's objections (and those of CCGs and other stakeholders), the inferences drawn by the Parties were clearly not justified in practice.

Upstream ASPs of Tablet suppliers

- 1.67 The CMA has gathered and evaluated a significant body of evidence to determine whether the upstream ASPs of Tablets (at the comparable level of the supply chain to Flynn) might themselves provide a meaningful comparator. The CAT's view was that, in the Previous Investigation, the CMA should have conducted an investigation into the competitive conditions in the market for the supply of Tablets to assess whether their ASPs were set in conditions of effective competition and might therefore themselves be a useful comparator to assess whether the Parties' prices for Capsules were fair.³⁹
- 1.68 The CMA finds that the Tablets market did not exhibit sufficiently effective competition during the period January 2005 to December 2021 for Tablets ASPs to provide any such meaningful comparator.⁴⁰
- 1.69 For the majority of that period, Teva was either a monopolist (January 2005 to September 2009) or in a duopoly with one other supplier (first Wockhardt (October 2009 to August 2012) then Milpharm (August 2014 to December 2021)).
- 1.70 There was a relatively brief period (22 months) of some increased competition when there were three Tablet suppliers in the market (Teva, Milpharm and Wockhardt) between September 2012 and July 2014. However, even though prices reduced during this period there were a number of factors which limited the effectiveness of competition, with the evidence demonstrating that Teva maintained a significant majority share of supply while also charging the highest prices for most of the period assessed. The entrants, Wockhardt and Milpharm, while gaining share of supply when they entered, were unable to grow their sales volumes despite the clear financial incentive on pharmacies to switch to their products. This shows that Teva maintained a substantial degree of market power at all times.

³⁸ See PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 37, lines 24 and 25 and page 38, lines 1-3.

³⁹ *Phenytoin*, CAT [11] 2018, paragraphs 384 to 391.

⁴⁰ See further section 6.C.II.e.

- 1.71 At the point of Milpharm's entry, the Tablets market continued to be distorted by the price increases imposed by Teva during a period of monopoly supply and maintained during a subsequent period of duopoly supply.
- 1.72 In addition, the period of three player competition was, in reality, limited to just 16 months following Milpharm's entry. It is likely that a longer period of more intense competition would have been needed to erode prices, previously distorted by market power, to competitive levels.
- 1.73 However, there were a range of factors that also significantly limited the scope and effect of competition even during this 16 month period:
- 1.73.1. First, both Teva and Wockhardt adopted strategies of ceding some customer volumes to avoid competition on price and stabilise their ASPs.
 - 1.73.2. Second, Milpharm and Wockhardt both experienced supply constraints which impacted on their ability to compete effectively and this was known by other suppliers.
 - 1.73.3. Third, the regulatory guidance recommending Continuity of Supply provided further barriers to expansion, particularly after the publication of the MHRA Guidance in November 2013 (just over a year after Milpharm's entry).
- 1.74 Notwithstanding the CMA's conclusion that Tablets ASPs do not provide a meaningful comparator, the CMA has nevertheless considered the Parties' supply prices during the Relevant Period alongside the ASPs of the Tablet suppliers, and the entrants into the Tablets market (Wockhardt and Milpharm) in particular, during the period of three player supply. The comparison shows that the Parties' ASPs were significantly higher than the ASPs of Wockhardt and Milpharm, and were even higher than Teva's ASPs despite Teva's position of market power.⁴¹
- 1.75 Accordingly, the CMA's analysis of Tablets ASPs does not indicate that the Parties' prices during the Relevant Period were fair or undermine the CMA's conclusion that the Parties' prices were unfair in themselves. If anything, it supports this conclusion.

Other AEDs

- 1.76 The CMA has also gathered and evaluated evidence relating to a number of other AEDs put forward by Pfizer as evidence that its prices were fair during the Relevant Period. The CMA finds that the comparisons presented by Pfizer's expert are not

⁴¹ See further section 6.C.II.e.iv.

meaningful and do not indicate that the Parties' prices were fair during the Relevant Period.⁴²

- 1.77 There are several significant clinical differences between Capsules and the other AEDs identified by Pfizer. In particular: Capsules have a number of undesirable product characteristics not present in the other AEDs; the other AEDs are used to treat different seizure types and patient groups; the other AEDs were all first line treatments during the Relevant Period, as reflected in clinical guidance; and the other AEDs continue to be prescribed to new patients (reflecting clinical views on their relative benefits) and have been increasing in volumes. From a product perspective, these AEDs are not, therefore, sufficiently similar to Capsules to allow for a meaningful comparison.
- 1.78 In addition, four of the five AEDs put forward by Pfizer as comparators are branded AEDs. The CMA's analysis demonstrates that the price of each of the four branded AEDs has been maintained at a high level following generic entry, while the vast majority of the market volumes have switched to cheaper generic versions of the drug. In these circumstances, the price of these branded AEDs cannot serve as a meaningful comparator in assessing the fairness of the Parties' prices for Capsules, as they are likely to be reflective of a strategy by respective suppliers to not compete on prices and only apply to a very small proportion of the overall volumes in their respective markets.
- 1.79 To the extent that any weight should be given to a comparison between the prices of these four AEDs and the Parties' prices for Capsules, the consistent comparison would be between the Parties' prices and the prices of the generic versions of the four branded AEDs put forward by Pfizer. The prices of these generic AEDs are, in fact, significantly below the prices for Capsules during the Relevant Period. This does not indicate that the Parties' prices during the Relevant Period were fair or undermine the CMA's conclusion that the Parties' prices were unfair in themselves.

C. Background to the remittal

I. The CMA's previous investigation

- 1.80 The DHSC made a complaint to the CMA about the increases to the prices of Capsules implemented in September 2012.
- 1.81 In May 2013, the CMA opened the Previous Investigation, having determined that it had reasonable grounds for suspecting that Pfizer had infringed the Chapter II prohibition and Article 102 of the Treaty on the Functioning of the European Union ('TFEU'), and that the Parties had infringed the Chapter I prohibition imposed by section 2 of the Act and Article 101 of the TFEU. In February 2014, the CMA extended the scope of the Previous Investigation having determined that it had

⁴² See section 6.C.III.

reasonable grounds for suspecting that Flynn had infringed the Chapter II prohibition and Article 102 of the TFEU.

- 1.82 Between May 2013 and April 2015, the CMA carried out evidence gathering. This included issuing a series of formal information requests to the Parties under section 26 of the Act, requesting documents from each of Flynn and Pfizer under section 27 of the Act, performing onsite inspections of those documents, and holding a series of information gathering and update meetings.⁴³ During this period, the CMA also requested information from and met with a number of third parties, including manufacturers, wholesalers and pharmaceutical retailers of phenytoin sodium capsules and Tablets, and key regulatory and patient groups.⁴⁴
- 1.83 On 6 August 2015, the CMA issued a statement of objections to the Parties setting out its provisional findings.⁴⁵ On 16 May 2016, the CMA issued a draft penalty statement to each of the Parties setting out the CMA's provisional decisions regarding the directions and financial penalties that it proposed to impose on Pfizer and Flynn respectively if the CMA were to reach an infringement decision against that Party.⁴⁶ On 25 May 2016, the CMA sent a letter of facts to both Flynn and Pfizer which identified additional evidence supporting the CMA's provisional findings, on which it proposed to rely.⁴⁷
- 1.84 Between November 2015 and June 2016, the Parties submitted representations to the CMA on the statement of objections, the draft penalty statement and the letter of facts.
- 1.85 On 7 December 2016, the CMA adopted the 2016 Infringement Decision finding that each of Pfizer and Flynn had abused their respective dominant positions by imposing unfairly high selling prices for Capsules in the UK in the period from 24 September 2012 to at least 7 December 2016. The 2016 Infringement Decision levied fines on Pfizer and Flynn of £84,196,998 and £5,164,425 respectively,⁴⁸ and directed them to revise their selling prices for Capsules having regard to the 2016 Infringement Decision (the '**Directions**') from 23 January 2017.⁴⁹

⁴³ 2016 Infringement Decision, pages 24 to 27, provides full details of the investigatory steps taken, and in particular the dates of information gathered from the Parties during the Previous Investigation.

⁴⁴ During 2013, 2014 and 2015, the CMA requested information from a number of third parties, including: the Chief Pharmaceutical Officers of England, Ireland, Scotland and Wales; the DHSC; the MHRA; NICE; the NHS Confederation; the Dispensing Doctors' Association; the Royal College of Physicians; the Royal Pharmaceutical Society; Epilepsy Action; Epilepsy Scotland; and Epilepsy Wales; Teva UK Limited; NRIM Limited; AAH Pharmaceutical Limited; Auden McKenzie (Pharma Division) Limited; Asda Group Limited; Boots UK Limited; Co-op Healthcare Holdings Limited; Belfast Co-Operative Chemists Limited; National Co-Operative Chemists Limited; Day Lewis plc; Lloyds Pharmacy Limited, WM Morrison Supermarkets plc; L Rowland and Company (Retail) Limited; J Sainsbury plc; Superdrug Stores plc and Tesco plc.

⁴⁵ On 15 September 2015, the CMA provided the Parties with amendments to the statement of objections, principally regarding certain common cost calculations and footnote references. A consolidated (revised) statement of objections was issued to the Parties on 17 September 2015.

⁴⁶ The CMA provided each Party with a non-confidential version of the other Party's draft penalty statement on 19 May 2016.

⁴⁷ Revised versions of the letter of facts were sent on 27 May 2016 to both Flynn and Pfizer.

⁴⁸ 2016 Infringement Decision, paragraph 7.150.

⁴⁹ 2016 Infringement Decision, Annex B, paragraphs 1(b) and 1(c).

1.86 On 30 January 2017, the Parties notified the CMA of their compliance with the Directions.⁵⁰

II. Appeal to the Competition Appeal Tribunal

1.87 On 7 February 2017, Pfizer and Flynn lodged appeals in the CAT against the 2016 Infringement Decision, under section 46 of the Act. The appeals were heard together between 30 October 2017 and 24 November 2017.

1.88 On 7 June 2018, the CAT handed down its judgment⁵¹ which upheld the CMA's findings on market definition and dominance⁵² and set aside the part of the 2016 Infringement Decision that related to abuse and any consequential findings, including penalties.⁵³

1.89 On 25 July 2018, the CAT ordered that the issue of abuse and any consequential matters be remitted back to the CMA for reconsideration in accordance with the CAT's judgment (the '**Remittal Order**').⁵⁴ In doing so, the CAT saw 'a clear public interest in the legality or otherwise of [Pfizer's and Flynn's] pricing behaviour over some four years being established'.⁵⁵

1.90 As part of the appeals to the CAT, additional factual and expert evidence was submitted in support of the Parties' appeals. The CMA has taken account of this evidence for the purposes of its investigation on remittal.

III. Appeal to the Court of Appeal

1.91 All parties applied to the Court of Appeal for permission to appeal the CAT's judgment. Leave to appeal was given to both the CMA and Flynn (on certain of its arguments) by order on 12 December 2018.⁵⁶

1.92 The Court of Appeal handed down its judgment on 10 March 2020. The Court of Appeal partially upheld the CMA's appeal, in particular in relation to hypothetical price benchmarks.⁵⁷ The Court of Appeal dismissed Flynn's appeal in its entirety.⁵⁸

1.93 The Court of Appeal upheld the CAT's judgment including the Remittal Order.⁵⁹ Where there is a difference between the views of the Court of Appeal and the CAT,

⁵⁰ PRE00712, Pfizer letter to the CMA dated 30 January 2017 and PRE00715, Flynn letter to the CMA dated 30 January 2017.

⁵¹ *Phenytoin* [2018] CAT 11.

⁵² *Phenytoin* [2018] CAT 11, paragraphs 198 and 253.

⁵³ *Phenytoin* [2018] CAT 11, paragraph 468.

⁵⁴ *Phenytoin*, Remittal Order [2018] CAT 12, paragraph 47.

⁵⁵ *Phenytoin*, Remittal Order [2018] CAT 12, paragraph 15.

⁵⁶ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 15.

⁵⁷ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 125, 184 to 189, 254 and 283.

⁵⁸ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 188 and 224.

⁵⁹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 189 and 283.

then the judgments of the Court of Appeal will govern the principles to be applied on the remittal.⁶⁰

D. The CMA's remittal investigation

- 1.94 On 2 June 2020, further to the Remittal Order, the CMA wrote to each Party to inform it that the CMA had decided to re-open the investigation into the remitted issues (the '**Remittal**'), having determined that it had reasonable grounds to suspect that each Party had infringed the Chapter II prohibition and Article 102 of the TFEU by charging unfairly high selling prices in respect of the supply of 25mg, 50mg, 100mg and 300mg phenytoin sodium capsules in the UK from 24 September 2012 to 23 January 2017.
- 1.95 On 29 January 2021, the CMA wrote to each Party to inform it that, following the end of the Brexit transition period,⁶¹ EU law would no longer be applied in the UK and therefore the Remittal would continue on the basis of the Chapter II prohibition only.
- 1.96 However, under section 60A of the Act, unless it considers it appropriate to act otherwise in light of specified factors, 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 provisional conclusion it has reached in this case, 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.

I. Engagement with the Parties

- 1.97 The CMA held initial state of play calls with Flynn and Pfizer on 10 and 24 July 2020 respectively.⁶²
- 1.98 Evidence was collected from the Parties through formal information requests under section 26 of the Act to: Flynn on 27 July 2020,⁶³ 21 August 2020,⁶⁴ and 22 September 2020;⁶⁵ and to Pfizer on 12 August 2020⁶⁶ and 27 April 2021.⁶⁷

⁶⁰ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 189.

⁶¹ As provided for by the UK/EU withdrawal agreement.

⁶² PRC00504, Meeting note of State of Play call with Flynn on 10 July 2020 - CMA version; PRC00506, Meeting note of State of Play call with Flynn on 10 July 2020 - Flynn version; and PRC00410, Meeting note of State of Play call with Pfizer on 24 July 2020.

⁶³ PRC00338, s.26 Notice issued to Flynn on 27 July 2020.

⁶⁴ PRC00425, s.26 Notice issued to Flynn on 21 August 2020.

⁶⁵ PRC00538, s.26 Notice issued to Flynn on 22 September 2020.

⁶⁶ PRC00401, s.26 Notice issued to Pfizer on 12 August 2020.

⁶⁷ PRC02306, s.26 Notice issued to Pfizer on 27 April 2021.

1.99 The CMA provided further state of play updates to Flynn by way of virtual meetings on 12 July 2021,⁶⁸ 1 April 2022,⁶⁹ and 23 June 2022; and to Pfizer by way of written update on 21 July 2021⁷⁰ and virtual meetings on 6 April 2022⁷¹ and 23 June 2022.

II. Evidence gathering in respect of phenytoin sodium tablets

1.100 During the Previous Investigation, the CMA took a number of steps to gather evidence and investigate the facts and circumstances relevant to Tablets.⁷² These included, *inter alia*, the following:

1.100.1. seeking information from the DHSC by way of issuing section 26 notices and additional calls;

1.100.2. seeking information from other industry stakeholders such as the MHRA and NHS England;

1.100.3. issuing section 26 notices to the ten largest UK pharmacy groups;

1.100.4. issuing section 26 notices to UK wholesalers of Tablets;

1.100.5. issuing a section 26 notice to Teva, a manufacturer of Tablets; and

1.100.6. considering relevant industry guidance and other publicly available information.

1.101 In the Remittal, between June 2020 and April 2021, the CMA gathered further information and evidence to investigate further competitive conditions in the supply of Tablets in the UK and the evolution of supply prices over time, as well as other facts relating to Tablets.

1.102 For this purpose, information relating to Tablets, including sales and volume data and relevant internal documents were collected via formal requests under section 26 of the Act issued to manufacturers, MA holders and wholesalers of Tablets. Third parties contacted for this purpose included: Accord UK Limited (**'Accord'**); [X]; [X]; Milpharm Limited (**'Milpharm'**); TEVA Pharmaceuticals Europe B.V; and Wockhardt UK Limited (**'Wockhardt'**).⁷³

⁶⁸ PRC02573A Note of State of Play call with Flynn on 12 July 2021 – Flynn version; and PRC02573B, Note of State of Play call with Flynn on 12 July 2021 – CMA version.

⁶⁹ PRC03913, Note of update call with Flynn on 1 April 2022.

⁷⁰ PRC02569, State of Play Letter to Pfizer, 21 July 2021.

⁷¹ PRC03915, Note of update call with Pfizer on 6 April 2022.

⁷² See further Annex D, which is a note provided by the CMA to the CAT during the appeal of the CMA's 2016 Infringement Decision. The note provides a detailed overview of the steps taken by the CMA during the previous administrative phase to investigate the supply of Tablets.

⁷³ PRC00195, s.26 Notice issued to Wockhardt on 29 June 2020; PRC00198, s.26 Notice issued to [X] on 29 June 2020; PRC00201, s.26 Notice issued to Milpharm on 29 June 2020; PRC00355, s.26 Notice issued to Teva on 31 July 2020; PRC00472, s.26 Notice issued to Accord on 8 September 2020; PRC00510, s.26 Notice issued to Accord on 17

- 1.103 The CMA also held a number of virtual meetings with Tablet suppliers, in particular two with Milpharm and one with Wockhardt, for the purposes of seeking additional information on competitive conditions.⁷⁴
- 1.104 Evidence relating to the purchasing and dispensing of Tablets was also collected via requests under section 26 of the Act issued to a number of retail pharmacies, including: [redacted] ('[redacted]') in respect of the retail activities of [redacted] ('[redacted]') and [redacted] ('[redacted]'); [redacted] ('[redacted]'); [redacted] ('[redacted]'); [redacted] ('[redacted]'); [redacted] ('[redacted]'); [redacted] ('[redacted]'); [redacted] ('[redacted]'); and [redacted] ('[redacted]').⁷⁵
- 1.105 Evidence relating to Tablets, including regarding purchasing activities, was also gathered from wholesalers under section 26 of the Act from: Alliance Healthcare Distribution Limited ('**Alliance**'); [redacted]; and [redacted].⁷⁶
- 1.106 The CMA requested information and documents from other relevant third parties relating to the supply of Tablets under section 26 of the Act, including the DHSC and the MHRA.⁷⁷
- 1.107 The CMA also gathered and assessed relevant information from public sources, including data relating to the volumes of Tablets prescribed, publicly available industry guidance relevant to Tablets and published Drug Tariff prices for Tablets over a number of years.
- 1.108 During the appeals of the CMA's 2016 Infringement Decision to the CAT, additional evidence relevant to Tablets was adduced by the Parties, and their factual and expert witnesses.⁷⁸ In particular, factual evidence relating to Tablets was adduced by [Former Teva Director] on behalf of Flynn and [Pfizer Director 1] on behalf of Pfizer. As part of its assessment of Tablets on remittal, the CMA has considered and taken account of all evidence relevant to Tablets adduced on appeal, as well as evidence gathered during its Previous Investigation.

September 2020; PRC00525, s.26 Notice issued to Milpharm on 18 September 2020; PRC00528, s.26 Notice issued to Wockhardt on 18 September 2020; PRC00531, s.26 Notice issued to Teva on 18 September 2020; PRC00812, s.26 Notice issued to Accord on 22 October 2020; PRC01146, s.26 Notice issued to [redacted] on 11 December 2020; PRC01334, s.26 Notice issued to Teva on 25 January 2021; PRC01341, s.26 Notice issued to Accord on 28 January 2021; and PRC01348, s.26 Notice issued to Milpharm on 29 January 2021.

⁷⁴ PRC01144a, Note of call with Wockhardt, 17 November 2020; PRC01623A, Note of call between CMA and Milpharm, 9 February 2021; and PRC01796, Note of call between CMA, [redacted] and Milpharm, 25 February 2021.

⁷⁵ PRC00011, s.26 Notice issued to [redacted] on 15 June 2020; PRC00014, s.26 Notice issued to [redacted] on 15 June 2020; PRC00017, s.26 Notice issued to [redacted] on 15 June 2020; PRC00021, s.26 Notice issued to [redacted] on 15 June 2020; PRC00024, s.26 Notice issued to [redacted] on 15 June 2020; PRC00027, s.26 Notice issued to [redacted] on 15 June 2020; PRC00030, s.26 Notice issued to [redacted] on 15 June 2020; PRC00037, s.26 Notice issued to [redacted] on 15 June 2020; and PRC00062, s.26 Notice issued to [redacted] on 17 June 2020.

⁷⁶ PRC00065, s.26 Notice issued to Alliance Healthcare on 15 June 2020; PRC00037, s.26 Notice issued to [redacted] on 15 June 2020; and PRC00043, s.26 Notice issued to [redacted] on 15 June 2020.

⁷⁷ PRC00279, s.26 Notice issued to DHSC on 7 July 2020; PRC00445, s.26 Notice issued to MHRA on 28 August 2020; PRC00523, s.26 Notice issued to MHRA on 18 September 2020; PRC00598, s.26 Notice issued to DHSC on 1 October 2020; PRC01076, s.26 Notice issued to MHRA on 26 November 2020; PRC01101, s.26 Notice issued to DHSC on 2 December 2020; and PRC01236, s.26 Notice issued to DHSC on 22 December 2020.

⁷⁸ See Annex A for an explanation of the relevant individuals that submitted evidence before the CAT.

III. Other Remittal evidence gathering

- 1.109 In order to gather further information relevant to Capsules' therapeutic characteristics, the CMA held a number of virtual meetings with [Professor of Neurology].⁷⁹ [Professor of Neurology] is a Professor of Neurology and [X]. He is also a consultant neurologist at the National Hospital for Neurology and Neurosurgery, with a specialist interest in epilepsy. In this role, he has approximately 1,200 people with epilepsy under his neurological care.⁸⁰
- 1.110 The CMA also held virtual meetings with certain CCGs and representative bodies of CCGs: the GMMM; Somerset CCG; and West Sussex CCG.⁸¹
- 1.111 The CMA also considered publicly available data relating to the sales volumes of the generic and branded versions of other AEDs put forward by the Parties as potential comparators during the appeals.⁸²

IV. Issue of the Statement of Objections and the appointment of a Case Decision Group

- 1.112 On 5 August 2021, the CMA issued a Statement of Objections ('SO') to the Parties setting out its provisional findings, as well as a Draft Penalty Statement ('DPS') to each of Pfizer and Flynn.
- 1.113 In the SO, the CMA set out the facts and the evidence on which it relied, the objections it raised in terms of the alleged infringements of the Chapter II prohibition, the action it proposed to take and its reasons for the proposed actions.
- 1.114 Each DPS set out the CMA's provisional findings regarding the financial penalties that it proposed to impose on Pfizer and Flynn respectively if the CMA were to reach an infringement decision against that Party.
- 1.115 Following the issue of the SO, the CMA appointed a Case Decision Group to decide whether or not, based on the facts and evidence before it, and taking account of the Parties' representations, the legal test for establishing an infringement had been met and the appropriate amount of any penalties.⁸³
- 1.116 Following the issue of the SO:

⁷⁹ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020; PRC01816, Note of call with [Professor of Neurology] on 7 January 2021; and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020.

⁸⁰ PAD00124, [Professor of Neurology]: University College London Hospitals NHS Foundation Trust.

⁸¹ PRC00817A, Note of call between CMA, [X] and [X] (NHS Oldham CCG), 7 October 2020; PRC00882, Note of call between the CMA and [X] (NHS Somerset CCG), 8 October 2020; PRC01037, Note of call with [X] (NHS Oldham CCG), 10 November 2020; PRC02571, Note of call with [X] and [X] (NHS Oldham CCG), 11 December 2020, PRC02294, Note of call between the CMA and [X] (West Sussex PCT), 8 October 2020.

⁸² PCA data for England, PAD00021, PAD00105-PAD00120.

⁸³ The role of the Case Decision Group is described in the guidance on the CMA's investigation procedures in Competition Act 1998 cases (CMA8, December 2021) ('CMA8'), paragraphs 9.7 and 11.35-11.37.

- 1.116.1. Flynn submitted written representations on the matters referred to in the SO and its DPS on 12 November 2021⁸⁴ and attended an oral hearing on 6 December 2021;⁸⁵ and
- 1.116.2. Pfizer submitted written representations on the matters referred to in the SO and its DPS on 11 November 2021.⁸⁶ On 2 November 2021, Pfizer informed the CMA that it did not wish to take the opportunity to attend an oral hearing.⁸⁷

V. Further evidence gathering following representations on the SO

- 1.117 Following the receipt of the Parties' written and oral representations on the SO and each DPS,⁸⁸ the CMA requested further information from Flynn. The CMA also requested further information from third parties, namely Teva, Milpharm and Accord.⁸⁹ In addition, the CMA held virtual meetings with the Tablets suppliers Teva, Milpharm and Wockhardt.⁹⁰
- 1.118 The CMA also considered and took account of additional evidence gathered during its Previous Investigation and additional publicly available information.

VI. Issue of Letter of Facts

- 1.119 On 14 April 2022, the CMA sent a Letter of Facts to the Parties which identified additional evidence supporting the CMA's provisional findings, as set out in the SO and each DPS, on which it proposed to rely.⁹¹
- 1.120 On 17 May 2022, Flynn and Pfizer each submitted written representations to the CMA on the matters referred to in the Letter of Facts.⁹²

⁸⁴ PRC03492, Flynn's response to the SO; and PRC03495, Flynn's response to the DPS.

⁸⁵ PRC03631, Transcript of Flynn's Oral Hearing.

⁸⁶ PRC03488, Pfizer's response to the SO and DPS.

⁸⁷ PRC03378, Pfizer's Letter of 2 November 2021 confirming that Pfizer does not require an oral hearing.

⁸⁸ As noted above, Pfizer chose not to make oral representations on the SO or DPS.

⁸⁹ PRC03586, s.26 Notice issued to Accord on 6 January 2022, response received on 11 January 2022 (PRC03597 and PRC03598); PRC03578, s.26 Notice issued to Milpharm on 5 January 2022, response received on 22 January 2022 (PRC03614); PRC03581, s.26 Notice issued to Teva on 5 January 2022, response received on 19 January 2022 (PRC03619 and PRC03620).

⁹⁰ PRC03750, Note of call with Teva on 4 March 2022; PRC03676, Note of call with Milpharm on 20 January 2022; PRC03714, Note of call with Wockhardt on 25 January 2022.

⁹¹ A version of the Letter of Facts for disclosure within the confidentiality ring only was disclosed to each Party on 19 April 2022, PRC03873, Pfizer Letter of Facts (confidentiality ring only) and PRC03847, Flynn Letter of Facts (confidentiality ring only), with a further unredacted version provided to Pfizer on 20 April 2022 (PRC03873).

⁹² PRC03901, Pfizer's response to the Letter of Facts received on 17 May 2022; PRC03903, Flynn's response to the Letter of Facts received on 17 May 2022.

2. Factual background

A. Phenytoin sodium capsules

I. Introduction

- 2.1 The CMA's investigation concerns the prices charged by Pfizer and Flynn for the supply of phenytoin sodium capsules between 24 September 2012 and 7 December 2016.
- 2.2 Phenytoin sodium is a very old drug used to treat epilepsy. Phenytoin was first synthesised in 1908⁹³ and was developed into an antiepileptic drug in 1938 due to its anticonvulsant properties.⁹⁴ It has long been off-patent.
- 2.3 Phenytoin sodium is available in several formulations:
- 2.3.1. as capsules or tablets, taken daily to control epilepsy seizures; and
 - 2.3.2. as an oral solution for injection or infusion, used for the treatment of status epilepticus, a medical emergency.⁹⁵
- 2.4 As a treatment for epilepsy, phenytoin sodium capsules have been largely superseded by newer, superior treatments.⁹⁶ In light of the clinical limitations of the drug compared to alternative medicines, phenytoin sodium capsules are now only very rarely used as a treatment for new patients and their use has been declining in the UK for a number of years.⁹⁷
- 2.5 The vast majority of patients treated with phenytoin sodium capsules during the Relevant Period (and currently) are legacy patients.⁹⁸ Phenytoin sodium capsules are still considered to be an effective treatment for controlling seizures and remain an essential drug for the significant number of legacy patients stabilised on them.
- 2.6 During the Relevant Period there were (and continue to be) significant limitations on switching a patient who has been stabilised on a particular manufacturer's phenytoin sodium capsule to an alternative treatment:

⁹³ PHT00121, Blitz H (1908), 'Über die Konstitution der Einwirkungsprodukte von substituierten Harnstoffen auf Benzil und über einige neue Methoden zur Darstellung der 5,5-Diphenyl-hydantoine' [Constitution of the Products of the Interaction of Substituted Carbamides on Benzil and Certain New Methods for the Preparation of 5,5-Diphenylhydantoin], *Chemische Berichte* (in German) 41 (1) (CMA document reference PD1), pages 1379 to 1393.

⁹⁴ PHT00122, Merritt H and Putnam T (1938), A new series of anticonvulsant drugs tested by experiments on animals, *Archives of Neurology and Psychiatry*, vol. 39, pages 1003 to 1015 (CMA document reference PD2); PHT00123, Blair, Bailey, McGregor (1939), Treatment of Epilepsy with Epanutin, *Lancet*, Volume 234, Issue 6050 (CMA document reference PD4), pages 363 to 367; and *Phenytoin* [2018] CAT 11, paragraph 16.

⁹⁵ The oral solution is supplied by Pfizer as 'Epanutin Ready Mixed Parenteral 250mg/5ml solution for Injection or Infusion': PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.1), page 4.

⁹⁶ See further paragraphs 2.25 and 2.44 below.

⁹⁷ See further paragraphs 2.25 and 2.44 to 2.47 below.

⁹⁸ See further paragraph 2.46 below.

- 2.6.1. First, there was clinical guidance advising generally against switching patients between different manufacturers of phenytoin products, including other manufacturers of phenytoin sodium capsules, due to patient safety concerns.⁹⁹
- 2.6.2. Second, there were clinical and patient concerns around switching patients stabilised on phenytoin sodium capsules to alternative AEDs or ceasing treatment.¹⁰⁰
- 2.7 In the UK, MAs for the supply of phenytoin sodium capsules are currently held by Flynn and Accord.¹⁰¹
 - 2.7.1. Flynn supplies capsules in four different strengths – 25mg, 50mg, 100mg and 300mg – sold as ‘Phenytoin Sodium Flynn Hard Capsules’. These are manufactured by Pfizer.
 - 2.7.2. Accord supplies 100mg strength capsules only, sold as ‘Phenytoin Sodium NRIM Capsules’.¹⁰² These are currently manufactured by Accord.
- 2.8 The majority of UK sales of phenytoin sodium capsules by capsule volume are of the 100mg strength.¹⁰³ In the UK, 25mg, 50mg and 300mg strength capsules are typically sold in packs of 28 capsules, whereas 100mg strength capsules are sold in packs of 84 capsules.¹⁰⁴
- 2.9 During the Relevant Period, the NHS dispensed approximately four times the number of 100mg phenytoin sodium capsules as compared with 100mg phenytoin sodium tablets in the UK.¹⁰⁵
- 2.10 Pfizer also supplies other phenytoin products which are phenytoin-based but are not phenytoin sodium:
 - 2.10.1. ‘Epanutin Infatabs 50mg Chewable Tablets’; and

⁹⁹ See further paragraphs 2.35 to 2.41 below. For example, guidance issued by the MHRA on 11 November 2013 identified phenytoin within category 1 of the guidance, which are AEDs where doctors were advised to ensure that the patient was maintained on a specific manufacturer’s product, see PHT00093, MHRA Guidance (2013) *Antiepileptics: Changing products* (CMA document reference PD19).

¹⁰⁰ See further paragraph 2.48 below.

¹⁰¹ The MHRA confirmed that as of 2 October 2020 there was a pending MA application for all strengths of capsules submitted by Generics (UK) Limited: PRC00640, MHRA response of 2 October 2020 to the CMA’s s.26 Notice of 18 September 2020,

¹⁰² 100mg Phenytoin Sodium NRIM Capsules were previously supplied by NRIM and manufactured by Marksans, see PHT00161, Amended note of OFT meeting with NRIM on 16 December 2013 (CMA document reference 00474.1).

¹⁰³ Sales of 100mg capsules have represented between 72% and 76% of all sales of phenytoin sodium capsules in the UK since 2004. Calculations are based on PCA data for England, Wales, Northern Ireland and Scotland, see PAD00021, PAD00057–PAD00060, PAD00063–PAD00065 and PAD00077–PAD00123.

¹⁰⁴ See, for example, PHT00081, Pfizer’s response of 29 May 2013 to the OFT’s s.26 Notice of 8 May 2013 (CMA document reference 00086.1), pages 11 to 12. In contrast, 100mg capsules are typically sold in other EU Member States (where Capsules are sold) in packs of 100 capsules. See, for example, PHT00124, *Phenytoin Market Status*: Annex 25c of Flynn’s response of 7 April 2014 to the OFT’s s.26 Notice of 5 March 2014 (CMA document reference 00505.40).

¹⁰⁵ Calculations are based on PCA data for England, Wales, Northern Ireland and Scotland, see PAD00021, PAD00063–PAD00065, PAD00083–PAD00086, PAD00098–PAD00101, PAD00113–PAD00116, PAD00121.

2.10.2. 'Epanutin 30mg/5ml Oral Suspension' (designed to be administered orally as a liquid).¹⁰⁶

II. The history of phenytoin sodium capsule supply in the UK

- 2.11 Phenytoin was first developed into an antiepileptic drug in 1938 by the US pharmaceutical company Parke-Davis. Parke-Davis sold phenytoin sodium capsules in the UK under the brand name *Epanutin*.¹⁰⁷
- 2.12 *Epanutin* has long been off-patent, meaning that the period of market exclusivity for the drug ended a long time ago, opening up the possibility of generic entry.
- 2.13 In 1970, Parke-Davis was acquired by Warner Lambert. In 2000, Warner Lambert was acquired by Pfizer and, as a result, Pfizer became the owner of *Epanutin*.¹⁰⁸ By the time Pfizer acquired *Epanutin*, it was no longer subject to patent protection.
- 2.14 From 2000 to September 2012, Pfizer manufactured and supplied 25mg, 50mg, 100mg and 300mg phenytoin sodium capsules in the UK without investing significantly in the development of the product. Pfizer sold Capsules under the brand name '*Epanutin*'.
- 2.15 On 23 March 2012, Flynn acquired Pfizer's UK MAs for phenytoin sodium capsules for the price of £1. Flynn received approval to de-brand the drug on 29 August 2012.
- 2.16 Following de-branding, Flynn began selling 25mg, 50mg, 100mg and 300mg 'Phenytoin Sodium Flynn Hard Capsules' on 24 September 2012. During the Relevant Period, Pfizer continued to manufacture Capsules which it supplied to Flynn on an exclusive basis in the UK.¹⁰⁹
- 2.17 In April 2013, NRIM began to supply its 100mg capsules under the name 'Phenytoin Sodium NRIM Capsules'.¹¹⁰ Since April 2013, therefore, phenytoin sodium capsules have been available in the UK as 25mg, 50mg, 100mg and 300mg Phenytoin Sodium Flynn Hard Capsules supplied by Flynn, 100mg Phenytoin Sodium NRIM Capsules supplied by NRIM, and as parallel imports manufactured by Pfizer and supplied by various third parties.

¹⁰⁶ PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.1).

¹⁰⁷ In certain countries, including the US, the brand was named Dilantin. See PHT00123, Blair, Bailey and McGregor, *Treatment of Epilepsy with Epanutin*, Lancet, Volume 234, Issue 6050, 12 August 1939 (CMA document reference PD4), page 363.

¹⁰⁸ PHT00125, *History of Epanutin and Warner Lambert* (CMA document reference PD26).

¹⁰⁹ See paragraphs 2.251 to 2.255 below.

¹¹⁰ *Phenytoin* [2018] CAT 11, paragraph 17.

III. Clinicians' choice of AED

- 2.18 Phenytoin sodium capsules are an AED. AEDs are used to treat epilepsy and are taken daily to prevent the recurrence of epileptic seizures.¹¹¹
- 2.19 The National Institute for Health and Care Excellence ('NICE') has estimated that two-thirds of people with active epilepsy have their epilepsy controlled satisfactorily with AEDs.¹¹²
- 2.20 The choice of which AED to prescribe is made by a specialist healthcare professional, such as a consultant neurologist. Repeat prescriptions are then managed by a patient's general practitioner ('GP').
- 2.21 When choosing which AED to use, clinicians will have regard to clinical guidelines and recommendations, the drug's licensed indications, the type of epilepsy, the balance of efficacy against side effects, the ease of use of the drug (ie how well it interacts with other drugs and how easy it is to regulate the dose), and experience with the drug.¹¹³ Clinicians will therefore consider the efficacy and tolerability of AEDs in the round when deciding which to use, with side effects and patient tolerability being a key factor.¹¹⁴ Cost is not a significant factor when clinicians select an initial AED for a patient or when switching a patient between AEDs.¹¹⁵
- 2.22 NICE guidance published in 2012 identifies three potential stages of AED prescribing in treating epilepsy:¹¹⁶
- 2.22.1. First-line AEDs, which are the first treatments recommended by NICE for the treatment of epilepsy.
 - 2.22.2. Second-line AEDs, which may be used in combination with a first-line AED as an adjunctive treatment if a patient's seizures are not completely controlled on any of the first-line AEDs.¹¹⁷

¹¹¹ PHT00157, Section 4.8.1 of the BNF Guidance (CMA document reference PD29).

¹¹² PAD00055, *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care*, NICE Clinical Guidance, CG137 (2012) (as last updated on 11 February 2020) ('NICE guidance') (this Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline, NG217, last updated on 27 April 2022), page 9. There are other possible forms of treatment for epilepsy, including surgery.

¹¹³ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 4.10.

¹¹⁴ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 7 and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 7. For a description of [Professor of Neurology] experience, see above at section 1.D.III.

¹¹⁵ PHT00160, Royal College of Physicians' response of 31 July 2013 to the OFT's request for information dated 4 July 2013 (CMA document reference 00325.1), page 3.

¹¹⁶ PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13) (this Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022). This guidance reflects a broad clinical consensus in the UK regarding the hierarchy of AED treatment options: PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraph 6.

¹¹⁷ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, page 6, paragraph 4.6.

- 2.22.3. Third-line AEDs, which may be considered if first-line and second-line AEDs are ineffective or not tolerated by a patient.¹¹⁸

IV. Phenytoin sodium capsules' use and characteristics

- 2.23 In 1993, when there were fewer AEDs available, phenytoin was the most prescribed AED in the UK.¹¹⁹ Since then, many new AEDs have become available and the use of phenytoin has declined in the UK.¹²⁰
- 2.24 In 2012, NICE guidance identified phenytoin sodium as a third-line AED (and only for certain epilepsy types), recognising this shift in clinical practice away from using phenytoin.¹²¹
- 2.25 Phenytoin sodium capsules were during the Relevant Period (and are) identified by NICE as a third-line AED because of the drug's clinical characteristics. This categorisation by NICE and the significant decline in its use reflect the fact that other AEDs have greater efficacy, fewer side effects, fewer drug interactions, and/or greater ease of clinical use.¹²²
- 2.26 Particular concerns over the treatment of epilepsy patients with phenytoin sodium capsules relate to the drug's NTI, non-linear pharmacokinetics, potential side effects and potential interactions with other drugs.
- 2.27 First, phenytoin sodium has particularly narrow therapeutic index¹²³ which means there is a relatively small difference between the blood level of the drug that is necessary to achieve therapeutic efficacy and the blood level that, if exceeded, might result in adverse side effects.¹²⁴
- 2.28 Second, phenytoin sodium's pharmacokinetics, ie how the drug moves through the body from its absorption to its eventual breakdown and excretion, are non-linear (ie

¹¹⁸ PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13), for example, paragraph 1.9.3.5. (This Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022).

¹¹⁹ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, page 7, paragraph 5.1.

¹²⁰ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 25 and *Phenytoin* [2018] CAT 11, paragraph 16.

¹²¹ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 25 and PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, page 8, paragraph 5.2.

¹²² PAD00017, National Clinical Guideline Centre, Pharmacological Update of Clinical Guideline 20, *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care, methods, evidence and recommendations* (as last updated in October 2019), for example, pages 212, 220, 317, 382 and 388; and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 19. Pfizer stated that phenytoin-based products have 'been superseded in many clinical situations by newer medicines which have a better safety and tolerability profile; a wider therapeutic index; no requirement for blood monitoring and fewer drug interactions': PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.1), question 1.

¹²³ PHT00094, MHRA's written response of 17 July 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00248.2), page 1.

¹²⁴ PHT00094, MHRA's written response of 17 July 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00248.2), page 1; and PHT00135, MHRA (2013), *Formulation switching of antiepileptic drugs: A Report on the Recommendations of the Commission on Human Medicines from July 2013* (CMA document reference PD18), pages 6 and 7.

the blood levels are not proportional to dose).¹²⁵ Phenytoin sodium is the only AED currently in use which has non-linear pharmacokinetics.¹²⁶ Phenytoin is also the only AED for which NICE indicates that monitoring of AED blood levels is required when adjusting the dose which is partly due to its non-linear pharmacokinetics.¹²⁷

- 2.29 Combined, the narrow therapeutic index and non-linear pharmacokinetics make it difficult for practitioners to regulate the appropriate dose for patients: small increases in dose can result in toxicity and small decreases in dose can result in the plasma concentration falling below a therapeutic level.¹²⁸ In turn, toxicity can lead to irreversible problems for patients and can cause patients to become ataxic and suffer issues with coordination and automatic movements (for example, patients may need to think consciously about how to walk).¹²⁹
- 2.30 Third, phenytoin sodium has problematic potential side effects.¹³⁰ Enzyme-inducing drugs such as phenytoin sodium are recognised as potentially causing side effects not associated with AEDs that are not enzyme inducers.¹³¹ Patients taking a strong enzyme inducer such as phenytoin sodium are likely to have a lower life expectancy.¹³² Phenytoin sodium is also the only enzyme-inducing AED with non-linear pharmacokinetics, which may result in additional side effects. Consequently, phenytoin sodium is the worst enzyme-inducing AED currently in use in terms of side effects.¹³³
- 2.31 Phenytoin sodium's chronic side effects can include osteoporosis and cerebrovascular disease.¹³⁴ Other potential side effects include low cancer survival rates, strokes, tremor and issues with cognition.¹³⁵ It is the only AED which can also cause distortion of facial features, gums and teeth.¹³⁶ Potential allergic side effects include a rash and Stevens-Johnson syndrome which, although rare, can be very serious.¹³⁷ Potential acute side effects include involuntary movement of the eyes and blurred vision.¹³⁸

¹²⁵ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraphs 5.4 and 6.5.

¹²⁶ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 9.

¹²⁷ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 19 and PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13) paragraph 1.9.17.9. (This Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022),

¹²⁸ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, page 8, paragraph 5.4 and pages 11 to 12, paragraph 6.5; PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 8; and *Phenytoin* [2018] CAT 11, paragraph 16.

¹²⁹ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 8.

¹³⁰ PAD00036, BNF, *Phenytoin*.

¹³¹ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraphs 10 and 18.

¹³² PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 11 and PAD00041, EMC, *Phenytoin Sodium Flynn Hard Capsules 100mg SmPC*.

¹³³ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 18.

¹³⁴ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 12.

¹³⁵ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 12 and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 16.

¹³⁶ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 12.

¹³⁷ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 13.

¹³⁸ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 15.

- 2.32 Fourth, phenytoin sodium can have problematic interactions with other drugs.¹³⁹ Phenytoin sodium is the most problematic AED currently in use in terms of drug interactions, which are not a significant concern with most new AEDs.¹⁴⁰
- 2.33 Phenytoin sodium is effective at controlling seizures¹⁴¹ and remains an essential drug for those legacy patients stabilised on it. However, the serious limitations of phenytoin sodium, including its side effects, mean that it is no longer a preferred treatment. Phenytoin sodium capsules are therefore prescribed only to a very few new patients, and only in very limited circumstances.¹⁴²
- 2.34 Phenytoin sodium solution (not capsules) administered intravenously was identified by NICE as a second-line treatment in hospital for patients experiencing convulsive status epilepticus, ie prolonged seizures, which is a medical emergency.¹⁴³ Most patients who receive treatment with phenytoin sodium solution in these circumstances will not go on to be treated with phenytoin sodium capsules.¹⁴⁴

V. Continuity of supply

- 2.35 Clinical guidance for healthcare professionals (including prescribers and pharmacists) recommended that patients who were stabilised on a particular manufacturer's phenytoin sodium product should generally be maintained on that product and not switched to another manufacturer's phenytoin sodium product (this Decision refers to this recommendation as Continuity of Supply). This section summarises the development of that guidance between 2004 and 2017.
- 2.36 NICE guidance published in October 2004 explained that changing the formulation or brand of AED a patient was using was not recommended because 'different preparations may vary in bioavailability or have different pharmacokinetic profiles and, thus, increased potential for reduced effect or excessive side effects'.¹⁴⁵
- 2.37 Updated NICE guidance on epilepsy published in January 2012:

¹³⁹ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, page 9, paragraph 5.9 and PHT00094, MHRA's written response of 17 July 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00248.2), page 1.

¹⁴⁰ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 11.

¹⁴¹ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 5 and PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 5.11.

¹⁴² See paragraphs 2.44 to 2.45.

¹⁴³ PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13), paragraph 1.14.2.3. (This Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022).

¹⁴⁴ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 13 and PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraphs 3 and 4.

¹⁴⁵ PAD00017, National Clinical Guideline Centre, Pharmacological Update of Clinical Guideline 20, *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care, methods, evidence and recommendations* (as last updated in October 2019), page 149.

- 2.37.1. recommended consistent supply of a particular manufacturer's AED unless the prescriber, in consultation with the patient and their family and/or carers as appropriate, considered that this was not a concern; and
 - 2.37.2. noted that different preparations of some AEDs may vary in bioavailability or pharmacokinetic profiles and care needed to be taken to avoid reduced efficacy or excessive side effects.¹⁴⁶
- 2.38 On 11 November 2013, the MHRA published guidance on AEDs (the '**MHRA Guidance**').¹⁴⁷ The MHRA Guidance adopted recommendations set out in a report by the Commission on Human Medicines ('**CHM**').¹⁴⁸ The MHRA Guidance:
- 2.38.1. identified phenytoin within category 1 of the guidance, which are AEDs where doctors were advised to ensure that the patient was maintained on a specific manufacturer's product. The guidance stated that if it was felt desirable for a patient to be maintained on a specific manufacturer's product, it should be prescribed by brand name or using the name of the manufacturer; and
 - 2.38.2. recommended that dispensing pharmacists should ensure continuity of supply of a particular product where the prescription specifies it. The guidance stated that if the prescribed product was unavailable, it may be necessary to dispense a product from a different manufacturer. It also noted that if a specific product was not stated, usual dispensing practice could be followed.¹⁴⁹
- 2.39 The CHM wrote to healthcare professionals on 11 November 2013 to draw their attention to the MHRA Guidance.¹⁵⁰
- 2.40 Phenytoin is within category 1 of the MHRA Guidance mainly due to its non-linear pharmacokinetics and NTI.¹⁵¹ Accordingly, the limitations of phenytoin sodium (in particular its non-linear pharmacokinetics and NTI) resulted in the regulatory guidance being issued recommending Continuity of Supply (which is a source of Pfizer and Flynn's substantial market power), rather than any qualities associated with the drug.

¹⁴⁶ PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13) (this Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022), paragraph 1.9.1.4.

¹⁴⁷ PHT00093, MHRA Guidance (2013) *Antiepileptics: Changing products* (CMA document reference PD19).

¹⁴⁸ PHT00135, MHRA (2013), *Formulation switching of antiepileptic drugs: A Report on the Recommendations of the Commission on Human Medicines from July 2013* (CMA document reference PD18) and *Phenytoin* [2018] CAT 11, paragraphs 27 and 28.

¹⁴⁹ PHT00093, MHRA Guidance (2013) *Antiepileptics: Changing products* (CMA document reference PD19).

¹⁵⁰ PHT00247, Letter dated 11 November 2013 from [X] Commission on Human Medicines re Antiepileptic drugs: new advice on switching between different manufacturers' products for a particular drug: Provided by [X] PCT on 13 November 2013 (CMA document reference 00444.1).

¹⁵¹ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, page 11, paragraph 6.3.

2.41 In 2017, the MHRA Guidance was updated. Phenytoin remained in category 1 of the guidance.¹⁵²

2.42 The CAT in *Phenytoin* described the clinical guidance on Continuity of Supply as 'just that – guidance' and '[i]t did not comprise any binding rule'.¹⁵³ The CAT found that the MHRA Guidance:

*was not absolute in its terms, but was qualified; in the case of doctors/prescribers by reference to patients that the prescriber assesses should be kept on a specific manufacturer's product, and for pharmacists by reference to non-availability of the prescribed product and usual dispensing practice.*¹⁵⁴

2.43 However, whilst the majority of prescriptions during the Relevant Period for phenytoin sodium capsules were open (ie did not specify a particular manufacturer or brand), the CAT in *Phenytoin* found that the guidance on Continuity of Supply had a significant impact, in practice, on pharmacists' dispensing practice, tending to favour the supplier of products on which patients were already stabilised. The CAT found that position was not unequivocal, however, as there was a limited degree of switching from Flynn's product to NRIM's product after the publication of the MHRA Guidance.¹⁵⁵

VI. Phenytoin sodium capsules mainly treated a historic patient population

2.44 The limitations of phenytoin sodium capsules as a treatment meant that, during the Relevant Period (and today), it would generally be a 'last resort' option for new epilepsy patients in the UK, used only when there are no alternative AEDs available.¹⁵⁶ Very few new patients are therefore prescribed phenytoin sodium capsules,¹⁵⁷ and such prescriptions would only be in certain limited circumstances as set out below.

¹⁵² PRC00579B, MHRA Guidance (2017) *Antiepileptic drugs: updated advice on switching between different manufacturers' products*.

¹⁵³ *Phenytoin* [2018] CAT 11, paragraph 131.

¹⁵⁴ *Phenytoin* [2018] CAT 11, paragraph 131.

¹⁵⁵ *Phenytoin* [2018] CAT 11, paragraphs 22 and 150.

¹⁵⁶ Tor reported [Pfizer Employee 1] of Pfizer's comments that 'Epanutin was a last resort medicine': Email chain of 17 September 2009 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re the Epanutin Proposal put forward by Tor: PHT00185, Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00141.28), page 1. If phenytoin sodium capsules were used for new patients, it is likely that non-AED treatment options available would also be limited as other treatments such as surgery or ketogenic diets are only suitable for a small subset of patients. Nerve stimulation as a palliative treatment for epilepsy might be considered if there was no other treatment option. See PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraphs 11 and 12 and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraphs 20 and 21.

¹⁵⁷ See PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 25; PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraphs 7 to 8; PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 4; PAD00030, [Pfizer Expert Witness 1] Cross Examination, day 5, page 54, lines 9 to 13; and *Phenytoin* [2018] CAT 11, paragraph 16. The CAT in *Phenytoin* also observed that 'relatively few patients newly diagnosed with epilepsy are now prescribed phenytoin sodium': *Phenytoin* [2018] CAT 11, paragraph 18.

- 2.45 Phenytoin sodium capsules may be prescribed to new patients in the following limited circumstances:
- 2.45.1. in combination with other AEDs where patients have not responded to first- or second-line AEDs, and typically where patients have also not responded to other third-line AEDs;¹⁵⁸ or
 - 2.45.2. after patients experiencing prolonged seizures (status epilepticus) have been given phenytoin sodium in an injectable solution formulation as an emergency treatment. In these circumstances, patients might then continue on phenytoin sodium capsules as an oral medication.¹⁵⁹ However, this use will be rare as, even after treatment for status epilepticus with phenytoin sodium solution, patients would usually either be put on first-line AEDs if required (for new epilepsy patients) or placed back onto their usual AED treatment (for patients already receiving an AED).¹⁶⁰
- 2.46 Most patients taking phenytoin sodium capsules during the Relevant Period and today are therefore patients taking it on a historic basis, rather than patients recently started on the drug.¹⁶¹ The majority of these historic patients would have been first prescribed phenytoin sodium at a time when it was a first- or second-line AED and when there were fewer AEDs available.¹⁶² If these patients were first treated during the Relevant Period or today, the vast majority would have been treated with a different AED.¹⁶³
- 2.47 The number of patients taking phenytoin sodium capsules is declining as its historic patient population ages. Total volumes of phenytoin sodium capsules dispensed show a constant year-on-year decline before, during and after the Relevant Period, which is consistent with an established and declining patient base.¹⁶⁴ In the UK, approximately 57,500 patients took phenytoin sodium capsules in 2012, whereas in 2019 this number had fallen to approximately 37,500.¹⁶⁵ This decline reflects the

¹⁵⁸ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 12 and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 21. See also PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 5.11.

¹⁵⁹ PAD00030, [Pfizer Expert Witness 1] Cross Examination, day 5, page 53, lines 7 to 15. See also PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 5.11.

¹⁶⁰ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 13 and PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraphs 3 and 4.

¹⁶¹ PAD00030, [Pfizer Expert Witness 1] Cross Examination, day 5, page 54, lines 4 to 13; PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 14; and *Phenytoin* [2018] CAT 11, paragraphs 16, 18 and 97.

¹⁶² PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 14.

¹⁶³ PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraph 5. [Professor of Neurology] noted that, if first treated today, these patients would be given a current first- or second-line treatment rather than Capsules. This applies equally to the Relevant Period, during which Capsules were only recommended as a third-line treatment.

¹⁶⁴ See Figure 2.3 below; PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 4; and PHT00158, NHS England's response of 23 July 2013 to the OFT's information request of 3 July 2013 (CMA document reference 00275.1), pages 2 and 4.

¹⁶⁵ Based on the PCA data, the total volume of phenytoin sodium capsules dispensed in 2012 and 2019 in defined daily dosage ('DDD') terms was 21,023,042 and 13,713,237 respectively. Dividing these figures by 365 days gives an estimate of 57,597 patients in 2012 and 37,571 patients in 2019. See PAD00082, PAD00083, PAD00098, PAD00113, PAD00121, PAD00088, PAD00089, PAD00104, PAD00119, and PAD00123.

fact that phenytoin sodium capsules are a third-line AED and, for the reasons set out above at paragraphs 2.26 to 2.33, are very rarely prescribed to new patients.

2.48 There remain, however, a significant number of historic patients taking phenytoin sodium capsules. This is due to the limited switching, in practice, of patients between different AEDs and limited withdrawal of treatment. Switching to other AEDs is limited due to:

- 2.48.1. many epilepsy patients not regularly seeing consultant neurologists¹⁶⁶ who are the clinical professionals which should take a decision regarding switching a patient's AED.¹⁶⁷ In particular, patients experiencing minor side effects may not be referred to consultants;¹⁶⁸
- 2.48.2. consultants' concerns regarding the risks of switching. Consultants have concerns in particular regarding loss of seizure control,¹⁶⁹ which can have severe consequences including death, injury, and negative impacts on work and home life;
- 2.48.3. the administrative effort of convincing patients to switch, and implementing this, which may also discourage some consultants from recommending a change to a patient's AED;¹⁷⁰ and
- 2.48.4. patients' concerns regarding switching, with many patients reluctant to make changes to their AED treatment due to their concerns regarding the risk of seizure recurrence or needing to stop driving for a period of time.¹⁷¹

VII. Phenytoin sodium tablets

2.49 As set out above, Tablets are a formulation of phenytoin sodium used to treat epilepsy. However, Tablets and Capsules are not generally interchangeable owing to concerns around Continuity of Supply.

2.50 Like phenytoin sodium capsules, Tablets are prescribed to patients with epilepsy in the UK for the purposes of controlling seizures.

¹⁶⁶ PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraph 16.

¹⁶⁷ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 24.

¹⁶⁸ PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraph 12.

¹⁶⁹ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, pages 15 to 16, paragraphs 6.17 to 6.20 and PHT00158, NHS England's response of 23 July 2013 to the OFT's information request of 3 July 2013 (CMA document reference 00275.1), page 3. The consequences of therapeutic failure (seizure recurrence) can be severe: see PHT00135, MHRA (2013), *Formulation switching of antiepileptic drugs: A Report on the Recommendations of the Commission on Human Medicines from July 2013* (CMA document reference PD18), page 4.

¹⁷⁰ PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraph 11.

¹⁷¹ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraphs 14 and 18 to 19; PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 23; PHT00160, Royal College of Physicians' response of 31 July 2013 to the OFT's request for information dated 4 July 2013 (CMA document reference 00325.1), page 4; and PRE00003, First Witness Statement of [X], 10 January 2017, paragraph 13.

- 2.51 During the Relevant Period, Tablets were available in the UK at a dosage strength of 100mg per tablet in packs of 28.¹⁷²
- 2.52 Tablets are prescribed to a substantially smaller set of patients in the UK than phenytoin sodium capsules. During the Relevant Period, the NHS dispensed approximately four times as many 100mg phenytoin sodium capsules (196 million) as 100mg phenytoin sodium tablets (47.5 million) in the UK.¹⁷³
- 2.53 Tablets and phenytoin sodium capsules have the same active ingredient. As a result:
- 2.53.1. Tablets have the same clinical characteristics as phenytoin sodium capsules, including their NTI, non-linear pharmacokinetics, potential side effects and potential interactions with other drugs.¹⁷⁴ Like phenytoin sodium capsules, Tablets are effective at controlling seizures;¹⁷⁵
 - 2.53.2. Tablets were also subject to the NICE guidance and the MHRA Guidance regarding Continuity of Supply,¹⁷⁶ which the CAT found had a significant impact, in practice, on pharmacists' dispensing practice in relation to phenytoin sodium capsules, tending to favour the supplier of products on which patients were already stabilised;¹⁷⁷
 - 2.53.3. Tablets were also categorised as a third-line AED by NICE¹⁷⁸ and would only rarely have been prescribed to new patients during the Relevant Period;¹⁷⁹ and
 - 2.53.4. Tablets were also mainly prescribed during the Relevant Period to a historic patient population which was declining over time.¹⁸⁰ In the UK, approximately 10,000 patients took Tablets in 2012, whereas in 2019 this number had fallen to approximately 6,000.¹⁸¹

¹⁷² PHT00222, Teva UK's response of 4 June 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00100.1) and *Phenytoin* [2018] CAT 11, paragraph 17.

¹⁷³ Calculations are based on PCA data for England, Wales, Northern Ireland and Scotland, see PAD00021, NHS Digital, *Prescription Cost Analysis, England, 2015*; PAD00063, Public Health Scotland, *Prescription Cost Analysis for financial year 2015/16*; PAD00064, NHS Wales Shared Services Partnership, *Prescription cost analysis: individual preparations, 2015*; and PAD00065, HSC Business Services Organisation (Northern Ireland), *Prescription Cost Analysis 2015*.

¹⁷⁴ See paragraphs 2.23–2.33 above.

¹⁷⁵ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 5 and PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 5.11.

¹⁷⁶ See paragraphs 2.35–2.43 above.

¹⁷⁷ *Phenytoin* [2018] CAT 11, paragraph 150.

¹⁷⁸ PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 25 and PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, page 8, paragraph 5.2.

¹⁷⁹ See paragraph 2.44 above.

¹⁸⁰ PAD00030, [Pfizer Expert Witness 1] Cross Examination, day 5, page 54, lines 9-13; PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 14; and *Phenytoin* [2018] CAT 11, paragraph 16.

¹⁸¹ Based on the PCA data, the total volume of phenytoin sodium tablets dispensed in 2012 and 2019 in DDD terms was 3,577,403 and 2,140,697 respectively. Dividing these figures by 365 days gives an estimate of 9,801 patients in 2012 and 5,865 patients in 2019. See PAD00082, PAD00083, PAD00098, PAD00113, PAD00121, PAD00088, PAD00089, PAD00104, PAD00119, and PAD00123.

2.54 Further background details relating to Tablets are provided in section 6.C.II.

B. The drug life cycle and the place of phenytoin sodium capsules in it

I. Drug Life Cycle

a. Introduction

2.55 As described above, phenytoin sodium is an old drug which has long been off-patent in the UK. Phenytoin sodium capsules are now in the third stage of the drug life cycle.

2.56 The drug life cycle is a central feature of the pharmaceutical sector and important context for understanding the pricing of drugs in the UK. In order to assess the legality of drug pricing under competition law, it is important to understand the broader context in which these prices were charged and in which any price increase was imposed. The position of Capsules within the drug life cycle is, therefore, one of a number of important factual elements relevant to the CMA's assessment of the Parties' pricing during the Relevant Period.

2.57 This section explains the role played by the drug life cycle in the UK and its relationship with drug pricing and the cost of drugs for the NHS.

2.58 Most drugs follow a common, relatively long, life cycle that has three distinct stages as seen in Figure 2.1:¹⁸²

2.58.1. First, the pre-launch period – where research and development ('R&D') as well as regulatory approval for new medicines take place. During this stage, competition between originators¹⁸³ is R&D-based with a race to be the first to successfully develop and register an invention.

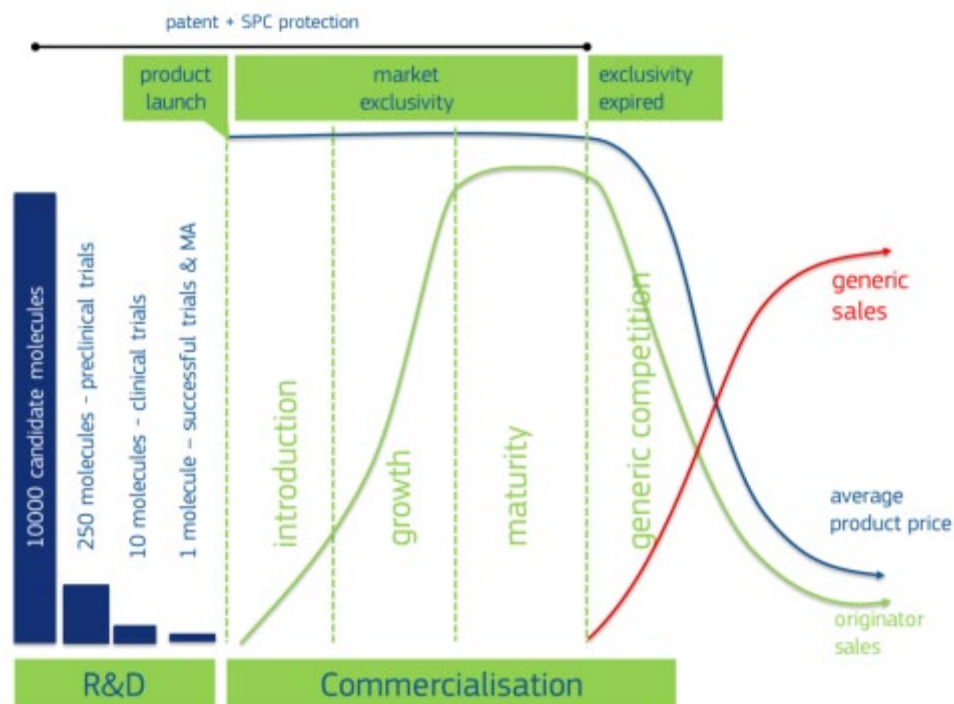
2.58.2. Second, the market exclusivity period – during which the product benefits from market exclusivity and the commercialisation cycle begins.

2.58.3. Third, the post-exclusivity period – the period when generic competition is possible. Competition at this stage is primarily focused on price because both the originator drug and competing generic drugs are effectively identical, making price the key differentiating factor.

¹⁸² PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 128.

¹⁸³ Originator companies are active in research, development, management of the regulatory process for new products including the clinical trials needed to obtain an MA, manufacturing, marketing and the supply of innovative medicines. PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, page 48.

Figure 2.1: Pharmaceutical product life cycle¹⁸⁴



2.59 Products sold by originator companies are largely patent protected during the first two stages of the drug life cycle. The third stage of the life cycle commences when, following patent expiry, other pharmaceutical companies can enter the market with generic drugs.¹⁸⁵ Generic drugs are typically sold at a substantially lower price than the originator drug was sold at during the second stage of the drug life cycle.¹⁸⁶ This is possible for two key reasons:¹⁸⁷

2.59.1. it is relatively cheap to bring a bioequivalent product to the market as R&D costs are lower;¹⁸⁸ and

2.59.2. the market for the drug and brand value already exists which reduces marketing expenses.

2.60 The Association of the British Pharmaceutical Industry ('ABPI') also recognises the same three stages of a medicine's life cycle. In particular, the ABPI notes that in

¹⁸⁴ PAD00003, European Commission, *Competition enforcement in the pharmaceutical sector (2009-2017)*, 28 January 2019, Figure 5.

¹⁸⁵ Generic drugs are bioequivalent replicas of originator drugs.

¹⁸⁶ Flynn claimed that generic medicines are not necessarily less costly than their equivalent originators and that prices may also rise above existing levels if certain features (eg limited demand, lack of supply) are present, PRC03492, Flynn's response to the SO, paragraph 3.2.1. Similarly, Pfizer submitted that, in broad terms, Pfizer agrees with the CMA that the price of generic drugs typically falls after patent expiry, but this does not describe the life cycle and behaviour of all generic drugs, PRC03901, Pfizer's response to the Letter of Facts, paragraph 22. The CMA acknowledges that the prices of generic medicines may rise in some circumstances. However, as explained in paragraphs 2.95 and 2.96 below, analysis shows that where a notable increase in generic prices did occur, the generic price was still, on average, one-fifth of the originator price before the loss-of-exclusivity date. Moreover, in a well-functioning market, any significant price rises should be reversed.

¹⁸⁷ PAD00002, The Milbank Quarterly, *Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending, 2017*.

¹⁸⁸ Most of the required testing for a drug is not necessary for a generic version because it can rely on the originator test results as to clinical safety and effectiveness and needs to only show bioequivalence to the originator drug.

the third and final stage of a medicine's life cycle, after patent expiry, 'when a medicine reaches that stage, it stays there forever. This is why a month's supply of cholesterol treatment today cost [sic] less than the price of a cup of coffee. [...] When the medicines life cycle works appropriately, for every medicine that comes onto the market and creates new costs for the NHS, older medicines are losing their patent exclusivity and becoming much, much cheaper.'^{189, 190}

- 2.61 Phenytoin sodium is a generic drug which is long off-patent and is now in the third stage of the drug life cycle. Further details on each of the three stages of the drug life cycle and the likely implications of these stages on drug pricing and pharmaceutical companies' behaviour¹⁹¹ are set out below.¹⁹²

b. Pre-launch period (Stage 1)

- 2.62 During the pre-launch period, innovation in the pharmaceutical market typically requires significant investment in R&D with no guarantee of commercial success. Some drugs will be developed successfully and so will be granted an MA (following the necessary testing) and sold on the market. The development of other drugs will be unsuccessful, despite originator companies sometimes having incurred heavy expenditure on research, development and testing.
- 2.63 Competition between originators to develop a new drug and win a patent award may occur during the pre-launch period. There are several stages in this period.¹⁹³ At the final stage, medicines must successfully complete the MA process in order to prove that they have a positive benefit-risk ratio as regards safety and efficacy, and are of good quality, before they can be placed on the market.¹⁹⁴
- 2.64 The precise costs to the originator company of bringing a new medicine to the market will vary between drugs. The European Commission's Pharmaceutical Sector Inquiry report in 2009 found that the cost of a new medicine from basic research to launch ranged between \$450 million and \$1 billion.¹⁹⁵ Irrespective of

¹⁸⁹ PAD00131, [Medicine life cycle video and transcript \(abpi.org.uk\)](#).

¹⁹⁰ Flynn submitted that (i) given the mission of the ABPI, the purpose of this video is likely the defence of the prices of branded medicines, rather than a considered appraisal of the generic life cycle; (ii) that a study by Oxera for the British Generics Manufacturers Association does not refer to a three stage life cycle where prices stay low forever; and (iii) from a commercial perspective it cannot be right that prices have to stay low where there are declining volumes such that a product becomes unprofitable, PRC03903, Flynn's response to the Letter of Facts, paragraphs 3.2 to 3.4. The CMA acknowledges that the prices of generic medicines may rise in some circumstances. However, as explained in paragraphs 2.95 and 2.96 below, analysis shows that where a notable increase in generic prices did occur, the generic price was still, on average, one-fifth of the originator price before the loss of exclusivity date. Moreover, in a well-functioning market, any significant price rises should be reversed.

¹⁹¹ Including investment levels, marketing and pricing of both the originator company and generic entrants.

¹⁹² Flynn claimed that the CMA fails to mention an element of the fourth stage of the product life cycle – discontinuation, PRC03492, Flynn's response to the SO, paragraph 3.2.5. However, neither the European Commission Pharmaceutical Sector Inquiry Report nor the ABPI video described above refers to a fourth stage in the drug life cycle.

¹⁹³ These stages include identification of molecular targets that are associated with the disease, testing to find the molecules which have the greatest potential to be developed into a safe and effective medicine and assessment of the safety and efficacy of the drug.

¹⁹⁴ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraphs 134-138. In the UK the MHRA is responsible for considering and approving MAs.

¹⁹⁵ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 149.

the exact cost, it is widely accepted that producing new pharmaceuticals requires a significant amount of investment with no guarantee of success.

- 2.65 To recoup the significant costs involved in bringing the product to market, an originator company will typically obtain a patent during or following extensive R&D. Patents effectively grant the originator freedom from direct competition on the same molecule for a certain period of time. The patent does not automatically equate to a monopoly because there may be some degree of competition between the molecule invented and other drugs. However, it is likely to result in limited price competition in the second stage of the life cycle.
- 2.66 A primary (or compound) patent is one that is used for new molecules which have a therapeutic use. The molecule will have never been disclosed previously, and so the primary patent will be the first ever patent to cover a particular active pharmaceutical ingredient ('API').¹⁹⁶ A primary patent in the EU usually lasts for 20 years from the patent application.¹⁹⁷ However, given that the patent is usually applied for at this initial stage, the 20-year period generally starts a long time before an MA for the drug is obtained and the drug enters the market. In addition, a manufacturing patent can be acquired that protects the manufacturing process used in creating the drug.
- 2.67 Supplementary Protection Certificates ('SPC') provide additional patent-related protection by extending the period of patent protection by up to 5 years. These are used to compensate for the period of exclusivity lost by the originator due to the time required to obtain the MA.
- 2.68 An originator can also obtain additional patents (often called secondary patents) that build on primary patents by applying the API in a new way.¹⁹⁸ Secondary patents can be related to different dosage forms or for particular pharmaceutical formulations and are obtained later during the development phase, and sometimes even after product launch.¹⁹⁹ Secondary patents which extend the patent protection for a specific molecule can protect the profits of an originator for a longer period of time.

¹⁹⁶ PAD00034, European Commission, *Pharmaceutical Sector Inquiry - Annexes*, Annexes to Chapter B – Part III, paragraphs 133 and 134.

¹⁹⁷ The time between filing an application for the first compound patent to the launch of the product varies significantly. It can take between two and ten years for a potential medicine to go through the three clinical trial phases, with an average duration of five years. PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 142.

¹⁹⁸ PAD00034, European Commission, *Pharmaceutical Sector Inquiry - Annexes*, Annexes to Chapter B – Part III, paragraph 134.

¹⁹⁹ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 138. Patent law does not make a distinction between 'primary' and 'secondary' patents and patents need to be evaluated on the basis of the statutory patentability criteria, not on the basis of the stage in which applications are made. The notion of the 'secondary patent' should therefore not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – they follow the primary patent.

- 2.69 The originator also has eight years of ‘data exclusivity’, during which a generic entrant cannot refer to the information of the original MA holder,²⁰⁰ and ten years of ‘market exclusivity’, which is the ten-year period from the date of the MA where generic medicines typically cannot enter the market and compete with the originator medicine.²⁰¹
- 2.70 Once the patent or SPC period has expired, generic suppliers can, in principle, produce and sell medicines containing the molecule in question. The original patent application covering the molecule must indicate how the invention can be reproduced. This allows society to freely reproduce the invention after patent expiry and acts as a return for guaranteeing the inventor an initial period of exclusive use.²⁰²
- 2.71 The granting of patent protection is essential to ensure that originator companies are willing to invest the significant amounts of money and time required to develop new drugs. Without the patent, and the consequent ability to charge prices above competitive levels for a period of time, there would be little incentive to heavily invest in R&D. This is particularly true because once a new drug has been developed it is relatively easy (and less costly) for rival companies to copy it.²⁰³

c. The market exclusivity period (Stage 2)

- 2.72 During the second stage of the drug life cycle the originator has exclusivity as it begins to commercialise its drug. This is also the first time that potential generic entrants will have the ability to begin to assess the success of a drug to help determine whether to enter the market. The following section therefore explains what a typical originator and potential generic entrants would consider during stage 2.

i. The originator

- 2.73 As discussed above, the originator acquires patents during the pre-launch period and is likely to bring its product to market under a patent which entitles it to a certain number of years of exclusivity. This restricts direct competition for a particular molecule in the second stage of the drug life cycle.
- 2.74 At the beginning of the market exclusivity period, the originator is likely to spend heavily on marketing to establish demand and develop brand value for its drug given that there may be other drugs, with a different molecule, that can be used to

²⁰⁰ The data of the original MA holder relating to (pre-) clinical testing is protected, PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, page 6.

²⁰¹ Competition between generic and originator companies may begin before patent expiry if the generic company finds a way of entering the market without infringing the patent protecting the originator product, or if the patent relied upon by the originator company is not valid. PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 April 2009, paragraph 464.

²⁰² *Paroxetine decision*, case CE-9531/11, 12 February 2016, paragraph 3.68.

²⁰³ PAD00003, European Commission, *Competition enforcement in the pharmaceutical sector (2009-2017)*, 28 January 2019, page 20.

treat the same disease. At this stage, the focus is predominantly on non-price attributes as GPs and consultants (who are responsible for deciding which drugs to prescribe to their patients) are typically not sensitive to price in making these decisions.²⁰⁴ A supplier of a drug will aim to persuade prescribers to use its drug based on its clinical characteristics and the overall package of benefits versus risks for patients.

- 2.75 As seen in Figure 2.1, during the introduction stage of commercialisation, patent protection means that the originator will be a monopoly supplier of a particular API. This allows the originator to charge a higher price than would prevail if there was competition. An originator would typically expect to initially achieve a low number of sales unless the drug is well-anticipated. As the product gains traction, volumes tend to increase whilst the price remains high because of limited, if any, competition due to patent protection.
- 2.76 Authorities in many jurisdictions seek to control profits made or prices during this phase of the life cycle. In the UK, during the Relevant Period, the PPRS served this purpose. The PPRS was a voluntary agreement between the DHSC and the ABPI with the aim of ensuring that branded medicines are available on reasonable terms to the NHS.²⁰⁵

ii. Generic entrants

- 2.77 The process of developing a generic drug can begin several years prior to patent expiry, starting with an ongoing horizon-scanning exercise to monitor which products will come off-patent up to ten years in the future.²⁰⁶ This means that whilst the originator is in the commercialisation phase and benefitting from market exclusivity, potential generic entrants will be assessing the success of the drug and determining whether, and when, they want to enter the market.
- 2.78 Various factors determine the likelihood and scale of generic entry, including:²⁰⁷
- 2.78.1. the difficulty/complexity of developing the drug;²⁰⁸
 - 2.78.2. the availability and the cost of the API;

²⁰⁴ PHT00160, Royal College of Physicians' response of 31 July 2013 to the OFT's request for information dated 4 July 2013 (CMA document reference 00325.1), page 3. A study by the OFT in 2007 found that doctors' ability to rank branded drugs in order of price was generally no better than chance. PHT00130, *The Pharmaceutical Price Regulation Scheme, an OFT market study* (CMA document reference PD7), box 2.3, page 23 and Annex C. These findings are based on a survey 1,000 English GPs conducted as part of research by the National Audit Office into value for money in primary care.

²⁰⁵ PHT00079, Department of Health, *The Pharmaceutical Price Regulation Scheme 2014* (CMA document reference PD20), paragraph 1.4.2.

²⁰⁶ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 3.8.

²⁰⁷ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraphs 1.11 and 2.15.

²⁰⁸ For example, the nature of the product: apart from a few companies, which specialise in the manufacture of oral liquids, generic companies concentrate on oral solid dosage forms, in particular tablets and generally avoid other presentations, see *Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc*, Case CE/8931/08, 12 April 2011, paragraph 2.89.

- 2.78.3. potential market size/total sales;
- 2.78.4. commercial expectations/profitability;
- 2.78.5. the size of the potential upfront costs of R&D; and
- 2.78.6. clinical advice/industry guidance.

2.79 Upon deciding to develop a generic version of a drug, generic entrants will begin to develop an identical medicine to the economically successful originator product. Whilst generic medicines are subject to the same requirements of quality, safety and efficacy, and this can involve a certain amount of work depending on the factors set out above, generic suppliers do not need to provide detailed information from pre-clinical tests and clinical trials as they can rely on the clinical data from the originator drug.²⁰⁹

d. Post-exclusivity period (Stage 3)

- 2.80 The final stage of the drug life cycle occurs when generic entry can begin. Usually, generic entry into the market is phased.²¹⁰ During this stage, competition initially takes place between the originator and the first generic entrant(s), and subsequently between these companies and any further generic entrants. This process and, in particular, the development of competition between suppliers of generic medicines, is expected to lead to generic drug prices which are significantly below the historic originator price. Competition between generic suppliers is then typically expected to ensure that generic prices remain low.
- 2.81 Initially, there may be competition between generic entrants to be the first to enter.²¹¹ It is expected that the first generic entrant will obtain the highest profits as it only needs to price slightly below the incumbent, assuming that the incumbent does not compete on price straight away. Price competition would typically be expected to be limited between the originator and the first generic entrant, due to incentives for the originator and first entrant to not compete too strongly on price and maintain higher margins.
- 2.82 Other generic entrants might enter the market at a later stage, and it is typically with subsequent entry, and the initiation of price competition between multiple generic entrants, that price competition becomes fiercer.
- 2.83 Generic companies have different cost structures to originators given that they typically do not have to research as heavily (although the cost of research will

²⁰⁹ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 91.

²¹⁰ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, Figure 17.

²¹¹ Some generic companies will have begun to develop the drug prior to the expiration of patents with the aim of being able to launch the product as soon as the patent on the originator's product expires: see Figure 2.1.

depend on the complexity of the product) and therefore incur lower R&D costs.²¹² Generic companies also do not have to incur the high levels of marketing expenditure incurred by the originator in order to build brand value and the market for the drug. This enables them to enter the market with lower prices than the originator and initiate competition.²¹³

2.84 Following the entry of generic competition, the originator typically has three strategies it can employ to continue making profits:²¹⁴

2.84.1. Option one: choose to compete on price to protect its sales. The originator is likely to maintain larger sales volumes when generics enter if it lowers its price and competes with the generic manufacturers.

2.84.2. Option two: choose not to compete on price and instead maintain a higher price for its branded product. The originator would continue to receive a higher price for any patients who are on closed prescriptions (which specify a particular branded product) whilst accepting that it is likely to lose patients on open prescriptions (which list the generic, non-proprietary, name of the medicine) to generic competitors charging a lower price.²¹⁵

2.84.3. Option three: choose not to compete on price and instead maintain a higher price for its branded product and introduce a generic version of the drug at a lower price. This would allow the originator to receive a higher price for any patients who are on a closed prescription but also allow it to protect some of its sales via the lower priced generic version.

2.85 The strategy adopted by the originator may vary over time depending on the pace and strength of generic entry. Irrespective of the strategy that the originator adopts, generic entry and subsequent competition would typically be expected to reduce the average prices due to encouragement of the use of open prescriptions in the UK.²¹⁶

2.86 If several suppliers enter the market, generic products usually become 'commoditised', meaning that suppliers of generic medicines are not able to use brand value or product quality to differentiate themselves.²¹⁷ This is the case even

²¹² PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 3.5; and PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 103.

²¹³ It is also possible that a manufacturer successfully develops a generic drug but looks to sell it to local distributors. The local distributors compete with the originator but do not have the initial R&D expenses that the manufacturer does.

²¹⁴ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 4.6, notes that different originators respond differently to competition.

²¹⁵ Originators can also enter into brand equalisation deals where they provide a discounted, blended price on the condition that the customer purchases all its requirements, generic and branded, from the same supplier. The originator could decide to introduce a 'branded' generic if they wished to differentiate their generic product offering on the value and recognition of the company. An originator may also be able to maintain some sales whilst charging a higher price as there may be some retained value in the brand with some patients preferring the branded product.

²¹⁶ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 1.2.

²¹⁷ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 3.21.

for life-saving medicines. The primary²¹⁸ focus of competition for suppliers of generic medicines is then the price offered to wholesalers and pharmacies. This competition causes the average drug price to gradually fall towards the cost level.

- 2.87 In 2016, the Secretary of State for Health and Social Care (the ‘**Secretary of State**’) stated in Parliament:²¹⁹

We rely on competition in the market to keep the prices of these drugs down. That generally works well and has, in combination with high levels of generic prescribing, led to significant savings.

- 2.88 Research in the sector indicates that competition from generic drugs typically results in significant price falls:

2.88.1. 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. Two years after entry, prices of generic medicines were on average 40% below the former originator price.²²⁰

2.88.2. A UK trade association found that generic drugs cost between 20% and 90% less than the original price of their brand-name equivalents.²²¹

2.88.3. A study by Oxera for the British Generics Manufacturers Association (‘**BGMA**’) found that, four years after generic entry, prices charged by generic suppliers of a sample of products within scheme M were on average 70% to 90% lower than the branded price at the time of entry.²²²

- 2.89 Several studies have found that the degree of price competition following patent expiry is notably affected by the number of generic entrants. In particular:

2.89.1. The Food and Drug Administration found that for drugs with a single generic producer, the generic average manufacturer price (‘**AMP**’) was 39% lower than the brand AMP before generic competition. With two competitors this increases to 54%, with four competitors this further increases to 79%, and with six or more competitors, generic prices show price reductions of more than 95% compared to brand prices.²²³

²¹⁸ Other parameters of competition can include breadth of portfolio, service levels and reputation.

²¹⁹ PAD00013, Hansard, 24 October 2016, *Health Service Medical Supplies (Costs) Bill*, Volume 616.

²²⁰ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 1560.

²²¹ PAD00026, British Generic Manufacturers Association, *About Generics*.

²²² PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 4.16.

²²³ PAD00033, FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* ([fda.gov](https://www.fda.gov)), December 2019.

- 2.89.2. The European Commission's Pharmaceutical Sector Inquiry found that increasing the number of generic producers tends to positively affect price competition.²²⁴
- 2.90 The European Commission's Pharmaceutical Sector Inquiry found that within two years of loss of exclusivity there were on average over seven generic producers of the same product in the UK.²²⁵ Oxera's analysis shows that the average number of suppliers for category M drugs three years after generic entry becomes possible is between four and five.²²⁶
- 2.91 All EU Member States encourage the penetration of generic medicines in an attempt to keep healthcare expenditure under control.²²⁷ In the UK, GPs are encouraged to write open prescriptions using the drug's generic name (where one exists), whether or not the product in question is out of patent, unless there are specific clinical reasons not to.²²⁸ For example, the British National Formulary ('BNF') states that '[w]here non-proprietary [generic] titles are given they should be used in prescribing'.²²⁹ An open prescription ensures that when a branded medicine's patent expires, generic equivalents that typically enter the market at a lower price can be dispensed. Open prescriptions are also used to address safety concerns.²³⁰
- 2.92 The reimbursement framework in the UK is designed to incentivise strong competition since the same reimbursement price will be paid to the pharmacy irrespective of the cost that they incurred to procure the medicine. Pharmacies therefore have an incentive to purchase the cheapest medicine in order to maximise their margins.²³¹
- 2.93 The prices of generic drugs are generally unregulated in the UK on the assumption that competition between suppliers in the third stage of the drug life cycle will keep prices low. If the price of a given drug was significantly above the competitive price during the third stage, it would typically be expected that the high price would act as a signal to incentivise new entrants to the market.²³² The market price should then correct as the introduction of more competitors supplying a homogenous generic medicine will inevitably lead to more intense price competition.

²²⁴ PAD00034, European Commission, *Pharmaceutical Sector Inquiry - Annexes*, 8 July 2009, page 575.

²²⁵ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, Figure 19.

²²⁶ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, Figure 4.1.

²²⁷ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 171.

²²⁸ PHT00130, OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007 (CMA document reference PD7), paragraph 2.34.

²²⁹ PAD00018, NICE, 'Non-proprietary titles' section of the chapter 'Guidance on Prescribing' in the *British National Formulary No. 58 (September 2008)*, page 4.

²³⁰ Using a single generic name when discussing and prescribing drugs could also reduce confusion or mistakes that may arise if there are several brand names for one medicine.

²³¹ Subject to the clawback which regulates a pharmacy's overall profit.

²³² PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 5.22 on entry barriers and long-term dynamics.

- 2.94 Following generic entry, overall sales volumes generally remain relatively unchanged. The originator's sales gradually fall whilst generic sales rise as patients are switched to the cheaper version of the drug.²³³ However, it is possible for overall volumes to rise if patients are able to switch from an expensive alternative drug still under patent protection to a cheaper generic which treats the same condition. It is also possible for overall volumes to fall if a drug has been superseded by superior medicines.
- 2.95 Significant generic competition can, in some circumstances, lead to prices being driven down below cost, making the drug unprofitable. In such a scenario it is likely that some suppliers would exit the market and, as the number of suppliers falls, generic prices are likely to increase as a more stable position is reached.²³⁴ Analysis shows that where a notable increase in generic prices did occur, the generic price was still, on average, one-fifth of the originator price before the loss-of-exclusivity date.²³⁵
- 2.96 Whilst it is possible that generic prices may rise even many years after generic entry,²³⁶ where generic competition works effectively any significant price rises should be reversed. In particular, one would expect that significant price changes are reversed when previous market conditions are reinstated, or that prices stabilise at a new equilibrium level reflecting changed market conditions.²³⁷
- 2.97 Research indicates that significant price falls for generic drugs typically correlate with volumes switching away from the originator's branded product to the generic version. The Commission found that in the UK generic companies' sales, on average, increased to around 40% of volumes in the first year after generic entry and neared 50% two years after first generic entry.²³⁸
- 2.98 The average switch in volumes of 40-50% from the originator's branded product to the generic version is likely to reflect a mixture of the strategies set out in paragraph 2.84. The switch away in volumes is likely to be higher where an originator chooses not to compete on price and instead maintains a higher price for its branded product. Whilst the originator would continue to receive a higher price for any patients who are on closed prescriptions, or who display brand loyalty, it is likely to experience a fall in volumes as a switch to the generic versions occurs.²³⁹ This is also shown in Figure 2.1, where the originator volumes fall whilst the generic volumes rise once generic competition can take place.

²³³ The extent to which an originator will lose sales is likely to depend on the extent to which it meets price competition.

²³⁴ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 4.23.

²³⁵ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 4.23.

²³⁶ PRC03488, Pfizer's response to the SO and DPS, paragraph 35.

²³⁷ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 4.32.

²³⁸ PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, page 88, Figure 29.

²³⁹ See, for example, section 6.C.III below.

II. Niche generics

- 2.99 Whilst the majority of drugs follow each stage of the drug life cycle as explained above, there are some drugs that do not experience the generic competition that typically occurs during the third stage. In particular, there is a subset of generic drugs that are typically older, off-patent and have limited competition, if any, from originators or generics manufacturers due to specific features of the market. For these drugs, commonly referred to as ‘niche’ generics, the assumption that competition between suppliers will keep prices low in the third stage of the drug life cycle breaks down.²⁴⁰ The freedom of pricing that arises due to a lack of regulation of generic drug pricing in the UK can then be exploited by suppliers to increase prices.
- 2.100 Markets for niche generics often have features that have the potential to shield a generic drug from effective competition. Market features that might act as barriers to entry and/or expansion resulting in limited competition include:
- 2.100.1. difficulties in producing the drug (which drive up the costs incurred by the generic manufacturers);²⁴¹
 - 2.100.2. a relatively small (and potentially declining) target patient population which may provide little financial incentive for potential competitors to enter the market and offer competing drugs;^{242, 243} and
 - 2.100.3. clinical guidance that advises against switching patients to other manufacturers’ products.
- 2.101 In particular, clinical guidance that advises against switching patients to other manufacturers’ products may both disincentivise entry and constitute a significant barrier to competition if entry does occur.

²⁴⁰ Flynn stated that it disagrees with this on the basis that the Oxera report makes clear that the assumption that prices will stay low does not exist, PRC03492, Flynn’s response to the SO, paragraph 3.2.7. The CMA disagrees: as set out in paragraph 2.96, the Oxera report recognises that generic prices may rise even many years after generic entry but if generic competition works effectively any significant price rises should be reversed. Additionally, the ABPI video referred to in paragraph 2.60 states ‘for every medicine that comes onto the market and creates new costs for the NHS, older medicines are losing their patent exclusivity and becoming much, much cheaper’.

²⁴¹ PAD00051, in [Former Teva Director]’s presentation it stated: ‘many of these products are old, with out-dated manufacturing processes, and were generally divested because they were difficult to make’; PAD00052, *Why many generic drugs are becoming so expensive*, Harvard Health Blog, Harvard Health Publishing, 22 October 2015.

²⁴² Government regulation/clinical guidance such as the line of treatment of a drug is likely to impact the overall target patient population over time. See PAD00051, section [B], [Former Teva Director] presentation; PAD00052, *Why many generic drugs are becoming so expensive*, Harvard Health Blog, Harvard Health Publishing, 22 October 2015.

²⁴³ Flynn claimed that niche generics are typically taken by elderly patients that are stabilised on these older medicines. As the patient population declines, there will inevitably be a higher cost in maintaining supply of this type of medicine and the less attractive new entry becomes as suppliers migrate their efforts to supplying higher volume medicines. The fact the UK health system values these medicines enough to continue prescribing them and dispensing them to these patients suggests that suppliers of niche generics play an important part of the health system, but this will result in increases in the prices of these medicines, PRC03492, Flynn’s response to the SO, paragraph 3.2.6. The CMA considers that whilst it may be the case that the prices of niche generics may be expected to rise in some circumstances, this case is concerned with whether the prices of Capsules were unfairly high, not with whether the price increased at all.

2.102 Some drug manufacturers seeking to maximise profits have sought to exploit the market malfunctions that arise in markets for niche generics. Identifying markets for a particular drug which other manufacturers will be less likely to enter, for instance due to the barriers to entry described in paragraph 2.100 above, allows a firm to enter a market where they have both the capacity to produce enough of a drug to meet market demand and the power to dictate the drug's price.²⁴⁴ This can also apply to drug manufacturers that are already in the market selling a branded version of a drug but that then decide to de-brand their product and sell it as a generic instead, allowing them to remove the product from price regulation and take advantage of the lack of generic competition to increase prices.

2.103 In 2016, the Secretary of State discussed the issue of niche generics in Parliament and stated:

... [w]e are aware of some instances where there is no competition to keep prices down, and companies have raised their prices to what looks like an unreasonable and unjustifiable level ... there are companies that appear to have made it their business model to purchase off-patent medicines for which there are no competitor products. They then exploit a monopoly position to raise prices.

...

*a handful of companies appear to be exploiting our freedom of pricing for unbranded generic medicines where there is no competition in the market, leaving the NHS with no choice but to purchase the medicine at grossly inflated prices.*²⁴⁵

2.104 The DHSC introduced legislation partly in order to address the problem identified by the Secretary of State. On 7 August 2017, the Health Service Medical Suppliers (Costs) Act 2017 entered into force.²⁴⁶ These statutory reforms are described further below at paragraphs 2.191 to 2.192.

2.105 This category of generic drugs – niche generics – is widely recognised in the pharmaceutical industry. Certain drug suppliers (and their investors) have identified the opportunities that niche generics provide to generate revenue that would not normally be expected of a drug in the third stage of its life cycle.

2.106 By way of example, at the Jefferies Healthcare Conference in November 2012, [Former Teva Director] ([X]) and [X] ([X]) delivered a presentation on behalf of Mercury Pharma.²⁴⁷ [Former Teva Director] subsequently described the

²⁴⁴ PAD00005, OECD, *Excessive Prices in Pharmaceutical Markets*, 3 October 2018, paragraph 109.

²⁴⁵ PAD00013, Hansard, 24 October 2016, *Health Service Medical Supplies (Costs) Bill*, Volume 616.

²⁴⁶ By virtue of the Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017.

²⁴⁷ PAD00051, [Former Teva Director], Jefferies Healthcare Conference Presentation.

presentation as a pitch to big pharmaceutical companies who might want to acquire the business in the future.²⁴⁸

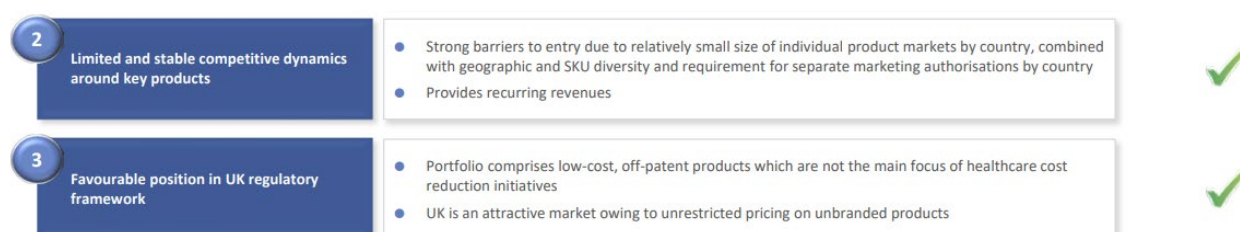
2.107 The presentation described Cinven's acquisition of Mercury Pharma as follows:

Cinven acquired Mercury Pharma in August of 2012 with the ambition of creating a significant pan-European specialty pharmaceutical company focused on niche products, with an asset-light business model.

2.108 Mercury Pharma was described in the presentation as a 'speciality pharmaceutical company focused on sale of niche prescription off-patent products with limited competition from originators or generics manufacturers'.

2.109 Figure 2.2 shows two of the 'Key Strategic Elements' that were highlighted in the presentation:

Figure 2.2: 'Key Strategic Elements'



2.110 [Former Teva Director] provided evidence to the CAT following the Parties' appeal of the CMA's 2016 Infringement Decision. As part of [Former Teva Director]'s oral evidence he also discussed the content of the presentation.

2.111 When it was put to him, [Former Teva Director] agreed that there is an attractive commercial opportunity in the UK for pharmaceutical companies that can find these drugs that are both off patent and subject to limited competition.²⁴⁹ He described how his 'normal description' of the system in the UK 'is one of free pricing, where prices freely fall but sometimes can be increased.'²⁵⁰

2.112 Figure 2.2 refers to the 'limited and stable competitive dynamics' around niche products. The presentation cited features such as complex manufacturing processes, higher regulatory hurdles for new entrants and the relatively limited sales potential for new entrants as examples limiting competitive dynamics.

2.113 When the point was put to him, [Former Teva Director] agreed in the CAT that strong barriers to entry help to ensure limited competition, and that limited

²⁴⁸ PAD00030, [Former Teva Director] Cross Examination, day 5, page 46, lines 1-3.

²⁴⁹ PAD00030, [Former Teva Director] Cross Examination, day 5, page 36, lines 8-13.

²⁵⁰ PAD00030, [Former Teva Director] Cross Examination, day 5, page 36, lines 16-18.

competition is attractive to investors because it means pricing is not constrained by competition and therefore revenues are sustainable.²⁵¹

- 2.114 As part of evidence submitted to the CAT, both Pfizer's and Flynn's expert witnesses addressed this category of generic drugs in respect of which there are significant barriers to competition.²⁵² [Flynn Expert Witness 2] referred to this category of drugs as 'specialist generics'. [Flynn Expert Witness 2] identified that these drugs may attract high margins in the third stage of the drug life cycle due to, for example, manufacturing difficulties, limited API availability, small and declining markets or 'unusual' clinical guidance inhibiting switching to cheaper drugs.²⁵³ [Flynn Expert Witness 3] used the term 'niche' generics and explained that, owing to market features shielding these drugs from competition, a niche generic supplier is likely to be able to sustain a higher than average gross margin until the arrival of additional competitors who consider that the market value in the UK makes it worth developing a bioequivalent product.²⁵⁴
- 2.115 Price competition ordinarily intensifies once multiple generic suppliers enter the market. Given the nature of a niche generic market, particularly where clinical guidance against switching manufacturers is present, it is unlikely that many generic suppliers would consider developing a bioequivalent product and entering the market. This allows higher margins to be sustained over a longer period of time by the incumbent.
- 2.116 In addition to barriers to entry and/or expansion, the regulatory framework in the UK also helps to make niche generic markets an attractive commercial opportunity. In particular, the freedom of pricing that arises due to a lack of regulation of generic drug pricing in the UK can be exploited by suppliers to increase prices as what typically happens during the drug life cycle breaks down. Figure 2.2 refers to the 'favourable position in the UK regulatory framework'. Regarding this, the presentation noted UK pharmaceutical reimbursement as being 'less at risk from austerity policies' than other areas of government expenditure and noted that '[p]harmaceutical 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'.
- 2.117 When it was put to him in cross examination, [Former Teva Director] agreed that because niche product markets are smaller there is little regulatory focus on them, which makes the commercial revenue stream attractive.²⁵⁵ [Former Teva

²⁵¹ PAD00030, [Former Teva Director] Cross Examination, day 5, page 32, lines 1-5.

²⁵² See, for example, PRE00150, Expert Report of [Flynn Expert Witness 3], 4 February 2017, paragraph 14(c); PRE00626, First Expert Report of [Flynn Expert Witness 2], 2 December 2015, paragraph 32(a) and (b), with which [Pfizer Expert Witness 2] agreed; and PAD00030, *Phenytoin* transcript, day 5, page 208, line 4 to page 210, line 6.

²⁵³ PRE00626, First Expert Report of [Flynn Expert Witness 2], 2 December 2015, paragraph 32(b).

²⁵⁴ PRE00150, Expert Report of [Flynn Expert Witness 3], 4 February 2017, page 5, paragraph 14(c).

²⁵⁵ PAD00030, [Former Teva Director] Cross Examination, day 5, page 35, lines 22-25 and page 36, lines 1-3.

Director]'s view was that the NHS' overall spend on a particular drug would have to be 'pretty eye watering' to attract regulatory attention.²⁵⁶

- 2.118 Overall, then, the ability to generate a higher-than-average gross margin for niche generics is not due to the importance of these drugs or their essential features, but rather the underlying market features that limit the likelihood and strength of further generic entry.

III. Phenytoin as a niche generic

a. Introduction

- 2.119 As explained above, some drugs do not follow the typical drug life cycle. Rather, for a limited number of drugs described as niche generics, patent expiry does not result in effective generic competition. Niche generics tend to face limited or no competition from originators or generic manufacturers due to specific features of the market.

- 2.120 The following market features make phenytoin sodium capsules a niche generic (and these factors are described further below):

- 2.120.1. a relatively small target patient population;
- 2.120.2. a declining market due to a lack of new patients being prescribed the drug;
- 2.120.3. the relative difficulty in producing phenytoin sodium capsules, which drives up the costs incurred by generic manufacturers; and
- 2.120.4. clinical guidance against switching patients to other manufacturers' phenytoin sodium capsules.

- 2.121 Flynn aims to 'acquire or develop underpromoted brands, niche products and generic products where barriers may exist to their development or manufacture'.²⁵⁷ Flynn submitted expert evidence before the CAT confirming that phenytoin sodium capsules are a niche generic. The expert evidence explained that, in order to avoid intense price competition arising from multiple suppliers in a commodity market, generic companies seek to obtain a competitive advantage by, amongst other things, launching 'niche' generics such as phenytoin.²⁵⁸ Further expert evidence explained that 'without doubt Phenytoin is in this specialist generic category'.²⁵⁹

²⁵⁶ PAD00030, [Former Teva Director] Cross Examination, day 5, page 37, lines 14-16.

²⁵⁷ PAD00126, Flynn Pharma (Holdings) Limited, Annual Report and Financial Statements, for the year ended 31 March 2020, page 1.

²⁵⁸ PRE00150, Expert Report of [Flynn Expert Witness 3], 4 February 2017, paragraph 5.

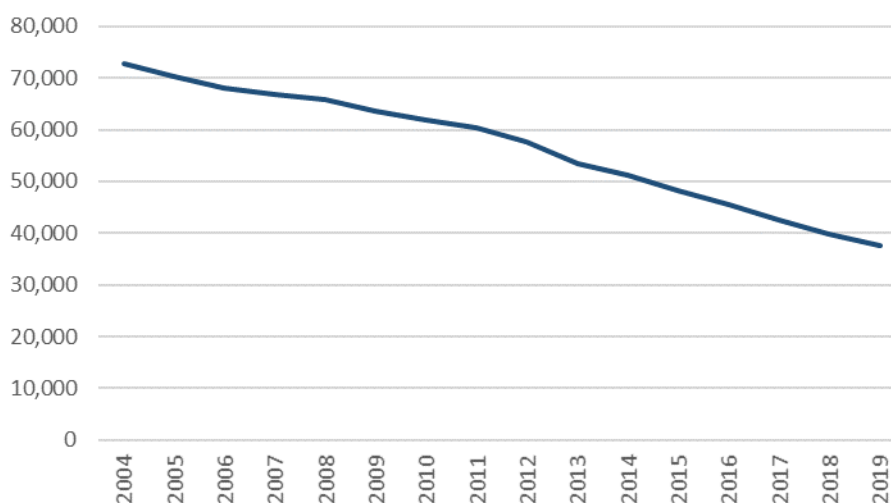
²⁵⁹ PRE00626, First Expert Report of [Flynn Expert Witness 2], 2 December 2015, paragraph 32(a).

b. Small (and declining) target patient population

2.122 Flynn recognised in submissions before the CAT that both of the first two points in paragraph 2.120 above (a small target patient population and a declining market) would apply to phenytoin sodium capsules.²⁶⁰ Phenytoin is an old drug that was first developed into an AED in 1938.²⁶¹ Since then, various AEDs have been developed that are used to treat epilepsy.²⁶² These AEDs are typically considered to be better in safety, efficacy and tolerance than phenytoin and do not have the same NTI and non-linear pharmacokinetics issues that phenytoin has.²⁶³ As such, phenytoin is now generally a last resort treatment and is rarely prescribed to new patients.²⁶⁴ This means that the vast majority of patients on phenytoin are legacy patients and the number of patients is declining year-on-year as these patients age. This can be seen in Figure 2.3.

2.123 As explained at paragraph 2.100, a small patient population and a declining market are likely to restrict the number of new entrants into the market as it will be harder for suppliers to find it economically viable to enter the market. During the Relevant Period, the estimated number of patients taking phenytoin sodium capsules fell from 57,500 (2012) to 45,000 (2016), with NRIM being the only new supplier to begin manufacturing phenytoin sodium capsules for distribution in the UK.²⁶⁵

Figure 2.3: Estimated number of patients on phenytoin sodium capsules²⁶⁶



²⁶⁰ PAD00040, *Phenytoin* transcript, day 11, page 100, lines 3 to 12, also referring to the evidence of [Flynn Expert Witness 2] before the CAT (see paragraph 2.114 above).

²⁶¹ See paragraph 2.11 above.

²⁶² See paragraph 2.23 above.

²⁶³ See paragraphs 2.23 to 2.33 above.

²⁶⁴ See paragraphs 2.44 to 2.45 above.

²⁶⁵ The CAT in *Phenytoin* found that competitive interaction between Flynn and NRIM was limited and that NRIM did not form part of the relevant markets in this case, which were the (i) manufacture of Pfizer-Manufactured Phenytoin Sodium Capsules that are distributed in the UK and (ii) distribution of Pfizer-Manufactured Phenytoin Sodium Capsules in the UK: *Phenytoin* [2018] CAT 11, paragraphs 196 to 198.

²⁶⁶ Based on the PCA data, the total volume of phenytoin sodium capsules dispensed in each year in DDD terms has been calculated. Dividing these figures by 365 days gives the estimated number of patients shown. See PAD00021, PAD00057–PAD00060, PAD00063–PAD00065 and PAD00077–PAD00123.

c. Difficulty in producing the drug

- 2.124 The more difficult or costly it is to produce a drug, all other things being equal, the less likely it is that potential competitors will take the risk in investing to bring the product to market. Given the specific features of phenytoin sodium described above (in particular its NTI), it is a difficult drug to produce. This is likely to be a key consideration for potential entrants. It took NRIM six years and cost approximately £1 million²⁶⁷ to develop the 100mg capsule and NRIM informed the CMA that this was double the length of time it would usually expect the development process to take.
- 2.125 Phenytoin sodium's NTI means that stricter testing is required in order to gain an MA. NRIM informed the CMA that bioequivalence is the most critical criterion for approval. In particular, the results for a product typically need to be within a band of 80 to 120. However, in the case of an NTI product like phenytoin, the range of acceptable results is narrower as per the regulatory guidelines necessary for the safety and efficacy of the drug, with results required to be within a band of 90 to 110 when compared to the original product.
- 2.126 NRIM also noted that the UK took a cautious approach and the MHRA accord importance to these stricter guidelines while, by comparison, some other European countries are less particular about this issue. Furthermore, for phenytoin sodium capsules, the API needed to be very close in specification to the Pfizer-manufactured phenytoin sodium capsule and there were very few companies that were able to provide the right quality and right specification of API.²⁶⁸

d. Clinical guidance

- 2.127 As set out at paragraphs 2.36 to 2.41 above, clinical guidance published by NICE in October 2004 and January 2012, and the MHRA in November 2013 and November 2017 recommended that patients who are stabilised on a particular manufacturer's phenytoin sodium capsule should be maintained on that manufacturer's capsule and should not be switched to another manufacturer's product. The MHRA placed AEDs within one of three categories. Phenytoin was placed into category 1, identified as posing the greatest potential harm when switching patients to another manufacturer's version of the exact same drug.
- 2.128 During the Relevant Period, new entrants marketing phenytoin sodium capsules would, therefore, be competing for:

²⁶⁷ 2016 Infringement Decision, paragraph 4.266.

²⁶⁸ PHT00161, Note of meeting with NRIM held on 16 December 2013 (CMA document reference 00474.1), paragraph 23.

- 2.128.1. patients not yet stabilised on a particular manufacturer's capsule (eg patients being treated with phenytoin sodium for the first time) and where the prescription was open; and
- 2.128.2. patients already stabilised on phenytoin sodium capsules but for which the pharmacy was willing to overlook the guidance described above recommending Continuity of Supply and where the prescription was open.
- 2.129 As described above, given the significant limitations of phenytoin sodium and its relegation to a third-line treatment, during the Relevant Period it would only very rarely be prescribed to new patients.²⁶⁹
- 2.130 Furthermore, clinical guidance on Continuity of Supply had a significant impact on the dispensing practices of pharmacies during the Relevant Period for patients already stabilised on a particular manufacturer's phenytoin sodium capsule. New entrants would therefore be restricted to competing for less than the entirety of the small target patient market that existed, further reducing the financial incentives of entering.
- 2.131 Flynn also used the guidance on Continuity of Supply to try to protect its own sales of phenytoin sodium capsules. In early 2014, Flynn wrote to Boots and Lloyds referring them to the guidance on Continuity of Supply and warning them of the risks in switching patients away from Flynn's Products to other manufacturers' phenytoin sodium capsules.²⁷⁰ Flynn also referred Boots to comments made by [Professor of Neurology] regarding the risks of switching:

[y]ou might also wish to take soundings of the patient advocacy groups to explore their levels of concern. As recently as Feb 3rd Prof [Professor of Neurology] ([redacted]) has articulated further continued concern and expressed the view that "it is essential for anyone with epilepsy to maintain a consistent supply of the same version of their AEDs".²⁷¹

- 2.132 On this point, the CAT's view was that the evidence showed that Flynn made considerable efforts in late 2013 and early 2014 'to persuade Boots and Lloyds to observe Continuity of Supply to continue to buy its product'²⁷² and that, notwithstanding the technicalities of Flynn's position as expressed to Boots and

²⁶⁹ See paragraphs 2.4 and 2.23 to 2.33.

²⁷⁰ PHT00108, Correspondence dated 8 October 2013 to 10 March 2014 with Boots/Alliance regarding phenytoin switching: Annex 16a of Flynn's response of 7 April 2014 to the CMA's s.26 Notice of 5 March 2014 (CMA document reference 00505.20), pages 16 to 18 and PHT00170, Correspondence dated 8 October 2013 to 10 March 2014 with Celesio regarding phenytoin switching: Annex 15 of Flynn's response of 7 April 2014 to the CMA's s.26 Notice of 5 March 2014 (CMA document reference 00505.19), pages 27 to 29.

²⁷¹ PHT00108, Correspondence dated 8 October 2013 to 10 March 2014 with Boots/Alliance regarding phenytoin switching: Annex 16a of Flynn's response of 7 April 2014 to the CMA's s.26 Notice of 5 March 2014 (CMA document reference 00505.20), page 17.

²⁷² *Phenytoin* [2018] CAT 11, paragraph 127.

Lloyds, 'the basic point remains that Flynn was relying on Continuity of Supply to try to protect its own sales'.²⁷³

- 2.133 As explained in paragraphs 2.42 to 2.43, the CAT found that the MHRA Guidance was not absolute in its terms; however it did find that the guidance on Continuity of Supply had a significant impact, in practice, on pharmacists' dispensing practice, tending to favour the supplier of products on which patients were already stabilised. The reluctance by the majority of pharmacists to switch patients demonstrates that the already small patient population would be notably smaller for any new entrant into the market for the supply of phenytoin sodium capsules.
- 2.134 Continuity of Supply also led to potential entrants abandoning their plans to bring a phenytoin sodium capsule product to market. While NRIM developed and began supplying a 100mg capsule product during the Relevant Period (in April 2013), NRIM also told the CMA that it abandoned its development of 25mg, 50mg and 300mg capsule strengths in view of stricter guidelines issued by the MHRA at the end of 2013.²⁷⁴
- 2.135 In combination, the impact of the guidance around Continuity of Supply, together with the small and declining patient base, meant that both during the Relevant Period and today there is little incentive for potential entrants to take the risk of investing in developing a new phenytoin sodium capsule product and bringing it to market.

C. Regulatory framework

I. Provision of drugs within the NHS

a. Introduction

- 2.136 This section sets out an overview of the structure of the NHS, and of NHS systems for the prescribing and funding of drugs in primary care, which includes phenytoin sodium capsules.
- 2.137 The NHS does not exist as a single corporate entity. There are numerous bodies involved in the operation of the NHS. These include: the Secretary of State and the DHSC which create national policies and legislation for health services; NHS national bodies;²⁷⁵ and CCGs.²⁷⁶ CCGs replaced Primary Care Trusts ('PCTs') in

²⁷³ *Phenytoin* [2018] CAT 11, paragraph 128.

²⁷⁴ PHT00161, Note of meeting with NRIM held on 16 December 2013 (CMA document reference 00474.1), paragraph 14.

²⁷⁵ NHS England, NHS Scotland, NHS Wales, and Health and Social Care in Northern Ireland. These bodies lead the NHS in their respective jurisdictions.

²⁷⁶ Other bodies include: special health authorities such as the NHS Business Services Authority, which amongst others is responsible for the reimbursement of pharmacists and the publication of the Drug Tariff; NICE, which provides guidance on best clinical practice; NHS hospital trusts, which are responsible for providing hospital services and healthcare in their local areas; and executive agencies, including the MHRA, which regulates medicines and medical devices for use in the UK, ensuring applicable safety, quality and efficacy standards are met.

April 2013 and are responsible for the planning and commissioning of healthcare services in their local areas.²⁷⁷

b. NHS prescribing

2.138 AEDs, such as phenytoin sodium capsules, are used to treat epilepsy. The choice of which AED to prescribe is made by a specialist healthcare professional, such as a consultant neurologist. Repeat prescriptions are then managed by a patient's GP.

2.139 A prescriber prescribing an AED can write either:

2.139.1. a 'generic' or 'open' prescription which specifies the active ingredient, formulation and strength of a medicine; or

2.139.2. a 'closed' prescription which specifies the particular brand, manufacturer or supplier of a medicine and the relevant strength.

2.140 Prescribers are generally encouraged to write open prescriptions, unless there are clinical reasons not to.²⁷⁸ The majority of phenytoin sodium capsule prescriptions were generic or open during the Relevant Period.²⁷⁹

2.141 Prescriptions are dispensed by retail pharmacists. Pharmacists buy their stock from specialist pharmaceutical wholesalers and/or direct from manufacturers. Within the parameters of the prescription (ie whether it is open or closed), the dispenser would typically be expected to choose the cheapest version of the drug. However, in the case of phenytoin sodium capsules, guidance on Continuity of Supply had a significant impact on pharmacists' dispensing practice, with pharmacists tending to favour the existing supplier of products on which patients were already stabilised.²⁸⁰

2.142 The recipient of the prescription is the patient, who generally does not choose or pay for the medicine.²⁸¹

c. NHS funding

2.143 As set out above, the clinical decision to prescribe a drug to a patient is taken by a healthcare professional. Neither the patient, the prescriber nor the pharmacist

²⁷⁷ The equivalent to CCGs in the devolved nations are: in Scotland, regional boards which devolve responsibility for health service budgets to health and social care partnerships; in Wales, local health boards; and in Northern Ireland, the health and social care board which works with six health and social care trusts.

²⁷⁸ PAD00039, The King's Fund, *Better value in the NHS*, July 2015, pages 22 to 23.

²⁷⁹ PAD00082, PAD00083, PAD00098, PAD00113 and PAD00121, 2012 PCA data. PCA data records the number of prescription items dispensed where the prescription was written generically but only a proprietary product was available. This allows an assessment of the number of open prescriptions pre-September 2012 when only *Epanutin* capsules were available. See also *Phenytoin* [2018] CAT 11, paragraph 22.

²⁸⁰ *Phenytoin* [2018] CAT 11, paragraph 150.

²⁸¹ Patients are typically required to make a payment towards the cost of medicines they are prescribed on an NHS prescription. However, epilepsy is listed as a specified medical condition and so patients with a valid medical exemption certificate are not required to make any contribution towards the cost of their NHS prescriptions: PAD00045, NHS Business Services Authority, *Medical exemption certificates*, page 2. See also *Phenytoin* [2018] CAT 11, paragraph 32.

ultimately funds the drug. Funding is provided to the pharmacist by the patient's local CCG, which neither chooses nor dispenses the drug.

- 2.144 CCGs do not negotiate the prices of phenytoin sodium capsules with suppliers or purchase the medicine directly from them. In practice, once the prescribing decision is taken by the prescriber, the NHS – in the form of the patient's local CCG – has no option but to fund the product from the CCG's budget.²⁸² The reimbursement price that CCGs pay pharmacists for dispensing: (i) branded drugs is based on the manufacturer's list price; and (ii) unbranded generic drugs is based on the Drug Tariff price.
- 2.145 The NHS is principally funded by UK taxpayers.²⁸³ Within the NHS's overall budget, there are budgets allocated for certain activities, such as prescribing pharmaceutical products, from which the cost of dispensing phenytoin sodium capsules is met.
- 2.146 Prescribing is the second highest area of spending in the NHS, with only staffing costs being higher.²⁸⁴ Between 2010/11 and 2015/16, NHS expenditure on medicines increased by over 20%.²⁸⁵ By 2015/16, the NHS in England spent £15.2 billion on medicines annually, of which nearly £4 billion was spent on unbranded generic medicines.²⁸⁶
- 2.147 Each year, NHS England sets each CCG a budget in accordance with a national allocation formula. Each CCG is under a statutory duty to ensure that its expenditure does not exceed its resource allocation and sums received.²⁸⁷ If a CCG is in deficit at the end of the financial year, any deficit must then be offset against its budget allocation for the following financial year.²⁸⁸
- 2.148 In practice, a large proportion of CCGs' budgets are already allocated in advance of funds being received. CCGs must, for example, pay for essential services provided by healthcare providers, such as hospitals, and pay staff and overhead costs.²⁸⁹ Once these costs are paid, CCGs can decide how to spend the rest of their budget.²⁹⁰
- 2.149 CCGs are in turn responsible for setting prescribing budgets against each GP practice within their organisation.²⁹¹ Whilst CCGs can give guidance to GPs, GPs retain full control over the prescriptions they make.²⁹² CCGs have to pay for the

²⁸² PRE00001, First Witness Statement of [REDACTED], 10 January 2017, paragraphs 21-22.

²⁸³ PAD00044, The King's Fund, *How the NHS is funded*, 26 September 2019.

²⁸⁴ PAD00069, NHS Digital, *Prescribing and medicines team*, 9 November 2020.

²⁸⁵ PAD00047, DHSC, *Health service medical supplies (costs) bill factsheet*, 8 November 2016, page 2.

²⁸⁶ PAD00047, DHSC, *Health service medical supplies (costs) bill factsheet*, 8 November 2016, page 2.

²⁸⁷ Section 223H of the National Health Service Act 2006.

²⁸⁸ PRE00001, First Witness Statement of [REDACTED], 10 January 2017, paragraph 17.

²⁸⁹ PRE00001, First Witness Statement of [REDACTED], 10 January 2017, paragraph 13.

²⁹⁰ PRE00001, First Witness Statement of [REDACTED], 10 January 2017, paragraph 14.

²⁹¹ PAD00048, NHS Business Services Authority, *Prescribing budgets*.

²⁹² PRE00001, First Witness Statement of [REDACTED], 10 January 2017, paragraph 22.

medicines that are prescribed and dispensed. CCGs therefore have no direct control over the prescribing process and the impact of prescriptions on their budgets.²⁹³

2.150 Increases in the price of any drug invariably result in a consequent decrease in the funds available to CCGs to spend on other healthcare services. Notwithstanding the significant scale of the NHS budget, legitimate demands for healthcare exceed its funding levels and resources have to be prioritised.²⁹⁴

2.151 In recent years, the NHS has also been required to make significant efficiency savings. In the period 2010 to 2015, NHS efficiency policy tasked the NHS with making £20 billion of efficiency savings in order to make more funds available to treat patients.²⁹⁵ The need for efficiency savings continued throughout the Relevant Period, with an NHS funding gap of £30 billion needing to be covered in the period 2015/16 to 2020/21.²⁹⁶

II. Regulatory framework for drug pricing

a. Introduction

2.152 This section discusses the regulatory framework for the pricing of branded and generic drugs in the UK. The prices of branded drugs (including branded generic drugs) are subject to a form of regulation, whereas the prices of unbranded generic drugs are generally unregulated. Capsules were a branded generic drug until Flynn ‘de-branded’ the products in September 2012. This allowed Flynn to increase the price of the products well beyond the limit of profit controls which applied to the drug when it was still branded.

b. The DHSC’s approach to branded drug pricing

2.153 During the Relevant Period, branded drugs were subject to regulation either through a voluntary scheme, the PPRS,²⁹⁷ or through a statutory scheme if a company chose not to become a PPRS scheme member.²⁹⁸

2.154 The PPRS was a non-contractual voluntary scheme, a form of which applied to manufacturers and suppliers of branded medicines to the NHS throughout the Relevant Period.²⁹⁹ The PPRS’s aims included ensuring that branded medicines

²⁹³ PRE00001, First Witness Statement of [X], 10 January 2017, paragraph 23.

²⁹⁴ PRE00001, First Witness Statement of [X], 10 January 2017, paragraph 26.

²⁹⁵ PAD00024, DHSC, *2010 to 2015 government policy: NHS efficiency*, 8 May 2015, page 3.

²⁹⁶ NHS funding between 2015/16 and 2020/21 implied a £22 billion efficiency requirement: PAD00025, NHS England, *NHS Five Year Forward View: Recap briefing for the Health Select Committee on technical modelling and scenarios*, page 4.

²⁹⁷ During the Relevant Period, a version of the PPRS applied at all times (the 2009 PPRS and subsequently the 2014 PPRS).

²⁹⁸ Regarding the statutory scheme, see paragraphs 2.178–2.182 below.

²⁹⁹ Section 261(2) of the NHS Act; PHT00078, *The Pharmaceutical Price Regulation Scheme 2009* (December 2008) (CMA document reference PD9); and PHT00079, Department of Health, *The Pharmaceutical Price Regulation Scheme 2014* (December 2013) (CMA document reference PD20).

were available to the NHS at reasonable prices.³⁰⁰ The PPRS did this by regulating ‘the profit that companies can achieve on sales to the NHS, rather than regulating prices directly’.³⁰¹ The PPRS was replaced in 2019 by a new voluntary scheme for branded medicines.³⁰²

- 2.155 While a PPRS scheme member had freedom to set the price of new active substances,³⁰³ once the price was set, the PPRS prevented the scheme member from increasing the price except in certain limited circumstances.³⁰⁴
- 2.156 A company could choose not to become a member of the PPRS or could be excluded by the Secretary of State.
- 2.157 Prior to September 2012, Pfizer sold Capsules under the brand name *Epanutin*, and this product fell under the PPRS. After being de-branded in September 2012, Capsules no longer fell under the PPRS, although Pfizer and Flynn were members of the PPRS.³⁰⁵ Teva, a manufacturer of Tablets, was also a member of the PPRS.

c. The DHSC’s approach to generic drug pricing

- 2.158 Phenytoin sodium capsules and Tablets are both unbranded generic drugs in the third stage of the drug life cycle. As set out above, Capsules were ‘de-branded’ by Flynn in September 2012.
- 2.159 In the UK, suppliers of unbranded generic drugs benefit from freedom of pricing.³⁰⁶ This is based on the assumption that competition will bring down prices once generic competitors are free to enter the market and compete on price.³⁰⁷ By the time a drug reaches the end of the period of patent protection, the expectation is that the cost of the innovation that led to its creation has been recouped and that, following generic entry, the price should fall.³⁰⁸ The DHSC did not, therefore, generally regulate the prices of unbranded generic drugs during the Relevant

³⁰⁰ PHT00079, Department of Health, *The Pharmaceutical Price Regulation Scheme 2014* (CMA document reference PD20), paragraph 1.4.2.

³⁰¹ PAD00007, ABPI, *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, page 1, paragraph 3 and *Phenytoin* [2018] CAT 11, paragraphs 37 and 38.

³⁰² PAD00053, DHSC, *The 2019 Voluntary Scheme for Branded Medicines Pricing and Access*.

³⁰³ PHT00079, Department of Health, *The Pharmaceutical Price Regulation Scheme 2014* (December 2013) (CMA document reference PD20), paragraph 7.14, which states ‘[n]ew medicines launched in the UK market following the granting of an EU or UK new active substance MA from the appropriate licensing authority may be priced at the discretion of the scheme member on entering the market. It is assumed that prices at launch will be set at a level that is close to their expected value as assessed by NICE.’

³⁰⁴ For example, a PPRS scheme member could (i) apply to the DHSC for approval to increase a price or (ii) modulate its prices by up to 20%, which would need to be offset by reductions in the price of other medicines so that the total overall NHS spend would be in line with PPRS commitments. See PHT00078, *The Pharmaceutical Price Regulation Scheme 2009 (December 2008)* (CMA document reference PD9), paragraphs 7.22, 7.23, and 7.46 to 7.48; PHT00079, Department of Health, *The Pharmaceutical Price Regulation Scheme 2014 (December 2013)* (CMA document reference PD20), paragraphs 7.1, 7.2, 7.34 and 7.36; and *Phenytoin* [2018] CAT 11, paragraph 39.

³⁰⁵ *Phenytoin* [2018] CAT 11, paragraph 37.

³⁰⁶ As noted by [Former Teva Director], [§]: PAD00030, [Former Teva Director] Cross Examination, day 5, page 36, lines 19 to 25.

³⁰⁷ PHT00082, Note of the CMA’s meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), page 4, paragraph 13.

³⁰⁸ See further paragraphs 2.80 to 2.93 above and PAD00001, European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 163.

Period. Its policy was instead to rely on competition to control generic drug selling prices.³⁰⁹

d. The Drug Tariff

- 2.160 The Drug Tariff is the primary mechanism for determining how dispensers are reimbursed for generic drugs. It is produced monthly by NHS Prescription Services³¹⁰ and governs the price that is reimbursed to pharmacies for fulfilling NHS prescriptions, subject to any price concessions agreed between the DHSC and the Pharmaceutical Services Negotiating Committee (**'PSNC'**).
- 2.161 The Drug Tariff provides that a dispenser is reimbursed for medicines dispensed at a 'basic price' less any clawback discount.³¹¹ The standardised Drug Tariff price incentivises dispensers to purchase the cheapest generic in order to maximise margins and therefore stimulate price competition.
- 2.162 Medicines listed under Part VIIIA of the Drug Tariff fall into three different categories which determine how the Drug Tariff price is calculated:³¹²
- 2.162.1. Category A: drugs which are readily available. Prices are based on the list price (ie the supplier's price before customer-specific discounts) of commonly used generics that are typically readily available from several sources. Category A Drug Tariff prices are set using a weighted average of list prices from a basket of two wholesalers and up to three generic manufacturers.³¹³ For a product to be considered for entry to category A, it must be listed either (i) by both wholesalers or (ii) by one wholesaler and by two manufacturers.³¹⁴
 - 2.162.2. Category C: drugs which are not readily available as a generic. This typically applies when a product is only available as a branded product or

³⁰⁹ PHT00082, Note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), page 4, paragraph 13.

³¹⁰ PAD00028, NHS Business Services Authority, *Drug Tariff*. 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. The English Category M Drug Tariff price was also applied in Scotland in Part 7 of the Scottish Drug Tariff: see PHT00083, *Cost of relevant comparators* in the Detailed Advice Document from the Scottish Medicines Consortium (CMA document reference PD34).

³¹¹ Pharmacies can buy some medicines cheaper than the Drug Tariff price. As such, the NHS applies a discount to pharmacies' payments. This discount is often referred to as 'clawback' and was designed to share with the NHS the profits pharmacies can make by purchasing medicines at below the price at which they are reimbursed. The clawback discount occurs when calculating the payment due to pharmacies by applying a deduction factor to the total reimbursement for medicines dispensed. The deduction factor varies according to the volume of items dispensed monthly by the particular pharmacy. See PHT00084, National Audit Office Report, *The Community Pharmacy Contractual Framework and the retained medicine margin* (CMA document reference PD41), page 18, paragraph 1.20. See also *Phenytoin* [2018] CAT 11, paragraph 33.

³¹² PHT00085, DHSC, *Drug Tariff Guidance Notes*, pages 2-3 (CMA document reference PD31) and *Phenytoin* [2018] CAT 11, paragraph 34.

³¹³ The particular suppliers have changed over time, see PRC00350, the DHSC's response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020, page 1.

³¹⁴ PRC00350, the DHSC's response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020, page 1.

from one or two sources. Category C Drug Tariff prices are based on the list price for a particular proprietary product, manufacturer or supplier.

2.162.3. Category M: typically applies to commonly used generics that are available from several sources. During the Relevant Period, category M Drug Tariff prices were set using a volume-weighted ASP based on retrospective data supplied to the DHSC by manufacturers in scheme M.³¹⁵ These averages were then adjusted by a formula to ensure that pharmacies retain the profit margin agreed as part of the funding of the community pharmacy contractual framework.³¹⁶ A drug could be considered for inclusion in category M where: (i) it was available from more than one scheme M manufacturer and (ii) the NHS Business Services Authority reported:

(a) its net ingredient cost (ie the cost of a drug used in primary care)³¹⁷ as at least £1 million and its annual dispensed volume as at least 50,000 items; or

(b) its annual dispensed volume as at least 200,000 items.³¹⁸

2.163 Whether a product moves into a category of the Drug Tariff, if it meets the criteria to do so, is determined by discussion between the DHSC and the PSNC. The DHSC told the CMA that that discussion is ‘fundamental’ and ‘just because a product fulfils the guidance criteria, it does not necessarily mean that the change will occur. The criteria are guidance only’.³¹⁹ At any point in time there will be products in a Drug Tariff category which do not fulfil the criteria.³²⁰

2.164 Following the product being de-branded in September 2012, Capsules were in category C of the Drug Tariff.³²¹ The Drug Tariff price for phenytoin sodium capsules was therefore determined by reference to Flynn’s list price.³²²

³¹⁵ Scheme M applies to manufacturers and suppliers of generic medicines for use in the NHS within the meanings set out in Section 266(6) of the NHS Act, but not distributors; that is, it applies to those who manufacture or supply generic medicines at the manufacturer level of the NHS medicines supply chain, including those engaged in supplying generic medicines to wholesalers, community pharmacies and dispensing doctors for use within the NHS, but not those who act solely as wholesalers. See also PAD00008, DHSC, *Revised long-term arrangements for reimbursement of generic medicines, Scheme M*, March 2010 (**‘Scheme M, 2010’**), paragraph 29.

³¹⁶ PHT00087, *Margin Survey Administration* (CMA document reference PD22).

³¹⁷ This is the cost at list price excluding VAT: see PAD00019, NHS Digital, *Practice level prescribing – glossary of terms*, page 5.

³¹⁸ PRC00350, the DHSC’s response of 30 July 2020 to the CMA’s s.26 Notice of 7 July 2020, pages 1-2.

³¹⁹ PRC00350, the DHSC’s response of 30 July 2020 to the CMA’s s.26 Notice of 7 July 2020, Q2.

³²⁰ PRC00350, the DHSC’s response of 30 July 2020 to the CMA’s s.26 Notice of 7 July 2020, Q1.

³²¹ After the Relevant Period, Flynn’s Capsules moved categories within the Drug Tariff. 25mg, 50mg and 300mg capsules moved to category A in October 2018. 100mg capsules moved to category A in February 2019 and then category M in April 2019. See PRC00350, the DHSC’s response of 30 July 2020 to the CMA’s s.26 Notice of 7 July 2020, Q6.

³²² PHT00086, NHS Business Services Authority’s response of 1 May 2015 to the CMA’s request for information of 16 April 2015 regarding the Drug Tariff (CMA document reference 01207.1), Q3. Following the de-branding of *Epanutin* on 24 September 2012, concession prices were established for phenytoin sodium capsules because dispensers could no longer purchase the products at the prices listed in the October 2012 Drug Tariff (as the Drug Tariff prices were

2.165 During the Relevant Period Tablets were (and still remain) in category M of the Drug Tariff.³²³

e. Scheme M

2.166 Scheme M was a non-contractual voluntary scheme which applied to those manufacturers and suppliers of generic medicines for use in the NHS which chose to join it.³²⁴ Scheme M provided a mechanism for the provision of quarterly generic drug pricing and volume data from manufacturers and suppliers who were scheme members to the DHSC for the purposes of calculating category M Drug Tariff prices.

2.167 Scheme M was first introduced on 1 April 2005 and was revised on 1 January 2010.³²⁵

2.168 Teva was a member of scheme M and Teva's Tablets were included in scheme M from its inception in April 2005.³²⁶ Neither Pfizer nor Flynn were members of scheme M during the Relevant Period.³²⁷

2.169 When calculating category M Drug Tariff prices during the Relevant Period, the DHSC:

2.169.1. used the retrospective sales and volume data provided by scheme M members to calculate a volume-weighted ASP for each drug;³²⁸ and

2.169.2. adjusted the volume-weighted ASP across all category M drugs to ensure that pharmacies were able to recover sufficient margin for their community prescribing services to be provided sustainably.³²⁹

2.170 Pharmacies earn margin on the products they dispense at the difference between their purchase price and the Drug Tariff price at which they are reimbursed. The DHSC agreed an £800 million funding target to be delivered to pharmacies through this margin made on sales of generic products (the retained margin).³³⁰

unchanged from the September 2012 Drug Tariff). The Drug Tariff prices for phenytoin sodium capsules were then changed in the November 2012 Drug Tariff by reference to Flynn's list prices. The concession prices applied in October 2012 were the same as the reimbursement prices based on Flynn's list prices in November 2012.

³²³ PRC00352, the DHSC's response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020, attachment 'Phenytoin_data_2020-07-30'.

³²⁴ Sections 261(2) and 266(6) of the NHS Act; PAD00009, DHSC, *New long-term arrangements for reimbursement of generic medicines Scheme M*, June 2005, paragraphs 3-8 ('**Scheme M, 2005**'); PAD00008, Scheme M, 2010, paragraphs 4-9; and *Phenytoin* [2018] CAT 11, paragraph 42.

³²⁵ PAD00009, Scheme M, 2005, paragraph 9; and PAD00008, Scheme M, 2010, paragraph 11.

³²⁶ *Phenytoin* [2018] CAT 11, paragraph 42.

³²⁷ *Phenytoin* [2018] CAT 11, paragraph 42.

³²⁸ Prior to July 2012, volume-weighted average prices were calculated at a product pack level. From July 2012, prices were calculated at the product level, using aggregated data for all pack sizes. See PRC00350, the DHSC's response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020, Q5.

³²⁹ PAD00010, *Side letter between DH and BGMA*, DHSC, paragraph 2.

³³⁰ Until 2014/15 this commitment was £500 million when it then increased to £800 million, see PAD00011, *PSNC Briefing 017/14: Purchase Margin and Margin Reforms*, PSNC, September 2014.

- 2.171 Whilst margin made on generic drugs outside of category M may also contribute to the retained margin, adjusting the margins on category M drugs is the key mechanism used by the DHSC to ensure that the retained margin target is met.³³¹ The revenue provided to pharmacies is monitored through the DHSC's margin surveys.³³² If margins deviate significantly from the target, Drug Tariff prices across all category M drugs may be adjusted by the DHSC until the sum, across all category M items, is as close as possible to the margin that needs to be delivered in order to meet the target retained margin.³³³ As a result of this process, the DHSC sets category M Drug Tariff prices at levels substantially above the selling prices notified by manufacturers.³³⁴
- 2.172 The retained margin is calculated based on ASPs, so pharmacies that achieve higher discounts than the average get a bigger share of the retained margin. Pharmacies are therefore incentivised to source products as cheaply as possible which generally leads to competition putting downward pressure on selling prices, in turn leading to lower category M Drug Tariff prices.³³⁵ The National Audit Office found that if prices had remained at their March 2005 levels (prior to the introduction of the community pharmacy contractual framework and scheme M), the NHS would have spent £3.26 billion more than it actually did on category M items over the period 2005/06 to 2008/09.³³⁶
- 2.173 As discussed above at paragraph 2.159, the DHSC's policy was to rely on competition to control generic drug selling prices.³³⁷ The DHSC's intention was that competition and pressure from pharmacies would restrain manufacturers' and suppliers' selling prices of drugs within category M.³³⁸ Scheme M therefore allowed

³³¹ PHT00084, *The Community Pharmacy Contractual Framework and the retained medicine margin*, National Audit Office Report (CMA document reference PD41), page 18, paragraph 1.19.

³³² PHT00087, News Article on NHS Business Services web page – *Margin Survey Administration* (CMA document reference PD22). The margin survey involves carrying out a survey of invoices, which show actual prices paid for a sample of medicines, from a sample of pharmacies. The margin survey was jointly administered by the DHSC and PSNC. However, from 2014/15 the margin survey was led by the DHSC with the PSNC having access to audit and validate the process.

³³³ See PHT00084, *The Community Pharmacy Contractual Framework and the retained medicine margin*, National Audit Office Report (CMA document reference PD41), paragraph 2.1. In the main, margin adjustments are applied uniformly across all category M products: PRC00350, the DHSC's response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020, Q5(b)(i).

³³⁴ PAD00020, PSNC, *Retained margin (Category M)*. [Former Teva Director], [X] described category M drugs' reimbursement prices as being 'significantly higher' than suppliers' selling prices, with at one stage category M Drug Tariff prices being 'two or three times higher than the prices that were being provided by generics companies': PAD00030, [Former Teva Director] Cross Examination, day 5, page 15, lines 1 to 13. A report by Oxera found that the retained margin uplift to category M Drug Tariff prices is on average in the region of 100%: PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 2.27.

³³⁵ PAD00012, DHSC, *Community pharmacy drug reimbursement reforms consultation*, July 2019, paragraphs 2.10 and 3.2.

³³⁶ Overall, the introduction of the community pharmacy contractual framework led to a cost saving to the NHS of around £1.8 billion over the period 2005/06 to 2008/09: PHT00084, National Audit Office, *The Community Pharmacy Contractual Framework and the retained medicine margin* (CMA document reference PD41), page 5, paragraph 10 and page 29, paragraph 3.5.

³³⁷ PHT00082, Note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), pages 3 to 4, paragraph 13.

³³⁸ PHT00084, National Audit Office, *The Community Pharmacy Contractual Framework and the retained medicine margin* (CMA document reference PD41), page 8, paragraph 12.

its members to alter the price at which a medicine was sold without any requirement to discuss such changes with the DHSC in advance.³³⁹

- 2.174 The scheme M arrangements did, however, include a paragraph which stated that the DHSC ‘may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned’ if it identified ‘any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure’.³⁴⁰ They also provided that a scheme M member may be required to provide on reasonable request information regarding costs and/or profit margins.³⁴¹ In the DHSC’s examination of the reasonableness of the member’s costs and prices, scheme M provided that the DHSC would have regard to a number of factors listed in the arrangements.³⁴²
- 2.175 However, the DHSC never used scheme M to intervene regarding generic drug prices. Scheme M did not provide an effective mechanism to do so and the DHSC lacked the capability and capacity to determine the fair and reasonable price of an individual drug.³⁴³

f. Scheme M after the end of the Relevant Period

- 2.176 In June 2018, the DHSC gave notice of its intention to end scheme M and replace it with new information regulations.³⁴⁴ Scheme M expired on 30 June 2019.³⁴⁵ Pricing information for determining category M Drug Tariff prices is now collected under regulations which provide for quarterly submissions of data on packs supplied and net sales income to the DHSC by all producers of unbranded generic drugs.³⁴⁶
- 2.177 As shown in Table 2.1 below, between April 2019 and January 2020, category M Drug Tariff prices were calculated using blended weighted averages based on data from manufacturers in scheme M and all manufacturers (ie including non-scheme M manufacturers). The weighting applied to the prices of manufacturers in scheme M was gradually reduced. From January 2020 onwards, category M Drug Tariff prices have been calculated exclusively using data from all manufacturers.³⁴⁷

³³⁹ PAD00008, Scheme M, 2010, paragraph 27.

³⁴⁰ PAD00008, Scheme M, 2010, paragraph 30.

³⁴¹ PAD00008, Scheme M, 2010, paragraph 31.

³⁴² PAD00008, Scheme M, 2010, paragraph 32. These included trends in the member’s and other companies’ prices for the same product; any special features of the member’s operation; any ratios inferred from the member’s non-generics business; each member’s reported costs and profit margins and the average of other similar companies; and information from external sources relating to the generics industry.

³⁴³ PHT00082, Note of the CMA’s meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), page 8, paragraphs 9 and 42. Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: PHT00088, Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.585), page 2, records that Flynn was told by the DHSC on 6 November 2012 that ‘Scheme M was not a pricing approval’ and in relation to the scheme M provisions that ‘nothing had been invoked since Schedule [scheme] M was introduced’.

³⁴⁴ PAD00016, DHSC, *Legal requirements to provide information about health service products*, June 2018.

³⁴⁵ PRC00350, The DHSC’s response of 30 July 2020 to the CMA’s s.26 Notice of 7 July 2020, Q3.

³⁴⁶ PAD00035, *The Health Service Products (Provision and Disclosure of Information) Regulations 2018, part 2*.

³⁴⁷ PRC00350, the DHSC’s response of 30 July 2020 to the CMA’s s.26 Notice of 7 July 2020, Q5(a)(ii).

Table 2.1: Category M Drug Tariff price calculation weighting to (a) manufacturers in scheme M and (b) all manufacturers

Drug Tariff month	Scheme M weight (%)	All manufacturers weight (%)
January 2019	100	N/A
April 2019	75	25
July 2019	50	50
August 2019	50	50
October 2019	25	75
January 2020	N/A	100

Source: PRC00350, The DHSC's response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020.

g. The DHSC's statutory powers to intervene in prices during the Relevant Period

2.178 The Secretary of State has certain statutory powers to monitor and intervene in drug pricing in specific circumstances. These powers are set out in sections 261 to 266 of the National Health Service Act 2006 (as amended) (the '**NHS Act**'). The Secretary of State's role is discharged through the DHSC, and so this Section will generally refer to the DHSC.

2.179 Section 261 of the NHS Act grants the DHSC the power to enter into voluntary schemes with industry members (such as the PPRS) for the purpose of controlling the cost of pharmaceutical medicines.

2.180 In addition, sections 262 and 263 of the NHS Act grant the Secretary of State the power, after consulting the relevant industry body, to:

2.180.1. limit the price charged by a manufacturer or supplier for the supply of a health service medicine under section 262(1) (the '**Reserve Power**'); and

2.180.2. introduce an industry-wide statutory scheme to control the price of medicines not covered by a voluntary scheme under section 263(1) (the '**Statutory Scheme**').

2.181 The Statutory Scheme in force during the Relevant Period only applied to branded medicines.³⁴⁸

2.182 As Flynn's Capsules were de-branded in September 2012 and Teva's Tablets were an unbranded generic drug, the Statutory Scheme was not applicable to them.

³⁴⁸ PAD00074, *The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008*; PAD00076, *The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007*, as amended; and see also *Phenytoin* [2018] CAT 11, paragraph 48.

h. Limitations to the DHSC's Reserve Power

- 2.183 Prior to 7 August 2017, the Reserve Power was not exercisable at any time in relation to a manufacturer or supplier who was a member of a voluntary scheme.³⁴⁹ This was consistent with the DHSC's interpretation of the relevant statutory provisions.³⁵⁰
- 2.184 The regulatory framework during the Relevant Period therefore meant that all unbranded medicines supplied by licence holders who were members of a voluntary scheme (such as the PPRS) were exempt from the Reserve Power. Only if the licence holder was not a member of any voluntary scheme could the unbranded medicines it sold potentially be subject to the Reserve Power.
- 2.185 Flynn and Teva were members of the PPRS. The Reserve Power was therefore not exercisable in relation to Flynn's Capsules and Teva's Tablets during the Relevant Period.

i. Statutory reforms to strengthen the DHSC's powers

- 2.186 After the Relevant Period, the scope of the Reserve Power changed as a result of an amendment to the NHS Act introduced by the Health Service Medical Supplies (Costs) Act 2017 (the '**Costs Act**').
- 2.187 As discussed above, the regulatory regime for generic drugs in the UK is predicated on competition controlling prices. The DHSC was concerned however that its statutory powers prior to the amendment were insufficient to deal with the challenge of suppliers of niche generic drugs exploiting freedom of pricing for unbranded generic medicines.
- 2.188 During the bill stage of the Costs Act, the Secretary of State said that the key reasons for introducing it were to:
- 2.188.1. remedy the fact that the government's existing powers did not allow it to place price controls on unbranded generic medicines where a company was a member of the PPRS; and
 - 2.188.2. prevent such firms from being able to exploit freedom of pricing for unbranded generic medicines where there is no competition in the market.³⁵¹

³⁴⁹ Section 262(2) of the NHS Act.

³⁵⁰ PAD00014, *Health Service Medical Supplies (Costs) Bill, Explanatory Notes*, paragraph 17.

³⁵¹ PAD00013, Hansard, *Health Service Medical Supplies (Cost) Bill, Volume 616 - UK Parliament*, 24 October 2016, Volume 616. See also PAD00047, DHSC, *Health service medical supplies (costs) bill factsheet*, 8 November 2016, paragraphs 2 and 2.1.

2.189 The Secretary of State said that:

We rely on competition in the market to keep the prices of [unbranded generic] drugs down. That generally works well and has, in combination with high levels of generic prescribing, led to significant savings. However, we are aware of some instances where there is no competition to keep prices down, and companies have raised their prices to what looks like an unreasonable and unjustifiable level. [...]

...there are companies that appear to have made it their business model to purchase off-patent medicines for which there are no competitor products. They then exploit a monopoly position to raise prices.

We cannot allow this practice to continue unchallenged. My Department has been working closely with the Competition and Markets Authority to alert it to any cases where there may be market abuse and provide evidence to support this, but we also need to tackle it within our framework for controlling the cost of medicines and close the loophole of de-branding medicines. Although the Government's existing powers allow us to control the price of any health service medicine, they do not allow controls to be placed on unbranded generic medicines where companies are members of the voluntary PPRS scheme.³⁵²

2.190 In *Phenytoin*, the CAT stated that the change 'suggests [...] that the DH considered it did not already have the necessary powers' to materially influence Pfizer's or Flynn's prices for Capsules.³⁵³

j. The DHSC's new powers as a result of the statutory reforms

2.191 The Costs Act entered into force from 7 August 2017, after the end of the Relevant Period.³⁵⁴ The Costs Act made a number of changes to the UK's pharmaceutical price regulation framework. These included:

2.191.1. making drugs outside a voluntary scheme subject to the potential for intervention under the Reserve Power even if the licence holder is a member of a voluntary scheme;³⁵⁵ and

³⁵² PAD00013, Hansard, *Health Service Medical Supplies (Cost) Bill*, Volume 616 - UK Parliament, 24 October 2016, Volume 616, page 6.

³⁵³ *Phenytoin* [2018] CAT 11, paragraph 207.

³⁵⁴ By virtue of the *Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017*.

³⁵⁵ Section 4 of the Costs Act amended section 262(2) of the NHS Act to state that '[i]f at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine'.

2.191.2. allowing for regulations requiring licence holders to provide cost and other financial information to the DHSC upon request.³⁵⁶

2.192 The Reserve Power is silent as to the method the DHSC should use to determine a price limit. The DHSC has publicly stated that it will consult with the relevant industry bodies (the BGMA and the Healthcare Distribution Association) in relation to any proposed policy and procedures for using the Reserve Power.³⁵⁷ In May 2019, it was reported that a planned consultation was delayed³⁵⁸ and as at the date of this Decision the DHSC has yet to issue any public consultation on the use of the Reserve Power. The DHSC is also required by section 262(1) of the NHS Act to consult with the relevant industry body before making a particular price determination using the Reserve Power.

D. Background to the Infringements

I. The Agreements between Pfizer and Flynn

2.193 In 2012, Pfizer and Flynn entered into a series of agreements under which Pfizer transferred its MA for phenytoin sodium capsules to Flynn and agreed to continue to supply the product to Flynn on an exclusive basis in the UK.

2.194 This section first explains, by way of background, Pfizer's earlier conversations with another generics manufacturer, Tor Generics Ltd ('**Tor**'), relating to a proposal for similar arrangements to those ultimately entered into between Pfizer and Flynn. It then provides details of Pfizer and Flynn's discussions, followed by details of the final agreements entered into by the Parties and the impact of those agreements on the structure of supply.

a. Pfizer's discussions with Tor

2.195 Tor supplies generic pharmaceutical products to wholesalers. In mid-2009, Tor approached Pfizer with a proposal whereby Pfizer would license *Epanutin* to Tor and Tor would change the name of the product and sell it as a generic at an increased price.

2.196 The Tor proposal took the price of Tablets as its starting point: Tor proposed to increase the price of phenytoin sodium capsules so that the 100mg capsules would be priced 15% below the Drug Tariff price of Tablets (which at this point was £30 for a pack of 28 tablets).³⁵⁹ Tor estimated that this price would result in a net profit

³⁵⁶ Section 8 of the Costs Act inserted a new section 264A into the NHS Act, allowing for such regulations for purposes including 'the exercise by the Secretary of State of any powers under section 260 to 264 and 265'. On 1 July 2018, under the Health Service Products (Provision and Disclosure of Information) Regulations 2018, the DHSC was given supporting information-gathering powers regarding costs information.

³⁵⁷ PAD00016, DHSC, *Legal requirements to provide information about health service products*, June 2018, page 35.

³⁵⁸ PAD00068, The Pharmaceutical Journal, *Government delays consultation with pharmaceutical industry over generics price limiting powers*, 8 May 2019.

³⁵⁹ PHT00184, *Epanutin/Phenytoin generic switch*: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 2 (CMA document reference 00141.636).

of £19.65 per 100mg pack, and proposed that this profit be split 60/40 between Pfizer and Tor respectively.³⁶⁰

2.197 The document setting out Tor's proposal explains that one advantage to Pfizer of using a partner such as Tor was that '[t]here would be no need for PFIZER to answer questions to the [DHSC] in relation to a generic presentation or product price'.³⁶¹

2.198 Internal emails demonstrate that, while Pfizer employees were enthusiastic about the 'significant upside' of Tor's proposal, they were conscious of concerns regarding ethics, patient safety, and viability.

2.199 In an email sent on 23 July 2009, [Pfizer Employee 1] ([X]) described the Tor proposal to [Pfizer Employee 2] ([X]) and [Pfizer Employee] ([X]). [Pfizer Employee 1] noted that the proposal would increase Pfizer's revenues by £19 million annually and explained that 'we have a profitability issue with this product'.³⁶²

2.200 [Pfizer Employee 1] also noted:

...[Tor's] proposal is that we do it via Tor to distance ourselves from the price increase.

*Clearly, we do not need Tor to do this and could just try to go down this route ourselves, however I believe that we would struggle to get the price increase required with the [DHSC].*³⁶³

2.201 [Pfizer Employee 1]'s email concludes:

My other concern is just an ethical one – the top line money looks great, however this would increase the price of phenytoin capsules to the NHS drastically and to be frank, doesn't feel right.

Clearly we need to make money on the product and therefore, I wonder if a conversation with the DOH [DHSC] with these findings could simply increase our pack price to enable profitability. It would certainly not add £19m to the top line but might sit better?

³⁶⁰ PHT00184, *Epanutin/Phenytoin generic switch*: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 3 (CMA document reference 00141.636).

³⁶¹ PHT00184, *Epanutin/Phenytoin generic switch*: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 2 (CMA document reference 00141.636).

³⁶² PHT00183, Internal Pfizer email chain of 23 July 2009 [from [Pfizer Employee 1] to [Pfizer Employee 2] and [Pfizer Employee]] re Tor Generics Proposed Project: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 1 (CMA document reference 00141.21).

³⁶³ PHT00183, Internal Pfizer email chain of 23 July 2009 [from [Pfizer Employee 1] to [Pfizer Employee 2] and [Pfizer Employee]] re Tor Generics Proposed Project: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 1 (CMA document reference 00141.21).

*Or on the other hand, maybe I'm just being to [sic] nice!!*³⁶⁴

2.202 In an email sent to colleagues on 13 September 2009, [Pfizer Director 1] ([REDACTED]) echoed these concerns:

*This could generate significant upside, but whilst legal, would increase the price of phenytoin capsules to the NHS significantly. How does that fit with [our] Trust initiative?*³⁶⁵

2.203 [Pfizer Employee 4] ([REDACTED]) responded to [Pfizer Director 1]'s email setting out his concerns as follows:

*Industry has, rightly, made a big deal of epilepsy drugs being one of the key medicines where you shouldn't mess with the presentation that a patient is stabilised on – with a great deal of expert medical and pharmacy support. I think we have to ask ourselves how this action might sit alongside that position, particularly given the narrow therapeutic window of phenytoin. My first reaction is that I suggest we have to think long and hard before considering any withdrawal of a branded AED.*³⁶⁶

2.204 [Pfizer Employee 5] ([REDACTED]) agreed with [Pfizer Employee 4]'s view:

*I have to agree ... I do not believe it is medically safe to switch between branded and generic AEDs and particularly with phenytoin as it has such a narrow therapeutic window. Loss of seizure control would have a major impact clinically and also in terms of losing a driving licence which may have been regained after a long period free of seizures. We also used AEDs in our feedback on the PPRS generic substitution initiative as an example of a class of drugs where this would not be recommended.*³⁶⁷

2.205 [Pfizer Employee] ([REDACTED]) replied, drawing attention to prescribing guidance:

³⁶⁴ PHT00183, Internal Pfizer email chain of 23 July 2009 [from [Pfizer Employee 1] to [Pfizer Employee 2] and [Pfizer Employee]] re Tor Generics Proposed Project: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013, page 2 (CMA document reference 00141.21).

³⁶⁵ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31), page 2. [Pfizer Director 1] explained that the 'trust initiative' was an internal Pfizer initiative that 'challenged [Pfizer employees] to be more transparent and to engage more with customers, with regulators, such that they understood the full context of the decisions that we made', PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 58, lines 5-13.

³⁶⁶ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013, page 2 (CMA document reference 00141.31).

³⁶⁷ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013, page 1 (CMA document reference 00141.31).

*If it helps there is specific guidance against switching and indeed that these products should be written by brand name to ensure consistency of medication within the BNF.*³⁶⁸

2.206 On 22 September 2009, [Pfizer Director 1] forwarded these internal discussions to [Pfizer Employee 2]. In his cover email, [Pfizer Director 1] noted: '[t]here seems to be a strong concern/reluctance on the advisability of doing this form [sic] a patient care / Trust perspective. I echo these.'³⁶⁹ [Pfizer Director 1]'s subsequent evidence before the CAT was that by mentioning these concerns he was 'expressing the view that we needed to satisfy ourselves that we were taking the right course of action before proceeding', given that 'Pfizer would have been extremely reluctant to enter into a transaction with a third party that would not have preserved the same formulation and manufacturing process'.³⁷⁰

2.207 In his cover email, [Pfizer Director 1] also raised the possibility of Pfizer approaching the DHSC directly:

*Is there not an option to point out to [the DHSC] this anomaly and how much it is costing them, and getting them to reset the tablets Cat M tariff in line with the Cat C branded tariff; thus saving them tens of millions and allowing us a level playing field on which we should be able to win [a] higher share.*³⁷¹

2.208 [Pfizer Director 1] later explained that the 'anomaly' referred to here was the fact that 'the generic version of the medicine [Tablets] was 30 times the price of the brand [Capsules]. [...] which is quite different from what you would normally expect'.³⁷²

2.209 [Pfizer Director 1] also explained that the reference to winning a 'higher share' reflected his understanding at the time that there would be some switching between Tablets and phenytoin sodium capsules; however, he did not think there would in general be significant switching between Tablets and phenytoin sodium capsules on account of phenytoin sodium's NTI.³⁷³ As the emails referenced above show, other Pfizer employees did not believe that phenytoin sodium capsules and Tablets were substitutable.

³⁶⁸ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013, page 1 (CMA document reference 00141.31).

³⁶⁹ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013, page 1 (CMA document reference 00141.31).

³⁷⁰ PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 37.

³⁷¹ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013, page 1 (CMA document reference 00141.31).

³⁷² PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 40, lines 14-23. See also PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 28.

³⁷³ PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 30.

2.210 Earlier, on 17 September 2009, [Pfizer Employee 2] (Pfizer) had emailed [Tor Employee] (Tor) querying the sustainability of Tor's proposal. [Tor Employee] responded saying:

...I see the opportunity re Epanutin for us sustaining realistically for 3 to 5 years...[✂] [Pfizer Employee 1] (Pfizer)] actually said in the meeting [in July 2009³⁷⁴] that Epanutin is such an old license [sic], that it would be Nigh [sic] on impossible to get a license granted for a generic based on the old trials and license that currently exist – the brand being @70 years old.. [sic] therefore, even if a generic company decided to throw tons of cash at it to go for it from scratch (which is exceedingly unlikely, due to costs and time for trials being @ minimum 2 years), and then they would then have to prove stability data etc; which they couldn't base on your brand – it would render it not viable as a short term opportunity ... the only reason you would have a license granted for the generic at Pfizer as an 'own livery product' as a generic own livery is because you possess the brand license [sic]...

...

I need you to confirm again with [✂] [Pfizer Employee 1] (Pfizer)] before we meet all of what she suggested at our last meeting regarding the uniqueness of the situation with the Epanutin [sic] in the UK; re the license [sic], the age of the product, and its' [sic] placement in the market re competition from alternatives (which [Pfizer Employee 1] did dispell [sic] to me some while ago, saying Epanutin was [a] last resort medicine).³⁷⁵

2.211 On 4 January 2010, [Pfizer Employee 2] of Pfizer emailed Tor to ask that Tor consider the potential risk that parallel imports presented to Tor's proposal to genericise *Epanutin*.³⁷⁶

2.212 Tor then met with Pfizer on 29 January 2010.³⁷⁷ Following that meeting, [Pfizer Director 1] emailed colleagues explaining that Pfizer needed to progress Tor's proposal as the 'potential upside is huge' and Pfizer could not 'afford to dismiss this lightly'. [Pfizer Director 1] then set out a list of unresolved questions. First, he queried the sustainability of the proposal:

³⁷⁴ A meeting took place on 6 July 2009 between [Tor Employee] of Tor and [Pfizer Employee 1] and [Pfizer Employee 2] of Pfizer which appears to be the first meeting between Tor and Pfizer: PHT00110, Email of 6 July 2009 from [Tor Employee] Tor Generics to [Pfizer Employee 1] and [Pfizer Employee 2] Pfizer re Email following on from earlier meeting and stating that a profit proposal for Epanutin all strengths will follow: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00141.19).

³⁷⁵ PHT00185, Email chain of 17 September 2009 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re the Epanutin Proposal put forward by Tor: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 1 (CMA document reference 00141.28).

³⁷⁶ PHT00186, Email chain of 11 January 2010 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re Email chain re Epanutin availability in other EU Markets - Tor and Pfizer EU Scripts Info in the Countries: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00141.51), page 3.

³⁷⁷ PHT00111, Presentation slides by Tor Generics Ltd entitled 'Addendum to the strategy for conversion of brand to Generic Epanutin to Phenytoin Capsules': Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00141.56).

1. I understand how the DT [Drug Tariff price] could be 'reset' to £25~30 for capsules by doing this. However I don't understand why this will be sustainable.

*a. Other companies may enter if caps are at a much more attractive price (caps are generally easier & cheaper to make than tablets) and inevitable discounts would become reflected in a reduced DT reimbursement price.*³⁷⁸

2.213 [Pfizer Director 1] questioned whether the proposed price increases would increase the amount of parallel imported product sold in the UK given the 'low prices in Europe' and also noted that increased volumes of parallel imported product into the UK from other countries 'would cause great difficulties for our colleagues in the other markets in supplying this essential medicine domestically'.³⁷⁹

2.214 In addition, [Pfizer Director 1] raised a concern regarding the 'positioning' of the proposal: 'We need to work out how we can position this as 'no change' with patients & physicians; and at the same time 'change' with [the DHSC] and payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in [a] time of funding crisis'.³⁸⁰ Finally, [Pfizer Director 1] again raised the possibility of approaching the DHSC directly:

*May be a 'no-goer' but as an alternative; is there an opportunity to go to [the DHSC] and have a sensible debate with them about the inequity in the tabs/caps prices, and explain (in the spirit of openness) that we cannot afford to sell it [Epanutin] at this price and that we could implement a scheme such as this (without going in to details). The aim being to obtain a special price increase outside of PPRS; or at least get them to cut the Cat M price of tabs to the same as caps and prevent TEVA making supernormal profits.*³⁸¹

2.215 In his evidence before the CAT, [Pfizer Director 1] explained that he did not personally hold any ethical concerns about the deal; however, he wanted to ensure that any potential criticism was taken into account as part of Pfizer's decision-making process.³⁸² When asked about this point during cross-examination, [Pfizer Director 1] noted that his comments regarding 'fleecing the NHS' were made in the context of anticipating 'the position that people would take if they didn't understand the full context and just focussed on something like a percentage increase'.³⁸³

³⁷⁸ PHT00187, Internal Pfizer e-mail chain of 2 February 2010 [from [Pfizer Employee] to [Pfizer Director 1]] re Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 1 (CMA document reference 00141.57).

³⁷⁹ PHT00187, Internal Pfizer e-mail chain of 2 February 2010 [from [Pfizer Employee] to [Pfizer Director 1]] re Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 1 (CMA document reference 00141.57).

³⁸⁰ PHT00187, Internal Pfizer e-mail chain of 2 February 2010 [from [Pfizer Employee] to [Pfizer Director 1]] re Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 1 (CMA document reference 00141.57).

³⁸¹ PHT00187, Internal Pfizer e-mail chain of 2 February 2010 [from [Pfizer Employee] to [Pfizer Director 1]] re Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 2 (CMA document reference 00141.57).

³⁸² PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 40.

³⁸³ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 59, line 23, to page 60, line 17. See also PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 33.

2.216 In relation to his statement regarding ‘supernormal profits’, [Pfizer Director 1]’s evidence was that this was ‘clearly not a serious comment’.³⁸⁴ He went on to explain that these remarks reflected his frustration regarding the apparent inconsistency of the DHSC’s approach to Tablets and Capsules:

*So on the one hand, it was very clear to us that from [the DHSC’s] initial intervention and then subsequent acceptance of the tablet price, that that represented the value that they believed that medicine gave to the NHS. Yet at the same time, the advice I was getting from our finance team, who’d raised this subject in previous discussions with the Department, was that they would not entertain any exceptional price rise or price reset of the capsules accordingly. So what I was expressing here was that how can the Department have that inconsistent position, because if – as you say if they truly believed that the Epanutin capsule price was the fair price, then they, the Department, must [have] believe[d] that Teva [was] making some sort of level of inappropriate profit’.*³⁸⁵

2.217 Ultimately, Pfizer decided not to pursue Tor’s proposal, and this decision was communicated to Tor in April 2010.³⁸⁶ By this point in time, Pfizer had already begun conversations with Flynn regarding *Epanutin*.

b. Pfizer and Flynn’s discussions

i. Initial meetings

2.218 In January 2010 [Pfizer Employee 3] ([X]) approached [Flynn Director 2] ([X]) to discuss divestment opportunities in relation to tail-end products.³⁸⁷ At initial meetings on 8 March and 1 June 2010 the Parties discussed the possibility of de-branding *Epanutin*.³⁸⁸

2.219 At a further meeting on 1 July 2010, Flynn presented its proposal for *Epanutin* to Pfizer, including suggestions in response to concerns regarding patient safety and parallel imports.³⁸⁹ Slide five outlined the ‘current position’:

³⁸⁴ PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 42.

³⁸⁵ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 43, line 14, to page 44, line 3.

³⁸⁶ PHT00109, Email chain of 16 April 2010 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re Any Further Thoughts on the Draft Divestment re Epanutin: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice of 8 May 2013, page 2 (CMA document reference 00141.63).

³⁸⁷ PHT00081, Pfizer’s response of 29 May 2013 to the OFT’s s.26 Notice of 8 May 2013 (CMA document reference 00086.1), page 10.

³⁸⁸ PHT00188, [Flynn Employee 1]’s Flynn’s Handwritten Note of Meeting between Flynn and Pfizer (NF Notebook) on 8 March 2012: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013, page 1 (CMA document reference 00145.8); and PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 16.

³⁸⁹ PHT00202, Email of 2 July 2010 from [Flynn Employee 1] Flynn to [Pfizer Employee 2] Pfizer Email attaching Epanutin Proposal June 2010 made by Flynn 1 July 2010: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.26); and PHT00164, Presentation slides entitled ‘A Specialty Care Pharma Company’: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.27).

Epanutin (phenytoin capsules), current position

- *Epanutin in the UK is economically unattractive at its current list price*
- *Competitor products (tablets) are sold at ~30x the price*
- *Tablets & capsules are not easily interchangeable*
- *Pfizer is unable to change the price of this branded product due to PPRS*
- *Nevertheless, phenytoin capsules must continue to be available to patients*
- *This document explores ways in which Pfizer can continue to fulfil patient needs and turn Epanutin into an economically attractive product*

2.220 Slide six set out Flynn's estimates of the value of *Epanutin* sales if sold at varying proportions of the price of Tablets:

Epanutin UK sales at generic tablet prices, based on pro-rata of current IMS sales value

	50%	75%	100%
<i>Epanutin</i>	£56.7M	£85.1M	£113.5M

2.221 Flynn recommended that the price of *Epanutin* was 'pitched at half of the price for Phenytoin tabs initially, ie £15 for 28 caps x 100mg'.

2.222 Slide seven identified four 'potential issues':

Potential Issues

- *Continued patient access to phenytoin caps*
- *Pharmacopolitical damage (Pfizer)*
- *Parallel imports*
- *PPRS considerations*

2.223 Slide eight set out the key features of Flynn's proposal:

Strategic options

- *Pfizer uses Flynn Pharma as the MA holder to avoid pharmacopolitical damage*
 - *Flynn debrands the product in the UK*
 - *Flynn sets the UK price of the generic capsules*
- *Flynn enters into exclusive supply and technical agreements with Pfizer*
- *The structure of the deal is flexible:*
 - *UK and/or EU*
 - *Supply price*
 - *Milestone payments, royalties*
 - *Flynn can, if required, take over responsibility for the supply chain at any stage present or future*

2.224 Slide 10 set out a series of proposals in relation to parallel imports:

Parallel imports

- *There are a number of strategic options which Pfizer could adopt to help prevent stock-out situations in lower-priced markets, resulting from parallel trade activity. These could include a combination of some or all of the following:*
 - *Change MA holder in the UK & Ireland to Flynn and add a Flynn mark to the capsule (100mg capsules are currently marked “Epanutin 100”)*
 - *Change the manufacturer for the UK (disassociate from Pfizer)*
 - *Change the presentation available in other EU source countries to 50mg only*
 - *Apply quotas to known PE wholesalers in Spain, Greece and Ireland.*

2.225 An earlier internal draft of Flynn’s presentation sent by [Flynn Employee 1] to [Flynn Director 2] used different wording on slide 10 to describe the same list of factors relating to parallel imports. The slide was instead headed ‘the strategic

options in preventing parallel imports to the UK include a combination of some or all of the following'.³⁹⁰

2.226 Similarly, the slides presented by Flynn at the earlier June 2010 meeting with Pfizer also included details regarding the potential competitive threat from parallel imports.³⁹¹ These slides referred to three existing parallel import licences and noted that the transfer of the MA to Flynn 'would prevent new licenses [sic]' as well as noting the 'need to deal with existing licence supplies'. The final slide in this set outlined proposals relating to existing competition for parallel imports:

The major presentation in the UK is 100mg. Imports of this can be halted, losses on other strengths are less significant.

2 x 50mg is clinically equivalent to 1 x 100mg

Proposal:

Withdraw 100mg from markets other than UK, replace with 50mg to allow greater flexibility of dosing in those markets.

Potential number of patients to be managed in Spain and Greece is small, estimates based on IMS cash divided by price of €2.50/pack, each patient 12 packs per year:

Spain ca. 30,000

Greece ca. 5,600

2.227 Slide 11 of the presentation made by Flynn at the 1 July meeting considered the potential impact of parallel imports on sales in the UK:

How much could PIs impact sales?

- *Should be no impact on 25mg, 50mg and 300mg in UK. These alone could be worth £15m*
- *Even if 50% of sales of 100mg were lost to PI the upside would still be >£20m*

2.228 Finally, slide 12 set out Flynn's views regarding patient impact:

Other considerations

- *Patient impact*

³⁹⁰ PHT00162, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013, slide 10 (CMA document reference 00145.91) (emphasis added).

³⁹¹ PHT00229, Presentation slides entitled 'Epanutin proposal, June 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013, slide 7 (CMA document reference 145.22) and PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 48.

Minimal: this strategy ensures continued availability in all markets; packaging in the UK would be designed to resemble Epanutin; the change will be communicated to all HCPs [healthcare professionals]

ii. Flynn's detailed proposal dated 29 October 2010

2.229 On 30 July 2010 [Flynn Director 2] (Flynn) sent a draft Heads of Terms document to Pfizer.³⁹² In this document, Flynn proposed that 'the total supply price shall be 50% of Flynn's net selling price, but not less than the current ex-factory price less distribution costs (3%)'.³⁹³

2.230 In October 2010 Pfizer requested a more detailed proposal from Flynn, to use for its internal approvals process. On 29 October 2010, [Flynn Director 2] (Flynn) sent [Pfizer Employee 2] (Pfizer) three documents:³⁹⁴ a briefing document outlining Flynn's proposal;³⁹⁵ a frequently asked questions document;³⁹⁶ and responses to certain questions received from Pfizer's lawyers.³⁹⁷ Some of the detail of these documents is set out below.

Flynn's briefing document

2.231 The briefing document begins with an executive summary:

- *Epanutin (phenytoin in capsule presentation) in the UK is economically unattractive to Pfizer at its current ex-factory price. PPRS restrictions prevent Pfizer achieving a price increase for the brand without modulating the price of other products.*
- *If Epanutin were to be discontinued in the UK, prescribers would be obliged to switch patients to the closest alternative, phenytoin tablets. The financial costs to the NHS of discontinuing Epanutin and switching to phenytoin tablets would be in excess of £100M.*
- *More importantly, there is a possibility that welfare of the patient might be impacted, as the capsules and tablets are not readily*

³⁹² PHT00190, Correspondence of 20 August 2010 between [Flynn Employee 1] Flynn to [Pfizer Employee 2] Pfizer: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.35) and PHT00189, 'Draft Heads of Terms - 30 July 2010 - between Pfizer and Flynn Pharma re Divestment of Epanutin': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.31).

³⁹³ PHT00189, 'Draft Heads of Terms - 30 July 2010 - between Pfizer and Flynn Pharma re Divestment of Epanutin': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.31), page 2.

³⁹⁴ PHT00191, Email of 29 October 2010 from [Flynn Director 2] Flynn to [Pfizer Employee 2] Pfizer attaching briefing document for the Epanutin Proposal together with the FAQ document and responses to lawyer's questions: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.63).

³⁹⁵ PHT00193, document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.65).

³⁹⁶ PHT00194, document entitled 'Flynn Pharma Epanutin Proposal October 2010 – FAQs': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.66).

³⁹⁷ PHT00192, document re Epanutin Heads of Agreement Queries and Responses of October 2010: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.64).

interchangeable. Such discontinuation would inevitably cause considerable pharmaco-political issues to Pfizer.

- *Flynn Pharma Ltd, a UK based company, has submitted a robust proposal in which phenytoin capsules would become more economically attractive to Pfizer, whilst maintaining excellent value for money for the DH and without impacting on patient safety or Pfizer's reputation. This document details how this could be achieved.*
- *The potential increased revenues to Pfizer are approximately £26M p.a.*³⁹⁸

2.232 The document goes on to outline Flynn's proposals in respect of certain 'potential issues'. In relation to patient impact, the document notes that:

*Healthcare professionals and other stakeholders (eg patient groups) would be notified of the change. Flynn stores and distributes its goods through [X], so this will require little change. Given good communication to all stakeholders, the impact on patients will be minimal ...*³⁹⁹

2.233 In relation to 'pharmaco-political issues', the briefing records:

Pfizer UK's position would be simple: Pfizer has divested the product to Flynn Pharma Ltd. Flynn would defend its right to make profit within the bounds of the PPRS and generic pricing regulations. The cost implications to the NHS would be preferable, in any event, to the alternative of discontinuing the product in the UK and switching patients to more expensive tablet presentations.

2.234 On the topic of parallel imports, the document states:

A price increase in the UK would lead to potential parallel imports from other EU markets, subject to local availability. Assignment of the trademark to Flynn in the UK would mean that parallel imports would risk infringing Flynn's trademark. In any event, some parallel importing would reduce but not remove the attractiveness of this strategy to Pfizer.

2.235 When asked about the threat from parallel imports during cross-examination before the CAT, [Flynn Director 2] confirmed that the availability of such imports was not guaranteed: '[s]upplies of parallel imports are by nature spasmodic. It depends upon the availability of stock in the country of origin'.⁴⁰⁰

³⁹⁸ Emphasis in original.

³⁹⁹ PHT00193, document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013, page 6 (CMA document reference 00145.65).

⁴⁰⁰ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 109, lines 10-12.

Flynn's frequently asked questions document

2.236 The second question posed in Flynn's frequently asked questions document⁴⁰¹ concerned whether the proposal would open the product to potential competition:

2. This change will mean loss of the brand equity inherent in the 30% of scripts that are written by brand and leave the business open to generic competition.

a. There have been no generic competitors to date.

b. As continuity and consistency of medication is encouraged in this therapeutic area prescribers could specify "phenytoin capsules, Flynn"⁴⁰²

c. Even if Epanutin is not genericised proactively by Flynn then the advent and availability of a generic competitor would quickly lead to scripts being written generically, driven by PCOs [Primary Care Organisations].

2.237 Question three concerned the reputational risk of the proposal:

3. Pharmaco-political fall-out, damage to reputation?

a. Flynn Pharma carries this risk.

2.238 Question six concerned parallel imports:

6. Would any price increase encourage PIs?

a. There is currently a level of PI which is limited by the availability of the stock. No more stock would be available to importers.

b. Transfer of the Trademark to Flynn would act as a further barrier to imports and sale of stock branded as Epanutin.

2.239 During cross-examination, [Flynn Director 2] explained that the statement that 'no more stock would be available' reflected his understanding that 100mg capsules were 'predominantly coming in from Spain and Greece. So basically there would be no reason ... why those supplies into Spain and Greece would be increased by Pfizer'.⁴⁰³

iii. Subsequent discussions between Pfizer and Flynn

⁴⁰¹ PHT00194, Document entitled 'Flynn Pharma Epanutin Proposal October 2010 – FAQs': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.66).

⁴⁰² Where a prescription specifies a particular product (whether by reference to the brand or by reference to a particular supplier), the dispenser must dispense that particular product (unless the dispenser goes back to the prescriber to change the prescription). As such, where a prescription specified 'phenytoin capsules, Flynn' the dispenser would be required to dispense Flynn's product.

⁴⁰³ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 137, lines 7-22.

- 2.240 On 10 December 2010 [Flynn Employee 1] (Flynn) emailed [Pfizer Employee 2] (Pfizer) suggesting a catch up to 'reassess where we are with things'.⁴⁰⁴ [Pfizer Employee 2] responded setting out the two 'key areas' for discussion, namely 'trust' and parallel imports:

The two key areas are the "Trust" agenda – [redacted] [Pfizer Employee 4] chairs the ABPI [Association of the British Pharmaceutical Industry] group on this subject and minimising the impact on patients for these two [sic]. I think we have all the info we need for this

The braider [sic] area is still one regarding parallel trade and as long as we have a level of control over supply we can manage this. Do you have any further tactics to add which would help manage the supply challenges across the EU?

Overall, I think we are OK: the Established Products team are all aligned; our legal advisor and medical advisor are comfortable with the proposal so far, so if we get the UKMF onside, I am confident we can press forward.

*Let me know if you think you have further info that can support our case otherwise I'll let you know the outcome of the discussion with [sic] [redacted] [Pfizer Employee 4] and [redacted] [Pfizer Employee 5] next week.*⁴⁰⁵

- 2.241 [Flynn Director 2] (Flynn) updated Flynn's Board of Directors on 15 December 2010. The minutes of that meeting record:

Pfizer. *The planned meeting on 6th December of the Pfizer UK leadership group was postponed until 20th December. They had raised a small number of questions which have been addressed. If our proposal is accepted by Pfizer, the product rights will be acquired by Flynn and a profit sharing agreement will be drawn up. Epanutin capsules & tablets are not interchangeable, so the number of scripts should be maintained when the product is sold generically. Need to get feedback from the meeting. **Action:** [Flynn Director 2]*⁴⁰⁶

- 2.242 At the meeting on 20 December 2010, Pfizer's UK Management Forum ('UKMF') approved the proposal in principle, but requested the project team consider certain points and report back. On cross-examination, [Pfizer Director 1] recalled the following details from the UKMF discussion:

⁴⁰⁴ PHT00195, Email of 27 January 2011 from [Flynn Employee 1] Flynn to [Pfizer Employee 2] Pfizer re re What do we need to do next: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.87).

⁴⁰⁵ PHT00195, Email of 27 January 2011 from [Flynn Employee 1] Flynn to [Pfizer Employee 2] Pfizer re What do we need to do next: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.87).

⁴⁰⁶ PHT00197, Minutes of Flynn Pharma Board Meeting of 15 December 2010: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.80).

*... when we had the discussion at the UK Management Forum, we came to the conclusion that this did fit very well with our trust initiative, because the easy thing to have done would have been to withdraw this product. It is a loss-making product, to withdraw it. We felt that what we did was the responsible thing, which was to find a way to maintain the product on the market, to return it to profitability on a sustainable basis, so that it wouldn't limp on year on year under the threat of withdrawal.*⁴⁰⁷

- 2.243 On 11 March 2011, [Pfizer Employee 2] (Pfizer) updated [Flynn Employee 1] and [Flynn Director 2] (Flynn) by email:

We have engaged with Patient groups and they have seen this approach as very positive in terms of helping them prepare their clients for any change and progress will be conditional on this being taken forward by Pfizer / Flynn

I (Finally) managed to nail the Medical / regulatory piece and earlier this week had confirmation that, even at a European regulatory level, there were not any significant challenges.

*These were the two main hurdles raised by the UKMF. I think we can be in a position to re-present our case to them in the next few weeks*⁴⁰⁸

- 2.244 A further meeting with the UKMF was held in April 2011, following which Pfizer and Flynn began to draft the relevant agreements, and Pfizer sought internal approval from the EPBU European President.

- 2.245 On 7 June 2011 [Pfizer Director 1] (Pfizer) wrote to [Pfizer President 2] ([X]) introducing the Flynn proposal ahead of a European-level meeting scheduled for 20 June 2011. [Pfizer Director 1] noted that:

There is a significant commercial upside for EPUK – approx. £25m per annum in revenues, practically all of which goes straight through to IBT [income before taxes].

*There are some potentially significant pharmaco-political and reputational consequences which would rule out Pfizer doing this on our own, rather than through a third party.*⁴⁰⁹

- 2.246 On cross examination, [Pfizer Director 1] stated that his personal view was that it was not credible that the involvement of Flynn would shield Pfizer from criticism;

⁴⁰⁷ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 58, line 19, to page 59, line 3.

⁴⁰⁸ PHT00196, Email chain between [Flynn Employee 1] Flynn and [Flynn Director 4] Flynn dated 1 April 2011 including discussion on the flow of finance: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013, page 3 (CMA document reference 00145.34).

⁴⁰⁹ PHT00213, Email of 7 June 2011 from [Pfizer Director 1] to [Pfizer President 2] and [Pfizer Employee 6] (CMA document reference 00141.136).

however, he included this in the email as it had been raised by both Flynn and Tor, and was a view shared by some of his colleagues.⁴¹⁰

- 2.247 In preparation for the meeting with Pfizer's European management, [Pfizer Employee 3] (Pfizer) had a discussion with [Flynn Director 2] (Flynn) on 17 June 2011. [Pfizer Employee 3] reported the details of this discussion to [Pfizer Director 1] and [Pfizer Employee 2] by email on 17 June 2011. It is clear from the email that [Flynn Director 2] believed that Pfizer could genericise the products by itself, but that Pfizer should proceed with Flynn's proposal in order to mitigate any reputational fallout it might suffer as a result of the price increases:

I spoke briefly to [Flynn Director 2] at Flynn.

[...]

Regarding the question of why not do it ourselves: -

1. We could, he doesn't think there are any PPRS issues.

2. It's ALL about reputation

a. He suggests Google Daily Mail Hydrocortizone [sic]..... I did and here is a link to the Daily Mail Article <http://www.dailymail.co.uk/news/article-1295610/NHS-doesnt-care-cost-medicine-Drugs-firms-accused-profiteering-raising-prices-ONE-THOUSAND-cent.html>

b. He says would Pfizer execs want the Daily Mail camped on their doorstep.

3. Also, he points out that we have been working with them under and [sic] NDA [non-disclosure agreement] to look at strategies on a range of products. He claims this was their idea and proposal and we might want to argue it would be a bit disingenuous to then do it ourselves.

4. He made the point that Pfizer red tape and corporate glue would probably stop us from doing it ourselves in anything like the timescales needed.⁴¹¹

- 2.248 The meeting with Pfizer's European leadership went ahead in Zurich on 20 June 2011. On 23 June 2011 [Pfizer Employee 2] (Pfizer) sent an email to [Flynn Employee 1] and [Flynn Director 2] (Flynn) providing an update:

*the meeting on Monday with our EU Leadership was very productive. [✂]
and I presented the plan and our reasons for working with you on this project.
The response was very positive.*

⁴¹⁰ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 62, line 18 to page 64, line 3.

⁴¹¹ PHT00198, Internal Pfizer e-mail [from: [Pfizer Employee 3] to: [Pfizer Director 1] and Pfizer Employee 2]] of 17 June 2011 re Flynn and the possible advantages of going with Flynn re divestment: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00141.137).

[Pfizer President 2], [X] want [sic] us to put this Epanutin case into our operating plan which we will present in the last week of July.

*Accordingly: we need to work up a full business case, including financials and timelines. We should look to meet up in early January to discuss, thrash out details and proposed timelines for transfer, generic application, brand withdrawal and Gx launch.*⁴¹²

- 2.249 In August 2011 the Pfizer team briefed [Pfizer President 1] ([X]), on the proposal. The executive summary section of the briefing document highlights that ‘potential revenues to Pfizer from Epanutin are estimated to increase from £2.3m p.a. up to approximately £20M p.a.’. Later in the document the pricing proposal is explained in more detail:

Were Flynn to increase the price to 35% of the current generic 100mg tablet price, which we believe is close to the optimum level and would still represent an attractive offering for the NHS; the revenues to Flynn would be approximately £19.5m p.a. (Based on our 2010 annual volume excluding PI). We believe that there is some incremental value available and so our selling price to Flynn should be at approximately this level; Flynn should then set a selling price to the market which would be above 35% of 100mg tablet price, and retain the increment.

...

*We estimate that it would take a competitor a minimum of 2 years to bring a competitor phenytoin capsules to the market and trigger price reductions. Until that time we can expect the Drug Tariff (reimbursement) price to remain unchanged.*⁴¹³

- 2.250 On 2 September 2011 [Pfizer Employee 2] (Pfizer) emailed [Flynn Employee 1] (Flynn) to confirm that Pfizer’s European management team had approved Flynn’s proposal:

*[X] [Pfizer Director 1] has had a very productive meeting and we have been given a “go” form [sic] our EP [Established Products] President, subject to the contract and the usual caveats etc. This is very good news and we will need to progress the legal documents ...*⁴¹⁴

⁴¹² PHT00199, Email chain of 30 June 2011 between [Pfizer Employee] Pfizer and [Flynn Director 2] and [Flynn Employee 1] Flynn re meeting between Pfizer and Flynn with regards the divestment of Epanutin, timelines and deal structure: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013, page 2 (CMA document reference 00145.100).

⁴¹³ PHT00200, Document of 1 August 2011 entitled ‘Briefing for [Pfizer President 1] about the Epanutin divestment’: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice of 8 May 2013, page 3 (CMA document reference 00141.154).

⁴¹⁴ PHT00095, Email chain of 2 September 2011 between [Pfizer Employee 2] Pfizer and [Flynn Employee 1] Flynn re Phenytoin Progress: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.142).

c. Overview of the final arrangements

2.251 During the course of 2012, Pfizer and Flynn entered into three key agreements. The relevant terms of these agreements were as follows:

2.251.1. The **Asset Sale Agreement** dated 27 January 2012.⁴¹⁵ Under the terms of this agreement, Pfizer agreed to sell the MAs for Epanutin for the nominal sum of £1,⁴¹⁶ and to provide Flynn with certain sales and marketing know-how, medical information, and documents.⁴¹⁷ Flynn agreed to submit change of ownership applications to the MHRA for the transfer of the MAs: these applications were approved on 23 March 2012.⁴¹⁸ However, the Asset Sale Agreement provided that, upon expiry or in the event that the agreement was terminated for any reason, the MAs would be transferred back to Pfizer.⁴¹⁹

2.251.2. The **Exclusive Supply Agreement** dated 17 April 2012.⁴²⁰ This agreement had an initial term of three years.⁴²¹ Pfizer agreed to supply Flynn on an exclusive basis in the UK, and Flynn agreed not to purchase phenytoin sodium capsules from another source.⁴²² The Exclusive Supply Agreement specified supply prices and minimum order volumes, and provided for an annual price review.⁴²³ Notably, clause 18 of the Exclusive Supply Agreement contained a broad set of indemnities given to Flynn by Pfizer, which protected Flynn in the event that it was found liable due to failures by Pfizer in the manufacturing process.

⁴¹⁵ PHT00096, Signed Asset Sale Agreement of 27 January 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.241).

⁴¹⁶ [Pfizer Director 1]'s evidence was that the MA was transferred for £1 because Flynn preferred not to fund the value of the assets upfront; the commercial value of the deal to Pfizer was contained in the ongoing supply price paid by Flynn to Pfizer: PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 59.

⁴¹⁷ PHT00096, Signed Asset Sale Agreement of 27 January 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.241), Clauses 2, 4 and 5.

⁴¹⁸ PHT00096, Signed Asset Sale Agreement of 27 January 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.241), Clause 6; PHT00097; PHT00098; PHT00099; PHT00100, various correspondence dated 23 March 2012 between [MHRA Employee] MHRA and [Flynn Employee] Flynn re Grant/renewal of MAs for Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document references 00141.310; 00141.311; 00141.312; 00141.313).

⁴¹⁹ PHT00096, Signed Asset Sale Agreement of 27 January 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.241), Clause 10.1. [Pfizer Director 1] gave evidence that this clause was included so that if Flynn decided to leave the market for any reason, Pfizer 'could continue to sell the capsules provided the price was at a commercially viable level': PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 54.

⁴²⁰ PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.280).

⁴²¹ PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.280), Clause 22.1.

⁴²² PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.280), Clause 2.2.

⁴²³ PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.280), Clause 14 and Schedule 1 (product prices) and Schedule 3 (minimum order quantity).

2.251.3. The **Quality Technical Agreement** dated 11 June 2012.⁴²⁴ This Agreement set out Pfizer and Flynn's responsibilities in relation to quality assurance.

2.252 Pfizer's MAs terminated on 23 September 2012 and, outside of its supplies to Flynn, Pfizer stopped all supplies of *Epanutin* in the UK from this date.

2.253 On 24 September 2012, Flynn launched its products under the MHRA-approved product name 'Phenytoin Sodium Flynn Hard Capsules' and at supply prices significantly above those historically charged by Pfizer under the PPRS.⁴²⁵

2.254 In accordance with the communication plan agreed with the MHRA, Flynn wrote to healthcare professionals on 21 September 2012 explaining the name change and confirming that:

*...the Flynn Pharma product is identical to Epanutin. There are no differences in formulation and the site of manufacture remains unchanged. The capsules continue to contain the same identicode markings as Epanutin, including the word 'Epanutin'.*⁴²⁶

2.255 Pfizer and Flynn subsequently entered into two agreements amending the Exclusive Supply Agreement. The first, agreed on 12 February 2014, set out a revised set of supply prices (see paragraphs 2.302 and 2.307 below).⁴²⁷ The second, agreed on 20 April 2015, extended the term of the Exclusive Supply Agreement.⁴²⁸ On 27 August 2014, Pfizer and Flynn also agreed to delete the term in the Asset Sale Agreement that provided for the MAs to be transferred back to Pfizer upon termination of the agreement.⁴²⁹

d. Impact of the arrangements on the structure of supply

2.256 The arrangements entered into between Pfizer and Flynn had the effect of introducing a second dominant supplier into the supply chain,⁴³⁰ without the

⁴²⁴ PHT00102, Signed Quality Agreement for Supply of Phenytoin Capsules between Pfizer Limited, Pfizer Manufacturing Deutschland GmbH and Flynn Pharma Limited of 11 June 2012; Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.299).

⁴²⁵ On 2 May 2012 Flynn applied to the MHRA to change the name of Epanutin to 'Phenytoin Sodium Capsules'. The MHRA expressed concern regarding the potential for the name change to cause confusion, and as a result Flynn resubmitted its application with the proposed name 'Phenytoin Sodium Flynn Hard Capsules'. This resubmitted application was approved on 29 August 2012. See, for example, PHT00105, Approval Letter of 29 August 2012 from MHRA to [X] Flynn re Phenytoin Sodium Flynn 25mg Hard Capsules; Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.469).

⁴²⁶ PHT00226, Letter of 21 September 2012 from Flynn to Healthcare Professionals (MHRA) re Announcement on Changes to the Prescribing Availability of Epanutin Capsules (all strengths); Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.388).

⁴²⁷ PRC00379, Annex 03 (00505.37) Amendment to pricing terms for the supply of Phenytoin Capsules: Enclosed with Flynn's response of 10 August 2020 to the CMA's s.26 Notice dated 27 July 2020.

⁴²⁸ PRC00383, Annex 07 (Amendment to ESA 20.04.15): Enclosed with Flynn's response of 10 August 2020 to the CMA's s.26 Notice dated 27 July 2020.

⁴²⁹ PRC00381, Annex 05 (Amendment to ASA 27.08.14): Enclosed with Flynn's response of 10 August 2020 to the CMA's s.26 Notice dated 27 July 2020.

⁴³⁰ *Phenytoin* [2018] CAT 11, paragraph 253.

addition of relevant commercial activity or financial investment in that supply chain.⁴³¹

2.257 The Parties also envisaged that the arrangements themselves were likely to increase barriers to competition from parallel imports.

i. Route to market

2.258 Flynn's inclusion in the supply chain had a limited impact on the route to market for Capsules. In summary:

2.258.1. Prior to the arrangements with Flynn, phenytoin sodium capsules were manufactured by Pfizer in Germany and delivered to Pfizer's pre-wholesaler, [X], in the UK. The capsules were then distributed to pharmacies by [X], Pfizer's logistics service provider.⁴³²

2.258.2. Following Flynn's entry, Capsules continued to be manufactured by Pfizer in Germany and delivered to [X] in the UK. Flynn placed an order with Pfizer on a weekly basis, and that order was then processed and sent to [X].⁴³³ [X] stored the Capsules and delivered them to Flynn's customers.⁴³⁴ Flynn had no warehousing or delivery facilities, and it did not at any point take receipt of, or dispatch, the Capsules.

2.259 Besides Flynn placing orders for the product, the route to market for the supply of Capsules in the UK in the Relevant Period was largely identical to that which existed prior to September 2012.

2.260 Table 2.2 summarises the allocation of responsibilities between Pfizer, Flynn, and their distributors and wholesalers during the Relevant Period.

⁴³¹ See paragraph 2.264 below.

⁴³² PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013, Q1(iii) (CMA document reference 00086.1).

⁴³³ PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013, Q1(iii) (CMA document reference 00086.1).

⁴³⁴ PHT00107, Flynn's response of 7 April 2014 to the CMA's s.26 Notice of 5 March 2014, Q4.2 (CMA document reference 00505.1).

Table 2.2: Activities involved in supplying Capsules in the UK during the Relevant Period

	Pfizer	Flynn	Pre-wholesaler ([§])	Wholesalers
Manufacturing				
Purchasing API	✓			
Manufacturing	✓			
Packaging	✓			
Delivery to UK pre-wholesaler	✓			
Supply to pre-wholesaler				
Ordering from supplier		✓		
Processing orders	✓			
Delivery to customer	✓			
Invoicing	✓			
Receipt of goods			✓	
Storage			✓	
Supply to wholesalers				
Ordering from supplier				✓
Processing orders			✓	
Delivering to customer			✓	
Invoicing			✓	
Receipt of goods				✓
Storage				✓
Supply to pharmacies and hospitals				
Processing orders				✓
Delivering to customer				✓
Invoicing				✓
Marketing and promotion				
Communications to customers (prescribers, pharmacists, patients)		✓		
Customer support (one clinical nurse)		✓		
Marketing and promotion (generics manager)		✓		
Licensing and compliance				
Regulatory compliance		✓		

2.261 Flynn and Pfizer have confirmed the accuracy of this summary table (although Flynn has previously submitted that only including one line for ‘regulatory compliance’ does not properly reflect the full extent of Flynn’s legal obligations as the MA holder).⁴³⁵

⁴³⁵ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 14, line 16, to page 15, line 18 ([Pfizer Director 1] confirmed the position insofar as it related to Pfizer only); PAD00031, [Flynn Director 2] Cross Examination, day 4, page 179, lines 2-18, and PHT00228, Flynn’s response of 2 March 2016 to Questions 1 and 4 of the CMA’s s.26 Notice of 17 February 2016 (CMA document reference 01790.1). Flynn made further representations regarding its risks and responsibilities as an MA holder which are set out along with the CMA’s response in Annex E.

ii. Financial risk

- 2.262 Flynn incurred very little financial risk in relation to the role it performed in the supply chain. Although the Exclusive Supply Agreement required Flynn to purchase minimum order volumes, these were a small fraction of Flynn's average monthly orders, and Flynn was able to rely on an established patient base to purchase these volumes.⁴³⁶ Aside from product purchase and distribution costs, Flynn's other specific costs in relation to Capsules were limited to marketing activity and customer management.
- 2.263 The CMA has assessed the pharmacovigilance activities that Flynn carried out for Capsules: these are primarily administrative in nature, and do not create any abnormally high commercial or legal risk. Further, as noted above, the Exclusive Supply Agreement contains a broad indemnity protecting Flynn in respect of failures in the manufacturing process, which would otherwise be one of the key sources of risk for Flynn.
- 2.264 In the proceedings before the CAT, Flynn denied that its commercial activities were limited and its level of risk low. The CAT's view supports the CMA's position set out above relating to Flynn's limited commercial activity, its limited business and regulatory risk, and its very high degree of confidence in selling the product to an established and largely captive user base. The CAT's judgment states:⁴³⁷

We prefer the CMA's view. Flynn took over an established product and undertook only very limited commercial activity. Admittedly it held levels of stock to keep the market supplied and appears to have explored the possibility, without success, of establishing an alternative source of supply to Pfizer. However, the contractual indemnity, together with the terms of the Exclusive Supply Agreement, in the context of Continuity of Supply

and the established user base and distribution arrangements, provided a very substantial degree of comfort to Flynn and meant that it was taking very little business risk. Flynn's involvement in these arrangements was not to provide risk-taking or significant commercial activity. Continuity of Supply meant that its customer base in the UK was to a significant degree guaranteed.

iii. Parallel imports

- 2.265 A number of documents created during the negotiations between Pfizer and Flynn refer to the design of the arrangements – specifically the transfer of the MA to Flynn – having the effect of further raising barriers to competition from parallel imports.

⁴³⁶ *Phenytoin* [2018] CAT 11, paragraph 346.

⁴³⁷ *Phenytoin* [2018] CAT 11, paragraph 346.

- 2.266 As noted at paragraph 2.225 above, a version of Flynn's initial slide presentation to Pfizer identified parallel imports as a 'potential issue' and went on to set out a list of options which it described as 'the strategic options in preventing parallel imports to the UK'⁴³⁸ (emphasis added).
- 2.267 In the final slide deck presented to Pfizer in July 2010, the list of strategic options listed in this slide remained the same. However, the slide was re-titled and described these options as 'strategic options which Pfizer could adopt to help prevent stock-out situations in lower-priced markets'.⁴³⁹
- 2.268 Following a request from Pfizer for a more detailed proposal from Flynn, on 29 October 2010 Flynn provided Pfizer with a briefing document, a frequently asked questions document and responses to certain questions received from Pfizer's lawyers. Both the briefing document and the frequently asked questions document refer to the impact of the proposed arrangements in raising barriers to parallel imports:

*A price increase in the UK would lead to potential parallel imports from other EU markets, subject to local availability. Assignment of the trademark to Flynn in the UK would mean that parallel imports would risk infringing Flynn's trademark.*⁴⁴⁰

*Transfer of the Trademark to Flynn would act as a further barrier to imports and sale of stock branded as Epanutin.*⁴⁴¹

- 2.269 In December 2010, [Pfizer Employee 2] of Pfizer sent an email to Flynn in which he referred to Pfizer's ability to manage parallel imports through its control over supply in the EU. [Pfizer Employee 2] also asked whether Flynn had any 'further tactics' to manage the issue created by parallel imports:

*The braider [sic] area is still one regarding parallel trade and as long as we have a level of control over supply we can manage this. Do you have any further tactics to add which would help manage the supply challenges across the EU?*⁴⁴²

⁴³⁸ PHT00162, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013, Slide 11 (CMA document reference 00145.91).

⁴³⁹ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013, Slide 10 (CMA document reference 00145.27).

⁴⁴⁰ PHT00193, 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013, Page 4 (CMA document reference 00145.65).

⁴⁴¹ PHT00194, 'Flynn Pharma Epanutin Proposal October 2010 – FAQs', Q6(b): Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.66).

⁴⁴² PHT00195, Email of 27 January 2011 from [Flynn Employee 1] Flynn to [Pfizer Employee 2] Pfizer re What do we need to do next: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.87).

- 2.270 By reference to strategic options described by Flynn in the slide deck presented to Pfizer, the Parties ultimately adopted the first of these, to '[c]hange MA Holder in the UK & Ireland to Flynn and add a Flynn mark to the capsule'.⁴⁴³
- 2.271 Previously, parallel importers were able to import *Epanutin* into the UK and compete with Pfizer by marketing and selling their product under the brand name *Epanutin*. Parallel imports of *Epanutin* could previously be used to fulfil both open prescriptions and closed prescriptions written specifically for Pfizer's Epanutin product.
- 2.272 Following the assignment of Pfizer's MA to Flynn, and the re-naming of the product to 'Phenytoin Sodium Flynn Hard Capsules', Flynn registered the word 'Flynn' as a trademark. As envisaged by Flynn in its briefing document for Pfizer, this allowed Flynn to enforce its trademark rights against any parallel importers using the Flynn name. Flynn was subsequently successful in enforcing its trademark rights against parallel importers in the UK courts.⁴⁴⁴ The result was that parallel importers of *Epanutin* were no longer able to compete to fulfil closed prescriptions for existing patients being treated with Pfizer's product.
- 2.273 When questioned by the CAT, [Flynn Director 2] denied that Flynn had taken any action to prevent parallel imports.⁴⁴⁵ In relation to the trademark litigation, [Flynn Director 2] explained that Flynn was concerned to stop parallel importers using the Flynn trademark, in part because it was not 'fair or right' for Flynn's name to be associated with products in relation to which it had no control over the manufacture and quality control process.⁴⁴⁶
- 2.274 The Parties were aware that following the price rises the attractiveness of the UK market for sales by parallel importers would rise materially. However, notwithstanding this, Flynn's initial presentation to Pfizer stated that (i) there should be no impact from parallel imports on sales of 25mg, 50mg and 300mg capsules in the UK which 'alone could be worth £15m'; and (ii) that, even if 50% of sales of 100mg capsules were lost to parallel imports 'the upside would still be >£20m'.⁴⁴⁷
- 2.275 In practice, the precise impact of the structure of the arrangements in raising barriers to competition from parallel imports is not clear. However, the potential for the arrangements to make it more difficult for parallel imports to compete with Flynn was explicitly envisaged by and discussed between the Parties when agreeing the design of the arrangements. Ultimately, during the Relevant Period,

⁴⁴³ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company', Slide 10: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.27).

⁴⁴⁴ *Flynn Pharma Limited v Drugsrus Limited* [2015] EWHC 2759; and *Flynn Pharma Limited v Drugsrus Limited* [2017] EWCA Civ 226.

⁴⁴⁵ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 187, line 23, to page 188, line 5.

⁴⁴⁶ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 188, line 15, to page 190, line 2.

⁴⁴⁷ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company', Slide 11: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.27).

parallel importers were unable to exert any meaningful competitive constraint on Flynn.⁴⁴⁸

- 2.276 Regarding the other 'strategic options' presented by Flynn to Pfizer for the purposes of 'preventing parallel imports to the UK' (see paragraph 2.225 above), the CMA has no further evidence as to whether any of these additional strategies were adopted by Pfizer.

II. The price increases

- 2.277 This section provides an overview of the significant price increases imposed by both Pfizer and Flynn pursuant to the arrangements described above.

a. Prices for Epanutin prior to September 2012

- 2.278 Prior to the arrangements with Flynn, Pfizer's list prices for Capsules had been stable for many years.
- 2.279 Prior to September 2012, and at least since January 2003, the Drug Tariff prices for Capsules had remained the same.⁴⁴⁹ The Drug Tariff prices for 25mg and 50mg capsules were £0.66 and £0.67 respectively, and for 100mg and 300mg capsules were both £2.83.⁴⁵⁰
- 2.280 In the period March 2004 until September 2012, Pfizer's ASPs for the supply of Capsules were £0.51 for 25mg capsules, £0.52 for 50mg capsules, £2.21 for 100mg capsules, and £2.20 for 300mg capsules.⁴⁵¹
- 2.281 The agreement between Pfizer and Flynn then led to significant increases in the supply prices of Capsules.

b. Flynn's request for a price increase within the PPRS was rejected

- 2.282 The DHSC was not aware of the arrangements between Pfizer and Flynn until 21 June 2012, when the MHRA contacted the DHSC to inform it of Flynn's acquisition of the MA for *Epanutin* and Flynn's proposal to de-brand the product.⁴⁵² Following this contact from the MHRA, the DHSC contacted Pfizer on the same day to

⁴⁴⁸ [Flynn Director 1] of Flynn noted that the supply of Capsules available to parallel importers was limited and 'spasmodic': PAD00031, [Flynn Director 2] Cross Examination, day 4, page 109, lines 4 to 12 and see also *Phenytoin* [2018] CAT 11, paragraphs 248 to 249 and 251.

⁴⁴⁹ PHT00163, Annex 3 to Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.2).

⁴⁵⁰ At this point in time, phenytoin sodium capsules were manufactured and distributed by Pfizer and the product fell under the PPRS.

⁴⁵¹ Based on sales value and volume data for the period March 2004 until September 2012 (excluding September 2012 sales by Pfizer to Flynn). These ASPs refer to the prices charged by Pfizer to wholesalers and/or pharmacists.

⁴⁵² PHT00041, Email chain dated 26 June - 21 June 2012 between various Department of Health staff regarding 'Epanutin - proposed removal of the trade name': Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.3).

request details of the divestment to Flynn.⁴⁵³ Later, on 3 July 2012, Flynn emailed the DHSC to request a meeting.⁴⁵⁴

2.283 On 18 July 2012, Flynn met with the DHSC. At the meeting, Flynn advised the DHSC that Flynn:

*felt that the company had two options available to them. They could genericise the product or alternatively, if they were awarded an increase on the current price of Epanutin capsules, they could create their own brand e.g. EpaFlynn.*⁴⁵⁵

2.284 If re-branding *Epanutin*, Flynn proposed launching the product at 25-30% below the Drug Tariff price of Tablets.⁴⁵⁶ If sold generically, Flynn suggested it would price the product at 10-20% below the Drug Tariff price of Tablets.⁴⁵⁷

2.285 At the meeting, the DHSC:

*confirmed that when looking at pricing of new products, some of the factors the Pricing [sic] Committee would consider is the effect on the drugs bill and the prices of comparable products. Whilst DH acknowledged the need for this product to remain on the market, DH expressed the difficulties in agreeing to a launch price that was significantly higher than [the prevailing price of] Epanutin.*⁴⁵⁸

2.286 The DHSC advised Flynn to submit a product launch application for the PPRS Pricing Committee to review.⁴⁵⁹

2.287 On 26 July 2012, the PPRS Pricing Committee considered Flynn's informal proposal from the meeting on 18 July 2012 to increase the price of *Epanutin* within the PPRS. The committee discussed whether Flynn qualified for any large price increase under the terms of the PPRS and the cost implications to the NHS of any

⁴⁵³ PHT00042, Email of 21 June 2012 from [DHSC Employee 8] Department of Health to [Pfizer Employee] Pfizer re Epanutin Divestment?: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.4); and see also *Phenytoin* [2018] CAT 11, paragraph 62.

⁴⁵⁴ PHT00227, Internal Flynn email chain of 4 July 2012 [from [Flynn Director 1] to [Flynn Director 2]] re Potential Supply Issue of Epanutin® Capsules and discussions with DH: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.322); and see also *Phenytoin* [2018] CAT 11, paragraph 63.

⁴⁵⁵ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.9), page 1, paragraph 5; and see also *Phenytoin* [2018] CAT 11, paragraphs 63 and 214.

⁴⁵⁶ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.9), page 1, paragraph 8.

⁴⁵⁷ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.9), page 1, paragraph 8 and see also *Phenytoin* [2018] CAT 11, paragraph 214.

⁴⁵⁸ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.9), page 2, paragraph 9.

⁴⁵⁹ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.9), page 1, paragraph 7.

large price increase. The committee decided there was no provision within the PPRS for the type of price increase envisaged by Flynn.⁴⁶⁰

2.288 The DHSC then emailed Flynn to inform it that, under the terms of the PPRS, the DHSC could not agree to Flynn's informal PPRS pricing proposal.⁴⁶¹

2.289 On 31 July 2012, Flynn responded to confirm that it would submit a name change variation application for *Epanutin* to the MHRA.⁴⁶²

2.290 Flynn then 'de-branded' Capsules and withdrew the products from the PPRS, meaning they were no longer subject to any form of profit control. From 24 September 2012, Flynn distributed the products under the name 'Phenytoin Sodium Flynn Hard Capsules' at a supply price significantly above the price historically charged by Pfizer under the PPRS. The Drug Tariff price paid by the NHS was consequently set by reference to Flynn's list price, significantly increasing the costs of the drug to CCGs purchasing similar volumes of the same products.⁴⁶³

c. Prices investigated by the CMA

2.291 The CMA's investigation relates to the following prices in the period from 24 September 2012 to 7 December 2016:

2.291.1. Pfizer's prices for the supply of Capsules to Flynn; and

2.291.2. Flynn's prices for the supply of Capsules to wholesalers and pharmacies. Flynn's Products are sold at different prices to different pharmacies and wholesalers and these prices vary across time. The CMA has therefore assessed Flynn's pricing on the basis of its ASPs (ie the average actual prices at which Flynn sold Flynn's Products to pharmacies and wholesalers, which is a discount to the Drug Tariff prices).

2.292 The CMA's investigation covers all strengths of phenytoin sodium capsules sold by Pfizer and Flynn, ie 25mg, 50mg, 100mg and 300mg capsules.

2.293 The CMA has also had regard to the category C Drug Tariff prices for phenytoin sodium capsules. These prices (less any clawback discount) determine the reimbursement paid to pharmacies for drugs they dispense. The Drug Tariff prices

⁴⁶⁰ PHT00070, DHSC, *Pricing Committee Meeting of 26 July 2012 – unconfirmed minutes* (CMA document reference 01904.3) and see also *Phenytoin* [2018] CAT 11, paragraph 214.

⁴⁶¹ PHT00051, Email of 26 July 2012 from [DHSC Employee] Department of Health to [Flynn Director 4] Flynn re Epanutin Capsules: Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.13); and see also *Phenytoin* [2018] CAT 11, paragraph 63.

⁴⁶² PHT00113, Email chain of 31 July 2012 between [Flynn Director 4] Flynn and [DHSC Employee] Department of Health responding to the Department of Health and acknowledging receipt of their email re the PPRS rules and that Flynn will be submitting their variation application: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.343).

⁴⁶³ Flynn submitted that de-branding Capsules involved Flynn making an application to the DHSC to assign the generic phenytoin capsules a reimbursement price: PRC03492, Flynn's response to the SO, paragraph 2.16. However, the Drug Tariff price for Capsules was determined by reference to Flynn's list price. The notification of the changed list price was not, therefore, an application that required in any sense approval of Flynn's prices.

for phenytoin sodium capsules are determined by reference to the list prices set by Flynn.⁴⁶⁴ They are the prices that CCGs (ie the NHS) ultimately pay.⁴⁶⁵

2.294 In this section all prices refer to the price of a single pack of Capsules.⁴⁶⁶

2.295 As explained in paragraph 2.278 above, prior to the arrangements with Flynn, Pfizer's list prices for Capsules had been stable for many years. Prior to September 2012, and since at least January 2003, the Drug Tariff prices for 25mg and 50mg capsules were £0.66 and £0.67 respectively, and for 100mg and 300mg capsules were both £2.83.⁴⁶⁷

2.296 The Parties chose the Drug Tariff price of Tablets as their reference point for the increases to their selling prices of Capsules. The price paid by the NHS for Tablets formed the basis of the negotiations between the Parties regarding their pricing of Capsules.⁴⁶⁸

2.297 Teva, as the monopoly supplier of Tablets, had increased its selling prices a number of times leading to an increase in the Drug Tariff price of Tablets from £1.70 in March 2005 to £113.62 by October 2007, before the Drug Tariff price dropped to £30 where it remained at the time of the negotiations between Pfizer and Flynn.⁴⁶⁹ The relevant factual background surrounding the pricing of Tablets is set out in section 6.C.

d. Significant increases in Pfizer's prices

2.298 During the Relevant Period, Pfizer's ASPs for Capsules were between 783% and 1,603% higher than its prices prior to entering into the arrangements with Flynn, and 1,603% higher for 100mg capsules (which by a significant margin contributed the most revenue from Pfizer's sales of Capsules).

2.299 Table 2.3 below shows Pfizer's ASPs for each capsule strength during the Relevant Period.

2.300 Table 2.4 below shows the percentage change in Pfizer's ASPs for each capsule strength relative to Pfizer's pre-September 2012 ASP.

⁴⁶⁴ As phenytoin sodium capsules fell within Category C of the Drug Tariff during the Relevant Period, reimbursement prices were determined by reference to a proprietary product. The proprietary products for phenytoin sodium capsules were Flynn's products and, as such, the Drug Tariff prices for phenytoin sodium capsules were determined by reference to Flynn's list prices.

⁴⁶⁵ Subject to any clawback by the NHS.

⁴⁶⁶ 84 capsules for 100mg capsules and 28 capsules for all other capsule strengths.

⁴⁶⁷ PHT00163, Annex 3 to Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.2). At this point in time, phenytoin sodium capsules were manufactured and distributed by Pfizer and the product fell under the PPRS.

⁴⁶⁸ See for example paragraphs 2.221 and 2.249.

⁴⁶⁹ PHT00040, Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.2), Q12, pages 14 to 15.

Table 2.3: Pfizer's ASPs for Capsules

	Pre-September 2012	Relevant Period	September 2012 to December 2013*	March 2014 to 7 December 2016
25mg	£0.51	£4.50	£4.50	£4.50
50mg	£0.52	£6.71	£7.03	£6.53
100mg	£2.21	£37.56	£40.94	£34.21
300mg	£2.20	£37.01	£41.72	£34.40

* Pfizer and Flynn renegotiated the Exclusive Supply Agreement in February 2014. A rebate was provided by Pfizer to Flynn in February 2014, but this was backdated to 1 January 2014.⁴⁷⁰ Therefore, the CMA has estimated the rebate which was provided by Pfizer to Flynn for sales which were made prior to December 2013. This rebate has been calculated by comparing Pfizer's actual revenue for each capsule strength in January and February 2014 to the revenue Pfizer would have received had those sales been made at Pfizer's ASPs for the period March-December 2014. The difference is then used as the estimate of the rebate provided by Pfizer to Flynn for sales made prior to 31 December 2013. The CMA has estimated the total value of this rebate to be £969,000.

Notes:

1. All calculations are based on the sales value and sales volume data submitted by Pfizer, see PHT00138, Pfizer's response of 26 August 2016 to the CMA's s.26 Notice of 2 August 2016 (CMA document reference 02129.2), Annex 1 and PRC00491, Pfizer's response of 11 September 2020 to the CMA's s.26 Notice of 12 August 2020, Annex 4.
2. Pre-September 2012 ASPs are based on sales value and volume data for the period March 2004 until September 2012 (excluding September 2012 sales by Pfizer to Flynn). These ASPs refer to the prices charged by Pfizer to wholesalers and/or pharmacists.
3. Post-September 2012 ASPs are based on sales and volumes data for Pfizer's sales to Flynn for the period September 2012 until 7 December 2016.
4. The CMA has not been able to include ASPs for Pfizer for January and February 2014 as Pfizer's sales value figures (which are used to calculate ASPs) submitted to the CMA for these months are net of the rebate that Pfizer paid to Flynn and therefore any ASP calculated would not be meaningful.
5. The unadjusted (ie without a rebate adjustment) figures for the period September 2012 to December 2013 are: £4.50, £7.08, £42.50 and £42.50 for the 25mg, 50mg, 100mg, and 300mg capsule strengths respectively. These unadjusted prices are those dictated under the Exclusive Supply Agreement after the supply prices were amended to account for a delay in Flynn obtaining an MA variation.⁴⁷¹

⁴⁷⁰ PHT00115, Email chain of 28 February 2014 between [Flynn Director 2] Flynn and [Pfizer Employee] Pfizer re Stock Discussion and Pfizer agreeing to a price reduction retrospectively for stock held by Flynn as at 31 December 2013: Annex 26h of Flynn's response of 7 April 2014 to the OFT's s.26 Notice of 5 March 2014 (CMA document reference 00505.48).

⁴⁷¹ PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013, pages 11-12 (CMA document reference 00086.1).

Table 2.4: Pfizer's ASPs for Capsules – percentage changes relative to Pfizer's pre-September 2012 ASP

	Pre-September 2012	Relevant Period	September 2012 to December 2013	March 2014 to 7 December 2016
25mg	£0.51	783%	783%	783%
50mg	£0.52	1,185%	1,246%	1,150%
100mg	£2.21	1,603%	1,756%	1,451%
300mg	£2.20	1,584%	1,798%	1,465%

Notes:

CMA's own calculations based on Table 2.3 above.

The ASPs presented in Table 2.3 have been presented to two decimal places; the percentage increases in Table 2.4 have been calculated using data that has not been rounded.

2.301 Table 2.4 shows that Pfizer's ASPs for all dosage strengths were significantly higher after September 2012 compared to prior to September 2012.

2.302 In February 2014, Pfizer and Flynn revised the Exclusive Supply Agreement and agreed new supply prices for 50mg, 100mg and 300mg capsules.⁴⁷² These lower supply prices were backdated to 1 January 2014 as 'a one-off concession due to the enhanced stockholdings that you [Flynn] have built'.⁴⁷³ Thus, a rebate was provided by Pfizer to Flynn in February 2014 which covered some sales which were made by Pfizer to Flynn prior to 1 January 2014. In calculating the ASPs for the period September 2012 to December 2013, the CMA has estimated the value of the rebate provided by Pfizer for sales made prior to 1 January 2014 and has adjusted the sales value data provided by Pfizer accordingly.⁴⁷⁴

2.303 Pfizer's ASPs for 50mg, 100mg and 300mg capsules were lower between March 2014 and December 2016 (the period following the agreed reduction in Pfizer's supply price) relative to the preceding period, September 2012 to December 2013. However, Pfizer's ASPs for this later period (March 2014 to December 2016) remained significantly above the ASPs which prevailed prior to September 2012.

e. Flynn's prices

2.304 During the Relevant Period, Flynn's ASPs were between 2,366% and 2,682% higher than Pfizer's supply prices prior to entering into the arrangements with

⁴⁷² PHT00116, Letter of 19 January 2014 from Pfizer's legal team to the OFT informing them that Pfizer and Flynn have agreed a new supply price in relation to Phenytoin capsules and attaching a copy of the new letter agreement (CMA document reference 00476.1). Under the revised Exclusive Supply Agreement, the agreed supply prices were: £4.50 for 25mg capsules, £6.50 for 50mg capsules, and £34 for 100mg and 300mg capsules. The CMA understands that the change in the price for 50mg capsules reversed an uplift which was originally applied to compensate Pfizer following the delays Flynn faced introducing their products: PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.1). See also *Phenytoin* [2018] CAT 11, paragraphs 100 and 166.

⁴⁷³ PHT00115, Email chain of 28 February 2014 between [Flynn Director 2] Flynn and [Pfizer Employee] Pfizer re Stock Discussion and Pfizer agreeing to a price reduction retrospectively for stock held by Flynn as at 31 December 2013: Annex 26h of Flynn's response of 7 April 2014 to the OFT's s.26 Notice of 5 March 2014 (CMA document reference 00505.48).

⁴⁷⁴ See notes to Table 2.3 above.

Flynn, and 2,366% higher for 100mg capsules (which contributed by far the most revenue from Flynn's sales compared to other Capsule strengths).

- 2.305 Table 2.5 below shows Flynn's ASPs to wholesalers and pharmacies. Pfizer's pre-September 2012 ASPs to wholesalers and pharmacies (ie the same customers as those supplied by Flynn post-September 2012) are also included for comparison and context.
- 2.306 Table 2.6 below presents the percentage change in Flynn's ASPs for each capsule strength relative to Pfizer's pre-September 2012 ASP. Flynn's ASPs since September 2012 have significantly exceeded the prices charged by Pfizer to the same customer base for the period prior to September 2012.
- 2.307 As set out above at paragraph 2.302, the Parties agreed new supply prices from Pfizer to Flynn in February 2014 which were backdated to 1 January 2014, and Pfizer provided a rebate to Flynn in February 2014. Flynn did not reduce its ASPs for 100mg and 300mg capsules until April 2014 and did not backdate its prices to customers to reflect the rebate received from Pfizer. Notwithstanding the price reduction in April 2014, Flynn's ASPs for 100mg and 300mg capsules in the period April 2014 to January 2017 remained significantly above the ASPs which prevailed prior to September 2012.
- 2.308 In May 2014, Flynn moved to a Reduced Wholesaler Model ('RWM') and decreased the standard discounts it offered wholesalers from the Drug Tariff price.⁴⁷⁵ As a result, Flynn increased its ASPs for 25mg and 50mg capsules to wholesalers compared to its ASPs in September 2012 to March 2014. The Drug Tariff prices were unaffected.

⁴⁷⁵ PHT00075, Flynn's response of 10 October 2014 to the CMA's s.26 Notice dated 15 September 2014, page 5 (CMA document reference 00872.1), and *Phenytoin* [2018] CAT 11, paragraph 176.

Table 2.5: Flynn's ASPs for Capsules

	Pfizer's ASPs Pre-September 2012	Flynn's ASPs Relevant Period	Flynn's ASPs September 2012 to March 2014	Flynn's ASPs May 2014 to 7 December 2016
25mg	£0.51	£14.19	£13.83	£14.45
50mg	£0.52	£14.40	£14.10	£14.64
100mg	£2.21	£54.40	£59.53	£48.93
300mg	£2.20	£55.21	£59.32	£52.57

Notes:

All calculations are based on sales value and sales volume data provided by Flynn, see PHT00145 (CMA document reference 00505.22), PHT00146 (CMA document reference 01148.2), PHT00147 (CMA document reference 01148.3), PHT00149 (CMA document reference 01839.13), PHT00152 (CMA document reference 01293.2), PHT00155 (CMA document reference 00872.3), PHT00156 (CMA document reference 00915.1), PHT00150 (CMA document reference 02115.2) and PRC00488, Flynn's response of 11 September 2020 to the CMA's s.26 Notice of 21 August 2020, Annex 1.

Flynn adjusted its prices in April 2014 and then moved to an RWM from May 2014. The move to an RWM involved a reduction in the discount wholesalers were provided from the Drug Tariff prices for Flynn's Products and led to an increase in Flynn's ASPs since May 2014 relative to those for April 2014. Flynn's ASPs for April 2014 are not included in Table 2.5 as Flynn's prices changed during this month; however, they were: £13.79, £14.01, £48.04 and £51.08 for the 25mg, 50mg, 100mg and 300mg capsules respectively.

Table 2.6: Flynn's ASPs for Capsules – percentage changes relative to Pfizer's pre-September 2012 ASP

	Pfizer Pre- September 2012	Relevant Period	September 2012 to March 2014	May 2014 to December 2016
25mg	£0.51	2,682%	2,612%	2,734%
50mg	£0.52	2,656%	2,599%	2,701%
100mg	£2.21	2,366%	2,598%	2,118%
300mg	£2.20	2,412%	2,599%	2,291%

Notes:

CMA's own calculations based on Table 2.5 above.

The ASPs presented in Table 2.5 have been presented to two decimal places; the percentage increases in Table 2.6 have been calculated using data that has not been rounded.

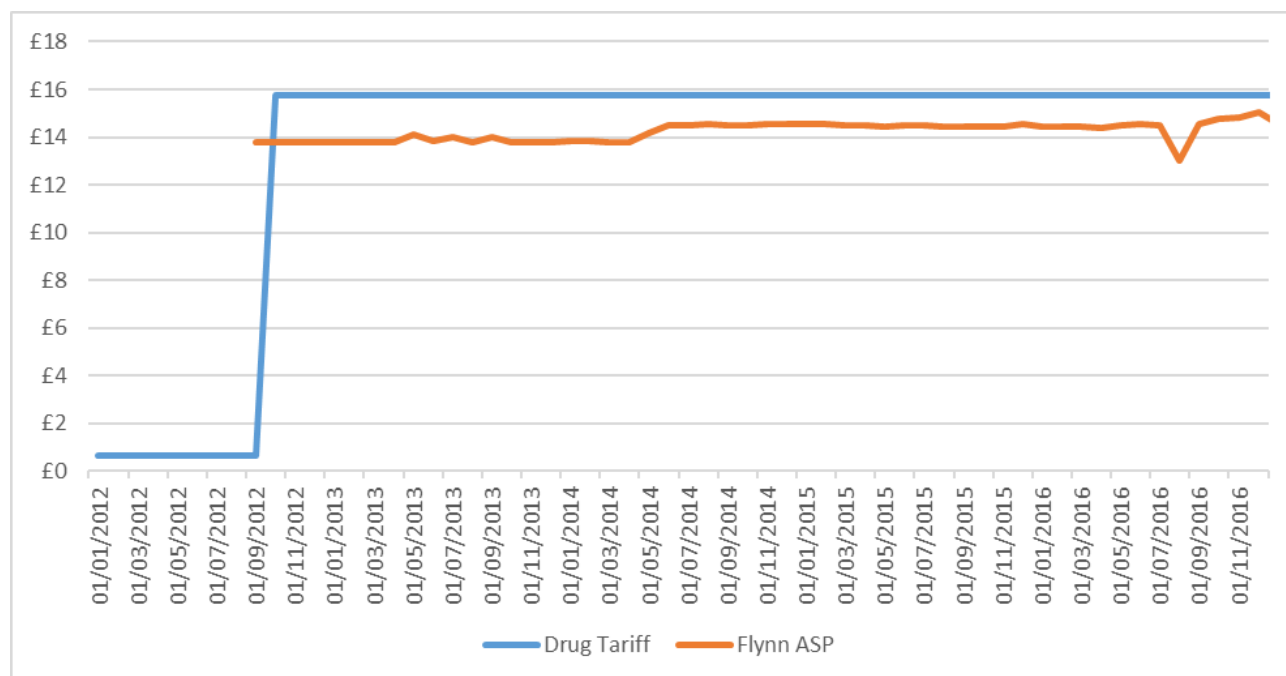
2.309 Figures 2.4 to 2.7 below show the evolution of Flynn's ASPs, as well as the Drug Tariff prices for 25mg, 50mg, 100mg, and 300mg capsules respectively.⁴⁷⁶

⁴⁷⁶ The CMA has included Figures 2.4 to 2.7 to illustrate the evolution of Flynn's ASPs and the discount from the Drug tariff that these ASPs represented (this is relevant to Flynn but not to Pfizer's ASPs and so this is not shown in the paragraphs describing Pfizer's ASPs above). The CMA does not present similar graphs for Pfizer above because Pfizer supplies to Flynn directly and not to pharmacies and wholesalers.

i. 25mg capsules

2.310 As Figure 2.4 shows, between September 2012 and March 2014, Flynn's monthly ASPs for 25mg capsules were stable, fluctuating only between £13.76 and £14.08, and Flynn's ASP for 25mg capsules for this period was £13.83.

Figure 2.4: 25mg capsules Flynn monthly ASP and Drug Tariff price

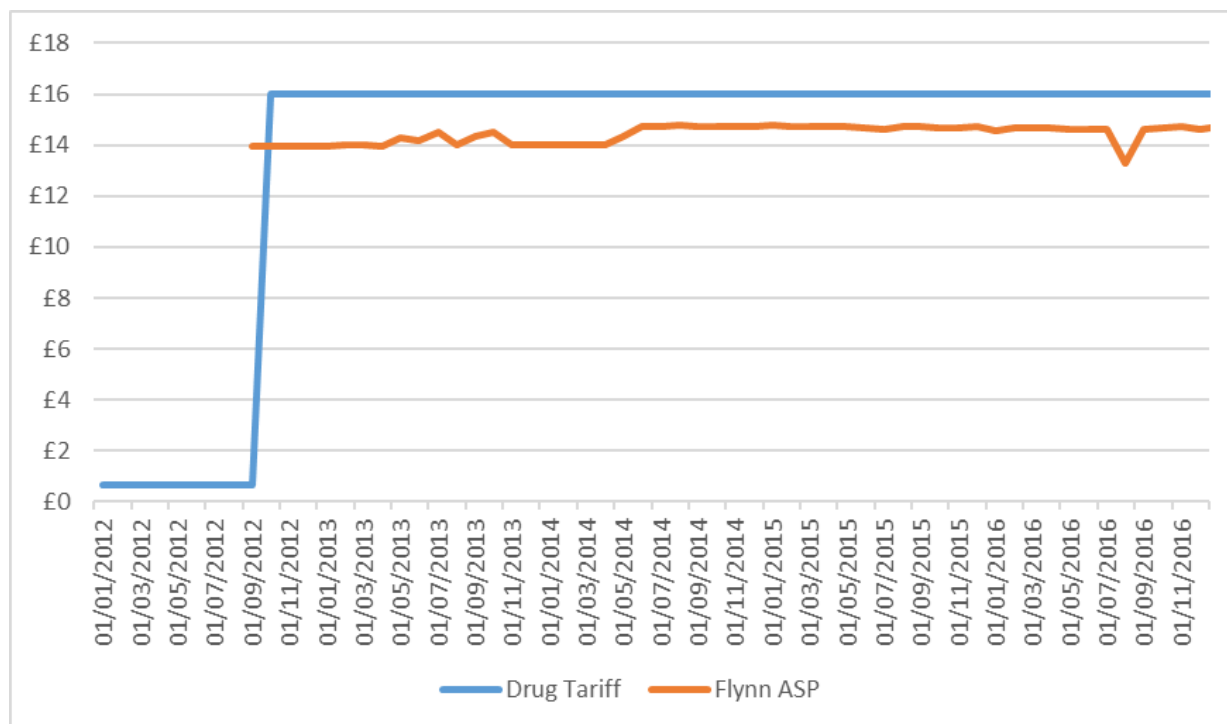


2.311 In May 2014, Flynn moved to an RWM and consequently reduced the standard discount from the Drug Tariff price which it had offered to wholesalers and pharmacies. This is reflected in the increase in Flynn's monthly ASP for 25mg capsules from May 2014. Between May 2014 and December 2016, Flynn's monthly ASPs for 25mg capsules fluctuated between £13.01 and £15.05, and Flynn's ASP for 25mg capsules for this period was £14.45.

ii. 50mg capsules

2.312 As Figure 2.5 shows, between September 2012 and March 2014, Flynn's monthly ASPs for 50mg capsules were stable, fluctuating between £13.97 and £14.50, and Flynn's ASP for 50mg capsules for this period was £14.10.

Figure 2.5: 50mg capsules Flynn monthly ASP and Drug Tariff price

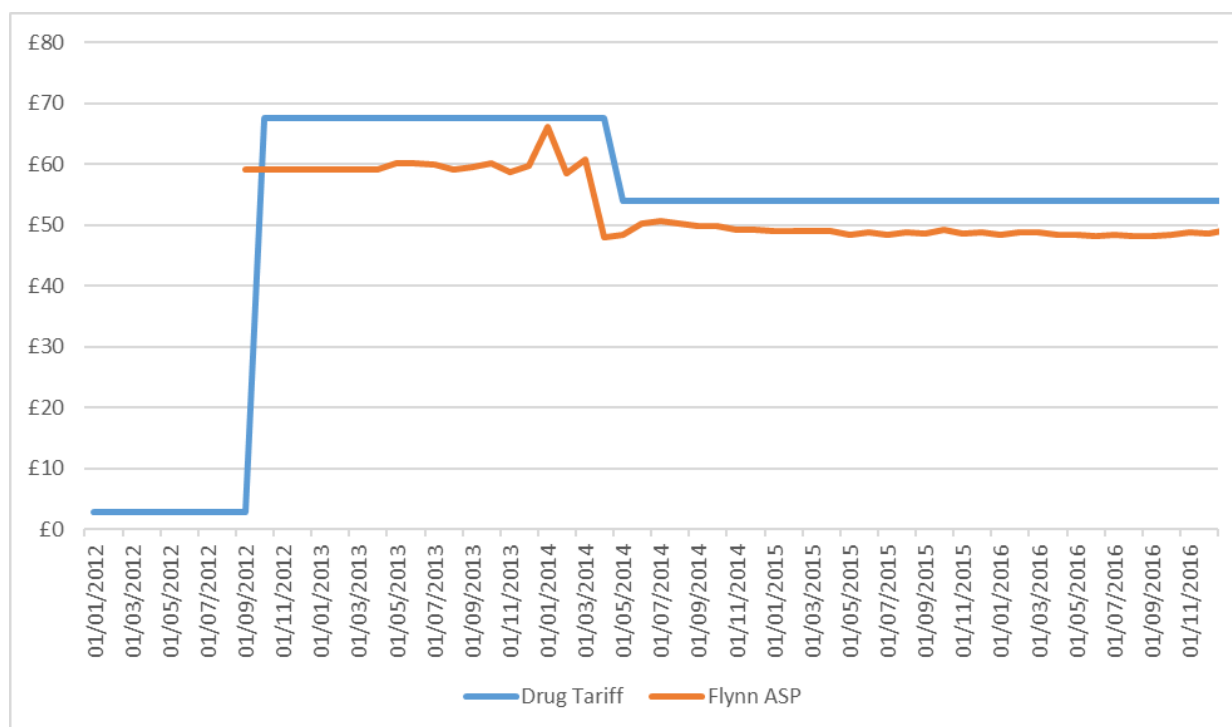


2.313 Flynn's monthly ASP for 50mg capsules then increased following Flynn's switch to an RWM in May 2014. Between May 2014 and December 2016, Flynn's monthly ASPs for 50mg capsules fluctuated between £13.32 and £14.78. Flynn's ASP for 50mg capsules for the period May 2014 until 7 December 2016 was £14.64.

iii. 100mg capsules

2.314 As Figure 2.6 shows, between September 2012 and March 2014, Flynn's monthly ASPs for 100mg capsules fluctuated between £58.43 and £66.09, and Flynn's ASP for 100mg capsules for this period was £59.53.

Figure 2.6: 100mg capsules Flynn monthly ASP and Drug Tariff price



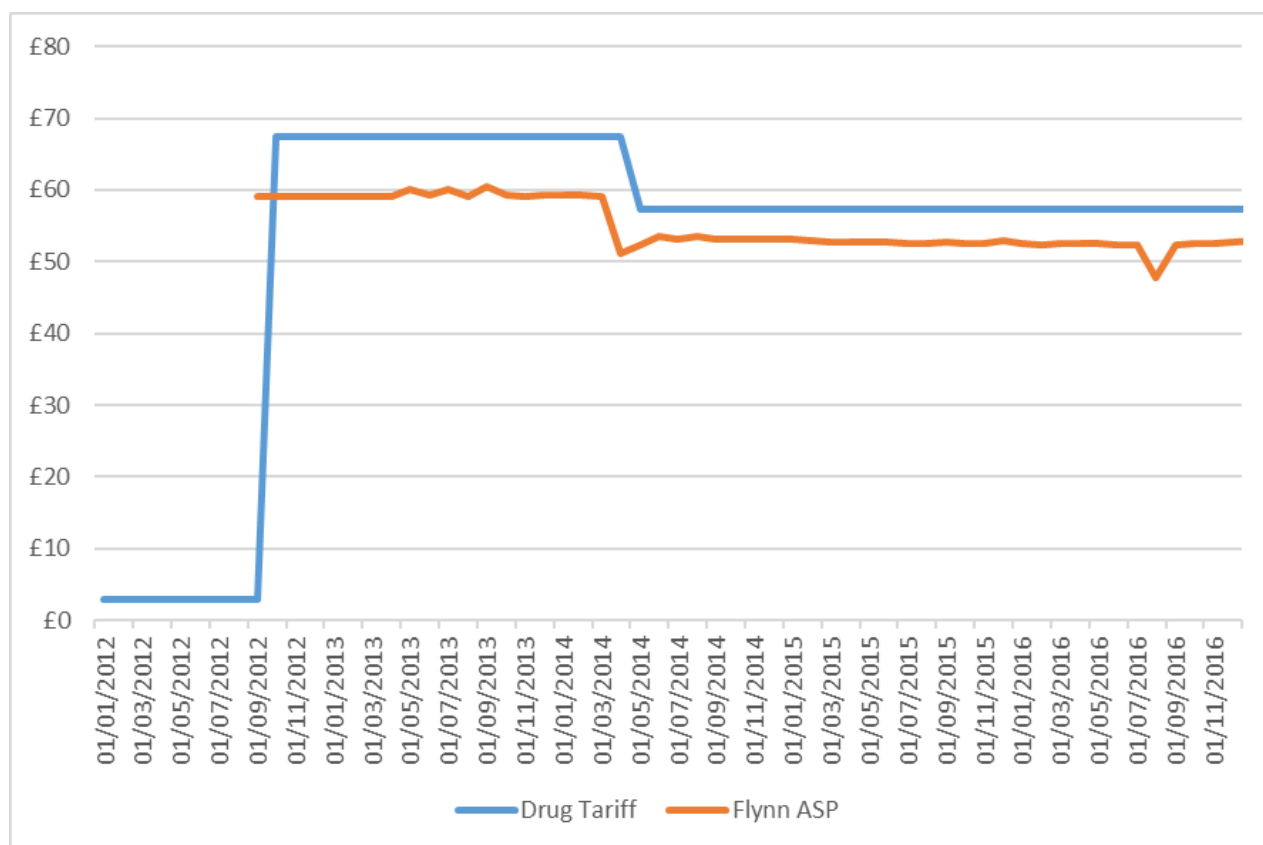
2.315 In April 2014, Flynn reduced its price for 100mg capsules and the Drug Tariff price fell. As a result, Flynn's ASP for 100mg capsules fell to £48.04 in April 2014.

2.316 However, Flynn then moved to an RWM in May 2014 which led to an increase again in Flynn's ASPs for 100mg capsules. Between May 2014 and December 2016, Flynn's monthly ASPs for 100mg capsules fluctuated between £48.20 and £50.58, and Flynn's ASP for 100mg capsules for this period was £48.93.

iv. 300mg capsules

2.317 Between September 2012 and March 2014, Flynn's ASPs for 300mg capsules were stable with its monthly ASPs for 300mg capsules fluctuating between £59.02 and £60.52, as shown by Figure 2.7. Flynn's ASP for 300mg capsules for this period was £59.32.

Figure 2.7: 300mg capsules Flynn ASP and Drug Tariff price



2.318 In April 2014, Flynn reduced its price for 300mg capsules and the Drug Tariff price fell. Consequently, Flynn's ASP for 300mg capsules for April 2014 was £51.08.

2.319 However, Flynn's ASPs for 300mg capsules increased again following Flynn's switch to an RWM. Between May 2014 and December 2016, Flynn's monthly ASPs for 300mg capsules fluctuated between £47.75 and £53.54, and Flynn's ASP for 300mg capsules for this period was £52.57.

2.320 Flynn's Prices as set out above had a significant impact on its overall profitability. Flynn made losses in each of the three financial years prior to commencing supply of Flynn's Products.⁴⁷⁷ In the following four financial years (ie those financial years that include the Relevant Period), it earned cumulative profits of over £33 million and distributed approximately £20 million in dividends.⁴⁷⁸

f. Significant increases in the Drug Tariff prices

2.321 The Drug Tariff prices for phenytoin sodium capsules were based on Flynn's list price and also increased significantly after September 2012 as shown in Figures 2.4 to 2.7 above. The Drug Tariff price is the price that the NHS (ie CCGs) pays dispensers for dispensing phenytoin sodium capsules. During the Relevant Period,

⁴⁷⁷ Flynn Pharma (Holdings) Limited financial statements for the years ending 31 March 2010 (PAD00061), 31 March 2011 (PAD00062) and 31 March 2012 (PAD00015).

⁴⁷⁸ Flynn Pharma (Holdings) Limited financial statements for the years ending 31 March 2013 (PAD00038), 31 March 2014 (PAD00073), 31 March 2015 (PAD00075) and 31 March 2016 (PAD00072).

the Drug Tariff prices of phenytoin sodium capsules increased by 2,285% compared to the Drug Tariff prices prior to Pfizer entering into the arrangements with Flynn.

- 2.322 Prior to September 2012, and since at least January 2003, the Drug Tariff prices for 25mg and 50mg capsules were £0.66 and £0.67 respectively, whilst the Drug Tariff prices for 100mg and 300mg capsules were both £2.83.⁴⁷⁹
- 2.323 With effect from October 2012, there were significant increases in the Drug Tariff prices for all four capsule strengths based on Flynn's list prices.⁴⁸⁰ The new Drug Tariff prices for 25mg and 50mg capsules were £15.74 and £15.98 respectively, and for both 100mg and 300mg capsules were £67.50.
- 2.324 The Drug Tariff prices for 100mg and 300mg capsules were subsequently reduced, with effect from May 2014, by 20% and 15% respectively.
- 2.325 Table 2.7 below shows the change in the Drug Tariff prices for phenytoin sodium capsules during the Relevant Period, which were significantly above the Drug Tariff prices that prevailed prior to September 2012.

Table 2.7: Phenytoin sodium capsules Drug Tariff prices*

	Pre-September 2012	October 2012 to April 2014	% change	May 2014 to December 2016	% change	% increase since pre-September 2012
25mg	£0.66	£15.74	2,285%	£15.74	0%	2,285%
50mg	£0.67	£15.98	2,285%	£15.98	0%	2,285%
100mg	£2.83	£67.50	2,285%	£54.00	-20%	1,808%
300mg	£2.83	£67.50	2,285%	£57.38	-15%	1,928%

Source: PAD00028, NHS Business Services Authority, Back Copies of the Drug Tariff and PHT00114, a spreadsheet providing an update on Sales Data: Pfizer's response of 8 June 2015 to the CMA's s.26 Notice of 2 June 2015 (CMA document reference 01287.1).

*Drug Tariff prices are shown for the period for which they were in effect. For example, the published Drug Tariff price for 25mg was increased from £0.66 to £15.74 in November 2012. However, the £15.74 price was applied to all prescriptions dispensed in October 2012 and so was in effect from that date.

Note: The Drug Tariff prices shown in this table are those for England, Wales and Northern Ireland. The CMA is aware that for Scotland the Drug Tariff prices for 100mg and 300mg phenytoin sodium capsules were not adjusted until April 2015.

⁴⁷⁹ At this point in time phenytoin sodium capsules were manufactured and distributed by Pfizer and the product fell under the PPRS.

⁴⁸⁰ PHT00086, NHS Business Services Authority's response of 1 May 2015 to the CMA's request for information of 16 April 2015 regarding the Drug Tariff (CMA document reference 01207.1). Following the de-branding of *Epanutin* on 24 September 2012, concession prices were established for phenytoin sodium capsules because, after the price increases, dispensers could no longer purchase the products at the prices listed in the October 2012 Drug Tariff (as the Drug Tariff prices were unchanged from the September 2012 Drug Tariff). The Drug Tariff prices for phenytoin sodium capsules were then changed in the November 2012 Drug Tariff by reference to Flynn's list prices. The concession prices applied in October 2012 were the same as the reimbursement prices based on Flynn's list prices in November 2012.

g. The immediate impact of the price increase on the NHS

2.326 Prior to the Parties' September 2012 price increases, the NHS's annual spend on phenytoin sodium capsules was approximately £2.3 million. As a result of the price rises, the NHS's spend on phenytoin sodium capsules in 2013 increased to approximately £50 million, more than 20 times its previous annual spend.

2.327 Table 2.8 below sets out the NHS's annual spend on phenytoin sodium capsules during the Relevant Period and immediately before.

Table 2.8: NHS annual spend on phenytoin sodium capsules

	Prior to September 2012 (£m)	2013 (£m)	2014 (£m)	2015 (£m)	2016 (£m)
NHS annual spend on phenytoin sodium capsules*	2.3	50	42	37	35

*The NHS's annual spend on phenytoin sodium capsules has been calculated using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices for phenytoin sodium capsules that were in effect at the time.

2.328 Of the NHS annual expenditure on phenytoin sodium capsules above, Pfizer accounted for £25.2 million of the 2013 figure, £13.3 million of the 2014 figure, £12 million of the 2015 figure and £12.5 million of the 2016 figure. Flynn accounted for £8.6 million of the 2013 figure, £11.1 million of the 2014 figure, £9.1 million of the 2015 figure, and £7.2 million of the 2016 figure.⁴⁸¹

2.329 Compared to NHS annual spending prior to the September 2012 price increases, NHS spending on phenytoin sodium capsules in 2013 increased by 2,073%.⁴⁸² This was at a time when the NHS budget was not rising significantly. Between 2010/11 and 2016/17, the average annual growth of the total NHS budget (not adjusted for inflation) was around 1.5% a year.⁴⁸³

2.330 As a result of the Parties' price increases, the NHS spent an additional £169 million⁴⁸⁴ on Capsules during the Relevant Period.

2.331 Shortly after the price increases imposed by the Parties, a significant number of CCGs raised their concerns regarding the impact of the additional expenditure. These are described in detail in Annex B.

⁴⁸¹ Pfizer's and Flynn's revenues from Capsules have been calculated using data provided by Pfizer and Flynn. Flynn's revenue is net of Pfizer's revenue to avoid double counting.

⁴⁸² Based on the CMA's estimates of expenditure in Table 2.8 above.

⁴⁸³ PAD00023, The King's Fund, *The rising cost of medicines to the NHS*, April 2018, page 6.

⁴⁸⁴ The CMA has calculated the NHS's annual spend on Capsules using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices. The CMA has calculated the NHS spend on Capsules over the Relevant Period at pre-2012 Drug Tariff prices and also at post-2012 Drug Tariff prices (taking into account the reduction of the Drug Tariff price in 2014) to calculate the additional spend as a result of the price increases.

h. Current supply prices

- 2.332 Within the CMA's 2016 Infringement Decision, the CMA gave directions to the Parties.⁴⁸⁵ The Directions required Pfizer and Flynn, amongst other things, to set revised prices having regard to the content of the 2016 Infringement Decision.⁴⁸⁶ Nothing in the Directions precluded the Parties from earning a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing Cost Plus in the 2016 Infringement Decision.⁴⁸⁷
- 2.333 Pfizer was required to apply revised supply prices for Pfizer's sales of phenytoin sodium capsules to Flynn and any other potential purchaser in the UK within 30 working days from the date of the 2016 Infringement Decision.⁴⁸⁸
- 2.334 Flynn was required to revise its NHS list prices: (i) within 30 working days from the date of the 2016 Infringement Decision, using Pfizer's supply prices at the date of the 2016 Infringement Decision (or, if different, the prices that Flynn actually paid Pfizer for the stock that it held) as its input prices; and (ii) within two working days of having sold any stock that it purchased at Pfizer's revised supply prices, or in any event by no later than four months from the date of the 2016 Infringement Decision, using Pfizer's revised supply prices as its input prices.⁴⁸⁹ These provisions were to take account of Flynn's stock holding already purchased at Pfizer's previous prices.
- 2.335 On 30 January 2017, Pfizer wrote to the CMA regarding its compliance with the Directions.⁴⁹⁰ Pfizer confirmed its revised supply prices to Flynn for Capsules were:
- 2.335.1. for 25mg capsules, [£1-£10.99];
- 2.335.2. for 50mg capsules, [£1-£10.99];
- 2.335.3. for 100mg capsules, [£1-£10.99]; and
- 2.335.4. for 300mg capsules, [£1-£10.99].
- 2.336 Pfizer maintained its supply prices at these levels from February 2017 to at least the end of 2019.⁴⁹¹
- 2.337 On 30 January 2017, Flynn also wrote to the CMA regarding its compliance with the Directions, notifying the CMA that it had submitted revised NHS list prices.⁴⁹²

⁴⁸⁵ 2016 Infringement Decision, Annex B, pages 480-482.

⁴⁸⁶ 2016 Infringement Decision, Annex B, paragraph 1(b) and (c).

⁴⁸⁷ 2016 Infringement Decision, Annex B, paragraph 1(d).

⁴⁸⁸ 2016 Infringement Decision, Annex B, paragraph 1(b)(i).

⁴⁸⁹ 2016 Infringement Decision, Annex B, paragraph 1(b)(ii) and (iii).

⁴⁹⁰ PRE00712, Pfizer letter to the CMA dated 30 January 2017.

⁴⁹¹ PRC00391, Flynn's response of 10 August 2020 to the CMA's s.26 Notice of 27 July 2020, Annex 15.

⁴⁹² PRE00715, Flynn letter to the CMA dated 30 January 2017. The revised prices submitted to the NHS Business Services Authority were: for 25mg capsules, £7.26; for 50mg capsules, £9.37; for 100mg capsules, £42.88; and for 300mg capsules, £41.94.

Flynn later wrote to the CMA on several occasions to notify the CMA that it had submitted further revised NHS list prices.⁴⁹³

2.338 As part of its investigation on remittal, the CMA asked Flynn to provide data on its sales of Capsules for 2017 to 2019. Flynn's ASPs for Capsules in 2019 were:

2.338.1. for 25mg capsules, [£1-£10.99];

2.338.2. for 50mg capsules, [£1-£10.99];

2.338.3. for 100mg capsules, [£1-£10.99]; and

2.338.4. for 300mg capsules, [£1-£10.99].⁴⁹⁴

i. Pricing in EU Member States

2.339 During the Relevant Period, Capsules were (and continue to be) sold in a number of other EU Member States under the *Epanutin* brand.⁴⁹⁵ The *Epanutin* capsules sold by Pfizer in other EU Member States are manufactured by Pfizer in the same factory in Germany as the capsules supplied to Flynn in the UK. In these countries, Pfizer is the holder of the MA and sells directly to wholesalers and pharmacies.⁴⁹⁶ Pfizer has not entered into any arrangements in other EU Member States equivalent to those entered into with Flynn in the UK.⁴⁹⁷

2.340 Between January 2011 and August 2012 (ie prior to the September 2012 price increase following Pfizer entering into the arrangements with Flynn), Pfizer's ASP to pharmacies in the UK for 100mg capsules was £2.18. As shown in Table 2.9 below, this price was higher than the ASPs charged by Pfizer to wholesalers for 100mg packs in Greece, Spain and, marginally, Sweden, and lower than those charged in Belgium and Ireland over the same period.

⁴⁹³ See for example, PRE00628, Flynn letter to the CMA dated 6 March 2017; PRE00713, Flynn letter to the CMA dated 13 March 2017; and PRE00714, Flynn letter to the CMA dated 7 April 2017.

⁴⁹⁴ PRC00391, Flynn's response of 10 August 2020 to the CMA's s.26 Notice of 27 July 2020, Annex 15.

⁴⁹⁵ PHT00077, Pfizer's 11 March 2016 response to the CMA's s.26 Notice of 11 February 2016 (CMA document reference 01836.2). Note: Pfizer discontinued the supply of Epanutin in Belgium and Luxembourg in October 2017. See PRC00564, Pfizer's response to Q3 of the CMA's 12 August 2020 s.26 Notice, received on 23 September 2020, pages 2 and 5.

⁴⁹⁶ PHT00077, Pfizer's 11 March 2016 response to the CMA's s.26 Notice of 11 February 2016, page 3 (CMA document reference 01836.2).

⁴⁹⁷ PHT00131, Pfizer's response to s.26 Notice of 5 March 2014 Q13, page 24 (CMA document reference 00519.2).

Table 2.9: Prices of 100mg packs of Capsules in the UK and other EU Member States

	January 2011 to August 2012	
	Average wholesale price (£)	Average pharmacy price* (£)
UK	-	2.18
Belgium	5.33	6.48
Greece	1.24	1.97
Ireland	4.88	6.41
Spain	1.52	1.83
Sweden	2.13	4.30

Source: PHT00165, EU Sales data update June 2016: Annex 2 of Pfizer's response of 26 August 2016 to the CMA's s.26 Notice of 2 August 2016 (CMA document reference 02129.3); converted to GBP using monthly spot exchange rates from the Bank of England.

*The average pharmacy price is the price at which pharmacies purchase the product in each country. Pfizer has noted that 'most countries also have an official price at which patients purchase medicines from pharmacies, or an official reimbursement price since this price is often wholly or partly reimbursed by the state. Additionally, pharmacies and wholesalers might apply discounts to the official prices.'⁴⁹⁸

Note: the CMA has used the price of the 100mg strength capsule because it is the only capsule strength that is sold in Belgium, Greece, Spain and Sweden. All capsule strengths are sold in Ireland.

i. National Regulatory Regimes

2.341 The price of *Epanutin* is subject to regulatory constraints in six out of seven EU Member States in which it is sold, with the exception being Malta.⁴⁹⁹

2.342 In the other six countries, Pfizer's decisions on pricing and its ability to increase its supply price for *Epanutin* are subject to these regulatory regimes. Subject to the specific limitations on price and approval of price increases by the relevant national authority, Pfizer has been able to secure increases in its supply price in a number of these countries.

ii. Price increases by Pfizer

2.343 In September 2012, Pfizer increased its 100mg capsule supply price in the UK from £2.29 to £42.50 and began to supply capsules exclusively to Flynn. Flynn set its downstream wholesale price at £59.06.

2.344 While Pfizer has increased its supply prices for *Epanutin* in some EU Member States, in each case these increases have been significantly smaller than the September 2012 increase in Pfizer's supply price in the UK. Table 2.10 below shows the price increases secured by Pfizer across other EU Member States

⁴⁹⁸ PRC00563, Pfizer's response to the CMA's s.26 Notice dated 12 August 2020, Q1, pages 2-4.

⁴⁹⁹ PHT00077, Pfizer's 11 March 2016 response to the CMA's s.26 Notice of 11 February 2016 (CMA document reference 01836.2).

between January 2010 and August 2020. All price increases relate to packs of 100 x 100mg capsules.

Table 2.10: Summary of Pfizer's price increases for the supply of *Epanutin* in other EU Member States since 2010

EU Member State	Year of application for price increase	From	To	Percentage increase
Belgium and Luxembourg	2010	An ex-factory price of EUR 3.63	An ex-factory price of EUR 6.64	83%
Sweden	2012	Pharmacy price of SEK 23.86	Pharmacy price of SEK 79.50	233%
Cyprus	2016	An official wholesale price of EUR 3.16	An official wholesale price of EUR 6.80	115%
Greece*	Separate successful applications in 2013, 2014 and 2017†	An ex-factory price of EUR 1.65 (2013)	An ex-factory price of EUR 5.09 (2017)	208%

* There is an annual review process by which prices are reviewed in Greece.

† Pfizer also requested an increase from the relevant national pricing authority in Greece in 2018, but the annual price revision process was not concluded due to elections in Greece resulting in a change of government. See PRC00564, Pfizer's 23 September 2020 response to Question 3 of the CMA's s.26 notice of 12 August 2020.

2.345 Pfizer has explained that the price increases requested and granted by the national authorities in Cyprus, Greece and Sweden were due to the low pre-increase supply prices and/or for the purposes of securing the commercial viability of the product in those countries.⁵⁰⁰ Pfizer has also explained that the price increase requested and granted for Belgium was to re-establish zero margin for the product.⁵⁰¹

iii. Pfizer's supply prices across EU Member States

2.346 Table 2.11 below sets out Pfizer's ASPs for 100mg phenytoin sodium capsules in all EU Member States during the Relevant Period. During this period, there is a substantial disparity between the ASPs charged in the UK by both Pfizer and Flynn, and Pfizer's supply prices for *Epanutin* across other EU Member States, including those in which Pfizer secured price increases.

⁵⁰⁰ PHT00077, Pfizer's 11 March 2016 response to the CMA's s.26 notice of 11 February 2016, pages 5, 6 and 8 (CMA document reference 01836.2).

⁵⁰¹ PRC00564, Pfizer's 23 September 2020 response to Question 3 of the CMA's s.26 notice of 12 August 2020, page 2.

Table 2.11: Prices and volumes of 100mg packs of Capsules across EU Member States⁵⁰²

	Post September 2012		
	Average Wholesale Price (£)	Average pharmacy price (£)	Average monthly volumes
Belgium/Luxembourg	£5.39	£6.20	405
Greece*	£2.79	£3.25	7,283
Ireland	£5.25	£6.03	3,316
Spain	£1.56	£1.74	22,523
Sweden	£6.28	£7.08	463
Cyprus*	£4.55	£5.13	280
Malta*	£5.02	-	1,095

*All prices and volumes are presented for the period September 2012 to December 2016, except for Cyprus and Malta.

Notes:

Pfizer supplies *Epanutin* into Cyprus and Malta through Greece by use of local distributors and sales data for Cyprus, Malta and Greece prior to April 2015 is held at an aggregated level only. Disaggregated data for Cyprus and Malta is only available for the period after April 2015.

Accordingly, the figures presented for Cyprus and Malta relate to the period April 2015 to December 2016.

All other figures are for the period September 2012 to December 2016. As a result of these aggregation issues, figures presented for Greece include sales data relating to Cyprus and Malta before April 2015.

The data provided in respect of Cyprus and Malta represents data for Pfizer's sales of *Epanutin* to distributors. Pfizer told the CMA that in Cyprus there is an official price at which pharmacies purchase from wholesalers/distributors. Pfizer provided these prices to enable the calculation of the average pharmacy price in Cyprus. For Malta, Pfizer told the CMA that there is no such official price and that it did not hold details of the pharmacy price in Malta.⁵⁰³ The average pharmacy price in Malta is therefore not included.

All prices have been converted to GBP using monthly average spot exchange rates from the Bank of England.

2.347 For the period September 2012 to December 2016, average monthly pack volumes sold in the UK were 19,813 packs. During this period, Pfizer's average price for a pack of 100mg capsules sold to Flynn (upstream from the wholesale prices set out in the table above) was £37.56. Flynn's average supply price to wholesalers and pharmacies was £54.40.

2.348 As such, Pfizer's average supply prices for 100mg capsules in the UK were many multiples of Pfizer's downstream wholesale prices in other EU Member States:

2.348.1. 24 times higher than in Spain;

2.348.2. 13 times higher than in Greece;

⁵⁰² PHT00165, EU Sales data update June 2016: Annex 2 of Pfizer's response of 26 August 2016 to the CMA's s.26 Notice of 2 August 2016 (CMA document reference 02129.3). PRC00565, Data provided by Pfizer in response to the CMA's 12 August 2020 s.26 Notice, received on 23 September 2020, Annex 4. All data converted to GBP using monthly average spot exchange rates for the period September 2012 to January 2017 from the Bank of England.

⁵⁰³ PRC00563, Pfizer's response to the CMA's 12 August 2020 s.26 Notice, received on 23 September 2020, page 2.

2.348.3. 8 times higher than in Cyprus;

2.348.4. 7 times higher than in Belgium, Luxembourg, Ireland and Malta; and

2.348.5. 6 times higher than in Sweden.⁵⁰⁴

2.349 Pfizer has told the CMA that it made only marginal profits for the sale of *Epanutin* in other EU Member States (and, in the case of Spain, losses) during the Relevant Period.⁵⁰⁵

2.350 Across the EU Member States where Pfizer is subject to varying degrees of price control, the largest single price increase sought and secured by Pfizer was in Sweden. The price increase in Sweden was requested and secured around the same time as Pfizer entered into the arrangements with Flynn and increased its supply price in the UK.

2.351 In 2012, Pfizer applied to the Dental Care and Medicines Benefits Agency in Sweden (the 'TLV') for a price increase for *Epanutin* from a pharmacy price of SEK 23.86 to SEK 79.50 (approximately £7.41),⁵⁰⁶ a price increase of over 230%.

2.352 The price increase request was granted by the TLV due to the following 'special reasons':

epilepsy is a life-threatening condition for which treatment is essential;

switching between different preparations of phenytoin can lead to differences in efficacy, seizure breakthroughs and side effects related to serum concentrations; and

the scale of the price rise was required to secure the long-term viability and supply of Epanutin for those patients established on the drug.

2.353 The approved higher price of SEK 79.50 took effect from 1 December 2012. The authority also approved a price increase in the final customer price (ie the price at which the drug is reimbursed by the national authority) to SEK 126 (approximately £11.74).⁵⁰⁷

⁵⁰⁴ Comparison of Pfizer's UK supply price of £37.56 compared to Pfizer's wholesale prices in other EU Member States set out in Table 2.11.

⁵⁰⁵ PHT00077, Pfizer's response of 11 March 2016 to the CMA's s.26 Notice of 11 February 2016, Q7, page 10 (CMA document reference 01836.2). Also see PRE00627, Pfizer's Closing Submissions to the CAT, paragraph 248.

⁵⁰⁶ Decision published by the Swedish Dental Care and Medicines Benefit Agency (TLV) in respect of application by Pfizer AB for a price increase for *Epanutin*, dated 5 November 2012. Decision Ref: 2670/2012. Swedish language version available at PAD00042. English language translation prepared by the CMA, PAD00043. Note: the figures of SEK 23.86 and SEK 79.50 represent the official 'pharmacy price' in Sweden (ie the official price at which pharmacies purchase from wholesalers). Sweden also has an official 'public price' for medicines (ie the official price from which patients purchase from pharmacies). The official 'public price' for *Epanutin* was SEK 60 per packet of 100 x 100mg capsules (exclusive of taxes) prior to January 2012 and SEK 126 per packet of 100 x 100mg capsules (exclusive of taxes) from January 2012. See PRC00563, Pfizer's response to the CMA's s.26 Notice dated 12 August 2020, page 4. The pharmacy price has been converted to GBP using the 2012 average exchange rate from the Bank of England.

⁵⁰⁷ Converted to GBP using the 2012 average exchange rate from the Bank of England.

2.354 However, the price rise requested was only approved for *Epanutin* being prescribed to existing patients. The reason given by the TLV for this was that phenytoin is not recommended for use in Sweden for new patients due to the difficulty in dosing, the risks of seizure breakthrough and its side effects.⁵⁰⁸

2.355 Malta is the only Member State where Pfizer's supply price is not subject to any price regulation scheme.⁵⁰⁹ Pfizer has explained that, for Malta, it does not follow any overall pricing strategy: it supplies to third party distributors and, typically, it is the distributor that will propose a price to Pfizer. According to Pfizer, it will evaluate the proposed price based on costs and other business interests and a negotiation might then take place.⁵¹⁰ Pfizer has not explained why, in view of its assessment that its supply prices for *Epanutin* outside the UK were either loss-making or only marginally profitable⁵¹¹ (and absent any regulatory restrictions on pricing), it has not increased its supply prices in Malta.

III. The DHSC's reaction and the Parties' explanations for the significant price increase

2.356 Shortly after the implementation of the significant price increases, the DHSC expressed concern and sought information from the Parties to understand how the price increases could be justified by reference to their cost of supply.⁵¹²

2.357 On 23 October 2012, [DHSC Employee 3] of the DHSC spoke with [Flynn Director 4] of Flynn to seek information on Flynn's costs. However, Flynn declined to provide the DHSC with details of its cost of goods. [DHSC Employee 3] reported back internally within the DHSC:

*Not surprisingly, he [Flynn Director 4] said that he could not divulge details of their arrangements with Pfizer as they were bound by strict confidentiality clauses in the contract.*⁵¹³

⁵⁰⁸ Decision published by the Swedish Dental Care and Medicines Benefit Agency (TLV) in respect of application by Pfizer AB for a price increase for Epanutin. Dated 5 November 2012. Decision Ref: 2670/2012. Swedish language version available at PAD00042. English language translation prepared by the CMA, PAD00043.

⁵⁰⁹ PHT00077, Pfizer's response of 11 March 2016 to the CMA's s.26 Notice of 11 February 2016, Q3, page 4 (CMA document reference 01836.2).

⁵¹⁰ PRC00563, Pfizer's response to the CMA's 12 August 2020 s.26 Notice, received on 23 September 2020, Q4 page 6.

⁵¹¹ PHT00077, Pfizer's response of 11 March 2016 to the CMA's s.26 Notice of 11 February 2016 (CMA document reference 01836.2) and PRE00627, Pfizer's Closing Submissions to the CAT, paragraph 248.

⁵¹² PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵¹³ PHT00053, Email of 24 October 2012 between [DHSC Employee 3] (DH) and [DHSC Employee 7] (DH) et al re Flynn stating that Flynn's agreement with Pfizer is a simple third-party manufacturing supply contract for Capsules: Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.15).

a. Meeting between Flynn and the DHSC in November 2012

2.358 On 6 November 2012, the DHSC and Flynn met to discuss the price and supply of Capsules.⁵¹⁴ Two notes of this meeting were produced, one by the DHSC and another by Flynn.

2.359 According to the DHSC's note, at the meeting, the DHSC told Flynn that it was 'unsighted' on how Flynn had arrived at its current prices.⁵¹⁵ The DHSC again explained that it did not know Flynn's cost breakdown and repeated that it would need to understand this to allow it to assess whether the price increase could be justified.⁵¹⁶

2.360 Flynn again refused to provide information on its cost of goods on the basis that it had a 'commercially confidential agreement in place with Pfizer that prevented the sharing of cost of goods information'. Instead of providing the DHSC with costs data as requested, Flynn explained that there were 'many additional costs involved'.⁵¹⁷

2.361 At the meeting, Flynn advised the DHSC that it was adding value to the product in the following areas:

Improvements to maintain the supply chain despite the problems experienced over the past weeks from our supplier. MHRA has supported batch specific variations which were important for maintaining supply in the short term in the face of significant supply chain issues.

Future plans to build safety stock at API and packed product levels

⁵¹⁴ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012, paragraph 6 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16), and PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵¹⁵ Flynn submitted that it was incorrect that the DHSC was unsighted about how Flynn had arrived at its prices as Flynn had previously indicated to the DHSC that it would base its prices off the Drug Tariff price of Tablets at the 18 July 2012 meeting: PRC03492, Flynn's response to the SO, paragraph 2.19. However, at the July 2012 meeting, having heard Flynn's proposals to price Capsules on the basis of the Drug Tariff price of Tablets, the DHSC expressed reservations to Flynn about a price for Capsules that was significantly higher than the prevailing price of *Epanutin*. The DHSC's note of the 6 November 2012 meeting indicates that the DHSC was 'unsighted' in terms of the costs information that might justify such a significant price increase, which is clear from Flynn's response which focussed on the 'many additional costs involved': PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16), paragraph 6.

⁵¹⁶ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012, paragraphs 6-7 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16).

⁵¹⁷ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012, paragraph 6 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16).

*We [Flynn] are looking to create a dual source for both API, secondary manufacture and packaging, supported in principal by Pfizer, but subject to detailed negotiations, to be commenced at earliest opportunity.*⁵¹⁸

- 2.362 In response to the DHSC's concerns regarding the price increase, at the meeting Flynn also told the DHSC:

That Flynn had 'benchmarked [its] price against the phenytoin sodium 100mg tablet NHS price £1.07 per tablet'.

That Flynn 'felt that the discussion with DH PPRS on price at launch was sanctioned by default as it went unchallenged'.

*That '[i]n 6 months we can expect competition from the other capsule licence holders'.*⁵¹⁹

- 2.363 Flynn's note of the same meeting also reports that the DHSC raised immediate concerns in relation to each of these points.

- 2.364 The DHSC told Flynn that it 'had never confirmed that it was content with the price of the tablets' and explained that it could not comment further because a third party was involved in the supply of that product. Flynn's note recorded:

*We [Flynn] should not (in [redacted]'s [DHSC Employee 6]'s) view; assume that the DH and NHS are happy with the price of the tablets.*⁵²⁰

- 2.365 The DHSC also made it clear that it did not consider comparisons with tablets to be relevant:

*Further, it [the DH] did not consider comparisons with the table [sic] relevant, as the products are not interchangeable. They were different formulations, which may incur different costs, and the tablets had significantly less of the market so had less economies of scale. Although a price increase might have been justified for Flynn's product, the scale of it was the concern.*⁵²¹

- 2.366 Flynn's note also records:

DH ([redacted]) [DHSC Employee 4] had commented that the much larger market share of the capsules made the total cost very difficult for them, more visible

⁵¹⁸ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵¹⁹ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵²⁰ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵²¹ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012, paragraph 7 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16).

*and hitting hard NHS pockets. The DH were struggling and trying to understand the justification.*⁵²²

2.367 Further, the DHSC explained that it could not be taken to have ‘sanctioned’ Flynn’s capsule price since the PPRS had no remit on pricing of generic products and Scheme M was not a pricing approval.⁵²³

2.368 Finally, the DHSC told Flynn that ‘due to the narrow therapeutic index of the medicine in question, the Department did not consider this was a competitive market’.⁵²⁴

2.369 According to Flynn’s note of the meeting, the DHSC recognised the need for some increase in price to ensure the commercial viability of the drug. However, the DHSC ‘needed to be able to justify the large increase as value for money’. In response, [Flynn Director 2] told the DHSC that Flynn ‘might have to discontinue the product if [it] didn’t make sufficient margin’.⁵²⁵

2.370 Flynn’s note records that, responding to [Flynn Director 2]:

*[redacted] [DHSC Employee 6] advised that we need to give a breakdown of all our costs or they would have to review what options were available to DH to enforce any powers they had, noting that nothing had been invoked since Schedule [Scheme] M was introduced.*⁵²⁶

2.371 In recognition of the DHSC’s concerns and its repeat requests for Flynn’s supply costs, Flynn agreed to approach Pfizer to discuss the DHSC’s reaction to the price increase and to request permission from Pfizer to disclose its supply price to Flynn to the DHSC. Flynn also agreed to establish with Pfizer whether it might be possible to negotiate a reduction in Pfizer’s supply price, which would enable it to pass a lower price on to the NHS.⁵²⁷

2.372 Finally, Flynn committed to write to the DHSC to explain further the price increase and to set out the reasons why the higher price could be justified as value for money. According to the DHSC’s note of the meeting:

⁵²² PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 1: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵²³ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵²⁴ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012, paragraph 7 (DH14): Enclosed with the Department of Health’s response of 15 August 2013 to the OFT’s s.26 Notice of 26 June 2013 (CMA document reference 00367.16).

⁵²⁵ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵²⁶ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵²⁷ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012, paragraph 9 (DH14): Enclosed with the Department of Health’s response of 15 August 2013 to the OFT’s s.26 Notice of 26 June 2013 (CMA document reference 00367.16).

*Flynn recognised the Department's concerns and agreed to consider what additional information it could provide by way of justification. It would come back to the Department on this but immediate thoughts centred on the one-off cost of the Marketing Authorisation; third party manufacturing costs; the cost of the active pharmaceutical ingredients (API); dual sourcing and buffer-stock building costs; bioequivalence studies; and packaging.*⁵²⁸

b. Flynn's letter to the DHSC

2.373 On 16 November 2012, Flynn wrote to the DHSC on the points discussed in the meeting of 6 November 2012.

i. The DHSC's requests for Flynn's cost of goods

2.374 In the 6 November meeting, the DHSC had told Flynn that it could not assess whether Flynn's price represented value for money or understand the justification for the price increase without information relating to Flynn's costs.

2.375 Flynn's letter did not include any additional information relating to its cost of goods from Pfizer. Instead, Flynn provided the following explanation:

*You asked us to request Pfizer's permission to disclose our cost of goods data. Their response to our request was, 'As a global supplier of phenytoin, information relating to the cost structure for production and delivery of Phenytoin Sodium Flynn Hard Capsules is commercially sensitive and confidential.'*⁵²⁹

2.376 Flynn previously told the DHSC that the main element of its costs was the cost of the finished product supplied by Pfizer.⁵³⁰ However, Flynn did not provide the DHSC with its supply price or any other information concerning its costs of supply.

2.377 Flynn's justifications for not providing its cost of goods to the DHSC were, firstly, that it was prevented from doing so under the terms of its 'confidentiality

⁵²⁸ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012, paragraph 8 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16). In its evidence before the CAT Flynn disputed that it made reference to the one-off cost of the MA to the DHSC: PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, pages 9-10, paragraph 30.

⁵²⁹ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 4: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

⁵³⁰ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585), page 2.

agreement' with Pfizer⁵³¹ and, secondly, that Pfizer had rejected its request for permission to do so.⁵³²

- 2.378 On the first of these reasons, the CMA notes that the Exclusive Supply Agreement allowed for certain 'Permitted Disclosures' to any 'Regulatory Body' under Clause 21.2.2, set out below:

Permitted Disclosures. Each party may disclose the other party's Confidential Information:

21.2.1 to its employees, officers, agents, consultants or sub-contractors ("Representatives") who need to know such information for the purposes of carrying out the party's obligations under this Agreement, provided that the disclosing party takes all reasonable steps to ensure that its Representatives comply with the confidentiality obligations contained in this clause 21 as though they were a party to this Agreement. The disclosing party shall be responsible for its Representatives' compliance with the confidentiality obligations set out this clause; and

21.2.2 as may be required by Law, court order or any Regulatory Body.

"Regulatory Bodies" means: (a) any court, tribunal, arbitrator, agency, commission, official or other instrumentality of the European Union or any relevant country, state, province, county, city or other political subdivision; and (b) those government departments and regulatory, statutory and other entities, committees and bodies which, whether under statute, rules, regulations, codes of practice or otherwise, are entitled to regulate, investigate, or influence the matters dealt with in this Agreement and "Regulatory Body" shall be construed accordingly

- 2.379 The CMA has not seen any evidence to suggest that Flynn considered the applicability of this exclusion before rejecting the request from the DHSC.
- 2.380 On the second of these, whilst Flynn informed the DHSC that Pfizer had rejected its request to provide its cost of goods,⁵³³ based on the documents on the CMA's file, it is not clear that Flynn specifically asked for Pfizer's permission to disclose its purchase price from Pfizer to the DHSC. On 12 November 2012, Flynn informed

⁵³¹ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585), page 2, and see also *Phenytoin* [2018] CAT 11, paragraph 224.

⁵³² PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 4: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

⁵³³ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 4: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

the DHSC that it was meeting with Pfizer that same day in order to 'discuss supply issues and to request release of cost information'.⁵³⁴

- 2.381 A Pfizer internal email sent by [Pfizer Employee 2] on 14 November 2012 described Flynn's request:

*Flynn made a commitment to ask Pfizer for our cost structure for the production and delivery of Phenytoin capsules. When asked, Flynn said [to the DH] that this information is confidential to Pfizer and that they have no sight of this.*⁵³⁵

- 2.382 [Pfizer Employee 2] concluded that Pfizer, therefore, needed 'a statement to Flynn setting out that our manufacturing process and cost structure is not appropriate to share'.⁵³⁶ Later that day, [Pfizer Employee 2] responded to Flynn by email setting out that 'Pfizer acknowledges your request for further visibility of our cost structure based on your ongoing discussions with the Department of Health. Here is our response:- As a global supplier of phenytoin, information relating to the cost structure for production and delivery of Phenytoin Sodium Flynn Hard Capsules is commercially sensitive and confidential.'⁵³⁷

- 2.383 Based on this correspondence, Flynn appears to have communicated to Pfizer simply that the DHSC was seeking information relating to Pfizer's manufacturing processes and cost structure. Flynn does not appear to have requested permission from Pfizer to disclose its own cost of goods, despite its later confirmation to the DHSC.

- 2.384 In any event, Flynn then failed to pursue the matter further⁵³⁸ and, instead of providing its cost of goods to the DHSC, set out in the letter a number of other factors designed to 'provide a level of detail and explanation' of what Flynn acknowledged was a 'significant price increase'. Flynn described the significant price increase as being 'the result of an exceptional if not unique set of circumstances' and referred specifically to (i) the potential for discontinuation of the product absent the arrangements between the Parties; (ii) the inevitable price reductions that would result from competitive entry; (iii) the declining turnover of the product and the need to ensure commercial viability; and (iv) the considerable effort being invested by Flynn to increase supply chain resilience. Flynn also

⁵³⁴ PHT00055, Email between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH) forwarding on email from Flynn following on from the meeting on 6th November 2012, page 1 (DH15) (CMA document reference 00367.17).

⁵³⁵ PHT00217, Email chain re Flynn being asked about Pfizer Phenytoin cost structure and manufacturing process by DH: Enclosed with Pfizer's s.27 response to the Notice of 8 May 2013, (CMA document reference 00141.520).

⁵³⁶ PHT00217, Email chain re Flynn being asked about Pfizer Phenytoin cost structure and manufacturing process by DH: Enclosed with Pfizer's s.27 response to the Notice of 8 May 2013, (CMA document reference 00141.520).

⁵³⁷ PHT00218, Email from [Pfizer Employee 2] to [Pfizer Employee]; [Pfizer Employee]; [Pfizer Employee], providing information from Pfizer with regards the Department of Health's Request for Information: Enclosed with Flynn's s.27 response to the Notice of 8 May 2013 (CMA document reference 00145.600).

⁵³⁸ *Phenytoin* [2018] CAT, paragraph 234.

referred to its continued efforts to discuss supply pricing with Pfizer in recognition of the DHSC's concerns.⁵³⁹

ii. The potential for discontinuation

2.385 Regarding the possibility of Pfizer discontinuing the product, the CMA has not seen any contemporaneous evidence which suggests that Pfizer was likely to discontinue its manufacture of capsules in the absence of entering into the arrangements with Flynn.

2.386 Pfizer submitted before the CAT that, whilst the product would not have been discontinued in 2012 if it had not entered into the arrangements with Flynn, *Epanutin* would have been discontinued between 2014 and 2017 as part of an internal project set up to look at discontinuing low-profit products.⁵⁴⁰

2.387 The CMA considers that concerns regarding patient safety,⁵⁴¹ as well as Pfizer's supply of Capsules across the EU⁵⁴² (all of which were manufactured at the same site as the capsules Pfizer supplied in the UK), meant that the possibility of discontinuation in the UK during the Relevant Period was not likely.⁵⁴³

2.388 The CAT made the following observation regarding the possibility of discontinuation by Pfizer:

*the most [Pfizer Director 1] could say about this was that he believed Epanutin would have been discontinued at some point in the future, whilst accepting that any decision to discontinue would not be taken lightly because of the patient concerns.*⁵⁴⁴

2.389 As described above, in the November 2012 meeting with the DHSC, [Flynn Director 2] told the DHSC that Flynn itself 'might have to discontinue the product if [it] didn't make sufficient margin'.⁵⁴⁵

2.390 This comment formed part of the 'negotiating leverage' that Flynn was able to exert over the DHSC.⁵⁴⁶ Ultimately, due to Flynn and Pfizer's refusal to provide the

⁵³⁹ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 3: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

⁵⁴⁰ PRE00627, Pfizer's written closing submissions in *Pfizer v CMA* Case No 1276/1/12/17, paragraph 278.

⁵⁴¹ PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013, (CMA document reference 00086.1), page 8.

⁵⁴² Because all of Pfizer's European supplies of *Epanutin* were manufactured in one location (in Freiburg, Germany), Pfizer would continue to incur manufacturing costs for the product even if it ceased supply in the UK. At no point has Pfizer suggested it considered discontinuing all supplies of *Epanutin* across Europe, and the CMA does not consider this to have been a likely outcome. Amongst other reasons, Pfizer has an obligation not to withdraw supply of *Epanutin* in Spain without the consent of the Spanish Agency of Medicines and Medical Devices: See PHT00077, Pfizer's response of 11 March 2016 to the CMA's s.26 Notice of 11 February 2016 (CMA document reference 01836.2), pages 3–4.

⁵⁴³ Flynn made submissions regarding the risk of discontinuation. These are set out along with the CMA's response in Annex F.

⁵⁴⁴ *Phenytoin* [2018] CAT 11, paragraph 423.

⁵⁴⁵ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin, page 2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

⁵⁴⁶ *Phenytoin* [2018] CAT 11, paragraph 233.

DHSC with Pfizer's supply price to Flynn, the DHSC was never in a position to form a view on or discuss with Flynn its interpretation of what would be a 'sufficient margin' in the circumstances.

iii. Flynn's efforts to increase the robustness of the supply chain

- 2.391 Flynn repeated its claim made at the November 2012 meeting that '[c]onsiderable effort is being invested by Flynn in strategies to increase the resilience of the supply chain'.⁵⁴⁷ In the letter to the DHSC dated 16 November 2012, Flynn referred specifically to its efforts to identify 'alternate/additional suppliers of the active ingredient' and 'alternate/additional manufacturers and packaging facilities for the finished product'.⁵⁴⁸
- 2.392 Whilst the evidence does show that Flynn took some preliminary steps to identify potential alternative API suppliers shortly after it had acquired the MA from Pfizer,⁵⁴⁹ Flynn ultimately never incurred any material costs in pursuing these strategies and no alternative route of supply was ever established.
- 2.393 Additionally, the terms of the Exclusive Supply Agreement with Pfizer prevented Flynn from sourcing Capsules 'or any product substantially similar'⁵⁵⁰ from any other source. During the lifetime of the Exclusive Supply Agreement, Flynn would therefore have required Pfizer's express permission to take supply from a second source of API that could be used to manufacture Capsules for Flynn. Pfizer's cooperation would also have been required for Flynn to take supply from an alternative API supplier during the lifetime of the Exclusive Supply Agreement.
- 2.394 In practice, Flynn appears to have stopped its engagement with alternative API suppliers around the end of 2012.⁵⁵¹ Whilst Flynn continued to discuss the possibility of a second source of API with Pfizer until January 2014, Pfizer remained in opposition to the proposal. This is clear from the notes of a meeting between Pfizer and Flynn in 2014:

Flynn want second source of API + packaging. Also want to buy in additional safety stocks from [Pfizer] (2 years). Adding value to DoH. [Pfizer] can

⁵⁴⁷ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 5: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

⁵⁴⁸ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 5: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

⁵⁴⁹ PHT00168, Internal Flynn e-mail chain of 24 Jan 2013 [from [Flynn Director 1] to [Flynn Director 2]] attaching Spec for Phenytoin Sodium: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.679).

⁵⁵⁰ PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma, clause 2.2.2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.280).

⁵⁵¹ PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 42.

investigate feasibility of second source, but do not normally do this, so very unlikely.

[...]

2nd source API + packaging + safety stock API

Pfizer do not normally provide 2nd sources because the network is so large, if 2nd sources were added, the capacity would be greater than we could manage.

We have confidence in our supply + safety margins

(additional)

3rd party arrangements are not catered for

Our global supplies are merged. Factories are large and capacity is finite + adequate (6-8 weeks safety)

*Critical medicines managed by large plants. If there was an issue, it would take precedence over other medicines.*⁵⁵²

2.395 Regarding the possibility of a second finished product manufacturer, Pfizer informed the CMA that it considered it 'necessary and non-negotiable' that the supply of Capsules was maintained from the same factory and for 'an audit trail to exist in this regard'.⁵⁵³

2.396 Pfizer also told the CMA that it was unrealistic to consider that Flynn would set up a new manufacturing site:

*the declining market for the product range made the prospect of Flynn establishing de novo facilities practically impossible, even leaving aside the safety concerns of doing so.*⁵⁵⁴

2.397 Flynn submitted that Pfizer did not need to be in support of Flynn's proposal to set up a second API supplier, and that the Exclusive Supply Agreement did not preclude Flynn from seeking to establish an alternative source of API and/or finding an alternative site of manufacture.⁵⁵⁵

2.398 However, whilst Flynn was not precluded from *seeking* alternatives, the CMA finds that the Exclusive Supply Agreement and Pfizer's position on alternative supplies in

⁵⁵² PHT00169, Pfizer's response of 16 April 2014 to the OFT's s.26 Notice of 5 March 2014, pages 15 and 17 (CMA document reference 00519.4) (original emphasis).

⁵⁵³ PHT00171, Draft note of meeting of 20 August 2013 between the OFT and Pfizer (CMA document reference 00412.1), paragraph 49, page 9.

⁵⁵⁴ PHT00172, Pfizer's written representations (non-confidential version exchanged with Flynn) of 27 November 2015 responding to the Statement of Objections (CMA document reference 01633.2), paragraph 122.

⁵⁵⁵ PRC03492, Flynn's Response to the SO, paragraphs 2.24 and 9.4.

effect precluded Flynn from *taking* supplies from another API supplier that could be used to supply phenytoin sodium capsules to Flynn or from another finished product manufacturer.⁵⁵⁶ The evidence demonstrates that Pfizer's cooperation would have been required for Flynn to take supply from an alternative API supplier.⁵⁵⁷ Pfizer remained responsible for the production of Capsules and the evidence shows that Pfizer would not have approved an alternative API supplier.⁵⁵⁸ In relation to the possibility of a second finished product manufacturer, Pfizer told the CMA that it was 'necessary and non-negotiable' that the supply of Capsules was maintained from the same factory.⁵⁵⁹

- 2.399 Flynn's letter to the DHSC also referred to the considerable effort being invested by Flynn in putting in place buffer stock policies to address the potential consequences of temporary interruptions.⁵⁶⁰ Whilst Flynn has subsequently pointed to the 'risk in holding stock',⁵⁶¹ in practice, and as recognised by the CAT, 'the context of Continuity of Supply and the established user base and distribution arrangements, provided a very substantial degree of comfort to Flynn and meant that it was taking very little business risk'.⁵⁶² In practice, Flynn appears to have had no material difficulty in selling the volumes it purchased from Pfizer during the Relevant Period.

iv. Flynn's commitment to approach Pfizer to discuss pricing

- 2.400 In its letter to the DHSC, Flynn also reiterated its commitment from the November 2012 meeting to continue to discuss with Pfizer a possible reduction in its supply price to Flynn:

*Flynn (and Pfizer) are fully aware of the Department and Stakeholder concerns in regard to the supply and pricing of this product within the UK and continue with best efforts, to pursue the strategies outlined in this letter. Flynn for its part has to ensure commercial viability and return is important, but we recognise also the legitimate concerns as to (NHS) cost and continue to discuss supply pricing with Pfizer.*⁵⁶³

⁵⁵⁶ The Exclusive Supply Agreement required Flynn to source Capsules 'or any product substantially similar' exclusively from Pfizer: PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma, clause 2.2.2: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.280), clause 2.2. The Exclusive Supply Agreement was extended until 31 December 2015: PRC00383, Annex 7 to Flynn's response to the CMA's section 26 notice dated 27 July 2020.

⁵⁵⁷ PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 49(a) and PHT00230, Minutes of Board Meeting for Flynn Pharma Ltd of 24 October 2012: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.576), page 2.

⁵⁵⁸ See paragraph 2.394.

⁵⁵⁹ See paragraph 2.395.

⁵⁶⁰ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 5: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

⁵⁶¹ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 180, lines 5-6.

⁵⁶² *Phenytoin* [2018] CAT 11, paragraph 346.

⁵⁶³ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 6: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).

2.401 The CMA has not seen any evidence that Flynn did, in fact, discuss supply pricing with Pfizer following the meeting between Flynn and the DHSC in November 2012. Instead, the next time pricing appears to have been discussed between the Parties was in December 2013 (over a year later) pursuant to the annual price review clause in the Exclusive Supply Agreement.⁵⁶⁴

c. The meeting between the DHSC and Pfizer and follow-up correspondence

2.402 Despite multiple requests by the DHSC for Flynn's cost of goods, the DHSC did not receive this from Flynn. The reasons provided by Flynn to the DHSC for not disclosing this information are described above.

2.403 Following the failure to secure costs information from Flynn (and based on Flynn's explanations that Pfizer's permission was necessary), the DHSC sought the information directly from Pfizer.

2.404 The DHSC met Pfizer on 10 January 2013. Under the item 'any other business', the DHSC 'sought comments from the company [Pfizer] in respect of the increased expenditure to the NHS' on *Epanutin*.⁵⁶⁵ In particular, the DHSC was seeking information from Pfizer on its supply price to Flynn.⁵⁶⁶

2.405 Pfizer explained that *Epanutin* had been 'sold to Flynn Pharma as it was no longer economically viable to keep it on' and agreed to look into the DHSC's concerns and revert in due course. In response to the DHSC's query as to whether *Epanutin* was still manufactured by Pfizer, Pfizer 'confirmed that it was manufactured in Ireland'⁵⁶⁷ and therefore [Pfizer] could offer no more information at the moment but would investigate the issues raised'.⁵⁶⁸

2.406 [Pfizer Employee] of Pfizer emailed [DHSC Employee 5] of the DHSC on 26 February 2013 to explain Pfizer's decision to divest *Epanutin* to Flynn:

Pfizer's decision to divest Epanutin followed a review of our portfolio and was in part based on the fact that for several years Pfizer had not realised a sustainable margin on Epanutin. Pfizer divested the UK Marketing Authorisation for Epanutin capsules to Flynn Pharma Ltd which specialises in maintaining and supporting the robust supply of mature products in the market. Given the narrow therapeutic index of this medicine, Pfizer continues

⁵⁶⁴ See also *Phenytoin* [2018] CAT 11, paragraph 234.

⁵⁶⁵ PHT00057, Redacted note of meeting of 10 January 2013 between Pfizer and DH at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.19).

⁵⁶⁶ PHT00060, Email of 27 February 2013 between Department of Health Staff [[DHSC Employee 5], [DHSC Employee 1], [DHSC Employee 3] and [DHSC Employee 8] (DH)] forwarding on redacted email from Pfizer - re Outstanding actions from the Meeting with DH on 10 January 2013: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.22).

⁵⁶⁷ This reference to Ireland was incorrect: Pfizer manufactures Capsules at its plant in Freiburg, Germany.

⁵⁶⁸ PHT00057, Redacted note of meeting of 10 January 2013 between Pfizer and DH at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.19).

*to manufacture the capsules to ensure the product is unchanged for UK patients and supplies phenytoin capsules to Flynn Pharma.*⁵⁶⁹

- 2.407 Like Flynn, Pfizer withheld from the DHSC any information regarding the supply price it charged to Flynn. Pfizer also declined to comment on the higher price now being paid by the DHSC: 'Since Pfizer no longer holds the UK marketing authorisation it would not be appropriate for us to comment on Flynn Pharma's marketed product nor it's [sic] pricing strategy'.⁵⁷⁰
- 2.408 As a result of both Flynn and Pfizer's refusal to provide the DHSC with information related to Flynn's cost of goods, the DHSC was ultimately never in a position to determine to what extent the price increase could be justified as value for money by the cost of goods, or was required to secure the commercial viability of the drug. Since the product was no longer part of the PPRS, the DHSC had no powers to compel the Parties to provide their costs data.⁵⁷¹

E. The impact of the price increases

- 2.409 The increased prices of phenytoin sodium capsules attracted strong criticism, in particular from CCGs, which pay the cost of phenytoin sodium capsules from their prescribing budgets. A number of those CCGs wrote to the Parties, the DHSC and others voicing concerns regarding the impact of the price increases on their budgets.
- 2.410 Full details of the complaints received from CCGs and other NHS stakeholders shortly after Pfizer and Flynn implemented their price increases are set out in Annex B.

I. Contemporaneous criticism

- 2.411 A significant number of CCGs and other NHS stakeholders raised concerns regarding the Parties' large price increases very shortly after their implementation in September 2012. The price increases also generated media and political interest.
- 2.412 On 10 October 2012, [✂] wrote on behalf of the GMMMG to the Secretary of State and other senior figures in the healthcare system, and Flynn and Pfizer.⁵⁷² The

⁵⁶⁹ PHT00060, Email of 27 February 2013 between Department of Health Staff [[DHSC Employee 5], [DHSC Employee 1], [DHSC Employee 3] and [DHSC Employee 8] (DH)] forwarding on redacted email from Pfizer - re Outstanding actions from the Meeting with DH on 10 January 2013: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.22).

⁵⁷⁰ PHT00060, Email of 27 February 2013 between Department of Health Staff [[DHSC Employee 5], [DHSC Employee 1], [DHSC Employee 3] and [DHSC Employee 8] (DH)] forwarding on redacted email from Pfizer - re Outstanding actions from the Meeting with DH on 10 January 2013: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.22).

⁵⁷¹ PHT00089, Draft note of meeting between the OFT and the DH held on 31 October 2013, paragraph 18 (with track changes) (CMA document reference 00468.1).

⁵⁷² PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.527).

GMMM is the coordinating group for decision-making around medicines for the 12 CCGs in the Greater Manchester region, and as at 2012 it served a population of 2.8 million people. The letter outlines GMMM's view that the manufacturers of phenytoin sodium capsules had engaged in a 'clear abuse of a virtual monopoly position for purely commercial gains', and warned that 'the needs of the NHS and patients are not best served by this cynical increase in costs, as the product cannot be switched to an alternative, equivalent formulation for the majority of indications'.

- 2.413 In concrete terms, the GMMM estimated that its expenditure of £24,450 per quarter on *Epanutin* would potentially increase to £583,000 per quarter. The GMMM urged the NHS to demonstrate that 'this unethical, anti-competitive behaviour at the expense of patient care will not be tolerated'.
- 2.414 In addition, the GMMM noted that the price increase breached the spirit of the PPRS scheme, as it did not deliver value for money, encourage innovation, promote access, or provide stability, sustainability, or predictability: 'this scheme places "unforeseen", unjustifiable and unacceptable "burdens" on the NHS, leading to a potentially unstable and unpredictable market in epilepsy treatment'.
- 2.415 Similarly, on 25 October [redacted] wrote to the Chief Pharmaceutical Officer on behalf of a group of nine CCGs including [redacted], [redacted], and [redacted].⁵⁷³ This letter notes that the CCGs 'have grave concerns about the huge cost pressures resulting from this change and the considerable logistical difficulties for GP practices and pharmacies' and goes on to state that 'this increase in cost will provide no additional health benefit for patients, but will undoubtedly compromise other services that we will not be able to afford to commission as a result'.
- 2.416 In October 2012 [redacted] of the [redacted] CCG emailed [Flynn Director 2] of Flynn with regards to the price increase.⁵⁷⁴ His email states: 'A staggering increase, not just sizeable, of 2000% plus! A increase of £102k to [redacted] alone. Some £50m nationally. Very difficult to understand. Patients and practitioners have very little option to change'.
- 2.417 [redacted] of the [redacted] CCG (population 650,000)⁵⁷⁵ and [redacted] of the Coastal West Sussex CCG (population 500,000)⁵⁷⁶ raised concerns with members of parliament, the DHSC, and the CMA.⁵⁷⁷ [redacted]'s email of 3 February 2013 states: 'As I have pointed out before, this will cost the NHS approximately £50m / year with absolutely no

⁵⁷³ PHT00118, Letter of 25 October 2012 from Nene CCG to [redacted] regarding Epanutin; Changes of Marketing Distribution; Impact on UK Patients: Enclosed with Nene CCG's e-mail of 10 July 2013 to the OFT about the Epanutin price increase (CMA document reference 00210.2).

⁵⁷⁴ PHT00119, Email chain of 8 October 2012 between [Flynn Director 2] Flynn and [redacted] [redacted] & [redacted] CCG discussing the change in price for Phenytoin Sodium Flynn Hard Capsules: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.455).

⁵⁷⁵ PRE00001, First Witness statement of [redacted], 10 January 2017, paragraph 24.

⁵⁷⁶ PRE00002, First Witness Statement of [redacted], 10 January 2017, paragraph 7.

⁵⁷⁷ PHT00120, Various e-mails: Email of 3 February 2013 from West Sussex PCT to the OFT discussing the price increase of Phenytoin capsules, Email correspondence dated 14 December 2012 to 3 February 2013 between [redacted] CCG and the OFT regarding the price increase of Phenytoin capsules and the cost to the NHS (CMA document reference 00014).

improvement in patient care, and indeed will need disinvestment in other medical services to fund’.

2.418 A Pfizer document dated 7 February 2013 summarises the media and political attention received:

2.418.1. Three ‘main pieces of media coverage’,⁵⁷⁸ namely (i) a Daily Telegraph article dated 13 October 2012 titled ‘Epilepsy drug price rise costs NHS an extra £44m a year’;⁵⁷⁹ (ii) a BBC Radio Leeds piece on the cost increase to West Yorkshire on 31 October 2012; and (iii) a letter to the British Medical Journal (‘BMJ’) from a GP dated 17 December 2012.⁵⁸⁰
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2.418.2. Three written parliamentary questions answered by Norman Lamb MP: two tabled by Andrew Stunell (MP in the Stockport area) and one tabled by Dr Julian Huppert (MP for Cambridge).⁵⁸²

2.419 The response of Norman Lamb MP, on behalf of the Secretary of State for Health, to the questions tabled by Andrew Stunell MP was: ‘the Department has estimated the additional cost to the national health service, from the repricing of the epanutin form of phenytoin, to be around £44 million per annum’. Norman Lamb confirmed that the government had ‘received a number of representations from hon. Members and colleagues in the NHS about the recent increase in the price of phenytoin capsules, [...] and the effects on NHS budgets’.⁵⁸³

II. Financial impact

2.420 CCG budgets are tightly managed: there is a significant amount of expenditure that is unavoidable; demand for any funds available for discretionary spending far outpaces the funds available; and CCGs have legal responsibilities to balance their budgets.⁵⁸⁴ Furthermore, during the Relevant Period the NHS was required to find significant efficiency savings. Between 2010 to 2015, for example, the Quality,

⁵⁷⁸ Pfizer was also contacted by the Health Editor of The Independent for comment on the ‘hefty increase in the price of the drug of the order of 24-fold’. In response, Pfizer suggested that all queries should be directed to Flynn. PHT00354, Email chain of 17 October 2012 between [Pfizer Employee] (Pfizer) and [X] (The Independent), RE: Epanutin (CMA document reference 00141.477).

⁵⁷⁹ Flynn was also aware of this coverage. On 17 October 2012, [Flynn Non-executive Director 2] forwarded to [Flynn Director 1] and [Flynn Director 2] (Flynn) six links to blogs discussing the Telegraph article. [Flynn Director 1] confirmed that he had ‘seen most of them’. PHT00383, Email chain of 17 October 2012 between [Flynn Director 1] (Flynn) and [Flynn Non-executive Director 2], (CMA document reference 00145.498).

⁵⁸⁰ Internal Pfizer correspondence dated 3-4 January 2013 shows that Pfizer decided to direct the BMJ to Flynn for questions. PHT00357, Email chain of 4 January 2013 between [Pfizer Employee] (Pfizer) and [Pfizer Employee 2] (Pfizer) and others, RE: The BMJ – Flynn Pharma and Epanutin (CMA document reference 00141.544).

⁵⁸¹ Flynn’s response to the letter was published in the BMJ online on 15 January 2013, PHT00360, Pfizer document titled *Epanutin Capsules UK Marketing Authorisation Divestment to Flynn Pharma: External Communications Activity To Date*, dated 7 February 2013 (CMA document reference 00141.562).

⁵⁸² PHT00360, Pfizer document titled *Epanutin Capsules UK Marketing Authorisation Divestment to Flynn Pharma: External Communications Activity To Date*, dated 7 February 2013, page 8 (CMA document reference 00141.562).

⁵⁸³ PHT00074, Hansard Written Answers – Andrew Stunell – 8 November 2012 Column 680W (CMA document reference PD48), page 16.

⁵⁸⁴ PRE00001, First Witness Statement of [X], 10 January 2017, paragraph 26.

Innovation, Productivity and Prevention initiative tasked the NHS with making up to £20 billion of efficiency savings in order to make more funds available to treat patients.⁵⁸⁵

- 2.421 As set out at paragraph 2.326 above, the NHS's total annual spend on phenytoin capsules increased from approximately £2.3 million prior to September 2012 to approximately £50 million in 2013. As a result of these increased costs, CCGs needed to commit extra money from their constrained budgets in order to continue to fund the supply of phenytoin sodium capsules (an essential treatment for patients stabilised on the drug). The redirection of these funds inevitably impacted CCGs' ability to fund other patient services and provide the planned level of patient care.⁵⁸⁶
- 2.422 In the months following the price increases, a number of CCGs wrote to the Parties, the DHSC, and others voicing concerns regarding the impact of the increases on their budgets. These complaints are set out in detail in Annex B.
- 2.423 In December 2016 Flynn applied to the CAT for interim relief, seeking a suspension of the Directions. As part of its response to this application, the CMA submitted evidence from CCG representatives as to how the increase in price had adversely affected CCGs' budgets and ability to fund patient care.
- 2.424 The evidence in relation to the direct impact on CCG budgets was summarised in the CAT's judgment refusing Flynn's request for interim relief in the following table:⁵⁸⁷

Table 2.12: CCG annual expenditure on phenytoin sodium capsules pre- and post-September 2012 price increase

CCG	Pre-2012 expenses (£)	Post-2012 expenses (£)
Gloucestershire CCG	24,000	400,000
Sussex CCG	20,000	320,000
Somerset CCG	20,000	440,000
GMMM	48,000	2,000,000

- 2.425 As noted at paragraph 2.421 above, this increased expenditure compromised CCGs' ability to provide other healthcare services. In evidence prepared for the interim relief hearing, [redacted] elaborated on the impact of the price increase on patients as follows:⁵⁸⁸

⁵⁸⁵ PAD00024, DHSC, 2010 to 2015 government policy: NHS efficiency, 8 May 2015, page 3.

⁵⁸⁶ PRE00004, First Witness Statement of [redacted], 10 January 2017, paragraphs 11 and 13; PRE00002, First Witness Statement of [redacted], 10 January 2017, paragraph 11; and PRE00003, First Witness Statement of [redacted], 10 January 2017, paragraph 16; and PRE00001, First Witness Statement of [redacted], 10 January 2017, paragraph 34.

⁵⁸⁷ Flynn v CMA, Judgment on Interim Relief, [2017] CAT 1, paragraph 86.

⁵⁸⁸ PRE00004, First Witness Statement of [redacted], 10 January 2017, paragraph 11.

Like all unforeseen cost increases, this will have impacted on the range of services the [Greater Manchester] CCGs could provide to patients and money which was earmarked for different treatments would have been diverted to cover the additional costs for Phenytoin Capsules. Other patients will have had their treatments delayed, stopped or changed as a result.

2.426 Likewise, [X] gave the following evidence as to the impact on the Somerset Clinical Commissioning Group:

*The approximate additional £1.2 million spent on phenytoin capsules over the period from September 2012 to date has meant that Somerset CCG has been unable to spend that money on commissioning other elements of patient care and at a time of growing demand on the NHS, the additional cost has contributed to the Somerset CCG now having a forecast deficit on its budget, which places additional pressures on the CCG and healthcare staff within Somerset.*⁵⁸⁹

2.427 The CAT noted that, while such evidence was not comprehensive, it provided 'examples of the problems faced by individual commissioning groups applying the discretionary element of expenditure within their control' and gave 'actual numbers of expenditure attributable to the overcharge found by the CMA'.⁵⁹⁰

⁵⁸⁹ PRE00003, First Witness Statement of [X], 10 January 2017, paragraph 16.

⁵⁹⁰ *Flynn v CMA*, Judgment on Interim Relief, [2017] CAT 1, paragraph 87.

3. Market definition and dominance

- 3.1 Market definition and dominance do not form part of this remittal as the CMA's findings were upheld by the CAT in its *Phenytoin* judgment. As such, this Decision does not include a detailed assessment of market definition and dominance. Instead, the CMA has set out the relevant markets and conclusions on dominance below.

A. Market definition

- 3.2 The CAT upheld the CMA's findings on market definition,⁵⁹¹ as such the relevant markets for the entire Relevant Period⁵⁹² are:
- 3.3 The manufacture of Pfizer-manufactured phenytoin sodium capsules (Capsules) that are distributed in the UK (which includes parallel imports as they are distributed in the UK).
- 3.4 The distribution of Pfizer-manufactured phenytoin sodium capsules (Capsules) in the UK (which includes parallel imports as they are also Pfizer-manufactured phenytoin sodium capsules).

B. Dominance

- 3.5 The CAT upheld the CMA's findings on dominance and concluded that 'the CMA was correct to find that Flynn and Pfizer each held dominant positions on their respective markets as defined'.⁵⁹³ Specifically:
- 3.6 Pfizer held a dominant position in the market for the manufacture of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK.
- 3.7 Flynn held a dominant position in the market for the distribution of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK.

⁵⁹¹ *Phenytoin* [2018] CAT 11, paragraphs 192-198.

⁵⁹² The CAT did not find it necessary to consider the CMA's alternative market definition as set out in its 2016 Infringement Decision (*Phenytoin* [2018] CAT 11, paragraph 197).

⁵⁹³ *Phenytoin* [2018] CAT 11, paragraphs 251-253.

4. Legal framework

A. Overview

- 4.1 Section 18(1) of the Act prohibits any conduct on the part of one or more undertakings which amounts to an abuse of a dominant position in a market if it may affect trade within the UK.
- 4.2 The concept of abuse is an objective one relating to the behaviour of an undertaking in a dominant position. The existence of an anti-competitive intent on the part of the dominant undertaking is not a requirement for a finding of abuse.⁵⁹⁴ However, evidence of such an intent, while it cannot be sufficient in itself, constitutes a fact that may be taken into account in order to determine that a dominant position has been abused.⁵⁹⁵
- 4.3 Section 18(2)(a) of the Act states that, directly or indirectly, imposing unfair selling prices constitutes an abuse.⁵⁹⁶
- 4.4 It is well established that the ‘*seminal*’⁵⁹⁷ judgment on unfair pricing is *United Brands v Commission*⁵⁹⁸ which provides that:

248 *The imposition by an undertaking in a dominant position directly or indirectly of unfair purchase or selling prices is an abuse to which exception can be taken under Article [102] of the Treaty.*

249 *It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.*

250 *In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse.*

251 *This excess could, inter alia, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin; however the*

⁵⁹⁴ C-549/10 P *Tomra v European Commission*, EU:C:2012:221, paragraph 21. See also *Hoffmann-La Roche*, EU:C:1979:36, paragraph 91.

⁵⁹⁵ C-307/18 *Generics (UK) Ltd and others v Competition and Markets Authority*, EU:C:2020:52, paragraph 162. See also C-549/10 P *Tomra v European Commission*, EU:C:2012:221, paragraphs 20, 21 and 24.

⁵⁹⁶ Section 18(2) of the Act and *United Brands*, EU:C:1978:22, paragraph 248.

⁵⁹⁷ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 56 and 219. See also *Albion Water and Another v Water Services Regulation Authority and Others* (*‘Albion Water II’*) [2008] CAT 31, paragraph 14; and *Phenytoin* [2018] CAT 11, paragraph 285.

⁵⁹⁸ C-27/76 *United Brands v Commission* EU:C:1978:22 (*‘United Brands’*).

Commission has not done this since it has not analysed [United Brands'] costs structure.

252 *The questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.*

253 *Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair’.*

4.5 As is clear from paragraph 253 of *United Brands*, there is no single method or ‘way’ in which an unfair pricing abuse can be established.⁵⁹⁹ Competition authorities have a ‘margin of manoeuvre’ or ‘discretion’ in deciding which methodology to use.⁶⁰⁰

4.6 One possible method for determining whether or not a price is unfair is set out in paragraphs 251 and 252 of *United Brands* and is commonly referred to as the ‘*United Brands* test’. The *United Brands* test involves comparing the selling price of the relevant product and its cost of production, which discloses the amount of the profit margin.⁶⁰¹ Under this method a price will be abusively high where the following cumulative, two limb test is met:

4.6.1. ‘the difference between the costs actually incurred and the price actually charged is excessive’ (Excessive Limb); and

4.6.2. ‘a price has been imposed which is either unfair in itself or when compared to competing products’ (Unfair Limb).⁶⁰²

4.7 This two-limb test has been consistently applied by the European Commission,⁶⁰³ competition authorities of Member States of the EU,⁶⁰⁴ the Court of Justice,⁶⁰⁵ the

⁵⁹⁹ *Phenytol CoA* [2020] EWCA Civ 339, paragraphs 84 to 86, 97(iii) to (iv) and 251.

⁶⁰⁰ *Phenytol CoA* [2020] EWCA Civ 339, paragraphs 97(iii), 107, 120, 121, 246 and 251.

⁶⁰¹ *United Brands*, EU:C:1978:22, paragraph 251.

⁶⁰² *United Brands*, EU:C:1978:22, paragraph 252. See also *Albion Water II* [2008] CAT 31, paragraph 7; *Attheraces Limited v the British Horseracing Board Limited* (‘*Attheraces High Court*’) [2005] EWHC 3015 (Ch), paragraph 294; and 36568 *Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004 (‘*Scandlines*’), paragraphs 102, 149, 150 and 215.

⁶⁰³ *Scandlines*, paragraphs 98 to 103 and 145 to 152.

⁶⁰⁴ See eg, *Aspen Italian NCA* (Case A480, Autorità Garante della Concorrenza e del Mercato) decision of 29 September 2016; and *CD Pharma Danish NCA* (Konkurrence- og Forbrugerstyrelsen) decision of 31 January 2018.

⁶⁰⁵ As a recent example, see C-177/16 *Autortiesību un komunikēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome* (‘*Latvian Copyright*’), EU:C:2017:689, paragraph 36.

High Court,⁶⁰⁶ the CAT,⁶⁰⁷ and the Court of Appeal⁶⁰⁸ (most recently in its *Phenytoin CoA* judgment dated 10 March 2020).⁶⁰⁹

- 4.8 Whilst the authority bears the legal burden of proof and must take a rigorous reasoned approach to the legal and factual questions,⁶¹⁰ it is not required to apply an approach or methodology that is so complex and time-consuming that the relevant authority has neither the time nor the resources to deal with cases of alleged unfair pricing.⁶¹¹

B. Limb one of the *United Brands* test: is the price excessive?

- 4.9 The first limb of the *United Brands* test asks ‘whether the difference between the costs actually incurred and the price actually charged is excessive’.⁶¹²
- 4.10 In *Phenytoin CoA* the Chancellor of the High Court observed that the first step in the analysis for the Excessive Limb is likely in most cases to be for the competition authority to consider whether the costs of production or the costs actually incurred in relation to the product in question, including a reasonable rate of return, can be ascertained. Where it can be done, there is no reason why the authority should not use that methodology to ascertain an appropriate counterfactual for the Excessive Limb.⁶¹³ This can be done by comparing the selling price to the cost of production plus a reasonable rate of return on sales (ROS) or to some other appropriate benchmark such as return on capital employed (ROCE).⁶¹⁴
- 4.11 There is no need to establish a hypothetical benchmark price or a range of prices, beyond a Cost Plus calculation, in order to determine whether the prices charged are excessive.⁶¹⁵
- 4.12 In each of *Ineos Vinyls v Huntsman Petrochemicals*,⁶¹⁶ *Attheraces*,⁶¹⁷ *Albion Water I*⁶¹⁸ and *Albion Water II*⁶¹⁹ a price/cost comparison was considered to be

⁶⁰⁶ *Ineos Vinyls Ltd v Huntsman Petrochemicals (UK) Ltd* [2006] EWHC 1241 (Ch), paragraphs 217 to 218.

⁶⁰⁷ *Albion Water and Another v Water Services Regulation Authority and Others* (*‘Albion Water I’*) [2006] CAT 23, paragraphs 308 and 314; *Albion Water II* [2008] CAT 31, paragraphs 14 to 15 and 20 to 21; and *Napp Pharmaceutical Holding Limited and Subsidiaries v Director General of Fair Trading* (*‘Napp’*) [2002] CAT 1, paragraph 387. In *Phenytoin* [2018] CAT 11, the CAT summarised the two limb *United Brands* test at paragraphs 285 and 288 but, when applying it, it set out at paragraph 443 an eight-pronged test for cases where the only alleged infringement is one of excessive pricing.

⁶⁰⁸ *Attheraces Limited v British Horse Racing Board Limited* (*‘Attheraces Court of Appeal’*) [2007] EWCA Civ 38, paragraphs 114 to 119.

⁶⁰⁹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(v) to (viii).

⁶¹⁰ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 243 and 246.

⁶¹¹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 244.

⁶¹² *United Brands* EU:C:1978:22, paragraph 252; *Latvian Copyright*, EU:C:2017:689, paragraph 36; and *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(v) and 249.

⁶¹³ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 252.

⁶¹⁴ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(v).

⁶¹⁵ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 254; see also *ibid* paragraphs 120 to 125, 185 and 249 to 250.

⁶¹⁶ *Ineos Vinyls v Huntsman Petrochemicals* [2006] EWHC 1241 (Ch), paragraph 217.

⁶¹⁷ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraphs 116 and 209.

⁶¹⁸ *Albion Water I* [2006] CAT 23, paragraph 314.

⁶¹⁹ *Albion Water II* [2008] CAT 31, paragraphs 20 and 194.

sufficient to satisfy the Excessive Limb and it was not considered necessary to apply more than one method.

I. Cost Plus

a. Costs

- 4.13 The measurement of ‘the costs actually incurred’⁶²⁰ in, or ‘reasonably attributable’⁶²¹ to, supplying the product in question will include:
- 4.14 The costs directly incurred in supplying the product or service;⁶²² and
- 4.15 An appropriate apportionment of the *indirect* costs that are reasonably attributable to the product or service.⁶²³
- 4.16 The case law does not prescribe a particular methodology for measuring cost. Competition authorities have a margin of manoeuvre or appreciation in deciding which methodology to use and which evidence to rely upon.⁶²⁴ In *Albion Water II*, the CAT stated that, rather, ‘it is a matter of fact, accounting technique and economic assessment’⁶²⁵ and went on to state that:

*Because there may be times when a competition authority or court needs the flexibility to examine more than one measure of cost in order to evaluate an allegedly excessive price, we do not prescribe a cost measure that would apply in all cases. The use of more than one credible methodology, even if only as a cross-check, helps to minimise the risk of false positives and to assure confidence in the results obtained.*⁶²⁶

- 4.17 The Court of Justice in *United Brands* recognised the need for flexibility in the methods used for calculating costs because of:

*the considerable and at times very great difficulties in working out production costs which may sometimes include a discretionary apportionment of indirect costs and general expenditure and which may vary significantly according to the size of the undertaking, its object, the complex nature of its set up, its territorial area of operations, whether it manufactures one or several products, the number of subsidiaries and their relationship with each other.*⁶²⁷

⁶²⁰ *United Brands*, EU:C:1978:22, paragraph 252. See also *Albion Water II* [2008] CAT 31, paragraph 20.

⁶²¹ *Albion Water II* [2008] CAT 31, paragraph 198.

⁶²² *Albion Water I* [2006] CAT 23, paragraph 314; and *Albion Water II* [2008] CAT 31, paragraph 89.

⁶²³ *United Brands*, EU:C:1978:22, paragraph 254.

⁶²⁴ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(iii).

⁶²⁵ *Albion Water II* [2008] CAT 31, paragraph 88.

⁶²⁶ *Albion Water II* [2008] CAT 31, paragraph 93.

⁶²⁷ *United Brands*, EU:C:1978:22, paragraph 254. See also *Scandlines*, paragraph 117.

4.18 Further, it is well-established that any costs must be reasonably and efficiently incurred.⁶²⁸ As the CAT explained in *Albion Water II*: ‘Community jurisprudence only permits the inclusion of efficiently incurred costs’.⁶²⁹

b. Reasonable rate of return

4.19 The judgment in *United Brands* only refers to the costs of production, without further definition.⁶³⁰

4.20 The European Commission recognised in *Scandlines*⁶³¹ that it is legitimate that a company may want to cover its cost of capital and stated in *Aspen* that ‘companies are entitled to make a reasonable rate of return, in order to cover their cost of capital’.⁶³² Similarly, the CAT recognised in *Albion Water II*⁶³³ that the relevant components of costs should ordinarily comprise a return on capital. Therefore, when establishing the ‘costs actually incurred’ it will normally be necessary to allocate a reasonable rate of return to cover the cost of capital.

4.21 It is not necessary to adopt any particular approach to the determination of the ‘plus’ part of the Cost Plus calculation.⁶³⁴ The identification of a reasonable rate of return is not a matter of ‘precise mathematics’.⁶³⁵ It is a question of judgement and appreciation on which experts may well take differing views.⁶³⁶ In exercising that judgement, where relevant, regard may be had to the interests of patients and the NHS.⁶³⁷

II. Differential

4.22 Having established the ‘costs actually incurred’ plus a reasonable rate of return, it is then necessary to compare it with the selling price and determine whether that margin is excessive.⁶³⁸

4.23 In *Albion Water II*, the CAT stated that:

The term “excessive” is an ordinary English word, which may be applied in accordance with its ordinary meaning, having regard to the overall purpose of the Chapter II prohibition. We note that the Authority submitted that a price may not be “excessive” within the meaning of the first United Brands question where the price exceeds costs but not by a material extent (see paragraph 11.3 of the Report). While we are prepared to accept that a

⁶²⁸ C-395/87 *Ministère Public v Tournier*, EU:C:1989:319, paragraph 42.

⁶²⁹ *Albion Water II* [2008] CAT 31, paragraph 88.

⁶³⁰ *United Brands*, EU:C:1978:22, paragraphs 251 and 254. See also *Albion Water II* [2008] CAT 31, paragraph 89.

⁶³¹ *Scandlines*, paragraph 224.

⁶³² AT.40394 *Aspen*, Commission decision of 10 February 2021 (*‘Aspen’*), paragraph 154.

⁶³³ *Albion Water II* [2008] CAT 31, paragraph 89.

⁶³⁴ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 253.

⁶³⁵ *Genzyme Limited v Office of Fair Trading* (*‘Genzyme Remedy’*) [2005] CAT 32, paragraph 279.

⁶³⁶ *Genzyme Remedy* [2005] CAT 32, paragraph 255.

⁶³⁷ *Genzyme Remedy* [2005] CAT 32, paragraph 256.

⁶³⁸ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).

*material difference between price and cost must be shown, we see no need to specify, in this case, when a particular difference is sufficiently large to be deemed excessive.*⁶³⁹

- 4.24 The assessment of whether the differential is excessive requires the exercise of judgement as it ‘involves a proper degree of discretionary judgment by the decision-maker’.⁶⁴⁰

C. Limb Two of the *United Brands* test: is the price unfair?

- 4.25 An excessive price may be unfair either:

4.25.1. ‘in itself’; or

4.25.2. ‘when compared to competing products’.⁶⁴¹

- 4.26 This is an alternative rather than a cumulative test.⁶⁴² Accordingly, it is sufficient to demonstrate that one of the alternatives of the Unfair Limb is satisfied to establish an infringement.⁶⁴³

- 4.27 It is therefore possible to use either alternative 1 (unfair in itself) or alternative 2 (unfair when compared to competing products) to determine unfairness.⁶⁴⁴ If the relevant undertaking does not adduce other methods or evidence, competition authorities may proceed to a conclusion upon the basis of that method and evidence alone.⁶⁴⁵ There is no fixed list of categories of evidence relevant to unfairness.⁶⁴⁶

- 4.28 However, irrespective of which alternative is chosen, ‘the competition authority will always need, at least as part of its duty of good administration, to give some consideration to prima facie valid comparators advanced evidentially⁶⁴⁷ by the undertakings’.⁶⁴⁸ As to that duty:

4.28.1. The law does not predetermine how intensive any particular evaluation by the authority will be. The extent of the duty on an authority to evaluate evidence adduced by an undertaking will be fact and context specific and

⁶³⁹ *Albion Water II* [2008] CAT 31, paragraph 199.

⁶⁴⁰ *Albion Water II* [2008] CAT 31, paragraphs 193 to 194.

⁶⁴¹ *United Brands*, EU:C:1978:22, paragraph 252. See confirmation of this test in *Latvian Copyright*, EU:C:2017:689, paragraph 36.

⁶⁴² C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255, where the CAT also held that the test was alternative in nature; and *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 259.

⁶⁴³ *Phenytoin* [2018] CAT 11, paragraph 366.

⁶⁴⁴ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 259 and 269.

⁶⁴⁵ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(vii).

⁶⁴⁶ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(vi).

⁶⁴⁷ See *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 114 and 116: ‘[t]here is an important evidential burden upon an undertaking being investigated’.

⁶⁴⁸ See *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 259 and 260. See also *ibid* paragraph 97(viii): ‘[i]f an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority then the authority must fairly evaluate it’.

is affected by the quality of that evidence. There is an important evidential burden upon an undertaking being investigated.⁶⁴⁹

- 4.28.2. The authority has a margin of manoeuvre or discretion as to how it performs that duty, including as to the depth and intensity of the inquiry.⁶⁵⁰ The competition authority ‘does not have any duty actively to investigate in every case, in the sense of obtaining evidence about, any comparators put forward by the undertakings’. Rather, the authority is obliged to evaluate the arguments and evidence advanced by undertakings fairly and impartially. It may reject comparators so advanced, but should give reasons for doing so.⁶⁵¹

I. Unfair in itself

- 4.29 The authority has a considerable margin of appreciation when assessing whether an excessive price is also unfair.⁶⁵²
- 4.30 A price which ‘significantly exceeds’ the economic value of the product supplied ‘will be prima facie excessive and unfair’.⁶⁵³ However, other factors are also relevant to that determination.
- 4.31 The CAT held in *Albion Water II* that, when assessing the potential unfairness of a price, it is necessary to ‘take into account the competitive conditions and any related abusive conduct that may enable the undertaking concerned to fulfil its pricing ambitions’.⁶⁵⁴
- 4.32 In this respect, the CAT found that factors establishing a dominant position may be relevant to assessing whether an excessive price is unfair:

*...factors that establish a dominant position, notably barriers to entry, may well be relevant to determining whether a price is so high as to amount to an abuse by an undertaking of its dominant position. This is particularly true in excessive pricing cases, in which it is important to distinguish excessive prices shielded from effective competitive pressure from temporarily high prices that are the subject of normal market forces in a competitive market.*⁶⁵⁵

⁶⁴⁹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 112, 114 and 116.

⁶⁵⁰ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 113, 116 and 270.

⁶⁵¹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 270.

⁶⁵² *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 135 and *Albion Water II* [2008] CAT 31, paragraphs 216, 261 and 263.

⁶⁵³ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 204. See also *Albion Water II* [2008] CAT 31, paragraph 265.

⁶⁵⁴ *Albion Water II* [2008] CAT 31, paragraph 266. See also the following judgments on the importance of taking into account the competitive conditions prevailing in the market when assessing whether an abuse of a dominant position has been committed: *Napp* [2002] CAT 1, paragraph 400; and *C-23/14 Post Danmark*, EU:C:2015:651, paragraph 30.

⁶⁵⁵ *Albion Water II* [2008] CAT 31, paragraph 213.

- 4.33 Such factors are naturally case-specific and the CAT found that, where present, they ‘suggest that the Tribunal should review with care the lawfulness of a price which was unconstrained by any competitive considerations whatsoever’.⁶⁵⁶ For instance, in *Albion Water II*, the CAT looked at ‘whether the relevant market is capable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value of the services to be supplied’.⁶⁵⁷
- 4.34 In *Albion Water II*, the CAT recognised the importance of taking end customers’ interests into account and looking beyond the immediate interests of competitors,⁶⁵⁸ on the basis that ‘the primary interest to be protected under the Chapter II prohibition is that of the consumer, rather than the private interest of a particular competitor’.⁶⁵⁹
- 4.35 The value added by a firm and the risks and activities it undertakes may also be relevant for assessing whether a price is unfair in itself.⁶⁶⁰ For example, a dominant undertaking may have taken risks, made investments, improved a product or innovated in a way that could render high profits, partially or entirely, a legitimate reward for pro-competitive efforts.⁶⁶¹
- 4.36 All other factors taken into account by the CMA in the 2016 Infringement Decision in *Phenytoin* could be relevant for the assessment of ‘unfair in itself’:

*...such factors as: the increase in price; the selective change of prices in the UK but not elsewhere; the impact on the buyer; the lack of any independent or objective justification; the commercial purpose of the arrangements and the approach of the parties to them; could all be factors which it was relevant for [the CMA] to weigh when considering the application of the “unfair in itself” test...*⁶⁶²

II. Unfair when compared to competing products

- 4.37 Alternatively, an excessive price can be unfair when compared to competing products.⁶⁶³
- 4.38 Any comparison must be ‘made on a consistent basis’ and comparators must be ‘selected in accordance with objective, appropriate and verifiable criteria’ according

⁶⁵⁶ *Albion Water II* [2008] CAT 31, paragraph 268. See also Opinion of Advocate General Jacobs in C-395/87 *Ministère Public v Tournier*, EU:C:1989:215, paragraph 43.

⁶⁵⁷ *Albion Water II* [2008] CAT 31, paragraph 268.

⁶⁵⁸ *Albion Water II* [2008] CAT 31, paragraph 271.

⁶⁵⁹ *Albion Water II* [2008] CAT 31, paragraph 218. See also *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 215.

⁶⁶⁰ See, to that effect, *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 215, and *Phenytoin* [2018] CAT 11, paragraphs 404 and 346. See also *Aspen*, paragraph 163.

⁶⁶¹ *Aspen*, paragraph 163.

⁶⁶² *Phenytoin* [2018] CAT 11, paragraph 369.

⁶⁶³ *United Brands*, EU:C:1978:22, paragraph 252.

to the circumstances of the case, allowing for the differing economic conditions in which the prices of comparators may have been set.⁶⁶⁴

4.39 Comparators do not have to be identical⁶⁶⁵ or on the same relevant market as the product at issue.⁶⁶⁶ However, it is necessary to ensure in every case that the comparator is sufficiently similar to the product concerned to allow for a 'meaningful' comparison.⁶⁶⁷ Comparisons must be made on a consistent basis and the figures that are compared must be comparable.⁶⁶⁸

4.40 A comparator cannot be considered meaningful simply on the basis that the customer is paying the price imposed.⁶⁶⁹ Comparisons should not be drawn with other products the price of which may also have been inflated by the exercise of substantial market power.⁶⁷⁰

4.41 As the CAT has noted:

*If the [price under consideration] is not cost-justified, and since the evidence strongly suggests that that price was excessive, it does not in our view assist that that price is based on a comparison with other prices which are not cost-justified either.*⁶⁷¹

4.42 These concerns are similarly reflected in the CAT's conclusion that even where a number of other companies providing the same service engage in similar pricing practices, this will 'not, in itself, show that the [price in question] is not unfair'.⁶⁷²

III. Economic value

4.43 In *Phenytoin CoA* the Court of Appeal held that economic value 'is an economic concept which describes what it is that users and customers value and will reasonably pay for and it arose in the *United Brands* judgment as an economic description of the abuse of unfair pricing'.⁶⁷³

⁶⁶⁴ *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 41, 44 to 46 and 51. See also *Phenytoin* [2018] CAT 11, paragraphs 392 and 444.

⁶⁶⁵ C-372-19 *SABAM v Weareone.World, Wecandance*, EU:C:2020:959, paragraph 32 and *Albion Water II* [2008] CAT 31, paragraph 252.

⁶⁶⁶ C-372-19 *SABAM v Weareone.World, Wecandance*, EU:C:2020:959, paragraph 32 and *Phenytoin* [2018] CAT 11, paragraph 373.

⁶⁶⁷ See for example *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin* [2018] CAT 11, paragraph 373.

⁶⁶⁸ See for example *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 44 to 46 and 51; *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin* [2018] CAT 11, paragraph 373.

⁶⁶⁹ See for example *Albion Water I* [2006] CAT 23, paragraphs 754 to 756.

⁶⁷⁰ This is consistent with the CAT's findings in *Albion Water I* [2006] CAT 23, paragraph 757; and *Albion Water II* [2008] CAT 31, paragraph 257. It is also consistent with PAD00022, the submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, paragraphs 49 and 50.

⁶⁷¹ *Albion Water I* [2006] CAT 23, paragraph 757.

⁶⁷² *Albion Water II* [2008] CAT 31, paragraph 257.

⁶⁷³ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 171.

- 4.44 The Court of Appeal set out that the reference in *United Brands* to ‘economic value’ is ‘as part of the overall descriptor of the abuse; it is not the test’.⁶⁷⁴ Rather ‘economic value needs to be factored in and fairly evaluated, *somewhere*, but it is properly a matter which falls to the judgment of the competition authority as to where in the analysis this occurs’.⁶⁷⁵ Competition authorities are not required to adopt any particular approach to the determination of economic value.⁶⁷⁶
- 4.45 Determining the ‘economic value’ of a product involves a considerable margin of appreciation⁶⁷⁷ with appropriate weight being given to factors on both the supply and demand side.⁶⁷⁸
- 4.46 The economic value of a product may exceed Cost Plus as a result of non-cost related factors including,⁶⁷⁹ where applicable, ‘additional benefits not reflected in the costs of supply’⁶⁸⁰ or any ‘particular enhanced value from the customer’s perspective’.⁶⁸¹
- 4.47 This was, for instance, the case in *Scandlines*⁶⁸² and *Attheraces*⁶⁸³ where the European Commission and the Court of Appeal found, respectively, that the ‘unique location close to Elsinore’ of the port of Helsingborg and ‘the relevance of the value of the pre-race data to ATR’ increased the economic value of the product and services concerned beyond their costs of production.
- 4.48 This is consistent with the CAT’s analysis of *Attheraces* in *Albion Water II*, where the CAT concluded that in that case, the economic value was greater than the cost of production because the customer was ‘readily willing to pay a premium’ for the product.⁶⁸⁴
- 4.49 The existence and scale of any ‘non-cost related factors’ vary on a case-by-case basis. Some products may have ‘non-cost related factors’ which increase the economic value above production costs. Others may have no, or few, ‘non-cost-related factors’, meaning the economic value of the product or service in question is either ‘not more, or not significantly more, than’ the production costs.⁶⁸⁵
- 4.50 For example, in *Albion Water II*, the CAT found that there was no additional economic value beyond the cost of providing the service in question.⁶⁸⁶ The

⁶⁷⁴ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.

⁶⁷⁵ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.

⁶⁷⁶ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 253.

⁶⁷⁷ *Albion Water I* [2006] CAT 23, paragraph 310 and *Albion Water II* [2008] CAT 31, paragraphs 216 and 263. See also *Phenytoin* [2018] CAT 11, paragraphs 407 and 425.

⁶⁷⁸ *Albion Water II* [2008] CAT 31, paragraph 225. See also *Phenytoin* [2018] CAT 11, paragraph 411.

⁶⁷⁹ See *Albion Water II* [2008] CAT 31, paragraph 222; and *Scandlines*, paragraph 226. See also *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 218.

⁶⁸⁰ *Albion Water II* [2008] CAT 31, paragraph 7.

⁶⁸¹ *Albion Water II* [2008] CAT 31, paragraph 222.

⁶⁸² *Scandlines*, paragraph 241.

⁶⁸³ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 218.

⁶⁸⁴ *Albion Water II* [2008] CAT 31, paragraph 226.

⁶⁸⁵ *Albion Water II* [2008] CAT 31, paragraphs 225 and 249.

⁶⁸⁶ *Albion Water II* [2008] CAT 31, paragraph 249.

European Commission reached the same conclusion in *Deutsche Post*.⁶⁸⁷ In those circumstances, the CAT has held in *Albion Water II* that neither *Scandlines* nor *Attheraces*:

*excludes the possibility that, in the absence of relevant non-cost-related factors, the very excessiveness of a price could be sufficient to establish that the price bears no reasonable relation to the economic value of the product/service being provided.*⁶⁸⁸

- 4.51 Economic value is not simply whatever price a product or service will fetch or ‘the market will reasonably bear’.⁶⁸⁹ That was confirmed by the Court of Appeal in *Attheraces*⁶⁹⁰ and *Phenytoin*:

But [what the customer is willing to pay] cannot serve as an adequate definition in an abuse case since otherwise true value would be defined as anything that an exploitative and abusive dominant undertaking could get away with. It would equate proper value with an unfair price. This is a well-known conundrum in international competition law [...]

*The simple fact that a consumer will or must pay the price that a dominant undertaking demands is not therefore an indication it reflects a reasonable relationship with economic value.*⁶⁹¹

- 4.52 The Advocate General in SABAM also noted that:

*...it is not always the case that there is a maximum price that the consumer is willing to pay for a product, with a result that, in those situations, there are no obstacles to the introduction of excessive prices. In the case of a life-saving medicine, for example, the only spending limit is the financial capacity of the purchaser (whether the patient or the national health service).*⁶⁹²

- 4.53 This is particularly relevant where the customer has no real choice when purchasing the product in question. In *Hoffmann-La Roche* the Court of Justice recognised that being an ‘unavoidable trading partner’ necessarily gives a dominant undertaking ‘freedom of action’ as to how it prices.⁶⁹³ The potential for abuse in such situations was also recognised by Advocate General Jacobs in his Opinion in *Ministère Public v Tournier*. When assessing the fairness of a product’s

⁶⁸⁷ COMP/C-1/36.915 *Deutsche Post AG*, Commission Decision of 25 July 2001 (*‘Deutsche Post’*), paragraph 162.

⁶⁸⁸ *Albion Water II* [2008] CAT 31, paragraph 225. See also paragraph 264.

⁶⁸⁹ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraphs 210 to 211. The Court of Appeal rejected this argument even when ‘reasonably’ was added to the proposition (see paragraph 211). See also *Albion Water II* [2008] CAT 31, paragraph 226, where the CAT distinguished between cases where the customer was ‘readily willing to pay a premium’ and ones where the customer was not. The CAT found that while Albion was paying the price charged, it was only doing so under protest. Consequently, the CAT held that Albion was ‘not a willing purchaser’ for the purposes of assessing economic value.

⁶⁹⁰ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 205.

⁶⁹¹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 154 to 155.

⁶⁹² Opinion of Advocate General Pitruzzella in C-372/19 *SABAM v Weareone World*, EU:C:2020:598, paragraph 25.

⁶⁹³ *Hoffmann-La Roche*, EU:C:1979:36, paragraph 41.

price, the Advocate General stated that it could be ‘superficially attractive’ to do so by reference to the product’s importance to the customer, but that ‘the usefulness of the criterion breaks down where a given category of users is completely dependent for its functioning on the supply of [the product] and where because of the absence of competition [those users] must, in effect, pay whatever price is required’.⁶⁹⁴

4.54 However, the Court of Appeal has explained that:

*...dependency and the inferences to be drawn from its existence are indeed matters of fact and degree. Even if there is dependency there might still be some economic value but not necessarily reflecting the full price demanded.*⁶⁹⁵

4.55 In circumstances where it is possible to ascertain what consumers are prepared to pay for the relevant good or service in an effectively competitive market, this may provide a proxy for the economic value of the product or service concerned.⁶⁹⁶

D. Other methodologies

4.56 Methods other than the *United Brands* test that have been used by EU and domestic courts for determining whether a price is unfair⁶⁹⁷ include for example: prices charged by: (i) the dominant firm at a different point in time;⁶⁹⁸ (ii) non-dominant firms;⁶⁹⁹ and (iii) the dominant firm or other firms in different geographical markets.⁷⁰⁰

4.57 For instance, in cases involving IP rights a comparison across different geographic markets has been the method most often used. In such cases, when an undertaking holding a dominant position imposes fees for its services which are appreciably higher than those charged in other Member States, and where a comparison of the fee levels has been made on a consistent basis, that difference must be regarded as indicative of an abuse of a dominant position. In those circumstances it is for the undertaking in question to justify the difference by reference to objective dissimilarities between the situation in the Member State concerned and the situation prevailing in all other Member States.⁷⁰¹

⁶⁹⁴ Opinion of Advocate General Jacobs in C-395/87 *Ministère Public v Tournier*, EU:C:1989:215, paragraph 65.

⁶⁹⁵ *Phenytol* CoA [2020] EWCA Civ 339, paragraph 167.

⁶⁹⁶ *Phenytol* CoA [2020] EWCA Civ 339, paragraphs 155 and 172.

⁶⁹⁷ *United Brands*, EU:C:1978:22, paragraph 253, and *Latvian Copyright*, EU:C:2017:689, paragraph 37. See also *Napp* [2002] CAT 1, paragraph 391.

⁶⁹⁸ C-226/84 *British Leyland v Commission*, EU:C:1986:421, paragraphs 27 to 30.

⁶⁹⁹ C-30/87 *Bodson v SA Pompes funèbres des régions libérées*, EU:C:1988:225, paragraph 31; and *Napp* [2002] CAT 1, paragraph 392.

⁷⁰⁰ C-395/87 *Ministère Public v Tournier*, EU:C:1989:319, paragraph 38; cases 110/88, 241/88 and 242/88 *Lucazeau*, EU:C:1989:326, paragraph 25; and *Latvian Copyright*, EU:C:2017:689, paragraph 38.

⁷⁰¹ C-395/87 *Ministère Public v Tournier*, EU:C:1989:319, paragraph 38; cases 110/88, 241/88 and 242/88 *Lucazeau*, EU:C:1989:326, paragraph 25; and *Latvian Copyright*, EU:C:2017:689, paragraphs 38 and 57.

- 4.58 There is, however, no rule of law requiring competition authorities to use more than one test or method to assess an unfair pricing abuse.⁷⁰²

E. Burden and standard of proof

- 4.59 The burden of proving an infringement of the Chapter II prohibition lies with the CMA.⁷⁰³ The evidence must be sufficient in the circumstances of the particular case, taking account of the presumption of innocence to which parties are entitled.⁷⁰⁴ However, this burden does not preclude the CMA from relying, where appropriate, on inferences or evidential presumptions.⁷⁰⁵

The standard of proof that the CMA is required to meet is the civil standard of balance of probabilities,⁷⁰⁶ nothing more and nothing less.⁷⁰⁷

⁷⁰² *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(iv).

⁷⁰³ *Napp* [2002] CAT 1, paragraphs 95 and 100. See also, *JJB Sports plc v OFT* ('**JJB Sports**') [2004] CAT 17, paragraphs 164 and 928 to 931; and *Tesco Stores Limited v Office of Fair Trading* ('**Tesco Stores**') [2012] CAT 31, paragraph 88.

⁷⁰⁴ *JJB Sports* [2004] CAT 17, paragraph 204. See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2004] CAT 24, paragraphs 164 to 166 and *Phenytoin* [2018] CAT 11, paragraph 92.

⁷⁰⁵ *Napp*, paragraph 110. On the CMA's duty to fairly evaluate all the evidence before it, see *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 110 to 117.

⁷⁰⁶ *AH Willis and Sons Limited v Office of Fair Trading* [2011] CAT 13, paragraphs 46 and 47 and *Tesco Stores* [2012] CAT 31, paragraph 88.

⁷⁰⁷ *Re S-B (Children)* [2009] UKSC 17, paragraph 34. See also *Re B (Children)* [2008] UKHL 35, paragraph 73. The CAT has expressly accepted the Supreme Court's reasoning in *North Midland Construction plc v Office of Fair Trading* [2011] CAT 14, paragraphs 15 to 16.

5. Excessive

5.1 For the reasons set out below, the CMA concludes that each of Pfizer's Prices and each of Flynn's Prices is excessive by reference to the first stage of the *United Brands* test. This section is structured as follows:

5.1.1 The CMA's approach to establishing Cost Plus for each of Pfizer's Products and Flynn's Products (section 5.A).

5.1.2 The CMA's assessment of whether Pfizer's Prices were excessive (section 5.B).

5.1.3 The CMA's assessment of whether Flynn's Prices were excessive (section 5.C).

A. The CMA's approach to establishing Cost Plus for each of Pfizer's Products and Flynn's Products

I. General Framework

5.2 As explained in section 4.B.I (Legal Framework), the first step in establishing Cost Plus is to determine the costs that each Party incurred in producing and supplying their products. This includes costs directly incurred in the supply of Capsules and an appropriate apportionment of indirect costs, such as corporate overheads.⁷⁰⁸

5.3 After establishing the costs actually incurred, a reasonable rate of return should be estimated and added to total costs, to determine Cost Plus.

5.4 This section sets out the approach that the CMA has adopted in determining those costs and in estimating a reasonable rate of return.

5.5 The CMA refers to the differential between the Parties' prices and Cost Plus as the Parties' 'excesses'.

II. Approach to establishing direct costs

5.6 Direct costs are those costs that can be directly attributed to a particular line of business; in this case the production, purchase and/or distribution of Capsules in the UK.

5.7 As regards its direct costs, Pfizer provided information relating to the internal transfer prices paid by Pfizer Limited to Pfizer Manufacturing Deutschland GmbH (which manufactures the Capsules). The CMA has assumed that all costs recovered by Pfizer's internal transfer price were reasonably incurred. In addition,

⁷⁰⁸ Section 4.B.I.

the CMA has included distribution costs incurred by Pfizer Limited within its measure of Pfizer's direct costs.

- 5.8 Flynn provided information as regards the purchase price that it pays to Pfizer for each pack of Capsules as well as the fees that it incurs in relation to storage, distribution and order services. The CMA has included each of these cost elements within its measure of Flynn's direct costs.

III. Approach to establishing indirect costs

- 5.9 In addition to direct costs, businesses also incur costs that are indirectly but necessarily incurred in order to supply a given product. A proportion of these costs needs to be included in the overall costs of Capsules to fully reflect the total costs actually incurred by each of Pfizer and Flynn.
- 5.10 Indirect costs include: (i) costs which are common across a number of products; and (ii) joint costs that arise when two or more products are necessarily produced together.
- 5.11 Neither Pfizer nor Flynn have any joint costs in relation to Capsules because no other products are produced as a direct result of the manufacturing process for phenytoin sodium capsules. Accordingly, only common costs are relevant to the assessment of the level of indirect costs that are actually incurred by each of Pfizer and Flynn in supplying Capsules.
- 5.12 Common costs are those costs that are incurred in the supply of more than one product.⁷⁰⁹ Typically, they include costs related to matters such as administrative employees (for example, finance and legal departments), manufacturing and distribution facilities and head office overheads (for example, utilities, rent and rates). To determine the relevant common costs for a particular product, a portion of total attributable common costs should be allocated to each of the products that a company supplies.
- 5.13 In this case, the CMA first identified the categories of common costs that it considered to be at least partly attributable to the supply of Capsules.
- 5.14 The CMA made several requests to the Parties to help it determine the various types and proportion of common costs which should be allocated to Capsules. However, Pfizer and Flynn provided only high level cost data to the CMA, covering broad categories of costs; for example, employee costs, IT expenses and depreciation.⁷¹⁰ Using such data, it has not been possible for the CMA to identify

⁷⁰⁹ In this case, Pfizer incurs costs related to the supply of all medicines that it sells into the UK. This includes but is not limited to phenytoin sodium capsules. Similarly, Flynn sells a number of medicines in the UK with phenytoin sodium capsules being just one of these.

⁷¹⁰ PHT00131, Pfizer's response of 16 April 2014 to the OFT's s.26 Notice information request of 5 March 2014 (CMA document reference 00519.2), Annex 1; PHT00133, Pfizer's draft response of 4 July 2014 to the CMA's draft s. 26 Notice

the specific costs in these categories that should be allocated wholly, or in part, to Capsules.

- 5.15 The CMA has, nevertheless, sought to carry out a robust analysis and where only the totals of a cost category (for example employment costs) are known and the CMA considers that a cost may reasonably be allocated to the production and supply of Capsules in respect of that cost category,⁷¹¹ then the total cost attributable to that cost category has been treated as relevant (ie used as the starting point for the allocation calculation).⁷¹²
- 5.16 Having identified the categories of common costs relevant to Capsules, the CMA is required to allocate a proportion of these costs to Capsules in order to properly assess the profitability of the relevant products.
- 5.17 The CMA understands that it is not common practice in the pharmaceutical industry to allocate common costs to individual products⁷¹³ and that, as a matter of their own commercial practice, the Parties themselves do not allocate common costs in this way. However, it is necessary to do so for the purposes of the CMA's Cost Plus assessment.⁷¹⁴
- 5.18 There are a number of different methodologies that may be adopted when allocating common costs as part of a Cost Plus assessment. There is no overriding preferred method and different methods may be appropriate for different cases.⁷¹⁵
- 5.19 As such, the CMA has considered the merits of various cost allocation methodologies in Annex I, based on the principles for common cost allocation identified by Oxera⁷¹⁶ and the Inter-Regulatory Working Group.^{717 718}
- 5.20 In exercising its margin of appreciation,⁷¹⁹ the CMA concludes that using an output-based cost driver – the volumes of packs sold – is the most appropriate

information request of 6 June 2014 (CMA document reference 00664.1); PHT00134, Pfizer's response of 7 October 2014 to the CMA's s.26 Notice information request of 16 September 2014 (CMA document reference 00863.1), Annex A; PHT00107, Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.1); PHT00132, Flynn's response of 19 June 2014 to the CMA's s.26 Notice information request of 6 June 2014 (CMA document reference 00607.1).

⁷¹¹ Given the lack of detail provided by the Parties, the CMA has only had limited scope to assess to what extent the Parties' costs have been efficiently incurred.

⁷¹² Exceptions were made to this approach for certain specific costs, see Annexes G and H for individual explanations.

⁷¹³ PRE00152, [Flynn Director 2] First Witness Statement, 6 February 2017, paragraph 61; PRE00150, First Expert Report of [Flynn Expert Witness 3], paragraphs 52-55; and PRE00711, Second Expert Report of [Flynn Expert Witness 2], paragraph 49.

⁷¹⁴ *Phenytoin* [2018] CAT 11, paragraph 351.

⁷¹⁵ *Phenytoin* [2018] CAT 11, paragraph 351.

⁷¹⁶ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, chapter 6.

⁷¹⁷ The Inter-Regulatory Working Group was established to identify and develop areas of consistency within published regulatory accounts.

⁷¹⁸ These principles are described in PAD00032, a paper from the Inter-Regulatory Working Group (2001), *'The Role of Regulatory Accounts in Regulated Industries: A Final Proposals Paper'* by the Chief Executive of Ofgem, Director General of Telecommunications, Director General of Water Services, Director General of Electricity and Gas Supply (Northern Ireland), Rail Regulator, Civil Aviation Authority, and Postal Services Commission. See Annex I for further details.

⁷¹⁹ Order of Rt. Hon. Lord Justice Newey of 12 December 2018, refusing Flynn's permission to appeal on this point.

basis for allocating common costs to Pfizer's Products and Flynn's Products. This is because:

5.20.1 It is transparent and practical to allocate common costs using output-based cost drivers because data on the number of packs sold is readily available.

5.20.2 Using volume (number of packs sold) to allocate common costs ensures that the cost allocation is objective and does not unduly benefit any particular product of Pfizer's or Flynn's.

5.21 The CAT also found that a sales volumes per pack approach, which was used to allocate Pfizer's and Flynn's respective common costs in the CMA's 2016 Infringement Decision, was reasonable in this case.⁷²⁰

5.22 Flynn subsequently objected to the Tribunal's finding that the CMA's approach was reasonable.⁷²¹ However, Flynn was refused permission to appeal on this point by the CAT on the grounds that it was attempting to re-argue points which had failed to gain acceptance before the Tribunal and attempting to re-argue findings which were part of the Tribunal's factual assessment, rather than matters of law.⁷²² The Court of Appeal subsequently also refused permission to appeal on this point, concluding that the appellants had no real prospect of success as the CAT was entitled to uphold the CMA's cost allocation as a reasonable and appropriate methodology, the more so in the light of the CMA's margin of appreciation.⁷²³

5.23 On this basis, the CMA considers that a sales volumes per pack approach to common cost allocation remains reasonable and appropriate in the circumstances of this case. Therefore, it has adopted this approach in its assessment below.

5.24 The CMA also remains of the view that a revenue-based approach in an excessive pricing case is inherently problematic because it creates a circularity problem. Where prices are high, revenues are high, leading to higher amounts of common costs being allocated to the product suspected of being excessively priced, which can be used (wrongly) to justify those high prices in the first place. This is a well-recognised concern⁷²⁴ and the 'risk of circularity bias' in using revenue-based allocation for excessive pricing cases was accepted by Flynn's own expert.⁷²⁵ [Flynn Expert Witness 2] agreed that 'if a product is excessively priced, it would

⁷²⁰ *Phenytoin* [2018] CAT 11, paragraph 351.

⁷²¹ *Phenytoin ruling (remittal and permission to appeal)*, paragraph 25.

⁷²² *Phenytoin ruling (remittal and permission to appeal)*, paragraph 38.

⁷²³ Order of Rt. Hon. Lord Justice Newey of 12 December 2018, refusing Flynn's permission to appeal on this point.

⁷²⁴ It is for this reason that use of a revenue-based cost allocation was rejected by the CAT in *Genzyme Limited v OFT* [2005] CAT 32, paragraph 268 and *Socrates v Law Society* [2017] CAT 10, paragraph 83. It was also rejected by the European Commission in case AT.40394 – *Aspen*, paragraph 112. The same concern is expressed in PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraphs 6.18-6.19.

⁷²⁵ PRE00153, Joint Statement of [Flynn Expert Witness 2] and [CMA Expert Witness 1], 25 September 2017, point 2.2.

attract under a revenue-based method of allocation an excessive proportion of common costs'.⁷²⁶

- 5.25 The CMA notes that in its response to the SO, Flynn continued to express its disagreement with an allocation approach based on sales volumes. Flynn stated that it 'adopts a holistic view that the totality of Flynn's sales must recover the totality of Flynn's costs' and explained that allocating common costs on the basis of sales volumes resulted in a negative ROS for some products in its portfolio. Flynn stated that this demonstrated the 'absurdity of the CMA's approach' as Flynn considered these products to be profitable.⁷²⁷
- 5.26 The fact that Flynn does not use this approach to determine the profitability of individual products does not mean it is inappropriate to do so for the purposes of the CMA's assessment.
- 5.27 The CMA accepts that Flynn may take a holistic approach to the recovery of common costs and that individual drugs may be considered profitable as long as they make a positive contribution towards the recovery of common costs (ie prices exceed direct costs). However, it would be misleading to assess the profitability of individual products by (i) assessing direct costs only; or (ii) allocating all common costs across only a subset of products. The CMA therefore allocates a portion of common costs to Flynn's Products as part of its assessment and maintains that it is appropriate to allocate common costs on the basis of sales volumes in this case, for the reasons set out above.
- 5.28 For completeness, the CMA has also carried out a sensitivity analysis to test the effect of adopting various alternative approaches to common cost allocation (and the effect on the excessiveness of Pfizer's Prices and Flynn's Prices) as part of Annex I. This analysis shows that the CMA's findings are unaffected by the choice of common cost allocation methodology.

IV. Approach to establishing a reasonable rate of return

- 5.29 Once a party's direct and indirect costs have been determined, a comparison of these costs with the selling price will disclose the actual return earned on the product. It is then necessary to determine whether that return is excessive.
- 5.30 This can be done by comparing the price actually charged against a benchmark which, in addition to the costs incurred in supplying the product, includes a reasonable rate of return (referred to as 'Cost Plus').⁷²⁸ Where the costs of production or the costs actually incurred, including a reasonable rate of return, can be ascertained, there is no reason why the authority should not be able to use such methodology to ascertain an appropriate counterfactual for the excessive limb of

⁷²⁶ PAD00070, *Phenytoin* transcript, day 6, page 24, lines 2-5.

⁷²⁷ PRC03492, Flynn's response to the SO, paragraph 7.57.

⁷²⁸ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).

the analysis.⁷²⁹ For the avoidance of doubt, Cost Plus does not determine the maximum price for a product. It is possible for an undertaking to price above Cost Plus without those prices being either excessive or unfair.

- 5.31 There are a number of different methodologies that may be adopted when determining the reasonable rate of return as part of a Cost Plus assessment. The aim is to determine a reasonable absolute return to be added to direct and indirect costs to form Cost Plus. The CMA sets out below two methodologies through which the reasonable rate of return may be established: the 'return on capital employed (ROCE) approach' and the 'return on sales (ROS) approach'.⁷³⁰

a. The ROCE approach

- 5.32 As set out in section 4.B.I.b (Legal Framework), it will normally be necessary to allocate a reasonable rate of return to cover the cost of capital. The cost of capital reflects the opportunity cost to investors of providing capital to a business to invest in acquiring assets and fund working capital requirements.
- 5.33 The ROCE approach is based on the principle that, under normal market conditions, profits are generated from the use of capital and are related to the level of risk taken. Where capital employed can be reliably measured, the ROCE methodology is generally accepted as the most objective way of calculating a reasonable rate of return and is usually preferable to other methods.⁷³¹ Put simply, the ROCE approach assumes that sufficient profits need to be made to pay providers of capital a market-based return on their investment.
- 5.34 In order to determine a reasonable rate of return following a ROCE approach, two inputs are required:
- 5.34.1 Capital employed: this is the amount of capital deployed in supplying the reference product. This includes all relevant tangible and intangible assets, such as buildings, machinery, office equipment and intellectual property, as well as (net) working capital to cover the day-to-day operational financing requirements of the business (eg stock, debtors and creditors).
- 5.34.2 Cost of capital: this is the average percentage return that debt and equity investors expect in return for providing funds to a company.

⁷²⁹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 252.

⁷³⁰ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(v) and 122.

⁷³¹ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003; PAD00140, Oxera, *A comment on the European Commission's profitability analysis (prepared for Royal Bank of Scotland)*, July 2006 [public]; PAD00138, Mark Williams, 2007, 'Excessive Prices' in *The Pros and Cons of High Prices*, Swedish Competition Authority.

- 5.35 The reasonable return is calculated, in absolute terms, by multiplying the capital employed in carrying out the relevant activities by the cost of capital. This amount is then added on top of direct and indirect costs to establish Cost Plus.
- 5.36 Where firms like Pfizer and Flynn fund their investments through a combination of debt and equity finance, it is appropriate to use the weighted average cost of capital (WACC) for the rate of return expected by investors.⁷³² It represents the average rate of return sought by debt and equity investors, and therefore represents the average cost of capital which can be applied to each Party's capital employed, in order to measure a reasonable rate of return.
- 5.37 Each component of the WACC is calculated by reference to observable, real-world market data:
- 5.37.1 **The cost of debt:** Returns to debt investors take the form of interest payments. The cost of debt can be calculated from observable actual market data, such as a company's actual interest costs, or corporate bond yields on debt issued by firms with a similar credit-rating. It reflects the risks associated with lending to a particular business.
- 5.37.2 **The cost of equity:** Returns to equity investors reflect the opportunity cost of investing in one business rather than another. The cost of equity is established in the capital markets, where similar investment opportunities with similar risk profiles compete for financing. It is therefore actual investment opportunities that are available to providers of capital in the real world that set the standard for equity investors' expected rate of return (ie for the cost of equity).⁷³³
- 5.38 The WACC is therefore based on empirical evidence of actual returns earned across the market over a long period of time. This includes markets of varying states of competition – some markets that have been highly competitive and others that have been less so. The WACC reflects real returns earned, on average, across a range of markets exhibiting differing degrees of competition (and therefore allows for the effects of imperfect competition on returns to investors). A return equal to the WACC ensures a company is appropriately compensated for investment in its activities. The authority can then estimate the level of additional

⁷³² Where a firm is financed entirely through debt or equity, then the respective cost of debt or cost of equity provides a more appropriate rate of return.

⁷³³ The cost of equity is commonly determined using the Capital Asset Pricing Model (CAPM), an established methodology which is used to determine an appropriate rate of return in a range of real world settings. For example, the CAPM is used widely to calculate the WACC for equity valuation and investment appraisal purposes. Financial analysts use the CAPM to measure the returns equity investors expect for the risk associated with investing in companies. The CAPM is also the approach typically adopted by the CMA when measuring profitability in market studies and investigations (see CMA, [Guidelines for market investigation: Their role, procedures, assessment and remedies](#), Annex A) and it is used by UK regulators to determine an appropriate rate of return when setting prices in regulated industries such as gas, electricity, and water.

profits remaining after providers of capital have received a reasonable (market-based) return on their investment.

- 5.39 The ROCE approach therefore provides both a clear framework and a relevant, real-world benchmark for what constitutes a normal return. It is grounded in fundamental economic logic, in that it links returns to the use of capital and the level of risk taken, and is well-recognised as an appropriate methodology for assessing whether prices are excessive.⁷³⁴ The ROCE model is also widely used by businesses, investors, financial analysts and regulators to assess rates of return and make investment decisions.⁷³⁵

b. The ROS approach

- 5.40 ROS is a measure of profit margins. It measures returns relative to revenues, after the deduction of both direct and indirect costs.
- 5.41 The ROS approach involves the identification of products or companies that are sufficiently similar to the reference product. Where sufficiently similar comparators can be identified, the authority may infer a reasonable rate of return by applying the comparator ROS to the reference product. In practice, the authority does this by calculating the uplift on costs that results in the required ROS.⁷³⁶
- 5.42 As ROS measures returns relative to revenues only, it is not directly informative of how returns compare with the capital, activities and risks that are necessary to supply the specific product or service. A ROS cannot be compared directly against the cost of capital for this reason. In fact, a key criticism of the ROS approach is that there is no direct link between the ROS of a company or product and an objective benchmark against which observed returns can be compared.⁷³⁷
- 5.43 Given this limitation, a ROS analysis is typically only undertaken where:
- 5.43.1 there are significant difficulties associated with the ROCE approach (for example, where the identification and valuation of the capital employed in the relevant activities is uncertain or particularly complex);⁷³⁸ and

⁷³⁴ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(v) and 122. See also, for example, the following papers, which each identify the ROCE approach as an appropriate and objective means of testing excessive pricing: PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003; PAD00140, Oxera, *A comment on the European Commission's profitability analysis (prepared for Royal Bank of Scotland)*, July 2006 [public]; PAD00138, Mark Williams, 2007, 'Excessive Prices' in *The Pros and Cons of High Prices*, Swedish Competition Authority.

⁷³⁵ Businesses use the ROCE approach to appraise investment projects; financial analysts use it to measure risk and returns investors expect when investing in companies; and UK regulators use the ROCE to determine an appropriate rate of return when setting prices in regulated industries such as gas, electricity, and water.

⁷³⁶ A ROS can be derived from a cost mark-up and vice versa. For the purposes of calculating Cost Plus, the reasonable ROS can therefore be applied as an uplift on costs.

⁷³⁷ A ROS can only be compared against other ROS figures. By comparison, the cost of capital provides an objective benchmark against which returns on capital can be assessed. See also PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, page 56.

⁷³⁸ CMA, [Guidelines for market investigation: Their role, procedures, assessment and remedies](#), Annex A, paragraph 15: 'In situations where capital employed cannot be reliably valued the CC may consider alternative measures, such as the

5.43.2 sufficiently similar products or companies can be identified which allow for reliable and meaningful comparisons to be drawn with the reference product.⁷³⁹

5.44 The critical issue in applying the ROS approach (or any other approach based on profit margin comparisons) is the selection of suitable comparators.⁷⁴⁰

5.45 The factors that determine appropriate comparators will vary on a case-by-case basis and will be dependent on the particular characteristics and circumstances of the specific product or company under investigation.

5.46 As explained further below, the characteristics and features of specific products may be expected to affect profitability on a ROS basis considerably. The selection of comparators should therefore be based on good reasons to believe that the comparators are sufficiently similar to the reference product (across all relevant product characteristics). The average returns of selected companies may not provide good comparators for a specific product for this reason (indeed, the profit margins of individual products within one company's portfolio can themselves be expected to vary considerably). Where there are unusual features associated with the reference product, the identification of suitable comparators may prove particularly problematic.

5.47 Typically, relevant factors may include that other products or companies are sufficiently similar to the reference product in terms of their activities, capital intensity, cost structure and level of risk,⁷⁴¹ and that the chosen comparators are not distorted by ineffective competition.

5.48 Each of these factors – capital intensity, cost structure and the level of risk – can be expected to influence profit margins such as ROS as follows:

5.48.1 **Capital intensity:** Capital intensity can be calculated as the ratio of capital employed to revenue. It measures how much capital is required to generate £1 of revenue. A higher capital intensity ratio normally requires

return on sales or other relevant financial ratios'. CRA also recognised this in PRE00728, CRA3, paragraphs 35 and 36, which state: '...it is important to note that papers discussing what is the appropriate measure of profitability in competition policy analyses suggest the use of relative measures of profitability... A report prepared by Oxera for the OFT on the assessment of profitability in competition policy analysis suggests relative, ie % measures of profitability. The paper suggests using an IRR methodology if cash flows and asset values can be accurately calculated or alternatively use relative profitability measures, such as percentage ROS... and compare them against corresponding measures of comparative companies. A paper by Alan Gregory (2011), commissioned by the OECD and presented in the OECD Roundtable on Excessive Prices, also suggests relative measures, namely an IRR or ROCE measure when measurement of asset values is not problematic or alternatively a sales margin analysis, such as percentage ROS.' (Emphasis added).

⁷³⁹ See section 4.C.II (Legal Framework) and PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 7.36. 'It is essential that the companies or industries have considerable similarity with the company or industry under investigation, since profitability can be expected to vary across companies, independently of whether or not profits are excessive'. Paragraph 7.41 states: 'The selection should be based on good reasons to believe that the comparators are subject to some degree of competitive pressure and operate in industries with similar cost structures and risk profiles'.

⁷⁴⁰ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 7.33.

⁷⁴¹ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 7.36.

higher margins on revenue (ie a higher ROS) so as to provide a reasonable level of return on a higher capital base.⁷⁴² Where sales volumes are high, capital requirements can be spread over a greater number of units and typically require lower margins on revenue (ie a lower ROS) as a result. ROS benchmarking therefore requires similar capital intensity among the investigated product or business and the proposed comparators.

5.48.2 Cost structure: The costs of supply are another key factor to consider. This is because, where the direct and/or indirect costs associated with a given product are very high, the application of a seemingly low percentage ROS can translate into high absolute returns per unit sold, and a relatively much higher return on capital. This is particularly relevant for Flynn, given that, as part of the arrangements between the Parties, it agreed to pay supply prices for Capsules which significantly exceeded those previously charged by Pfizer. This agreement has the effect of significantly increasing Flynn's cost base. Conversely, where a high percentage ROS is applied to a low-cost product, the absolute returns generated may be low. A high percentage ROS may therefore mask low returns on capital. Accordingly, cost structure must be taken into account when seeking to identify appropriate ROS benchmarks.

5.48.3 Level of risk: The level of risk associated with the relevant activities can be expected to affect profitability levels, with greater risk-taking being rewarded by higher returns. The economic consultancy Oxera recognised this in its report for the Office of Fair Trading ('OFT') on Assessing Profitability in Competition Policy Analysis, stating:⁷⁴³

Unlike the cost of capital benchmark, comparing rates of return across firms or industries does not encapsulate the risk–reward balance. Returns may simply be higher because investors need to be rewarded for bearing greater risks. For the comparison to be meaningful, comparators should therefore be of similar risk to the firm or industry under investigation. Both business and financial risk characteristics should be considered.

5.49 Given that ROS is dependent on various product-specific factors, where possible, the authority may carry out cross-checks of its ROS assessment against an estimated capital employed figure. Notwithstanding any limitations associated with the ROCE approach in these circumstances (ie which result in the authority adopting ROS), this analysis enables the authority to assess whether the reasonable rate of return, as inferred from its comparator analysis, allows the entity under investigation to recover its cost of capital. It allows the authority to consider the specific investment and risk profile of the product or company under

⁷⁴² PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 7.36.

⁷⁴³ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 7.36.

investigation and to assess whether seemingly high profit margins translate to low returns on capital, and vice versa.⁷⁴⁴

c. The CMA's approach to establishing a reasonable rate of return in this case

5.50 As set out in section 4.B.I.b (Legal Framework), it is not necessary to adopt any particular approach to the determination of the reasonable rate of return. Depending on the circumstances of each case, different methods may be suitable for different products and businesses. Accordingly, the CMA has had regard to a range of profitability metrics when considering possible measures of the reasonable rate of return for Pfizer's Products and Flynn's Products.

5.51 In the following section, the CMA explains the approach adopted for each Party in determining a reasonable rate of return. In doing so, the CMA also provides details of the approaches applied in its 2016 Infringement Decision.

i. Approach to establishing a reasonable rate of return for Pfizer's Products

5.52 In its 2016 Infringement Decision, the CMA stated that ROCE would be its preferred measure of return for Pfizer's Products, but considered that there were limitations in the available asset data which reduced reliability when estimating the value of Pfizer's capital employed. In particular, the CMA found that there were difficulties in allocating Pfizer's capital assets to individual capsule strengths.⁷⁴⁵ The CMA therefore adopted ROS as its primary method for determining a reasonable rate of return for Pfizer's Products.⁷⁴⁶ The CMA considered various benchmarks for what would be a reasonable ROS for Pfizer's Products⁷⁴⁷ and, consistent with paragraph 5.49, carried out a ROCE assessment to cross check the results of its ROS analysis.⁷⁴⁸

5.53 In response to this analysis, Pfizer's own economic expert accepted during the appeal before the CAT that Pfizer's prices were clearly in excess of the costs of supply and above 'normal profits':

Since there is no dispute that the post-genericisation supply prices charged by Pfizer created margins that comfortably exceeded the costs of supply, and therefore generated profits above the textbook definition of "normal profit", this means that [CMA Expert Witness 1]'s conclusions on the technical question of whether prices were "excessive" is at best only a very

⁷⁴⁴ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraphs 4.50 to 4.52: 'When using ROS as a measure of profitability, results could be cross-checked using implicit asset values... Having imputed the implicit asset value, the competition authority can then apply the company's cost of capital to the asset value to obtain the level of operating profits that would be made if the company were making normal (non-excessive) rates of return. This imputed level of returns can then be compared with the company's actual level of operating profits. If it were making normal returns, its ROS should not be significantly in excess of the ROS of its comparators; and its imputed and actual level of operating profits should be roughly the same'.

⁷⁴⁵ 2016 Infringement Decision, paragraph 5.80-5.82.

⁷⁴⁶ 2016 Infringement Decision, paragraph 5.86.

⁷⁴⁷ 2016 Infringement Decision, paragraphs 5.87 and 5.88.

⁷⁴⁸ 2016 Infringement Decision, paragraph 5.107.

partial part of the total picture. If [CMA Expert Witness 1]'s conclusion is in effect that the supply prices charged by Pfizer created returns in excess of normal profit, then this is not a point of contention.⁷⁴⁹ (Emphasis added)

5.54 Having reconsidered the matter, and in particular the points made by the CMA in the 2016 Infringement Decision and by the experts during the appeals, the CMA considers that the approach to establishing a reasonable rate of return for Pfizer's Products set out in the 2016 Infringement Decision remains appropriate. That is, the CMA considers that:

5.54.1 it is able to identify ROS comparators with sufficiently similar characteristics to Pfizer's Products, taking into account relevant factors such as those identified in paragraph 5.48; and

5.54.2 difficulties remain in allocating Pfizer's capital base to individual capsule strengths but sufficient asset data is available to apply the ROCE method as a cross-check.

5.55 On remittal, the CMA has therefore updated its original Cost Plus analysis for Pfizer's Products to account for the full infringement period to 7 December 2016 and considered various data points to estimate a suitable ROS for Pfizer's Products. The CMA also carried out an updated ROCE assessment in determining a reasonable rate of return for Pfizer.

ii. Approach to establishing a reasonable rate of return for Flynn's Products

5.56 As regards Flynn, the CMA considered in its 2016 Infringement Decision that ROCE would not be an appropriate methodology for determining a reasonable return for Flynn's Products, due to difficulties in measuring the level of capital assets employed by Flynn.⁷⁵⁰ The CMA therefore chose to adopt the ROS approach. Having identified a relevant ROS benchmark (the PPRS), the CMA then assessed the risk and investment profile of Capsules against that benchmark. The CMA concluded that Flynn's supply of Capsules was less risky and required less investment than the benchmark average. The CMA chose to adopt the benchmark average ROS as a conservative proxy for a reasonable rate of return for Flynn's Products.⁷⁵¹

5.57 As part of the appeal before the CAT, the CMA's financial expert, [CMA Expert Witness 1], applied the ROCE framework to test the reasonableness of the ROS applied by the CMA.⁷⁵²

⁷⁴⁹ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 6.

⁷⁵⁰ 2016 Infringement Decision, paragraph 5.157.

⁷⁵¹ 2016 Infringement Decision, paragraph 5.166 to 5.212

⁷⁵² PRE00708, First Expert Report of [CMA Expert Witness 1], 4 April 2017, paragraphs 4.25 to 4.38.

- 5.58 In considering the appropriate methodology for determining a reasonable rate of return for Flynn's Products on remittal, the CMA has reviewed the data provided by Flynn as part the 2016 Infringement Decision, the evidence provided by Flynn and its experts before the CAT and the Court of Appeal and Flynn's representations on the SO.
- 5.59 The CMA notes in particular that Flynn adduced evidence at trial that there was 'very little fixed capital employed by Flynn for phenytoin'⁷⁵³ and accepted that:
- 5.59.1 it had not invested heavily in relation to phenytoin during the Relevant Period;⁷⁵⁴
- 5.59.2 it had not innovated in relation to the relevant products;⁷⁵⁵ and
- 5.59.3 it had incurred zero sales and promotion costs during the Relevant Period.⁷⁵⁶
- 5.60 When discussing the activities undertaken by Flynn in supplying Capsules (ie those activities which give Flynn the opportunity to earn a return), Flynn referred in its evidence before the CAT only to: (i) the need to cover the cost of its working capital; and (ii) the need to strengthen the supply chain by identifying a second API supplier.⁷⁵⁷
- 5.61 In view of all of the available evidence, including the evidence obtained after the 2016 Infringement Decision, the CMA considers that the difficulties previously perceived in measuring Flynn's capital base are no longer well founded. In practice, the evidence shows that the ROCE methodology can be applied to Flynn's Products because:
- 5.61.1 the information and submissions provided by Flynn clearly identify the capital that is employed in its supply of Capsules;
- 5.61.2 the data provided by Flynn allows this capital to be quantified and valued reliably (and for sensitivities to be applied); and
- 5.61.3 the CMA is able to identify a reliable estimate of Flynn's cost of capital.
- 5.62 On this basis, the CMA has applied the ROCE methodology to establish a reasonable rate of return for Flynn's Products. The CMA explained the framework underlying the ROCE methodology in paragraphs 5.32 to 5.39 and considers it to

⁷⁵³ PAD00056, [Flynn Expert Witness 1], day 7, page 37, lines 14-19.

⁷⁵⁴ PAD00056, [Flynn Expert Witness 1], day 7, page 37, line 20 to page 38, line 2. See also PRE00155, Second Expert Report of [Flynn Expert Witness 1], 6 February 2017, paragraph 31.

⁷⁵⁵ PAD00056, [Flynn Expert Witness 1], day 7, page 38, lines 3-5.

⁷⁵⁶ PAD00056, [Flynn Expert Witness 1], day 7, page 38, lines 6-11. See also PRE00155, Second Expert Report of [Flynn Expert Witness 1], 6 February 2017, paragraph 32.

⁷⁵⁷ PRE00152, [Flynn Director 2] First Witness Statement, 6 February 2017, paragraphs 40 and 41. See also PAD00031, [Flynn Director 2] Cross Examination, day 4, page 186.

be an appropriate and objective way of calculating a reasonable rate of return for Flynn's Products.

5.63 Conversely, for the reasons explained in paragraphs 5.102 to 5.119, the CMA considers there to be significant conceptual issues which render the use of a ROS analysis problematic in Flynn's case. These conceptual issues include that:

5.63.1 the high input cost that Flynn agreed to pay to Pfizer as part of the Parties' arrangement suppresses Flynn's profit margins, such that significant profits earned by Flynn can be associated with a low computed percentage margin. Profit margin analysis thus allows Flynn to rely on its position in the supply chain and its arrangement with Pfizer to insulate Flynn's own supply prices from the effective application of Chapter II.

5.63.2 the combination of a number of product-specific factors (including high sales volumes and a very low level of commercial risk as well as the high input cost incurred by Flynn) result in unusual economics of supply, with the consequence that it is very difficult to identify meaningful ROS comparators for Flynn's supply of Capsules.

5.64 The CMA therefore applies the ROCE framework in establishing a reasonable return for Flynn's Products.

5.65 Given that the CMA considers Flynn's capital base can be estimated reliably, it also tests the reasonableness of the ROS figures put forward by Flynn during the course of the Remittal by calculating the return on capital that those figures would imply for Capsules (in line with paragraph 5.49).

5.66 To cross-check the results of its ROCE analysis, and as a further test of its view that a ROS analysis is problematic in the particular circumstances of Flynn's Products, the CMA also assesses absolute measures of profitability before concluding on a reasonable rate of return. The CMA calculates the absolute returns that are given by its ROCE analysis and various ROS percentages (as put forward by Flynn). It then tests the reasonableness of these absolute returns against those of Flynn's other products and against the reasonable return calculated for Pfizer.

iii. *Flynn's representations on the use of ROCE*

5.67 In response to the SO, Flynn made the following representations on the CMA's approach to establishing a reasonable rate of return for Flynn's Products:

- 5.67.1 The CMA had previously rejected the use of a ROCE measure for Flynn in its 2016 Infringement Decision⁷⁵⁸ and ‘the CMA’s change in approach is entirely without justification or merit’.⁷⁵⁹
- 5.67.2 ROCE is not an appropriate measure for Flynn’s Products as Flynn is an ‘asset-light’ business and there exist ‘material issues’ in applying the ROCE methodology to such businesses.⁷⁶⁰ Flynn submitted that this was demonstrated by:
- (a) PPRS rules ‘which state... that any company with a sales to capital employed ratio higher than 3.5 to 1 “is better off being assessed on a ROS basis than a ROCE basis”’;⁷⁶¹ and
 - (b) CRA analysis of the application of a ROCE analysis to Flynn’s other products (ie other than phenytoin), ‘which shows that most of Flynn’s products (where there are no allegations of excessiveness) have an extremely high rate of return on capital’.⁷⁶²
- 5.67.3 A ROCE analysis identifies only a ‘floor’ price ‘below which no reasonable investor would choose to supply the product’.⁷⁶³
- 5.67.4 Analysis provided by Flynn’s expert, [Flynn Expert Witness 2], explained that ROCE is ‘never used in the pharmaceutical industry for determining prices’ and the CMA’s expert, [CMA Expert Witness 1], had previously ‘accepted that he had no empirical evidence that any pharmaceutical company has ever set its prices using ROCE’.⁷⁶⁴
- 5.67.5 Other competition authorities had taken the view that a ROS approach is better suited to pharmaceutical companies (eg in the Commitments Decision of the European Commission in Aspen).⁷⁶⁵ Flynn submitted that,

⁷⁵⁸ PRC03492, Flynn’s response to the SO, paragraph 7.1.

⁷⁵⁹ PRC03492, Flynn’s response to the SO, paragraphs 7.3 to 7.5. Flynn submitted that the CMA had all of the necessary information during its Previous Investigation on Flynn’s cost base (including its capital costs) to determine an appropriate methodology. It also stated that the CAT ‘did not give the CMA “carte blanche” to apply a method of its choosing that had no basis in any economic reality in the relevant industry’.

⁷⁶⁰ PRC03492, Flynn’s response to the SO, paragraphs 7.6-7.8 and 7.11. Flynn submitted that these issues had been recognised in the CMA’s 2016 Infringement Decision and during the cross-examination of the CMA’s expert witness before the CAT.

⁷⁶¹ PRC03492, Flynn’s response to the SO, paragraph 7.12 and PRC03720, CRA5, paragraph 15. Flynn submitted that its revenues on phenytoin (as calculated by the CMA) are £22.6 million relative to working capital of £3.5 million, resulting in a ratio of approximately 7.5:1.

⁷⁶² PRC03492, Flynn’s response to the SO, paragraph 7.13.

⁷⁶³ PRC03492, Flynn’s response to the SO, paragraph 7.9. Flynn stated that the CMA’s expert witness [CMA Expert Witness 1] had accepted these points before the CAT and that, ‘as one of the Tribunal panel members [X] put it, the function of a ROCE analysis is to identify a company’s “break even” point, below which it would theoretically decide to discontinue a product... The Tribunal’s judgment also concluded that [CMA Expert Witness 1]’s approach “proceeded on the basis of theoretical or idealised competition”, did not “add greatly to the overall picture”, and erred by “not focussing, as a start point, on the prices that would have pertained in circumstances of normal and sufficiently effective competition”’.

⁷⁶⁴ PRC03492, Flynn’s response to the SO, paragraph 7.16.

⁷⁶⁵ PRC03492, Flynn’s response to the SO, paragraph 7.17.

had the CMA applied the Commission's approach, it would not have found Flynn's prices to be excessive.⁷⁶⁶

- 5.68 In the following section, the CMA explains why it considers ROCE to be the most appropriate method for establishing a reasonable rate of return for Flynn's Products (as opposed to adopting the ROS approach). In doing so, the CMA addresses the specific criticisms raised by Flynn as regards the application of a ROCE methodology in the circumstances of this case.

The CMA's decision to use ROCE to determine a reasonable rate of return for Flynn's Products

- 5.69 The CMA explained in paragraph 5.33 that the ROCE framework is well-established as a robust and objective methodology for determining a reasonable rate of return in excessive pricing cases, provided that the relevant inputs can be determined with sufficient accuracy. Paragraph 5.34 explained that the inputs required are: (i) the capital employed in supplying the reference product and (ii) the cost of capital.
- 5.70 The CMA notes Flynn's submission that the application of the ROCE framework represents a change in approach from the Previous Investigation and that this change is without justification. The CMA explained above that it has reconsidered the totality of the evidence received during the Previous Investigation, the subsequent appeals and during the Remittal. In light of all of this evidence, the CMA considers that the difficulties previously perceived in applying the ROCE framework to Flynn's Products are no longer well founded. The CMA considers the evidence and data provided by Flynn shows this to be the case and that the inputs required to estimate a reasonable rate of return for Flynn's Products on a ROCE basis are available and can be calculated reliably.
- 5.71 Flynn has submitted that the ROCE approach is inappropriate for 'asset-light' businesses such as Flynn. In relation to this representation, the CMA makes two points:
- 5.71.1 First, Flynn employs considerable working capital in maintaining safety stocks. Indeed, the CMA estimates that Flynn employed a similar level of capital as Pfizer during the Relevant Period: an average annual value of around £3.5 million.⁷⁶⁷
- 5.71.2 Second, it is important to distinguish between two possible situations where a business might appear 'asset-light':

⁷⁶⁶ PRC03492, Flynn's response to the SO, paragraph 1.12.

⁷⁶⁷ Paragraphs 5.168 and 5.258.

- (a) first, where the business is tangible asset-light but employs significant intangible assets; and
- (b) second, where the business is both tangible and intangible asset-light.

- 5.72 In the first situation, the identification, valuation and inclusion of intangible assets as part of the capital base would lead to substantially lower observed ROCEs. While there can be difficulties in identifying and measuring these types of assets, the CMA frequently undertakes such analysis in its assessments of firms' financial performance. The CMA, therefore, does not consider the existence of material intangible assets per se to be grounds for moving away from the ROCE framework entirely and adopting a different (potentially less reliable) measure in its place. Instead, it requires the authority to undertake careful analysis of the value of intangibles. In this case, the CMA has carefully considered Flynn's submissions on the presence of intangible assets in its supply of Capsules. The CMA has found that Flynn's capital base can be measured reliably and the evidence and representations provided by Flynn do not support the existence of material intangible assets in the capital base required for the supply of Capsules. The CMA's consideration of Flynn's representations on intangible assets is set out at paragraphs 5.243 to 5.257.
- 5.73 In relation to the second situation, where businesses are genuinely asset-light, ie do not possess either significant tangible or intangible assets, the authority should be careful to appraise whether high observed ROCEs result in a material and sufficiently large excess over Cost Plus in absolute terms. This is in order to avoid a finding of excessiveness where a high ROCE percentage leads to absolute levels of profitability that are immaterial and insufficiently large to be properly considered excessive for the purposes of United Brands (either in total or per pack).⁷⁶⁸ Accordingly, the CMA considers Flynn's excesses in absolute terms in paragraphs 5.392 to 5.399 below, to avoid a Type I error in this case (ie falsely finding prices to be excessive).
- 5.74 As to Flynn's argument that PPRS rules state that any company with a sales to capital employed ratio higher than 3.5 to 1 'is better off being assessed on a ROS basis than a ROCE basis', the CMA first notes that the PPRS is not intended to function as a discussion of the appropriate framework for assessing profitability in competition policy analysis. While the specific rates of return identified in the PPRS can be considered of some relevance for the CMA's assessment,⁷⁶⁹ it does not follow that the overarching methodological steps set out in the PPRS can be transposed to an assessment of excessive pricing under Chapter II. The CMA explained in the paragraphs above how a ROCE approach may be applied to 'asset-light' businesses for the purposes of establishing Cost Plus and that careful

⁷⁶⁸ A low level of capital employed can result in an apparently high ROCE percentage but a relatively low percentage excess and/or absolute excess.

⁷⁶⁹ *Phenytoin* [2018] CAT 11, paragraph 339.

analysis and cross-checks can be applied in these circumstances, to appraise whether prices can be properly considered excessive.

- 5.75 In any case, the CMA notes that the PPRS sets a profit target of 6% ROS for scheme members that are assessed as having a low capital base.⁷⁷⁰ The CMA applies this rate of return to Flynn's Products as a cross-check of the robustness of its findings (at paragraphs 5.408 to 5.416).
- 5.76 Flynn also submitted analysis produced by CRA which showed that 'most of Flynn's products have an extremely high rate of return on capital'. CRA's analysis calculated returns on capital among non-phenytoin products for the years 2013 to 2017 and found a median return of between 57% and 149%, and a mean return of 150% to 291%.⁷⁷¹ Flynn submitted that this analysis showed that ROCE is ill-suited to measuring the profitability of 'asset-light businesses'.⁷⁷²
- 5.77 The CMA reviewed CRA's analysis and found it to be problematic and unreliable for the following reasons:
- 5.77.1 CRA had excluded all products making a return below the benchmark used in the CMA's SO (ie all products that earned a return on capital below 9%) from its estimates of mean and median returns. The CMA finds this selectiveness to be unjustified, resulting in a materially skewed overall picture of returns. The inclusion of these products significantly reduces these estimates.
- 5.77.2 Flynn's mean and median estimates were unweighted, giving undue weight to small products of minimal importance to Flynn's overall financial performance. Instead, the CMA considers a weighted average return across all non-phenytoin products to be more relevant.
- 5.77.3 CRA did not include the value of intangible assets in capital employed. However, it is evident from Flynn's statutory accounts that at least some of its other products have significant intangible assets in the form of 'know-how and licences'.⁷⁷³ For example, Flynn submitted at its oral hearing that it had invested '£7 million to £8 million... in acquiring knowhow and rights

⁷⁷⁰ PHT00079, *The Pharmaceutical Price Regulation Scheme 2014* ('PPRS 2014'), published by the DH and the Association of the British Pharmaceutical Industry (CMA document reference PD20). Paragraph 8.13 states: '*The allowable ROS that may be earned by individual scheme members from home sales of NHS medicines will be 6% of sales a year.*'

⁷⁷¹ PRC03720, CRA5, table 1, page 7. These figures reflect CRA's calculation of product returns after allocating common costs on the basis of sales volumes. CRA also calculated product returns and median and mean ROCE figures after allocating common cost on the basis of revenue. This analysis produced similar results, with median returns on capital ranging between 67% and 155% and mean returns on capital of between 116% and 225%.

⁷⁷² PRC03492, Flynn's response to the SO, paragraphs 7.12 to 7.13.

⁷⁷³ The CMA observes for example that as of 31 March 2016, Flynn Pharma (Holdings) Limited had know-how and licence assets with a gross book value (GBV) of £14.7 million. The CMA notes that Flynn Pharma (Holdings) Limited also has other intangible assets on its balance sheet in the form of goodwill and brand names. However, the CMA typically does not recognise goodwill in capital employed as it is a balancing item that arises on acquisition rather than a cost that a firm needs to incur in seeking to provide a product or service and may often reflect the expectation of earning supernormal profits in the future.

in relation to a number of speciality products, includ[ing] snake antivenoms'⁷⁷⁴ and had pursued development of a potential therapeutic antibody treatment for Ebola disease, for which it had reached 'the gold standard of proof of concept'.⁷⁷⁵ The CMA has examined the evidence and argumentation put forward by Flynn and found that no such intangibles are employed in the supply of Capsules. However, for CRA's ROCE comparisons to be robust, it is necessary that such intangibles are identified, valued appropriately and included in the capital employed for each drug (as relevant).

- 5.78 Given the limitations described above, the CMA considers the analysis presented by CRA to be insufficiently robust to function as a proper assessment of the ROCE of Flynn's other products. The exclusion of all intangible assets, for example, means that the capital employed balances used in CRA's analysis are incomplete and likely to be understated (and materially so for some of its products). This, in turn, leads to an overstatement of the estimated returns on capital.
- 5.79 The CMA considers that the true value of the capital employed in supplying Flynn's non-phenytoin products cannot be imputed without a full and proper assessment of the economic activities associated with each product.
- 5.80 The CMA does not consider that it is required to carry out a full appraisal of the capital employed in supplying Flynn's other products in order to test whether Flynn's prices for Capsules during the Relevant Period were excessive. The CMA has examined the evidence and argumentation put forward by Flynn as regards the capital employed in supplying Capsules and is satisfied that the relevant assets for the CMA's assessment can be fully identified and reliably measured.
- 5.81 Nonetheless, the CMA notes Flynn's representation that the figures calculated by CRA undermine the use of ROCE as a profitability measure in this case. The CMA has therefore carried out a high-level analysis of the ROCE earned across Flynn's other products, which seeks to take account of the issues identified in paragraph 5.77. The CMA has updated CRA's analysis to include a value for Flynn's intangible assets, using data from Flynn's statutory accounts, and calculated the weighted average ROCE across all of Flynn's non-phenytoin products. The CMA considers this analysis represents a more reliable estimate of the ROCE earned by Flynn's other products than the median and mean returns calculated by CRA, for the reasons set out in paragraph 5.77.
- 5.82 For the avoidance of doubt, the CMA considers this analysis represents a very high-level estimate only and that a robust calculation of the ROCE earned across the rest of Flynn's business would require (i) a full and proper assessment of the economic activities associated with each of Flynn's other products; and (ii) a full

⁷⁷⁴ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 14, lines 13-15.

⁷⁷⁵ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 14, line 25 to page 15, line 4.

appraisal of the true value of the capital employed in those activities. In particular, the CMA notes that the true economic value of Flynn's intangible assets may be different from accounting values.

- 5.83 Notwithstanding these limitations, the CMA notes that a high-level analysis carried out on this basis produces a weighted average ROCE across Flynn's non-phenytoin products ranging between 18% and 26% in the years 2013 to 2016 (and a weighted average ROCE of 22% across the period as a whole).⁷⁷⁶ In comparison, the CMA calculates the average ROCE earned on Flynn's supply of Capsules during the Relevant Period to be 247%.
- 5.84 The CMA has also considered the absolute returns earned by Flynn's other products, in line with paragraph 5.73. Data provided to the CMA by Flynn shows that in the years 2013 to 2016, Flynn earned an average return across its entire portfolio of non-phenytoin products of £3.8 million per year.⁷⁷⁷ That is, Flynn earned £3.8 million per year in total across thirteen other products. In comparison, the CMA's analysis estimates that Flynn earned an average return of £8.7 million per year on Capsules:⁷⁷⁸ more than double the return earned across all of Flynn's other thirteen products combined.
- 5.85 This analysis demonstrates that:
- 5.85.1 the true returns on capital earned across Flynn's business are likely to be significantly lower than those presented by CRA; and
 - 5.85.2 the returns earned on Capsules during the Relevant Period were significantly higher than the rest of Flynn's product portfolio.
- 5.86 Accordingly, the CMA considers that a proper consideration of the returns on capital earned across Flynn's non-phenytoin products does not undermine the

⁷⁷⁶ The CMA has adjusted CRA's analysis to include a value for Flynn's intangible assets. In doing so, the CMA highlights that for the purposes of an economic profitability analysis, capital employed should reflect the economic cost of the resources involved. The economic cost is the cost of resources used at a price at which they would be traded in a competitive market, where entry to and exit from the market is easy. In the absence of a full appraisal of the intangible assets employed across the entire Flynn business and the economic cost of those assets, the CMA has used accounting values as a proxy for the value of Flynn's intangible assets. On a conservative basis, the CMA includes only the value of Flynn's know-how and licences in its analysis and excludes the value of brand names and other intangible assets. The CMA has used gross book value (GBV), ie historic cost, in valuing Flynn's know-how and licences. The CMA considers it appropriate to use GBV as the value of intangible assets does not generally decline over time in the same way as physical assets such as plant and machinery. Accordingly, the CMA has added the respective GBV of know-how and licences disclosed in Flynn's accounts in each year between 2013 and 2016 to the total working capital figures used in CRA's analysis for each year. The CMA uses this figure as a proxy for total capital employed in each year. As the CMA uses GBV in its updated analysis (ie a measure of asset values before amortisation charges), it also adjusts the total return earned across Flynn's other products to remove the effect of amortisation. That is, the CMA adds back any in-year amortisation charges in its calculation of total returns. The CMA then divides the total return earned across all of Flynn's non-phenytoin products in the years 2013 to 2016 by its updated capital employed figures to calculate ROCE.

⁷⁷⁷ CMA analysis of Flynn data pack received as part of PRC03720, CRA5. The CMA calculates the total return across Flynn's non-phenytoin products in each year from 2013 to 2016. The CMA then calculates the average annual return.

⁷⁷⁸ The CMA calculated Flynn's total return on Capsules during the Relevant Period as total revenues minus all direct and indirect (common) costs. The CMA then divides the total return on Capsules over the Relevant Period by a factor which reflects the number of years in the Relevant Period, to derive an average annual return.

application of the ROCE methodology to Flynn's business, nor demonstrate ROCE to be an inappropriate means of testing whether Flynn's Prices were excessive.

- 5.87 In addition, as a cross-check of the robustness of its findings, the CMA carries out a sensitivity analysis in relation to the reasonable rate of return. In doing so, the CMA applies a rate of return to Flynn's Products that is above even its high-level estimate of the ROCE earned across Flynn's non-phenytoin products (as calculated in paragraph 5.83 above).⁷⁷⁹ The CMA's consideration of the level of excess observed for each of Flynn's Products under this scenario is set out at paragraphs 5.408 to 5.416. It shows that, even applying this generous rate of return to Flynn's Products, Flynn's Prices would remain materially above Cost Plus.
- 5.88 As to Flynn's observation that a ROCE analysis identifies only a 'floor' price 'below which no reasonable investor would choose to supply the product', the CMA explained in paragraph 5.38 that the cost of capital reflects actual returns earned on average across a range of markets. By definition, some companies will in practice have achieved returns lower than this amount. In addition, the CMA explained that the cost of capital is calculated by reference to actual, observed returns across a range of markets with different degrees of competition, including highly competitive markets and others that have been less competitive. The cost of capital does not therefore reflect 'theoretical' returns expected only in perfectly competitive markets. For these reasons, the CMA considers that the cost of capital is an appropriate anchor point for its Cost Plus assessment.
- 5.89 Moreover, and for the avoidance of doubt, the CMA does not consider that any profits earned above the cost of capital are automatically 'excessive' in the context of the United Brands Test. The CMA expects to observe variations in the level of returns earned between firms, on different products and over time. It recognises that, at some points in time, observed returns may exceed what might otherwise be termed a 'normal' profitability level.⁷⁸⁰ It is for this reason that a proper degree of discretionary judgment is required in considering whether any observed differential above the cost of capital is 'excessive' and that prices are likely to be considered excessive for the purposes of Chapter II only where the profitability of a dominant firm exceeds the cost of capital by a material amount, and over a sustained period of time.
- 5.90 With regard to [Flynn Expert Witness 2]'s evidence that ROCE is 'never used in the pharmaceutical industry for determining prices', the CMA first notes that, for the purposes of the Excessive Limb of the United Brands test, there is no need to establish a hypothetical benchmark price (or a range of prices) beyond a Cost Plus

⁷⁷⁹ For the reasons explained in paragraph 5.408 to 5.412, the CMA carries out a cross-check of its findings using a ROS of 6%. The absolute return given by a 6% ROS is equivalent to applying a WACC of 31% to Flynn's capital employed balance (based on the CMA's estimate of Flynn's capital base). This compares to the CMA's high level estimate of 18%-26% return on capital across 2013 to 2016 (and 22% for the period as a whole).

⁷⁸⁰ There may be several reasons for this, including cyclical factors, transitory price or other marketing initiatives, and some firms earning higher profits as a result of past innovation, or superior efficiency.

calculation.⁷⁸¹ [Flynn Expert Witness 2]’s evidence fails to recognise this distinction and does not undermine the use of ROCE in determining Cost Plus as a result.

- 5.91 The ROCE model is well-documented as an appropriate and objective methodology for the purposes of establishing a reasonable rate of return as part of Cost Plus. The ROCE approach was recognised as a possible method for calculating Cost Plus and determining whether prices are excessive in the Court of Appeal’s Phenytoin judgment⁷⁸² and in the European Commission’s Aspen Decision⁷⁸³ (both of which concerned pricing in the pharmaceutical industry). It was also recognised in Scandlines and Albion Water II that the relevant components of Cost Plus include a reasonable return to cover the cost of capital.⁷⁸⁴

Flynn’s representations that ‘other competition authorities had taken the view that a ROS approach is better suited to pharmaceutical companies’

- 5.92 Flynn submitted that other competition authorities ‘had taken the view that a ROS approach is better suited to pharmaceutical companies’, citing the Commitments Decision of the European Commission in Aspen.⁷⁸⁵
- 5.93 The CMA considers that Flynn’s representations are misconceived and mischaracterise Aspen in a number of important ways.
- 5.94 First, the Commission does not express the view that a ROS approach is a ‘better’ methodology for determining a reasonable rate of return for pharmaceutical companies. In fact, the Aspen Decision explicitly states that ‘depending on the circumstances of each case, different methods may be suitable and used to determine a reasonable rate of return’.⁷⁸⁶
- 5.95 Second, the Commission recognises that the main purpose of including a reasonable rate of return as part of Cost Plus is to allow the entity to recover its cost of capital. The Commission states that:

The Commission’s Preliminary Assessment accounted for the fact that undertakings need to earn a reasonable profit margin and, in particular, a rate of return of capital employed... Indeed, in markets working under conditions of “normal and sufficiently effective competition”, undertakings are active in the market, because they can expect to earn a financial return that is sufficient to compensate their investment.⁷⁸⁷ (Emphasis added)

- 5.96 The Commission’s Aspen Decision goes on to state that:

⁷⁸¹ Section 4.B (Legal Framework).

⁷⁸² *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).

⁷⁸³ *Aspen*, paragraph 154.

⁷⁸⁴ Section 4.B.I.b (Legal Framework).

⁷⁸⁵ Paragraph 5.67.5.

⁷⁸⁶ *Aspen*, paragraph 128.

⁷⁸⁷ *Aspen*, paragraph 127.

- 5.96.1 The Commission ‘recognises that companies are entitled to make a reasonable rate of return, in order to cover the cost of capital’⁷⁸⁸ (emphasis added);
- 5.96.2 the ‘plus’ element of the Commission’s assessment ‘allows recovering the costs of capital’ (emphasis added);⁷⁸⁹
- 5.96.3 The Commission ‘looked at alternative methods to assess the excessiveness of Aspen’s profits, allowing for a reasonable rate of return’. It identified that ‘an alternative method could have been to directly compute the capital employed in the Products and the associated cost of capital (rather than inferring a reasonable rate of return from the Profitability Comparators)’;⁷⁹⁰ and
- 5.96.4 The Commission considered there to be a ‘large difference between the return realised by Aspen and its cost of capital’ and that this confirmed the Commission’s assessment of excess profitability.⁷⁹¹
- 5.97 From the above, it is clear that the Commission recognised the purpose of a reasonable rate of return is to allow for the recovery of the cost of capital and that, where circumstances allow, the ROCE approach can be applied to estimate this amount directly.
- 5.98 Third, the Commission found there to be considerable complexity in identifying the underlying capital employed in supplying the reference products in the Aspen case. It therefore chose to infer a reasonable rate of return using profit margin comparators and, having found ‘clear concerns’, determined that a detailed assessment of the underlying capital employed was not required.⁷⁹² This represents very different circumstances to the CMA’s assessment of Flynn’s Products, where the capital employed in Flynn’s supply of Capsules, and the associated cost of capital, can be directly and reliably measured.
- 5.99 In addition to the above, and as explained further in the following section, Flynn’s percentage profit margins are suppressed by the arrangements it entered into with Pfizer. This means that significant profits earned by Flynn can be associated with a low computed percentage margin. Therefore, an isolated assessment of Flynn’s percentage profit margins would allow it to rely on its position in the supply chain and its arrangements with Pfizer to insulate its own supply prices from the effective

⁷⁸⁸ *Aspen*, paragraph 154.

⁷⁸⁹ *Aspen*, paragraph 154.

⁷⁹⁰ *Aspen*, paragraph 155.

⁷⁹¹ *Aspen*, paragraph 158. The Commission considered that the acquisition price paid by Aspen did not provide a suitable proxy for the capital employed in the relevant products for a number of reasons. It nevertheless assessed the returns on capital that would be implied had it considered the return on the acquisition price as a proxy for the ROCE of the relevant products. The Commission found that ‘the return is several-fold greater than Aspen’s cost of capital’ and that this supported its finding of excessiveness.

⁷⁹² *Aspen*, paragraph 155.

application of Chapter II.⁷⁹³ No such concerns apply to the use of profit margin comparators in the Commission's case against Aspen.

5.100 In summary, the CMA considers that:

5.100.1 The Commission does not take the view in Aspen that a ROS approach is 'better suited' to pharmaceutical companies. Indeed, the Commission explicitly recognised in its decision that the 'plus' element of Cost Plus should reflect a return on investment or capital employed.

5.100.2 The Commission's discussion on measures of a reasonable rate of return in Aspen is consistent with the framework set out by the CMA in paragraphs 5.32 to 5.49.

5.100.3 Different methods may be suitable in different cases and the adoption of a ROS approach in Aspen does not undermine the CMA's application of the ROCE methodology to Flynn's Products. This is particularly the case given that there are considerable differences in the underlying facts in Aspen and in the circumstances of this case.

5.101 For these reasons, the CMA disagrees with Flynn's representations on this point and does not accept that other competition authorities have taken the view that ROS is 'better suited' to assessing the profitability of pharmaceutical companies. Rather, the ROS approach will be suitable in some cases but should not be considered universally applicable nor uncritically applied across different cases.

The suitability of applying the ROS approach to determine a reasonable rate of return for Flynn's Products

5.102 The CMA has given careful consideration to Flynn's submissions that a ROS analysis should be undertaken in this case and Flynn's representations that, had the CMA's analysis been based on profit margins, it would not have found Flynn's Prices to be excessive.

5.103 After careful consideration of Flynn's representations and the evidence submitted by Flynn's experts, the CMA considers there to be a number of conceptual problems with Flynn's argument.

5.104 First, and as explained in paragraph 5.42, a standalone ROS analysis does not compare returns with the assets and activities that are necessary to supply Capsules, nor the risks assumed in doing so. In some cases, it may be that a company is able to generate positive profits and a seemingly high percentage ROS, but that these profits are insufficient to cover its cost of capital. Conversely, a seemingly low percentage ROS may translate into very high absolute returns which

⁷⁹³ See paragraphs 5.110 to 5.118 for further explanation.

are significantly above the cost of capital. A standalone ROS analysis therefore provides an incomplete picture of profitability.

- 5.105 It is for this reason that, in its 2016 Infringement Decision, the CMA carried out analysis of the risk and investment profile of Capsules to supplement its ROS assessment before concluding on a reasonable rate of return.⁷⁹⁴
- 5.106 Therefore, even in circumstances where the CMA had adopted a ROS approach as its starting point for Flynn, it would usually still seek to understand Flynn's returns relative to the capital employed by Flynn in supplying Capsules and the risks that it assumes. The adoption of the ROS approach does not mean that the authority should consider profit margins in isolation without regard to the returns on capital that are implied (and how they compare to the cost of capital). This is particularly the case where a reliable estimate of capital employed can be made, as is the case for Flynn.
- 5.107 Flynn's representations suggest that the authority should be content, in every case and irrespective of the specific circumstances, to carry out an analysis of profit margins only and that, where observed profit margins are consistent with those observed for other companies, the authority could not find the prices in question to be abusive. The CMA does not agree and considers that, for the effective application of Chapter II, the assessment must have regard to:
- 5.107.1 The underlying economic profitability of the reference product, which, as above, takes into account the risks and investment profile associated with the relevant supply. Applying this type of analysis helps the authority avoid Type I errors, where high observed profit margins may translate to low returns on capital, and Type II errors, where low profit margins result in returns far above the cost of capital.
- 5.107.2 The specific facts of the case, including the specific characteristics of the reference product, which might undermine the suitability of a profit margin analysis (or any other specific methodology).
- 5.108 As regards paragraph 5.107.1, the limitations of a ROS analysis as a measure of economic profitability are well-recognised. A 2006 paper prepared by the economic consultancy Oxera, for example, highlighted that:

It is important to assess the validity of the cost mark-up as a measure of economic profitability. The cost mark-up – as with the return on sales (ROS)... is sometimes used where assets are difficult to measure, or where firms have a relatively small amount of capital employed... However, cost mark-ups and ROS suffer from a number of significant methodological and

⁷⁹⁴ Paragraph 5.56 and 2016 Infringement Decision, paragraphs 5.166 to 5.182 and paragraph 5.210.

conceptual problems that prevent them being an accurate measure of the economic profitability of an activity or business.⁷⁹⁵ (Emphasis added)

- 5.109 Flynn's representations fail to engage with the well-recognised limitations in looking at ROS in isolation. Its representations make no attempt to consider the reasonable rate of return in the context of a risk-return framework (given that profit margins are not compared or benchmarked against the risks that a business incurred in undertaking the relevant activities) or to assess the extent to which Flynn earned profits over and above the amount required to provide a sufficient return to its investors (ie above its cost of capital). For these reasons, the adoption of Flynn's advocated approach would afford only a partial view of its profitability and does not provide a robust basis for assessing allegedly excessive prices (which the CMA considers must consider the capital invested in and the risks associated with the relevant activities).
- 5.110 As regards paragraph 5.107.2, and notwithstanding the limitations of an isolated ROS analysis described above, the approach advocated by Flynn introduces a circularity problem in the specific circumstances of this case. The CMA explained above how the reasonable rate of return is calculated as a mark-up on total costs when adopting the ROS approach.⁷⁹⁶ In Flynn's case, this means that its reasonable return would be increased by the inclusion of an excessive price (the Pfizer supply price)⁷⁹⁷ in its cost stack. In turn, this would increase Flynn's Cost Plus, reducing the scale of its observed profitability and potentially 'hiding' the excessiveness of its prices.
- 5.111 In failing to recognise and control for the distortionary effect of the (jointly agreed) Pfizer supply price on Flynn's margins, Flynn's proposed ROS comparisons proceed on a flawed basis and would undermine the effective application of Chapter II.
- 5.112 The Tribunal previously found that the percentage return for Flynn is highly dependent on the high input price paid by Flynn to Pfizer and that this is a 'critical issue' for the assessment.⁷⁹⁸

This highlights a fundamental factual aspect of Flynn's position; that its input price from Pfizer is the critical issue for the economics of the supply of Pfizer-Flynn Capsules and explains why, on the Cost Plus model, as applied to each party, Pfizer has a computed 'excess' of 443% (£[...][□]) but Flynn of a much smaller 41% (£[...][□]).

⁷⁹⁵ PAD00140, Oxera, *A comment on the European Commission's profitability analysis: Prepared for Royal Bank of Scotland*, July 24 2006, page 6.

⁷⁹⁶ Paragraph 5.41.

⁷⁹⁷ The prices charged to Flynn by Pfizer significantly exceeded historic prices for Pfizer's Products. These prices have been found to be excessive by the CMA, for the reasons set out in paragraphs 5.188 to 5.199.

⁷⁹⁸ *Phenytoin*, paragraph 453.

- 5.113 Flynn's case on the appropriate means of establishing a reasonable rate of return fails to engage with this critical issue. Indeed, Flynn submitted at its oral hearing that the average ROS of the companies included in its comparator set would be reasonable for Flynn's Products, regardless of the level of the Pfizer supply price.⁷⁹⁹ That is, in effect, Flynn considered that the level of the Pfizer supply price could be ignored in determining a reasonable rate of return for Flynn.
- 5.114 However, this argument ignores (as the CAT recognised) a critical feature of Flynn's supply of Capsules and, in fact, has parallels with arguments previously put forward by Pfizer before the Tribunal. Pfizer previously argued that it could not be in breach of Article 102, because of the vertical nature of its relationship with Flynn and its distance from Flynn's pricing⁸⁰⁰ ('Pfizer's Ground 4').
- 5.115 The Tribunal rejected Pfizer's Ground 4. The Tribunal concluded that Pfizer is not able to rely on the exclusive arrangements and, in particular, Flynn's introduction into the supply chain, for the purposes of avoiding liability for its upstream supply price to Flynn. In rejecting Pfizer's Ground 4, the Tribunal made the following findings:⁸⁰¹

Pfizer's submission has the consequence [...] that a dominant party would only have to interpose a third party (on contractual and commercial terms that were highly attractive to that dominant party but which still left the third party technically free to determine its own pricing in the downstream market) to evade entirely any possible finding of abuse. Pfizer did not indicate, in the hearing or elsewhere, that there were any limits or constraints on its submission. This has the consequence that, for example, if a dominant party were to set its prices to the third-party intermediary at (say) 100, or a 1000, times the preceding retail price (with no other change in the economic or commercial position) at a level that bore no relation whatsoever to the economic value, then that dominant party could still never commit an abuse, at least in the case where the third party priced at a level which was determined not to be abusive, by it, in the light of that very high input price. This would, on Pfizer's case, simply be so because the dominant party had interposed a third party.

We consider that would be a surprising outcome which is not consistent with the effective application of Article 102 and the protection of consumers from unfair pricing that it imposes.

- 5.116 Similarly, Flynn's case on the appropriate methodology for determining a reasonable rate of return would allow it to rely on its position in the supply chain and the arrangements with Pfizer (in particular, the high input price paid to Pfizer)

⁷⁹⁹ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 43.

⁸⁰⁰ *Phenytoin*, paragraph 446.

⁸⁰¹ *Phenytoin*, paragraphs 454 and 455.

to suppress its profit margins and insulate its own supply prices from the effective application of Chapter II.

- 5.117 For these reasons, the CMA does not consider it appropriate to test the excessiveness of Flynn's Prices exclusively by reference to simple, unadjusted ROS comparisons with other products and other companies, which fail to take account of Flynn's arrangements with Pfizer. To do so would be to ignore specific (and highly relevant) features of Flynn's supply of Capsules and to introduce a circularity problem in the calculation of Flynn's reasonable rate of return.
- 5.118 Therefore, and consistent with the Tribunal's rejection of Pfizer's Ground 4, the CMA considers there to be significant conceptual flaws which make Flynn's proposed approach (ie an isolated ROS analysis) inappropriate for the purposes of determining a reasonable rate of return for Flynn's Products.
- 5.119 In addition to the conceptual difficulties resulting from the high input cost that Flynn agreed to pay to Pfizer, the CMA notes that there are other notable features in Flynn's supply of Capsules, including very high sales volumes and the very low level of commercial risk assumed by Flynn.⁸⁰² The combination of these features results in unusual economics of supply and means that, even if the CMA were to consider it appropriate to apply the ROS approach to Flynn's Products, it is very difficult to identify truly comparable products and companies that can be relied upon sufficiently for the purposes of the CMA's assessment. These unusual features were also recognised by the CAT in its 2018 judgment.⁸⁰³

Conclusion on the approach to establishing a reasonable rate of return for Flynn's Products

- 5.120 For the reasons set out above, the CMA considers it appropriate to apply the ROCE methodology to establish a reasonable rate of return for Flynn's Products. Where capital employed can be reliably measured, as is the case for Flynn, the CMA maintains that ROCE is the most objective way of calculating a reasonable rate of return.
- 5.121 The CMA also considers there to be significant conceptual issues which render the use of a ROS analysis problematic in Flynn's case. These conceptual issues are driven primarily by the high input cost that Flynn itself agreed to pay to Pfizer as part of the arrangements between the Parties. Notwithstanding these issues, the CMA nonetheless carries out various analyses to test the suitability of those ROS comparators put forward by Flynn during the course of its Previous Investigation and the Remittal. Given that the CMA is able to estimate Flynn's capital base

⁸⁰² See Annex E and paragraph 5.274. The CMA explained in paragraph 5.48 how these factors can be expected to influence the required ROS for Flynn's Products.

⁸⁰³ *Phenytoin*, paragraph 343: '[CMA Expert Witness 1] [the CMA's expert] was correct to point to some highly unusual features of Flynn's phenytoin business, namely the fact that its supplies were bought at a high price, it had high volumes and the Pfizer-Flynn Capsules did not involve as much commercial risk to Flynn as did some other products'.

reliably, this includes testing the reasonableness of those ROS figures put forward by Flynn by calculating how each translates to returns on capital for Capsules (in line with the framework set out above). This analysis is set out at paragraphs 5.334 to 5.342.

- 5.122 To cross-check the results of its ROCE analysis, and as a further test of its view that a ROS analysis is problematic in the particular circumstances of Flynn's Products, the CMA also assesses absolute measures of profitability before concluding on a reasonable rate of return. The CMA calculates the absolute returns that are given by its ROCE analysis and various ROS percentages (as put forward by Flynn). It then tests the reasonableness of these absolute returns against those of Flynn's other products and against the reasonable return calculated for Pfizer. This analysis is set out at paragraphs 5.356 to 5.366.

B. The CMA's assessment of whether Pfizer's Prices were excessive

- 5.123 For the reasons set out below, the CMA finds that each of Pfizer's Prices were excessive throughout the Relevant Period. The CMA's analysis, set out below, follows the overall approach and methodology set out in paragraphs 5.2 to 5.55 above.

I. Pfizer's Prices and costs

a. Data used to calculate Pfizer's Prices and costs

- 5.124 The CMA has relied on the data it has obtained from Pfizer during the course of the Previous Investigation and the Remittal in order to assess whether its prices were excessive.
- 5.125 In the case of prices and direct costs, the CMA has obtained data from Pfizer for the period of the infringement, from September 2012 to December 2016.
- 5.126 In the case of indirect costs, the CMA has obtained data from Pfizer for the period September 2012 to November 2013. The CMA has not identified any reason why Pfizer's indirect costs attributable to Pfizer's Products would be expected to have changed significantly between November 2013 and December 2016.
- 5.127 In particular, Pfizer has confirmed to the CMA that 'common costs in 2014 may be likely to be reasonably approximated using 2013 data'.⁸⁰⁴ Pfizer also confirmed to the CMA that it had reviewed both Pfizer Limited's 2014 accounts and its 2015 final draft accounts and considered that there were no changes to indirect costs (either in total, or for the EPBU) which would materially affect the CMA's estimate. Pfizer also stated that it had reviewed the 2016 accounts for Pfizer Limited and, while the accounts showed an increase in total indirect costs from £164.7 million in 2013 to

⁸⁰⁴ PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice information request of 6 June 2014 (CMA document reference 00725.1), Annex A, question 6.

£195.1 million in 2016, Pfizer did not consider that this increase was attributable to the EPBU for phenytoin sodium capsules.⁸⁰⁵ To the extent that any costs were attributable to it, Pfizer stated that it did not consider such costs would materially affect the CMA's estimate of indirect costs related to phenytoin sodium capsules.⁸⁰⁶

b. Pfizer's Prices

5.128 The CMA's analysis of Pfizer's Prices over the Relevant Period is set out in section 2.D.II (Factual Background).

5.129 Table 5.1 below shows Pfizer's revenue and ASPs for each capsule strength during the Relevant Period.

Table 5.1: Pfizer's revenues and Pfizer's Prices for Pfizer's Products, September 2012 to December 2016

	Revenue	Average price per pack
25mg	£2,406,053	£4.50
50mg	£7,254,162	£6.71
100mg	£37,094,139	£37.56
300mg	£24,532,890	£37.01

Source: PHT00137, Pfizer's response of 7 October 2014 to the CMA's s.26 Notice information request of 16 September 2014 (CMA document reference 00863.2), Annex 1; PHT00138, Pfizer's response of 26 August 2016 to the CMA's s.26 Notice information request of 2 August 2016 (CMA document reference 02129.2), Annex 1 and PRC00491, Pfizer's response to CMA s.26 Notice dated 12 August 2020, Annex 4.

5.130 In its assessment of whether Pfizer's Prices were excessive, the CMA has used revenue rather than unit prices. However, the overall result is identical whether revenue or unit prices are used.⁸⁰⁷ This is consistent with the approach adopted in the CMA's 2016 Infringement Decision.⁸⁰⁸

c. Pfizer's direct costs for Pfizer's Products

5.131 The CMA has taken account of Pfizer's production, purchase and distribution costs for the supply of Pfizer's Products.

5.132 Pfizer records a Corporate Cost of Goods Sold ('COGS') for each pack of its own-manufactured products and submitted to the CMA that this is the most appropriate measure of its manufacturing costs.⁸⁰⁹ COGS represents the internal price that

⁸⁰⁵ PRC00490, Pfizer's response of 11 September 2020 to the CMA's s.26 Notice dated 12 August 2020, question 6.

⁸⁰⁶ PRC00490, Pfizer's response of 11 September 2020 to the CMA's s.26 Notice dated 12 August 2020, question 6.

⁸⁰⁷ Converting revenues into ASPs would simply require actual revenues to be divided by actual volumes. A similar conversion would be required for costs in order to compare like-for-like.

⁸⁰⁸ 2016 Infringement Decision, paragraph 5.64.

⁸⁰⁹ PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice information request of 6 June 2014 (CMA document reference 00725.1), Annex A, question 1.

Pfizer Manufacturing Deutschland GmbH charges Pfizer Limited for each pack of phenytoin sodium capsules. It comprises:

5.132.1 Standard manufacturing costs, comprising the acquisition of the API;⁸¹⁰ sieving, mixing and capsule filling; packaging; storage and destruction of defective or out of date stock.⁸¹¹

5.132.2 Global overhead contribution comprising an inter-company adjustment to cover a share of unallocated global common costs. This charge is included so that Pfizer Limited makes a contribution to global head office staff and management costs. (Pfizer Limited's common costs are allocated under indirect costs.⁸¹²)

5.133 The CMA agrees that COGS is the most appropriate available measure of Pfizer's manufacturing costs as it includes all of the costs directly attributable to manufacturing Pfizer's Products. As well as COGS, the CMA has included the distribution costs incurred by Pfizer Limited to deliver Pfizer's Products from the Pfizer Manufacturing Deutschland GmbH factory at Freiburg to Flynn's UK pre-wholesaler⁸¹³ ([X]) for supply to the UK market within its measure of Pfizer's direct costs.

5.134 Table 5.2 sets out Pfizer's total direct costs (COGS and distribution)⁸¹⁴ for each of Pfizer's Products throughout the Relevant Period.⁸¹⁵ These costs are also shown on a per pack basis.

⁸¹⁰ The API is manufactured by Pfizer in Kalamazoo, USA.

⁸¹¹ The manufacture of phenytoin sodium capsules for the European market (including the UK) is carried out by Pfizer Manufacturing Deutschland GmbH at its factory in Freiburg, Germany.

⁸¹² See Annex G for further details.

⁸¹³ 'Pre-Wholesaler' refers to the logistics company which receives and stores the products and transfers them to Flynn's wholesalers (Flynn itself does not receive or distribute the products).

⁸¹⁴ A detailed breakdown of Pfizer's direct costs is included in Annex J.

⁸¹⁵ Using COGS (which represents the internal price charged to Pfizer Limited) rather than the standard manufacturing costs incurred by Pfizer's manufacturing facility, results in a higher direct costs figure for Pfizer's Products. The use of COGS in the CMA's assessment of direct costs is favourable to Pfizer, as it results in increased direct costs, a higher Cost Plus figure and, therefore, reduces the level of any excesses.

Table 5.2: Pfizer's direct costs for Pfizer's Products in total and on a per pack basis, September 2012 to December 2016

	Total direct costs	Direct costs per pack
25mg	£507,939	£0.95
50mg	£918,484	£0.85
100mg	£2,073,830	£2.10
300mg	£1,405,138	£2.12

Source: CMA calculation based on PHT00137, Pfizer's response of 7 October 2014 to the CMA's s.26 Notice information request of 16 September 2014 (CMA document reference 00863.2), Annex 1. PHT00138, Pfizer's response of 26 August 2016 to the CMA's s.26 Notice information request of 2 August 2016 (CMA document reference 02129.2), Annex 1. PRC00491, Case 50908 S 26 Pfizer's response of 12 August 2020, Annex 4.

5.135 Packs of 100mg capsules contain three times as many capsules as the packs containing other capsule strengths. As a result, the direct cost of a 100mg pack is similar to that of a 300mg pack.

5.136 To understand the relationship between costs per pack and capsule strength (in particular, the differences between the 25mg and 50mg packs on the one hand, and the 100mg and 300mg packs on the other hand), the CMA looked at the detailed composition of direct costs. Details of the differences between the costs for different capsule strengths are set out in Annex J. The CMA has found that the differences in costs do not undermine the use of Pfizer's COGS and distribution costs as the measure of Pfizer's direct costs for Pfizer's Products.

d. Pfizer's common costs for Pfizer's Products

5.137 Pfizer accounts for its common costs (not including the global overhead costs referred to in the preceding section) under the heading 'Sales, Informational and Administrative expenses' ('SI&A'). These costs cover expenses such as employee costs and office expenses and were incurred at both the business unit level and the whole entity level which, respectively, were:

5.137.1 The EPBU within Pfizer Limited. The EPBU was the commercial business unit which managed the supply of Pfizer's Products until November 2013.⁸¹⁶

5.137.2 Pfizer Limited. These costs relate to all products supplied by Pfizer Limited.

⁸¹⁶ At the beginning of 2014 Pfizer undertook a restructuring resulting in phenytoin sodium capsules moving from being managed by the EPBU to the Global Established Pharma division. For the reasons set out in paragraphs 5.126 to 5.127, the CMA has used pre-November 2013 data for its analysis as this was the most comprehensive and the most conservative basis to assess cost after November 2013.

- 5.138 For the reasons set out in paragraphs 5.9 to 5.28, the CMA has allocated Pfizer's indirect costs on the basis of sales volumes (using number of packs sold).
- 5.139 Table 5.3 shows the CMA's allocation of Pfizer's indirect costs on a total and per pack basis. Full details of the CMA's assessment of Pfizer's indirect costs are set out in Annex G. The effect of adopting different common cost allocation methodologies is shown in Annex I.

Table 5.3: Pfizer's common costs allocated to Pfizer's Products in total and on a per pack basis, September 2012 to December 2016

	Total common costs	Common costs per pack
25mg	£1,238,838	£2.32
50mg	£2,503,683	£2.32
100mg	£2,288,129	£2.32
300mg	£1,535,712	£2.32

Source: PHT00139, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice information request of 6 June 2014 (CMA document reference 00725.3), Annex A; PHT00140, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice information request of 6 June 2014 (CMA document reference 00725.4), Annex B; and PRC00491, Pfizer's response to CMA s. 26 Notice dated 12 August 2020, Annex 4.

II. Establishing a reasonable rate of return for Pfizer's Products

- 5.140 Having estimated the total costs actually incurred in, or reasonably attributable to, the supply of each of Pfizer's Products, the CMA must establish the 'Plus' element of Cost Plus: that is, a reasonable rate of return.
- 5.141 In its 2016 Infringement Decision, the CMA allocated a ROS of 6% to Pfizer's Products, based on a consideration of: (i) Pfizer's internal average ROS; (ii) Pfizer's contribution margin threshold (below which Pfizer would place a product under review); (iii) the CMA's analysis of the capital employed by Pfizer in producing and supplying Pfizer's Products; and (iv) the allowable ROS under the PPRS.⁸¹⁷ As explained in paragraph 5.54, the CMA considers that the approach to establishing a reasonable rate of return for Pfizer's Products set out in its 2016 Infringement Decision remains appropriate.
- 5.142 On remittal, the CMA has updated its original Cost Plus analysis for Pfizer's Products to account for the full infringement period to 7 December 2016⁸¹⁸ and considered various data points to estimate a suitable ROS for Pfizer's Products, including carrying out an updated ROCE assessment.

⁸¹⁷ 2016 Infringement Decision, paragraph 5.85 and following.

⁸¹⁸ For the purposes of its 2016 Infringement Decision, the CMA collected data for the period from September 2012 to June 2016. Data was not available up to the date of the 2016 Infringement Decision due to time delays in actual sales activity and the relevant financial data becoming available. See 2016 Infringement Decision, paragraph 5.59. As part of the Remittal, the CMA has collected data pertaining to the full Relevant Period.

5.143 In carrying out its updated analysis, the CMA finds that it is appropriate to increase the ROS allocated to Pfizer's Products, from 6% in the CMA's 2016 Infringement Decision to 10% on remittal. In determining a reasonable ROS for Pfizer's Products, the CMA has considered:

5.143.1 The average ROS earned by the business units within Pfizer which managed the supply of Pfizer's Products (ie the EPBU before 2014, and the Global Established Pharma ('GEP') division after 2014);⁸¹⁹

5.143.2 Pfizer's contribution margin threshold;

5.143.3 the allowable ROS under the PPRS; and

5.143.4 the results of the CMA's updated ROCE analysis.

a. EPBU and GEP average ROS

5.144 Pfizer's Products were historically managed by the EPBU before an internal reorganisation resulted in phenytoin sodium capsules moving to the GEP.

5.145 The EPBU managed 'human prescription pharmaceutical products that had lost patent protection or marketing exclusivity in certain countries and/or regions'⁸²⁰ and the CMA understands that the GEP carries out a similar function. Pfizer explained that, from 1 January 2014, the GEP was created and incorporated all products from the EPBU as well as some products from other business units which were approaching loss of patent protection.⁸²¹

5.146 Pfizer submitted profit and loss (P&L) data relating to the EPBU for the years 2011 to 2013.⁸²² In doing so, Pfizer explained that it incurs common costs at both the business unit level and the whole entity level. The P&L data provided by Pfizer in relation to the EPBU included those costs that were common across the EPBU but did not include an apportionment of those common costs which related to all products supplied by Pfizer Limited. The CMA notes that a ROS calculated without taking account of these costs may overstate what would be a reasonable ROS for the purposes of the CMA's Cost Plus assessment. The inclusion of these additional common costs would serve to reduce the reported ROS. The CMA therefore adopts a favourable approach to Pfizer by using the unadjusted numbers in its analysis.

⁸¹⁹ At the beginning of 2014 Pfizer undertook a restructuring resulting in phenytoin sodium capsules moving from being managed by the EPBU to the GEP division. The CMA has gathered profitability data for the EPBU prior to this restructuring and for the GEP in the remaining years for the Relevant Period (ie 2014 to 2016).

⁸²⁰ See PAD00029, Appendix A of Pfizer's 2012 Financial Report.

⁸²¹ PHT00131, Pfizer's response of 16 April 2014 to the CMA's s.26 Notice dated 5 March 2014, question 13 (CMA document reference 00519.2).

⁸²² PHT00140, Pfizer's response to the CMA's s.26 Notice dated 6 June 2014, Annex B, tab 'pre-2014 EPBU template' (CMA document reference 00725.4).

- 5.147 Notwithstanding this point, the P&L data provided by Pfizer shows that the ROS earned by the EPBU was 14% in 2011, 8% in 2012 and 7% in 2013.
- 5.148 Pfizer subsequently provided P&L data relating to the GEP for the years 2014 to 2016.⁸²³ This data was subject to the same limitations as described in paragraph 5.146 above and showed that the ROS earned by the GEP was 11% in 2014, 9% in 2015 and 4% in 2016.
- 5.149 From this data the CMA has calculated that the EPBU and GEP earned an average ROS between 2011 and 2016 of 9%.⁸²⁴
- 5.150 The CMA has also considered the data provided for the EPBU only, as this data is not affected by the inclusion of certain products which were transferred to the GEP but which had not yet lost patent protection. From the data provided by Pfizer, the CMA has calculated that the EPBU earned a simple average ROS and a weighted average ROS between 2011 and 2013 of 10%.
- 5.151 The CMA considers that it is reasonable to assume that the average ROS earned by the EPBU can act as a suitable comparator for the purposes of establishing a reasonable rate of return for Pfizer's Products. As explained in paragraph 5.47, a suitable comparator will typically take into account factors such as capital intensity, cost structure, risk profile and competitive conditions.
- 5.152 The CMA understands that the EPBU focussed on the management of mature, off-patent drugs and that, while the GEP performed a similar role, the GEP also managed products which have not yet lost patent protection. For this reason, the CMA considers the average ROS earned by the EPBU to be more informative for its assessment, although the ROS percentages are very similar. The CMA considers that the products managed by the EPBU are likely to be broadly comparable to phenytoin sodium capsules in terms of the amount of investment required to support their ongoing supply and in terms of their risk profile.
- 5.153 Data submitted by Pfizer also shows that phenytoin sodium capsules were among the higher volume products sold by the EPBU.⁸²⁵ As a result, the CMA considers that the use of the average ROS earned across the EPBU as a comparator for a reasonable ROS for Pfizer's Products is likely to be favourable to Pfizer (all else equal, higher volumes lead to higher revenues and a lower capital intensity ratio – in turn, requiring lower margins on revenue, as explained in paragraph 5.48.1).
- 5.154 Finally, as regards costs and competitive conditions, the CMA has not seen evidence to suggest that the costs associated with the production and supply of

⁸²³ PRC02387, Pfizer's response of 13 May 2021 to the CMA's s.26 Notice dated 27 April 2021, Annex 1.

⁸²⁴ The CMA has calculated both the simple average ROS and weighted average ROS between 2011 and 2016. Both methods result in a ROS of 9%.

⁸²⁵ PHT00139, Pfizer's response of 30 July 2014 to the CMA's s.26 Notice dated 6 June 2014, (CMA document reference 00725.3), Annex A.

phenytoin sodium capsules differ materially from those of Pfizer's other established products, and has no reason to consider that the remaining products managed by the EPBU were not subject to a reasonable degree of competitive pressure.

- 5.155 For these reasons, the CMA considers that it is reasonable to use the average ROS earned by the EPBU (ie a ROS of 10%) as one benchmark for a reasonable ROS for Pfizer's Products.
- 5.156 While the CMA recognises that returns across the EPBU will vary, with some products earning in excess of the average and some below, the CMA considers that average profitability provides a useful input for the purposes of assessing what would be a reasonable ROS for Pfizer's Products. The CMA considers this to be one data point which provides useful insight for the purposes of its assessment and has sought to corroborate its reasonableness by reference to various other data points as follows.
- 5.157 The CMA also notes that a 10% ROS is considerably in excess of the average ROS earned across Pfizer's UK business as a whole in each year of the Relevant Period other than 2016, and exceeds the simple and weighted average ROS earned by Pfizer's UK business across the Relevant Period (which were 5% and 4% respectively).⁸²⁶ The CMA considers that this supports a view that the adoption of a 10% ROS for Pfizer's Products is fair to Pfizer and so reasonable for the purposes of the CMA's assessment.

b. Pfizer's contribution margin threshold

- 5.158 Pfizer told the CMA that it has a policy to put a product under review if the returns on the product fall below a 15% contribution margin threshold, defined as revenue minus COGS.⁸²⁷
- 5.159 The CMA recognises that a 15% contribution margin is not equivalent to a target level of return that Pfizer seeks to achieve in the market and that Pfizer could, legitimately, earn returns above this threshold on its sales of Pfizer's Products.
- 5.160 Nevertheless, the CMA considers that the 15% contribution margin threshold is informative in assessing whether a 10% ROS is reasonable for Pfizer's Products. This is because Pfizer's internal contribution margin thresholds are a relevant consideration in its decision making. Indeed, Pfizer stated to the DHSC that the decision to divest Pfizer's Products was taken in part because it 'had not realised a sustainable margin on Epanutin'.⁸²⁸ This demonstrates that Pfizer's contribution

⁸²⁶ Based on CMA analysis of PHT00144, Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return and publicly available data for Pfizer Limited (CMA document reference 0903.3), Annex B.

⁸²⁷ PHT00131, Pfizer's response of 16 April 2014 to the OFT's s.26 Notice information request of 5 March 2014 (CMA document reference 00519.2), Annex 1. Pfizer stated that 'a product will not be considered wholly sustainable if its return is less than 5% above COGS. Products that are contributing anything less than 15% above COGS will also be under review'.

⁸²⁸ Section 2.D.III.c (Factual Background).

margin threshold has economic meaning and is fundamentally linked to the process through which Pfizer's capital is deployed.

- 5.161 The CMA has therefore calculated the contribution margin that is implied by a 10% ROS for Pfizer's Products and found that a ROS of 10% is equivalent to an average contribution margin of 66%. This equates to a contribution margin of 75% for 25mg capsule strengths, 77% for 50mg capsule strengths, and 58% for 100mg and 300mg capsule strengths.
- 5.162 A 10% ROS results in a return for Pfizer's Products that is over four times the margin below which Pfizer would put a product under review. The CMA considers that this corroborates the reasonableness of adopting a 10% ROS for the purposes of calculating Cost Plus for Pfizer's Products.

c. The allowable ROS under the PPRS

- 5.163 Pharmaceutical companies are allowed to earn a ROS of up to 6% on their portfolio of branded products within the PPRS.^{829, 830}
- 5.164 The CMA recognises that there are limits to using the PPRS as an indicator of a reasonable ROS for Pfizer's Products. The CAT found that there were factors which pointed to the need for caution in placing too simple a reliance on the PPRS, noting that there were doubts as to its continuing relevance and that it applies to a portfolio of products rather than to any one product.⁸³¹
- 5.165 The CAT found that the CMA had placed undue weight on the PPRS in its 2016 Infringement Decision⁸³² but recognised that it was nevertheless a relevant factor to be examined as part of the CMA's assessment of a reasonable rate of return.⁸³³ It also stated that it was 'sympathetic to the point that a drug in the circumstances of phenytoin might be expected to be at the lower end of return in such a portfolio'.⁸³⁴

⁸²⁹ See PHT00079, *The Pharmaceutical Price Regulation Scheme 2014* ('PPRS 2014'), published by the DH and the Association of the British Pharmaceutical Industry (CMA document reference PD20). Paragraph 8.13 states: 'The allowable ROS that may be earned by individual scheme members from home sales of NHS medicines will be 6% of sales a year'.

⁸³⁰ The allowable ROS of 6% is associated with a margin of tolerance (MOT) which allows pharmaceutical companies to retain profits of up to 150% of the 6% ROS target. See PHT00079, PPRS 2014 (CMA document reference PD20), paragraph 8.17. In its judgment on the CMA's 2016 Infringement Decision, the CAT found that the CMA was not obliged to increase the 6% ROS to account for the MOT in the PPRS. See *Phenytoin* [2018] CAT 11, paragraph 336.

⁸³¹ *Phenytoin* [2018] CAT 11, paragraphs 333-335.

⁸³² *Phenytoin* [2018] CAT 11, paragraphs 334 and 335. The CAT noted that 'the PPRS appears to have decreasing relevance as the pharmaceutical industry changes its UK orientation. Moreover... there seems to be at least some level of official doubt... about the continuing relevance of the 6% figure from a DH[SC] perspective.' It also noted that 'the PPRS applies to a portfolio of products rather than to any one product'.

⁸³³ *Phenytoin* [2018] CAT 11, paragraph 339 (emphasis added): 'It is clearly a relevant factor to be examined, as an indicator, which, with other indicators, might establish whether the CMA was looking in the right range of percentage figures as appropriate or reasonable rates of return applying a ROS measure, all in the context of seeking to set a benchmark price'.

⁸³⁴ *Phenytoin* [2018] CAT 11, paragraph 335.

5.166 In the circumstances, a ROS of 10% exceeds by some margin the allowable ROS under the PPRS. The CMA considers therefore that a comparison with the PPRS ROS benchmark supports the reasonableness of the adoption of a 10% ROS as part of the CMA's Cost Plus assessment for Pfizer's Products.

d. ROCE analysis

5.167 Finally, the CMA has carried out an updated ROCE assessment, in order to test the level of return that would be required to appropriately compensate investors in Pfizer's Products. In accordance with the ROCE methodology outlined in paragraphs 5.32 to 5.39, the CMA first estimates the capital employed by Pfizer in the production and supply of Pfizer's Products. An estimate of the WACC is then applied to this capital employed balance to calculate a reasonable return for Pfizer's Products.

5.168 The CMA's estimate of the capital employed by Pfizer in the production and supply of Capsules is set out in Annex K. On the basis of submissions and data provided by Pfizer, the CMA has estimated the annual value of the capital employed by Pfizer during the Relevant Period for the production and supply of Pfizer's Products to have been £3.5 million.⁸³⁵ While the CMA considers that difficulties remain in allocating Pfizer's capital employed to individual capsule strengths, it considers that a ROCE analysis which assesses the required return across Pfizer's supply of Capsules in totality provides a relevant cross-check of its ROS comparator analysis.

5.169 As above, applying the appropriate WACC to this capital employed balance enables the calculation of the return that would be required to appropriately compensate Pfizer's investors for the activities and risks associated with Pfizer's Products.

5.170 Pfizer submitted that it calculates the WACC for Pfizer Limited in the ordinary course of business⁸³⁶ and provided figures for Pfizer Limited's WACC for the two years ending 30 November 2012 and 2013, which were 8.7% and 9.3% respectively. Pfizer also stated that this benchmark was not materially different for Pfizer Inc or Pfizer's Freiburg facility.⁸³⁷

5.171 The CMA also reviewed a cost of capital analysis conducted by KPMG, which was relied on by Flynn's expert on appeal before the CAT. This analysis showed that the average cost of capital for pharmaceutical companies was between 8.2% and

⁸³⁵ The CMA has used net book value (NBV) as the basis for valuing Pfizer's fixed assets. Fixed asset values are affected by the age of the assets and the entity's depreciation policy. As such, they are usually revalued to reflect value to the entity. In this case, a top down approach using the total assets of the entity was used as a revaluation was not practical. For this purpose, the CMA considers the net book value (NBV) of assets to be a more reliable measure of the current replacement value of fixed (tangible) assets than gross book value (GBV).

⁸³⁶ PHT00141, Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.1).

⁸³⁷ The WACC of Pfizer Inc is around 0.5 percentage points lower than Pfizer Limited, while the WACC of Pfizer's Freiburg facility is around 0.4 percentage points lower than Pfizer Limited.

7.7% between 2010 and 2014.⁸³⁸ In addition, the CMA reviewed the WACC of various pharmaceutical companies, which according to publicly available data sits within a range of 8% to 12%.⁸³⁹

5.172 Based on those cost of capital estimates identified above, the CMA considers that Pfizer's WACC submissions are consistent with common levels of return in the pharmaceutical industry and represent an appropriate cost of capital for inclusion in the CMA's Cost Plus analysis. It has therefore used a WACC of 9% to calculate the reasonable rate of return for Pfizer's Products.⁸⁴⁰

i. ROCE calculation

5.173 Using the capital employed figure in paragraph 5.168 and a WACC of 9% as above, the CMA calculates that the allowance for a reasonable return on a ROCE basis over the entire Relevant Period is £1,350,095.⁸⁴¹

5.174 Table 5.4 below sets out the resultant Cost Plus figures for Pfizer's Products, calculated on a ROCE basis. Table 5.4 is calculated as the sum of Pfizer's direct costs in Table 5.2, Pfizer's common costs in Table 5.3 and Pfizer's reasonable return in paragraph 5.173.

Table 5.4: Cost Plus for Pfizer's Products on a ROCE basis, September 2012 to December 2016

	Total phenytoin sodium capsules sales
Direct costs	£4,905,391
Common costs	£7,566,362
Allowance for reasonable return	£1,350,095
Cost Plus	£13,821,849
Implied ROS	10%

5.175 The CMA has included the ROS margin that is implied by its ROCE calculation in Table 5.4 (that is, the ROS margin that produces the same level of return as the

⁸³⁸ PRE00150, First Expert Report of [Flynn Expert Witness 3], 4 February 2017, Annex 4.

⁸³⁹ The companies the CMA considered in making this assessment and their WACCs were: AstraZeneca 10% (pre-tax); GSK 10% (pre-tax); Bayer 9.0 – 9.3% (pre-tax); Alliance Pharma stated that its WACC was lower than its 10% discount rate; Meda AB 12% in Europe (excluding Nordic countries); Recordi S.p.A 9.65% (pre-tax), excluding Turkey, and Stada Arzneimittel AG 11.2% in Central Europe and 8.9% in Germany. Where it was not explicitly stated, the CMA assumed that the stated WACC is pre-tax as this is the usual figure given. The CMA did not look at all potential comparator companies given the similarity in values which arose from its initial review.

⁸⁴⁰ This return of 9% is considered to be Pfizer's average WACC, given that this figure was 8.7% in 2012 and 9.3% in 2013.

⁸⁴¹ The allowable return is calculated by multiplying capital employed by the WACC and the number of years in the Relevant Period. In calculating the allowable return, the CMA has updated the ROCE analysis for Pfizer's Products in its 2016 Infringement Decision to account for the full infringement period to 7 December 2016. The CMA's ROCE analysis in the 2016 Infringement Decision reflected the allowable return for Pfizer's Products for the period from September 2012 to April 2015 only. Updating this analysis to reflect the full infringement period to December 2016 produces an allowable return of £1.35 million.

CMA's ROCE calculation). The implied ROS can be calculated by dividing the allowable returns calculated in the CMA's ROCE analysis by the total Cost Plus.

5.176 From Table 5.4, it can be seen that the ROS implied by the CMA's ROCE analysis is approximately 10%.

e. Conclusion on a reasonable rate of return for Pfizer's Products

5.177 The CMA considers that a 10% ROS represents a reasonable rate of return for Pfizer's Products.

5.178 This level of return reflects the average ROS earned by the EPBU, the business unit within Pfizer which managed those products which are most similar to Capsules. The CMA's ROCE analysis also produces a reasonable return which is equivalent to a 10% ROS, supporting that this level of return appropriately compensates the activities and risks associated with the supply of Pfizer's Products.

5.179 The reasonableness of adopting a 10% ROS for the purposes of the CMA's Cost Plus assessment is also supported by a consideration of how this level of return compares to Pfizer's contribution margin threshold and the allowable ROS under the PPRS.

III. Calculation of the reasonable rate of return and Cost Plus for Pfizer's Products

5.180 Having assessed what is a reasonable rate of return for Pfizer's Products, this section sets out the results of the calculation of the reasonable rate of return and the resultant Cost Plus for each of Pfizer's Products.

5.181 Using a ROS of 10%, Table 5.5 below sets out the allowance for a reasonable return for each of Pfizer's Products, on a total revenue and per pack basis for the entire Relevant Period.

Table 5.5: Allowances for a reasonable rate of return for Pfizer's Products (total and per pack), September 2012 to December 2016

Capsule strength	Allowance for reasonable rate of return (total)	Allowance for reasonable rate of return (per pack)
25mg	£189,093	£0.35
50mg	£370,457	£0.34
100mg	£472,192	£0.48
300mg	£318,354	£0.48

Note: The allowance for a reasonable rate of return in Table 5.5 is calculated under the ROS approach (ie through a mark-up on costs). The ROS that is used as the basis for this calculation is the ROS which is implied by the CMA's ROCE analysis.

5.182 Table 5.6 sets out the resultant Cost Plus figures for each of Pfizer's Products on a total revenue and per pack basis for the entire Relevant Period. Table 5.6 is calculated as the sum of Pfizer's direct costs in Table 5.2, Pfizer's common costs in Table 5.3 and Pfizer's allowances for a reasonable rate of return in Table 5.5.

Table 5.6: Cost Plus figures for Pfizer's Products (total and per pack), September 2012 to December 2016

Capsule strength	Cost Plus (total)	Cost Plus (per pack)
25mg	£1,935,870	£3.62
50mg	£3,792,624	£3.51
100mg	£4,834,151	£4.90
300mg	£3,259,203	£4.92

IV. Pfizer's profit in excess of Cost Plus

5.183 Having established Pfizer's Prices, Pfizer's costs (both direct and indirect) and a reasonable rate of return for Pfizer's Products, this section sets out the CMA's findings regarding the amount by which Pfizer's Prices exceed Cost Plus: that is, the size of Pfizer's excesses.

5.184 The assessment of whether the differential between Prices and Cost Plus is excessive involves the exercise of a proper degree of discretionary judgement by the CMA.⁸⁴² In assessing Pfizer's excesses, the CMA considers the size of the excess in both absolute and percentage terms.

5.185 The CMA therefore expresses Pfizer's excesses in the following two ways:

5.185.1 as the absolute amount (in pounds sterling) by which Pfizer's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Pfizer's Prices); and

5.185.2 as the percentage by which Pfizer's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Pfizer's Prices then dividing the result by Cost Plus).

5.186 In calculating Cost Plus for each of Pfizer's Products, the CMA has adopted an approach which fully allocates costs – both all direct costs and an appropriate allocation of all relevant indirect costs – as well as a reasonable rate of return. As such, the amount by which each of Pfizer's Prices exceed Cost Plus reveals the excess that Pfizer is earning over and above what would be a reasonable return for its activities in the production and supply of Pfizer's Products.

⁸⁴² Section 4.B.II (Legal Framework).

5.187 The results set out in Table 5.7 below show that Pfizer's Prices exceeded Cost Plus by 24% for 25mg capsules, 91% for 50mg capsules, 667% for 100mg capsules and 653% for 300mg capsules.

Table 5.7: Pfizer's excesses on Pfizer's Products, September 2012 to December 2016

	Capsule strength				Total sales
	25mg	50mg	100mg	300mg	
Revenue	£2,406,053	£7,254,162	£37,094,139	£24,532,890	£71,287,245
Cost Plus	£1,935,870	£3,792,624	£4,834,151	£3,259,203	£13,821,849
Excess (revenue)	£470,184	£3,461,538	£32,259,988	£21,273,687	£57,465,397
Excess (per pack)	£0.88	£3.20	£32.67	£32.10	N/A
Excess (%)	24%	91%	667%	653%	416%

V. Conclusion on whether Pfizer's Prices were excessive

5.188 The CMA concludes that each of the excesses set out in Table 5.7 is (in the words of the Albion Water II judgment) 'material' and 'sufficiently large to be deemed excessive' in the context of the Excessive Limb of the United Brands Test.

5.189 The CMA's analysis in Annex I provides further support to this conclusion. Allocating Pfizer's common costs under the per capsule or Daily Defined Dose ('DDD') method results in significantly greater excesses on Pfizer's lower capsule strengths (Pfizer's excesses on 25mg capsules increase to 80% and 223% respectively and on 50mg capsules increase to 181% and 314% respectively) and excesses on 100mg and 300mg capsules remain above at least 460% under all methods.

5.190 For the reasons set out above, a 10% ROS represents a reasonable rate of return for Pfizer's Products. Pfizer's actual ROS across the Relevant Period, however, was over 80%⁸⁴³ and results in average excesses over Cost Plus of 416%. Pfizer's Prices are clearly materially higher than those that would be required to earn a reasonable rate of return. The result is that, over the Relevant Period, Pfizer accrued approximately £57.5 million in excess profit.

5.191 The scale of Pfizer's excesses can be further demonstrated through a comparison of its returns with those that would ordinarily be expected by investors in the pharmaceutical sector.

5.192 Over the Relevant Period, Pfizer generated profits which equate to a return on capital employed of 392% on average. That is to say, for every £100 that Pfizer invested in the production and supply of phenytoin sodium capsules, it earned an average return of £392 per year and, in total, an investor would have earned nearly

⁸⁴³ Note that ROS is bounded at 100%. ROS measures profits relative to revenues. Profits cannot exceed revenues and thus profit margins cannot exceed 100%.

£1,700 by the end of the Relevant Period from £100 invested. In contrast, the data reviewed by the CMA shows that investors in the pharmaceutical sector ordinarily expect to earn returns of around 8%-12% per year,⁸⁴⁴ equivalent to £35-£50 by the end of the Relevant Period from £100 invested. In the context of a low risk, off-patent generic drug with an established user base and stable manufacturing arrangements (which require no investment to support ongoing innovation nor investment for the purposes of making product improvements), Pfizer's returns far exceed any reasonable rate of return. Indeed, Pfizer's own economic expert has previously accepted that Pfizer's prices were in excess of 'normal' levels of profit, stating that:

*Clearly there is a big margin over costs here. There is no question about that.*⁸⁴⁵

*I certainly acknowledge that the price increases that we are talking about in this case are price increases that took the price well above the costs of supply.*⁸⁴⁶

*Since there is no dispute that the post-genericisation supply prices charged by Pfizer created margins that comfortably exceeded the costs of supply, and therefore generated profits above the textbook definition of "normal profit", this means that [CMA Expert Witness 1]'s conclusions on the technical question of whether prices were "excessive" is at best only a very partial part of the total picture. If [CMA Expert Witness 1]'s conclusion is in effect that the supply prices charged by Pfizer created returns in excess of normal profit, then this is not a point of contention.*⁸⁴⁷ (Emphasis added)

- 5.193 Similarly, [Pfizer Director 1] for Pfizer accepted that, absent the Tablet price, Pfizer's Prices would have had no justification. This implicitly acknowledges that Pfizer's Prices could not be justified by reference to the costs incurred:

*... we were looking at price, and the reason why this project was able to even be considered was because we had an established benchmark price in the market for the same medicine. If that price benchmark hadn't been there, we couldn't have done this. We would have had no justification.*⁸⁴⁸ (Emphasis added)

- 5.194 The scale of Pfizer's excesses over Cost Plus on 50mg, 100mg and 300mg capsules is significantly greater than the levels of excess which have been found to

⁸⁴⁴ Paragraphs 5.170 and 5.171.

⁸⁴⁵ PAD00030, [Pfizer Expert Witness 2] Cross Examination, day 5, page 225, lines 22-23.

⁸⁴⁶ PAD00030, [Pfizer Expert Witness 2] Cross Examination, day 5, page 97, lines 5-8.

⁸⁴⁷ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 6.

⁸⁴⁸ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 79, line 1 to page 80, line 5.

be excessive in other cases. Pfizer's excesses on 25mg capsules are consistent with those found to be excessive in *Deutsche Post*.

- 5.195 An excess of 25% was found to be excessive in *Deutsche Post* and an excess of at least 46.8% was found to be excessive in *Albion Water II*. While the assessment of excessiveness should be made on a case-by-case basis and the level of excess in earlier cases is not determinative, Pfizer's excesses over Cost Plus on 50mg, 100mg and 300mg capsules are nonetheless striking by comparison, at 91%, 667% and 653% respectively. Each of these excesses, in particular the excesses earned on 100mg and 300mg which are by far the strengths that generate the greatest revenues, is clearly and significantly above the level of excess found to be excessive in *Deutsche Post* and in *Albion Water II*. Pfizer's excesses on 25mg capsules are consistent with the level of excess found to have been excessive in *Deutsche Post* and are materially above Cost Plus (and considerably above the excesses in *Deutsche Post* and *Albion Water II* under the CMA's alternative common cost allocation approaches).
- 5.196 The scale of Pfizer's excesses is also evident from a comparison of its excess profits with its Pre-September 2012 Prices. The excess profits on each of Pfizer's Products (ie pure profit on top of a reasonable rate of return) amount in themselves to several multiples of their respective historic prices:
- 5.196.1 Pfizer's excess on 25mg capsules (£0.88) is over one and a half times Pfizer's pre-September 2012 ASP for that product (£0.51);
- 5.196.2 Pfizer's excess on 50mg capsules (£3.20) is over six times Pfizer's pre-September 2012 ASP for that product (£0.52);
- 5.196.3 Pfizer's excess on 100mg capsules (£32.67) is almost 15 times Pfizer's pre-September 2012 ASP for that product (£2.21); and
- 5.196.4 Pfizer's excess on 300mg capsules (£32.10) is almost 15 times Pfizer's pre-September 2012 ASP for that product (£2.20).
- 5.197 Further, Pfizer has been able to maintain the excesses set out above for a substantial period of time (over four years). This confirms that Pfizer's Prices were excessive, rather than temporary anomalies in an otherwise competitive market.
- 5.198 Finally, that Pfizer's Prices for each of Pfizer's Products were excessive continues to hold true if Pfizer's Prices are considered separately before and after its price decreases in January 2014. These figures are shown in Annex L.
- 5.199 For these reasons, the CMA concludes that Pfizer's Prices were excessive and have been throughout the Relevant Period, thereby satisfying the first stage of the United Brands Test.

C. The CMA's assessment of whether Flynn's Prices were excessive

5.200 For the reasons set out below, the CMA finds that Flynn's Prices for each of Flynn's Products were excessive and have been throughout the Relevant Period. The CMA's analysis, set out below, follows the overall approach and methodology set out in paragraphs 5.2 to 5.66 above.

I. Flynn's Prices and costs

a. Data used to calculate Flynn's Prices and costs

5.201 The CMA has relied on the data it has obtained from Flynn during the course of the Previous Investigation and the Remittal to assess whether Flynn's Prices were excessive.

5.202 The data that the CMA has obtained from Flynn on prices, direct costs and indirect costs relates to the period of the infringement, from September 2012 to December 2016.

b. Flynn's Prices

5.203 The CMA's analysis of Flynn's Prices over the Relevant Period is set out in section 2.D.II (Factual Background).

5.204 Table 5.8 below shows Flynn's revenue and Flynn's Prices for each of Flynn's Products during the Relevant Period.

Table 5.8: Flynn's revenues and Flynn's Prices, September 2012 to December 2016

	Revenue	Average price per pack
25mg	£7,499,989	£14.19
50mg	£15,317,886	£14.40
100mg	£52,700,832	£54.40
300mg	£35,881,444	£55.21

Source: PHT00145, Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.22), Annex 17; PHT00146, Flynn's response of 4 March 2015 to the CMA's s.26 Notice information request of 23 February 2015 (CMA document reference 01148.2), Annex 1; PHT00147, Flynn's response of 4 March 2015 to the CMA's s.26 Notice information request of 23 February 2015 (CMA document reference 01148.3), Annex 2; PHT00148, Flynn's response of 12 June 2015 to the CMA's s.26 Notice information request of 2 June 2015 (CMA document reference 01293.1); PHT00149, Flynn's response of 11 March 2016 to Questions 2,3,5,7,9-14 of the CMA's s.26 Notice information request dated 17 February 2016 (CMA document reference 01839.13), Annex 14.1; PHT00150, Flynn's response of 17 August 2016 to the CMA's s.26 Notice information request dated 2 August 2016 (CMA document reference 02115.2), Annex 1; and PRC00488, Flynn's response of 11 September 2020 to CMA s.26 Notice dated 21 August 2020, Annex 1.

5.205 In its assessment of whether Flynn's Prices were excessive, the CMA has used revenue rather than unit prices. However, the overall result is identical whether

revenue or unit prices are used.⁸⁴⁹ This is consistent with the approach adopted in the CMA's 2016 Infringement Decision.⁸⁵⁰

c. Flynn's direct costs for Flynn's Products

5.206 The CMA has taken account of Flynn's purchase, distribution and sale costs for the supply of Flynn's Products.

5.207 Flynn identified the following direct costs in relation to Flynn's Products:

5.207.1 cost of goods (that is, the supply prices it pays for Pfizer's Products); and

5.207.2 storage, distribution and order services fee charged by Flynn's pre-wholesaler, [redacted].⁸⁵¹

5.208 In its submission to the CMA, Flynn allocated total distribution costs for phenytoin sodium capsules to different capsule strengths based on Flynn's selling prices.⁸⁵² However, the CMA considers it more appropriate to allocate distribution costs based on sales volumes as that is more likely to drive distribution cost than the price of the product.⁸⁵³ As such, the direct costs outlined in Table 5.9 below include distribution costs which have been allocated to different capsule strengths based on the volume of packs sold by Flynn.⁸⁵⁴ Adopting a volume allocation approach rather than a price allocation approach for the allocation of distribution costs across capsule strengths has a negligible effect on the total direct costs allocated to any particular capsule strength, as input prices for each capsule strength are considerably higher than distribution costs.

5.209 Table 5.9 shows Flynn's direct costs for each of Flynn's Products during the Relevant Period. These costs are also shown on a per pack basis.

⁸⁴⁹ Converting revenues into ASPs would simply require actual revenues to be divided by actual volumes. A similar conversion would be required for costs in order to compare like-for-like.

⁸⁵⁰ 2016 Infringement Decision, CE/9742-13, 7 December 2016, paragraph 5.144.

⁸⁵¹ PHT00107, Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.1), question A.2.1.

⁸⁵² PHT00151, Flynn's estimates of costs on a purchase price basis are set out in section 16 of Annex 11 of Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.15).

⁸⁵³ Volumes is one of the most common methods a distribution company will use when pricing its deliveries. The CMA notes that this is also the approach taken by Pfizer when allocating its distribution costs.

⁸⁵⁴ This approach also means distribution costs are allocated on the same basis as indirect costs.

Table 5.9: Flynn's direct costs for Flynn's Products in total and on a per pack basis, September 2012 to December 2016

	Total direct costs	Direct costs per pack
25mg	£2,475,663	£4.68
50mg	£7,315,505	£6.88
100mg	£36,931,355	£38.12
300mg	£24,068,824	£37.03

Source: PHT00145, Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.22), Annex 17; PHT00146, Flynn's response of 4 March 2015 to the CMA's s.26 Notice information request of 23 February 2015 (CMA document reference 01148.2), Annex 1; PHT00147, Flynn's response of 4 March 2015 to the CMA's s.26 Notice information request of 23 February 2015 (CMA document reference 01148.3), Annex 2; PHT00152, Flynn's response of 12 June 2015 to the CMA's s.26 Notice information request of 2 June 2015 (CMA document reference 01293.2), Annex 1; and PRC00488, Flynn's response of 11 September 2020 to the CMA's s.26 Notice dated 21 August 2020, Annex 1.

5.210 Packs of 100mg capsules contain three times as many capsules as the packs containing other capsule strengths. As a result, the direct cost of a 100mg pack is similar to that of a 300mg pack.

d. Flynn's common costs for Flynn's Products

5.211 Flynn's common costs comprise varying types of administrative expenditure, including employee costs, professional fees and office expenses.

5.212 After making adjustments to Flynn's administrative expenditure to remove those amounts which are directly attributable to products other than phenytoin sodium capsules (eg development costs and amortisation related to other products) and certain discretionary spend, the CMA has calculated a total value of common costs for Flynn of approximately £15.6 million between 1 April 2012 and 7 December 2016.⁸⁵⁵ Flynn's expert previously accepted that common costs calculated on this

⁸⁵⁵ Data for the financial years ending 31 March for each of 2013 (FY2013), 2014 (FY2014), 2015 (FY2015) and 2016 (FY2016) and the period to 23 January 2017 was provided to the CMA, split into varying categories of administrative costs. Figures for the period to 23 January 2017 were provided in a more detailed format and were assigned to the different cost categories by the CMA. The CMA collected data to 23 January 2017 as the Relevant Period proposed in the SO began on 24 September 2012 and ended on 23 January 2017 (being the date from which the Parties were directed to revise their selling prices): see SO, paragraphs 6.8–6.11. In this Decision, the CMA has now reverted to a Relevant Period ending on 7 December 2016 (the date on which the 2016 Infringement Decision was issued). Although data to 23 January 2017 covers a period after the Relevant Period (ie the period between 7 December 2016 and 23 January 2017), the CMA has allocated common costs using sales volumes across Flynn's portfolio for the period to 23 January 2017. Similarly, data for FY2013 covers a period before which Flynn was selling phenytoin sodium capsules in the UK (ie the period between 1 April 2012 and 24 September 2012). Accordingly, the CMA has allocated common costs incurred in FY2013 using sales volumes across Flynn's portfolio for the 12 months from 1 April 2012. The CMA considers that this methodology leads to a reasonable proxy for the level of common costs that would have been attributable to phenytoin sodium capsules if data specific to the periods between (i) 24 September 2012 and 31 March 2013 and (ii) 1 April 2016 and 7 December 2016 were available. In calculating total common costs to 7 December 2016, the CMA pro-rates the data received for the period to 23 January 2017. PHT00153, Flynn's response of 19 June 2014 to the CMA's s.26 Notice information request of 6 June 2014 (CMA document reference 00607.2), Annex 4; PHT00154, Flynn's response of 19 June 2014 to the CMA's s.26 Notice information request of 6 June 2014 (CMA document reference 00607.3), Annex 6.3; and Flynn's response to CMA s.26 Notice dated 21 August 2020, PRC00485, Annex 2.1, and PRC00486, Annex 2.2.

basis reflect the total value of its common costs for the period being assessed (ie those costs that are not directly attributable to any product).⁸⁵⁶

5.213 For the reasons set out in paragraphs 5.9 to 5.28, the CMA has allocated a proportion of Flynn's indirect costs to Capsules on the basis of sales volumes (using number of packs sold).

5.214 Table 5.10 shows the CMA's allocation of Flynn's indirect costs on a total and per pack basis. Full details of the CMA's assessment of Flynn's indirect costs are set out in Annex H. The effect of adopting different common cost allocation methodologies is shown in Annex I.

Table 5.10: Flynn's common costs allocated to Flynn's Products in total and on a per pack basis, September 2012 to December 2016

	Total common costs	Common costs per pack
25mg	£554,068	£1.05
50mg	£1,114,757	£1.05
100mg	£1,015,307	£1.05
300mg	£681,095	£1.05

Source: PHT00153, Flynn's response of 19 June 2014 to the CMA's s.26 Notice information request of 6 June 2014 (CMA document reference 00607.2), Annex 4; and PHT00154, Flynn's response of 19 June 2014 to the CMA's s.26 Notice information request of 6 June 2014 (CMA document reference 00607.3), Annex 6.3; and Flynn's response of 11 September 2020 to the CMA's s.26 Notice dated 21 August 2020, PRC00485, Annex 2.1, and PRC00486, Annex 2.2.

II. Establishing a reasonable rate of return for Flynn's Products

5.215 Having estimated the total costs actually incurred in, or reasonably attributable to, the supply of each of Flynn's Products, the CMA must establish the 'Plus' element of Cost Plus: that is, a reasonable rate of return.

5.216 As set out in paragraph 5.120, the CMA considers that it is appropriate to use the ROCE methodology in establishing a reasonable return for Flynn's Products on remittal.

5.217 Paragraphs 5.102 to 5.119 set out the CMA's view on the suitability of applying the ROS approach to Flynn's Products. In summary, the CMA considers that:

5.217.1 an approach based on ROS suffers generally from a number of limitations in comparison to the ROCE approach (principally that it is not based on

⁸⁵⁶ PRE00153, Joint Statement of [Flynn Expert Witness 2] and [CMA Expert Witness 1], dated 25 September 2017, issue 4.1, page 20. [Flynn Expert Witness 2], Flynn's Expert Witness, states that 'approach[ing] the calculation of Cost Plus from first principles, ignoring any precedent set by the PPRS... there is no difference between the common costs used by GH [CMA Expert Witness 1], the CMA's expert witness and [Flynn Expert Witness 2] (approximately £14.1 million). [Flynn Expert Witness 2] accepts that these are the correctly calculated shared costs of the business for the period in question, which cannot be attributed to any particular product'.

the fundamental economic and financial principles that link returns to the use of capital and the level of risk taken); and

5.217.2 a ROS approach is particularly problematic to apply in Flynn's case. This is because Flynn's agreement to pay very high supply prices to Pfizer distorts an assessment of the appropriate ROS for Flynn's Products. It means that significant profits earned by Flynn can be associated with a low computed percentage margin⁸⁵⁷ and that truly comparable products or companies are very difficult to identify for Flynn's supply of Capsules.

5.218 The CMA therefore applies the ROCE framework in its assessment below.

5.219 The CMA also carries out various analyses to test the suitability of those ROS comparators put forward by Flynn during the course of its Previous Investigation and the Remittal (notwithstanding those issues identified above). Given that the CMA is able to estimate Flynn's capital base reliably, this includes calculating how each of Flynn's ROS figures translates to returns on capital for Capsules, in line with paragraph 5.49 and to address the limitations of looking at ROS in isolation, as described at paragraphs 5.104 to 5.109.

5.220 To cross-check the results of its ROCE analysis, and as a further test of Flynn's ROS comparators, the CMA also assesses absolute measures of profitability before concluding on a reasonable rate of return. The CMA calculates the absolute returns that are given by its ROCE analysis and those ROS comparators put forward by Flynn. It then tests the reasonableness of these absolute returns against those of Flynn's other products and against the reasonable return calculated for Pfizer.

5.221 The CMA's assessment is set out below.

a. ROCE analysis

5.222 The first step in establishing a reasonable return for Flynn based on a ROCE methodology is to estimate the capital employed by Flynn in the production and supply of Flynn's Products. An estimate of the WACC is then applied to this capital employed balance to calculate the reasonable return.

i. Capital employed

5.223 As set out in section 2.D.I.d (Factual Background), Flynn's responsibilities in supplying phenytoin sodium capsules in the UK are limited to the ordering and

⁸⁵⁷ The Parties' jointly established arrangement results in significant upstream excesses being paid to Pfizer by Flynn (particularly for 100mg and 300mg capsules, where Pfizer's prices result in excesses of greater than 650%). The starting point in adopting the ROS approach for Flynn is therefore an inflated cost base resulting exclusively from the jointly established arrangement between the Parties. Flynn's inflated cost base, in turn, has the effect of suppressing Flynn's own profitability, when expressed as a percentage margin. As explained in paragraphs 5.110 to 5.116, the consequence is that a simple ROS analysis allows Flynn to rely on its position in the supply chain and its arrangement with Pfizer to obscure the true scale of its profitability and to insulate its own supply prices from the effective application of Chapter II.

holding of stock, marketing and promotional activities and ensuring regulatory compliance. Flynn is not involved in the manufacturing process, responsibility for which remains with Pfizer.⁸⁵⁸

5.224 Flynn accepted during the CAT Appeal that there was ‘very little fixed capital employed by Flynn for phenytoin’⁸⁵⁹ and that it had not invested heavily in relation to phenytoin during the Relevant Period,⁸⁶⁰ nor had it innovated in relation to the relevant products⁸⁶¹ or incurred any sales and promotion costs during the Relevant Period.⁸⁶²

5.225 The CMA notes that this is consistent with Flynn’s financial statements, which do not indicate investment in tangible assets in relation to the supply of Capsules.⁸⁶³ The CAT also found that Flynn’s commercial activities and risks were limited.⁸⁶⁴

5.226 During the Previous Investigation and in its submissions before the CAT and Court of Appeal, Flynn referred only to the following when describing the capital employed in its supply of Capsules:

5.226.1 the need to cover the cost of its working capital; and

5.226.2 the need to strengthen the supply chain by identifying a second API supplier.⁸⁶⁵

5.227 The CMA notes that the above submissions are consistent with Flynn’s contemporaneous statements to the DHSC when Flynn was asked to consider what information it could provide as justification for its prices.⁸⁶⁶ The CAT also recognised that Flynn held a level of stock to ensure market supply and that Flynn had appeared to have explored the possibility (without success) of establishing an alternative source of supply to Pfizer.⁸⁶⁷

⁸⁵⁸ Table 2.2.

⁸⁵⁹ PAD00056, [Flynn Expert Witness 1], day 7, page 37, lines 14-19.

⁸⁶⁰ PAD00056, [Flynn Expert Witness 1], day 7, page 37, line 20 to page 38, line 2. See also PRE00155, Second Expert Report of [Flynn Expert Witness 1], paragraph 31.

⁸⁶¹ PAD00056, [Flynn Expert Witness 1], day 7, page 38, lines 3-5.

⁸⁶² PAD00056, [Flynn Expert Witness 1], day 7, page 38, lines 6-11. See also PRE00155, Second Expert Report of [Flynn Expert Witness 1], paragraph 32.

⁸⁶³ Flynn’s financial statements indicate that tangible assets are relatively limited, with a value of between £67,354 and £86,522 between 31 March 2012 and 31 March 2015, PAD00015, PAD00038, PAD00073, PAD00075. Flynn’s tangible assets increased to £1.1 million in 2016, largely as a result of additions to its freehold property. See PAD00015, PAD00038, PAD00073, PAD00075 and PAD00072, Flynn Pharma (Holdings) Limited financial statements for the years ending 31 March 2012-2016.

⁸⁶⁴ *Phenytoin* [2018] CAT 11, paragraph 346. ‘Finally, we note here that as a further justification for the 6% ROS, the CMA relied on the limited commercial activity undertaken by Flynn and the limited commercial risk it accepted, given the indemnity clause in the Exclusive Supply Agreement (see paragraph 57(2) above). Flynn denied that its commercial activities and level of risk undertaken were low and relied on [Flynn Expert Witness 3]’s evidence in support of this view. We prefer the CMA’s view’.

⁸⁶⁵ PRE00152, [Flynn Director 2] First Witness Statement, 6 February 2017, paragraphs 40 and 41. See also PAD00031, [Flynn Director 2] Cross Examination, day 4, page 186.

⁸⁶⁶ Section 2.D.III.a (Factual Background).

⁸⁶⁷ *Phenytoin* [2018] CAT 11, paragraph 346.

- 5.228 In response to the SO, Flynn submitted that the CMA's ROCE analysis did not take account of 'the value created by Flynn in the form of intangible assets'.⁸⁶⁸ In its oral hearing, Flynn explained its operations 'require a high level of human capital and... individuals with skill and experience to supply the product. It is therefore primarily skilled labour and not physical capital that generates revenue for Flynn'.⁸⁶⁹
- 5.229 Flynn's experts also commented that, even were the CMA to reflect the value of Flynn's intangible, human capital in Flynn's capital base, the ROCE approach remained 'not appropriate in this context, because it does not take into account... what is essentially driving the businesses of asset-light businesses'.⁸⁷⁰
- 5.230 The CMA's assessment of Flynn's capital base, including Flynn's representations on its deployment of intangible (human) capital, is set out below.

Working capital

- 5.231 Working capital is the amount of capital that is employed in financing short-term assets, net of the capital provided by short-term liabilities. Working capital is typically calculated by taking the value of stock and debtors less the value of creditors.
- 5.232 Flynn submitted that it set out to develop a safety stock holding policy in September 2012, to provide a buffer against supply interruptions. Flynn stated that it built stocks equivalent to two to three months' market requirements, amounting to approximately £4-5 million.⁸⁷¹
- 5.233 Flynn's submissions as regards its working capital requirements focus on its need to retain buffer stocks. The CMA agrees that it is legitimate for Flynn to earn a return on capital invested in holding an efficient level of stock as this is capital that could be invested elsewhere, and capital employed in the supply of Flynn's Products, on which Flynn is entitled to earn a return. In addition to Flynn's stock requirements, the CMA has included debtors and creditors in its analysis.
- 5.234 The CMA has calculated Flynn's working capital requirements based on Flynn's actual purchases and sales data during the Relevant Period (which can be used to estimate stock balances) and estimates of average debtors and average creditors days based on Flynn's contractual terms with Pfizer and [X]. On this basis, the CMA estimates net debtors of £0.7 million.

⁸⁶⁸ PRC03720, CRA5, paragraph 16.

⁸⁶⁹ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 23, lines 10-12.

⁸⁷⁰ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 42, lines 18-20. Also PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 43, lines 4-7: *(Miss Bon): So you are saying when it is an asset-light business, even if you could somehow quantify these intangible assets, you do not think ROCE would be appropriate. ([X]): We are saying that. Yes.*

⁸⁷¹ PRE00152, [Flynn Director 2] First Witness Statement, 6 February 2017, paragraph 40.

- 5.235 As regards Flynn's stock requirements, the CMA first calculated Flynn's average stock value during the Relevant Period, giving an average of £2.1 million. As this average stock value was below the £4-5 million estimate submitted by Flynn, the CMA reviewed Flynn's actual closing stock balances as at each of 31 March 2013 and 31 March 2014, as provided by Flynn. Flynn's actual phenytoin stock at 31 March 2013 was valued at approximately £2.7 million and approximately £2.8 million at 31 March 2014. The CMA has used a figure of £2.8 million as the value of Flynn's stock for the purposes of its Cost Plus assessment, based on the higher value of Flynn's observable closing stock balances. The CMA therefore estimates Flynn's annual total working capital requirements during the Relevant Period to have been £3.5 million.⁸⁷²
- 5.236 In addition, as a test of the robustness of its findings, the CMA has carried out an additional sensitivity adopting Flynn's upper estimate for the value of its stock (ie £5 million). The CMA notes that Flynn's data suggests that a value of £5 million would be highly generous to Flynn, and that an efficient level of buffer stock is likely to be lower than Flynn's estimate. The CMA considers that it has adopted a generous approach in including Flynn's upper estimate in its sensitivity analysis. The results of this analysis are set out at paragraph 5.400 below and demonstrate that the results of the CMA's assessment are not materially affected by the adoption of the highest buffer stock valuation submitted by Flynn.
- 5.237 As regards Flynn's debtor balance, the CMA considers that debtors relating to Flynn's Products (ie amounts owed to Flynn from sales of Capsules) should ordinarily be reduced as part of the calculation of its working capital. This is because Flynn's debtor balance would be inflated by the allegedly excessive selling price charged by Flynn. This leads to a circularity problem in the analysis whereby the high price charged by Flynn would increase its working capital balance (and therefore, its capital employed) and reasonable return on capital, consequently increasing Flynn's Cost Plus and reducing the scale of any excesses. The CMA has nevertheless included an unadjusted debtor balance as part of Flynn's working capital which, for the reasons above, is favourable to Flynn.
- 5.238 While Flynn's creditor balance (which reduces working capital and thus the level of capital employed) would be similarly affected by the allegedly excessive supply prices charged to Flynn for Pfizer's Products, Flynn's purchase costs represent direct costs actually incurred by Flynn during the Relevant Period. The CMA's assessment of Flynn's working capital has therefore taken account of Flynn's full creditor balance.

⁸⁷² Flynn's total working capital is the sum of its stock value and net debtors.

Alternative API supply

- 5.239 Flynn submitted that it took preliminary steps to identify a second API supplier in October 2012, when it experienced its first supply issues, with the purpose of strengthening the supply chain and, in the long-term, reducing costs by replacing Pfizer as the API manufacturer entirely.⁸⁷³
- 5.240 However, Flynn explained that, due to the uncertainty caused by the CMA's investigation, it had not incurred any actual expenditure for this purpose.⁸⁷⁴
- 5.241 As Flynn has not incurred any expenditure nor invested any capital for the purpose of establishing an alternative source of API supply to Pfizer, the CMA considers that no allowance should be made as part of Flynn's capital employed for any such requirement. Put simply, Flynn has made no investment for this purpose, on which it would be entitled to earn a return.
- 5.242 The CMA also notes that, had Flynn established a second source of API supply, this would likely reduce the efficient level of buffer stock required to be held by Flynn, as a result of a stronger supply chain and lower stockout risks. The effect on Flynn's total capital employed figure in circumstances where it had established an alternative source of API is therefore uncertain.

Intangible (human) capital

- 5.243 In its response to the SO, Flynn submitted that the CMA had failed to take account of the 'human capital' that it employed in its operations. It stated that:
- 5.243.1 Flynn is 'responsible for pharmacovigilance with an ongoing duty to monitor and update scientific advice about the product to pharmacists, doctors and patients, and it is simply not fair or accurate for the CMA ... to describe those duties as "purely administrative". They are duties that entail responsibilities that require skill and care.'⁸⁷⁵
- 5.243.2 The supply of Capsules 'require[s] a high level of human capital and it requires individuals with skill and experience to supply the product'.⁸⁷⁶
- 5.244 The CMA agrees with Flynn that there is a need to carefully appraise the relevance and value of intangible assets as part of an assessment of Flynn's capital base.
- 5.245 In various contexts (including profitability analysis in market investigations and in other excessive pricing cases) the CMA considers whether certain intangible assets should be included in its assessment of capital employed and, if so, how

⁸⁷³ PRE00152, [Flynn Director 2] First Witness Statement, 6 February 2017, paragraph 41.

⁸⁷⁴ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 193, lines 1-10. See also PAD00049, [Flynn Director 2] First Witness Statement, 6 February 2017, paragraph 48.

⁸⁷⁵ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 20, lines 19-23.

⁸⁷⁶ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 23, lines 10-11.

those assets can be valued reliably. The CMA undertakes this same exercise in respect of Flynn's submissions with respect to its human capital.

- 5.246 In the first instance, the CMA notes that the relevant factor for its analysis is not, as Flynn asserts, the 'value created by Flynn in the form of intangible assets' but rather the efficient cost to the business of any such assets, since the analysis being undertaken is identification of 'Cost Plus'.
- 5.247 Second, the CMA observes that the costs to a business of its human capital are generally reflected in salaries and other employment costs (such as national insurance contributions and pension costs). The level of salaries can generally be assumed to reflect the level of knowledge, skills and expertise of the staff. All such costs have been included in Flynn's indirect costs, a proportion of which have been allocated to phenytoin as part of the CMA's analysis (as explained in paragraphs 5.211 to 5.213 above). That is to say, the CMA's analysis already reflects Flynn's actual costs of human capital.
- 5.248 The CMA's criteria for the recognition of intangible assets in capital employed, rather than recognising expenses within costs, are:
- 5.248.1 it must comprise a cost that has been incurred primarily to obtain earnings in the future;
- 5.248.2 this cost must be additional to costs necessarily incurred at the time in running the business; and
- 5.248.3 it must be identifiable as creating such an asset separate from any arising from the general running of the business.⁸⁷⁷
- 5.249 Flynn has provided neither evidence nor argumentation that it has incurred costs that meet these criteria in respect of its staff; rather its submissions emphasise the level of skill, responsibility and expertise of staff in carrying out their day-to-day functions. The available evidence also shows that Flynn outsourced many of its activities in relation to Capsules, including at least part of its pharmacovigilance activities (as referred to at paragraph 5.243.1).⁸⁷⁸ All of Flynn's outsourcing costs are reflected in direct or indirect costs (as appropriate) as part of the CMA's Cost Plus.
- 5.250 Given the above, the CMA considers that the most appropriate treatment is to allocate a portion of Flynn's 'human assets' (as measured by its employee costs) to Capsules as a part of Flynn's indirect costs. Under this approach, the CMA recognises a value in its Cost Plus which reflects the actual costs incurred by Flynn

⁸⁷⁷ CMA, [Guidelines for market investigation: Their role, procedures, assessment and remedies](#), Annex A, paragraph 14.

⁸⁷⁸ See PHT00245, Email chain between [[MHRA Employee] and [MHRA Employee]] MHRA and others dated 15 - 21 June 2012 re Validated Type IB variation - Epanutin - Flynn Pharma - out of stock situation: MHRA's email of 20 August 2013 to the OFT providing its chronology of events concerning its interactions with Flynn with supporting documents (CMA document reference 00380.20).

in employing individuals with the requisite skill and experience. In the event that the CMA was of the view that the criteria for recognition within capital employed (rather than costs) had been met, a corresponding reduction to the employee cost category would be required (to avoid double counting). The CMA notes that Flynn's representations did not recognise that the CMA's Cost Plus already allocates £2.5 million of employee costs to Capsules as part of Flynn's indirect costs.⁸⁷⁹

- 5.251 In addition, the CMA notes that Flynn's common costs did not increase following the introduction of Capsules to its portfolio.⁸⁸⁰ The CMA's Cost Plus however, on a cautious basis, still allocates a significant proportion (over 20%) of those costs that pertain to Flynn's cost of human capital (ie its employee costs) to Capsules.
- 5.252 Finally, the CMA also considered Flynn's submission that, even if its human capital were to be included in capital employed, ROCE would remain an inappropriate measure 'because it does not take into account... what is essentially driving the business of asset-light businesses'.
- 5.253 Flynn has, however, provided neither argumentation nor evidence which seeks to define any additional factors which 'drive its business' beyond its submissions on its human capital (which, as above, is accounted for as part of the CMA's Cost Plus). In circumstances where Flynn itself is unable to identify value-creating activities which are unaccounted for in the CMA's ROCE analysis, the CMA considers the ROCE approach provides a robust and reliable basis for determining a reasonable rate of return for Flynn's Products (which appropriately rewards all of the activities undertaken by Flynn).
- 5.254 The CMA observes that an argument that the ROCE framework cannot be applied, despite accounting for all of Flynn's activities in supplying Capsules, would be to seek to undermine the basis of a 'Cost Plus' analysis altogether, notably that there should be a reasonable relationship between the costs of supplying a product (direct, indirect and capital) and its price. Therefore, the CMA does not accept this argument.

Other intangible assets

- 5.255 Further to Flynn's submissions on its deployment of human capital, the CMA has considered whether there are other intangible assets that are relevant to Flynn's supply of Capsules and which should be included in Flynn's capital base.
- 5.256 The CMA notes that Flynn has not provided any submissions or evidence that identify or value additional intangible assets for inclusion in the CMA's assessment, other than human capital.

⁸⁷⁹ Annex H, Table H.1.

⁸⁸⁰ PRE00716, Flynn Pharma Ltd, March 2013 accounts, page 5. Flynn's 'Administrative expenses' decline between FY 2012 and FY 2013.

5.257 The CMA considers that there are no intangible assets that are applicable to Flynn's Products. Typically, a firm may have a brand name that is a significant asset and pharmaceutical companies might be expected to hold intangible assets in the form of patents or to incur research and development costs that may be included in the capital base.⁸⁸¹ In the circumstances of this case, Flynn's Products have been de-branded, are off-patent and Flynn has not invested in development activities nor made recent innovations in relation to the supply of phenytoin sodium capsules.⁸⁸² As such, assets of this type have been excluded from the CMA's assessment.

Flynn's total capital employed

5.258 Based on the above, the CMA has estimated the annual value of the capital employed by Flynn during the Relevant Period for the production and supply of Flynn's Products to have been £3.5 million (ie the value of its annual working capital requirements). Table 5.11 below shows the CMA's estimate of Flynn's annual capital employed by capsule strength.

Table 5.11: CMA estimate of Flynn's annual capital employed during the Relevant Period allocated to Flynn's Products, September 2012 to December 2016

	Capital employed
25mg	£241,471
50mg	£499,392
100mg	£1,536,343
300mg	£1,257,927

ii. Flynn's WACC

5.259 Applying the appropriate WACC to Flynn's capital employed balance enables the calculation of the return that would be required to appropriately compensate Flynn's investors for the activities and risks associated with Flynn's Products.

5.260 As set out in paragraphs 5.170 and 5.171, Pfizer submitted that its WACC is around 9% and Flynn's own expert relied on an analysis by KPMG to demonstrate that the average cost of capital for pharmaceutical companies was between 7.7% and 8.2% between 2010 and 2014.

5.261 Based on this range of cost of capital estimates, the CMA considered in the SO that it was appropriate to use a WACC of 9% as the reasonable rate of return for the calculation of Cost Plus for Flynn's Products. This allowed Flynn to earn the

⁸⁸¹ Research and development expenditure may not meet the accounting criteria for recognition as an asset on the balance sheet. In such circumstances, potentially relevant expenditure would not be captured by the CMA's review of Flynn Pharma Limited's financial statements.

⁸⁸² Paragraph 5.59.

same rate of return as Pfizer and a return which exceeded the estimated cost of capital relied on by Flynn's own expert on appeal before the CAT.

5.262 In response to the SO, Flynn submitted that it was inappropriate to use Pfizer's WACC as the relevant WACC for Flynn because:⁸⁸³

5.262.1 Flynn's smaller size and reliance on a single product (phenytoin) meant that equity investors' required return was expected to be higher for Flynn than the required return on large, diversified pharmaceutical companies such as Pfizer; and

5.262.2 it is well accepted in finance that smaller capitalisation stocks demand a higher equity risk premium than large cap stocks.

5.263 More generally, Flynn disputed the use of the WACC as a benchmark for assessing excessiveness, stating that:⁸⁸⁴

5.263.1 the WACC 'is the minimum return that investors would require on invested capital' and therefore 'cannot be used as a benchmark to assess whether returns are or might be excessive';

5.263.2 most industries are not characterised by perfect competition and ROCE is therefore likely to exceed WACC, but this cannot imply that profits are excessive; and

5.263.3 the WACC is an average ex ante return which fails to take into account that successful products will earn higher returns ex post.

5.264 Starting with Flynn's submissions on the risks it faces as a small company and whether these risks should be reflected through the inclusion of an additional risk premium in the WACC, the CMA first notes that there is no theoretical basis for the inclusion of a small company premium within the Capital Asset Pricing Model (CAPM), which seeks to identify the level of returns required by fully diversified investors. Indeed, the fundamental insight of the CAPM is that investors do not require any return for assuming firm-specific risks, whether arising from firm size or other idiosyncratic characteristics, but only for assuming the systematic risks of an investment, as measured by the beta of a stock.⁸⁸⁵

5.265 Second, a number of academics in the field of corporate finance reject the use of small company premia on the basis that the historical evidence does not support

⁸⁸³ PRC03492, Flynn's response to the SO, paragraph 7.21 and PRC03720, CRA5, paragraphs 20-22.

⁸⁸⁴ PRC03492, Flynn's response to the SO, paragraph 7.23-7.24 and PRC03720, CRA5, paragraphs 23-27.

⁸⁸⁵ Since investors can insure against company specific risks by holding a diversified portfolio, no additional return is required to compensate for the diversifiable risks of specific investments. However, a diversified portfolio still moves up and down with the general economy and stock market. These movements correspond to undiversifiable (systematic) risk and investors are compensated for assuming these risks. The beta value is a firm-specific measure of exposure to these non-diversifiable risks. See also Brealey, Myers and Allen (2010), 'Principles of Corporate Finance: Tenth Edition', chapter 9 which explains that the beta of a stock measures the extent to which the returns earned by the firm covary with the average returns earned on the market.

the existence of higher returns on smaller firms (see for example, Damodaran (2015)⁸⁸⁶ and Cochrane (2005)⁸⁸⁷). Damodaran states:

I argue that these practices are misguided because the small cap premium is no longer supported by the historical data, does not seem to be priced in by investors in markets today, and is based on faulty intuition.

- 5.266 The CMA therefore disagrees with the need to include a small company premium in its estimate of Flynn's WACC.
- 5.267 In addition, the CMA has identified that an investment bank, Jefferies, carried out valuation analysis of Flynn in December 2012. This analysis included projections of Flynn's profitability and discounted Flynn's future cashflows using a WACC of 10%, with a sensitivity analysis using a range of 8-12% WACC.⁸⁸⁸
- 5.268 Flynn submitted that 'limited weight can be attributed to this document' because:
- 5.268.1 'a DCF [discounted cashflow] based valuation uses as its discount rate the WACC of the acquiror of a business, not the target business itself'; and
- 5.268.2 the analysis prepared by Jefferies used 'a 10% valuation for a trade (typically large pharmaceutical business) acquiror'.^{889 890}
- 5.269 The CMA first notes that the Jefferies' presentation does not state that it uses a 10% WACC 'for a trade acquiror' and that a DCF prepared on this basis would require knowledge of the identity of the buyer. This is counterintuitive in the context of a document that provides a valuation overview for the Flynn business.
- 5.270 Moreover, and contrary to Flynn's submissions, correct practice is in fact to use the WACC of the target business in valuation analysis. This is because the objective of a DCF is to discount future cashflows at a rate that reflects the risk profile of the investment, rather than the investor. As Brealey Myers and Allen (2010) put it: 'the cost of capital depends on the use to which that capital is put'.⁸⁹¹

⁸⁸⁶ Damodaran, A (2015), 'The Small Cap Premium: Where is the beef?'.
⁸⁸⁷ Cochrane, J (2005), 'Asset Pricing: Revised Edition', Princeton University Press, page 452.

⁸⁸⁸ PHT00399, Report from Jefferies to Flynn dated December 2012, titled 'Ideally Positioned to Achieve Superior Outcomes for Flynn Pharma and Its Shareholders' (CMA document reference 00145.640), pages 15 and 16.

⁸⁸⁹ PRC03903, Flynn's response to the Letter of Facts, paragraph 4.4.1.

⁸⁹⁰ Flynn also submitted that 'the inappropriateness of using this valuation to support the CMA's determination of a reasonable rate of return to be earned by Flynn on phenytoin capsules is highlighted by the fact the same slide contains a "leveraged buy-out" ('LBO') valuation which uses an internal rate of return ('IRR') for a venture capitalist (with typically significantly higher return expectations based on its cost of capital) of between 25%-30%'. PRC03903, Flynn's response to the Letter of Facts, paragraph 4.4.2. LBO analysis is a separate part of the analysis carried out by Jefferies and the CMA considers this does not undermine the fact that a 10% WACC was adopted in Jefferies' valuation of Flynn's business. For the avoidance of doubt, the CMA does not consider that the target rates of return of venture capitalists are appropriate for estimating the efficient cost of finance. These rates of return are effectively hurdle rates, reflecting the rate of return that venture capitalists would hope to generate and may include a premium above the cost of capital. The CMA does not consider that a premium above the cost of capital should be included when estimating efficient costs of finance in Cost Plus.

⁸⁹¹ Brealey, Myers and Allen (2010), 'Principles of Corporate Finance: Tenth Edition', page 214.

- 5.271 The inclusion of a 10% WACC in Jefferies' analysis therefore indicates that this level of return appropriately compensates investors for providing capital to Flynn, taking into account the relevant features of its business. The CMA notes that this is consistent with Pfizer's submissions on its own WACC and the WACC of various pharmaceutical companies, which according to publicly available data sits within a range of 8% to 12%.⁸⁹² The CMA considers it appropriate to use the base case WACC of 10% (as adopted by Jefferies) in its ROCE calculations for Flynn for these reasons.
- 5.272 As to Flynn's representations on the use of WACC as a benchmark more generally, the CMA explained the conceptual underpinnings of the ROCE framework in paragraphs 5.32 to 5.39. This included that:
- 5.272.1 The cost of capital reflects real equity returns earned on average across a range of markets exhibiting differing degrees of competition. It is therefore an average (not a minimum) that allows for the effects of imperfect competition on returns to investors.
- 5.272.2 Comparing returns against the WACC allows the CMA to estimate excess profits remaining after providers of capital have received a market-based return on their investment. Comparison between actual prices and prices that allow for the recovery of the cost of capital is a well-recognised means of assessing excessive profitability.⁸⁹³
- 5.273 As to Flynn's argument that successful products will earn higher returns ex-post, the CMA agrees that outturn returns may be higher than the cost of capital, where upside project specific risks are realised (known as the 'fair-bet principle'). A 'fair bet' allows providers of capital to realise some upside benefit when, for example, demand turns out to be higher or costs lower than anticipated (in which case providers of capital may realise returns in excess of the cost of capital). This is to balance out the presence of downside risks which may result in returns below the cost of capital where demand is lower than expected or costs turn out to be higher than anticipated.
- 5.274 In the circumstances of this case, the commercial activities carried out by Flynn and the risks it incurred in supplying Capsules are limited. With regard to commercial activities, as set out in section 2.D.I.d (Factual Background), Flynn's activities are limited to the ordering of stock, marketing and promotional activities and ensuring regulatory compliance. In relation to risks, the CMA considers there to be little commercial risk associated with these responsibilities, given:

⁸⁹² Paragraph 5.171.

⁸⁹³ As described in section 4.B.I.b (Legal Framework), that the cost of capital can provide an appropriate benchmark for determining a reasonable rate of return has been recognised by the European Commission in *Scandlines* and *Aspen* and by the CAT in *Albion Water II*.

5.274.1 the guidance on Continuity of Supply meant that Flynn's customer base in the UK was to a significant degree guaranteed;⁸⁹⁴

5.274.2 Flynn was committed only to minimum order volumes that were much lower than actual product demand;⁸⁹⁵

5.274.3 the level of investment required to market and promote the product was low, as there was no immediate threat of entry from competitors (Flynn accepted that it incurred zero costs for this purpose⁸⁹⁶ and the CAT recognised that Continuity of Supply operated as a significant barrier to entry⁸⁹⁷);

5.274.4 the likelihood of incurring ancillary costs, for example, to improve customer services or manage bad debt risks, was low as purchases were guaranteed from a single, publicly-funded customer;

5.274.5 while Flynn employs working capital to acquire buffer stock, it has not incurred additional investment to innovate or improve the product (again, Flynn accepted that it incurred zero costs for this purpose⁸⁹⁸); and

5.274.6 the broad set of contractual indemnities included in the Parties' Exclusive Supply Agreement provided a significant degree of commercial protection to Flynn, including in respect of failures in the manufacturing process.⁸⁹⁹

5.275 As identified in paragraph 5.225, the CAT also found that Flynn's commercial activities and risks were limited:

*Flynn took over an established product and **undertook only very limited commercial activity**. Admittedly it held levels of stock to keep the market supplied and appears to have explored the possibility, without success, of establishing an alternative source of supply to Pfizer. However, the contractual indemnity, together with the terms of the Exclusive Supply Agreement, in the context of Continuity of Supply and the established user base and distribution arrangements, provided a very substantial degree of comfort to Flynn and meant that it was taking very little business risk. **Flynn's involvement in these arrangements was not to provide risk-taking or significant commercial activity**. Continuity of Supply meant that its customer base in the UK was to a significant degree guaranteed. (Emphasis added).⁹⁰⁰*

⁸⁹⁴ *Phenytoin* [2018] CAT 11, paragraph 346.

⁸⁹⁵ Section 2.D.I.d.ii (Factual Background).

⁸⁹⁶ PAD00056, [Flynn Expert Witness 1], day 7, page 38, lines 6-11. See also PRE00155, Second Expert Report of [Flynn Expert Witness 1], 6 February 2017, paragraph 32.

⁸⁹⁷ *Phenytoin* [2018] CAT 11, paragraph 151.

⁸⁹⁸ PAD00056, [Flynn Expert Witness 1], day 7, page 38, lines 3-5.

⁸⁹⁹ Section 2.D.I.c (Factual Background).

⁹⁰⁰ *Phenytoin* [2018] CAT 11, paragraph 346.

- 5.276 It follows from the above that the project specific risks associated with Flynn's supply of Capsules do not justify high ex-post returns in accordance with the 'fair-bet principle'.
- 5.277 The CMA therefore uses a WACC of 10% in its base case calculation of the reasonable return for Flynn's Products, consistent with the cost of capital used in Jefferies' analysis of Flynn's business.
- 5.278 In any event, to the extent that upside variations from the ex-ante expected returns are material to the CMA's assessment of excessiveness, they are captured by the inclusion of cross-checks as part of the CMA's analysis and by the CMA's approach to assessing the excess above Cost Plus because:
- 5.278.1 The CMA undertakes a cross-check of its assessment which equates to the application of a 31% WACC (see paragraphs 5.408 to 5.416).⁹⁰¹ The CMA notes that this is considerably higher than the 12% WACC used in Jefferies' sensitivity analysis; and
- 5.278.2 Prices are only found to be excessive where the differential above Cost Plus is material and sufficiently large.
- 5.279 Both of the above elements of the CMA's analysis allow for the possibility that firms may make ex post returns which are higher than the ex-ante expected return (ie higher than the WACC).
- 5.280 Further, the CMA gives due consideration to those factors that might justify high ex-post returns as part of its assessment of Limb 2 of the United Brands test (whether Flynn's Prices were 'unfair').

iii. ROCE calculation

- 5.281 Using the capital employed figures in Table 5.11 and a WACC of 10% as above, Table 5.12 below sets out the allowance for a reasonable return for each of Flynn's Products, on a total revenue and per pack basis for the entire Relevant Period.

⁹⁰¹ As explained in paragraphs 5.408 to 5.413, the CMA carries a cross-check of its findings using a ROS of 6%. The absolute return given by a 6% ROS is equivalent to applying a WACC of 31% to Flynn's capital employed balance (based on the CMA's estimate of Flynn's capital base).

Table 5.12: Allowances for a reasonable rate of return for Flynn's Products (total and per pack), September 2012 to December 2016

Capsule strength	Allowance for reasonable rate of return (total)	Allowance for reasonable rate of return (per pack)
25mg	£103,028	£0.19
50mg	£213,074	£0.20
100mg	£655,506	£0.68
300mg	£536,715	£0.83
Total	£1,508,323	N/A

5.282 Table 5.13 below shows the Cost Plus figures for each of Flynn's Products on a ROCE basis. It is calculated as the sum of Flynn's direct costs in Table 5.9, Flynn's common costs in Table 5.10 and Flynn's allowances for a reasonable rate of return in Table 5.12.

Table 5.13: Cost Plus for Flynn's Products on a ROCE basis, September 2012 to December 2016

	25mg	50mg	100mg	300mg
Direct costs	£2,475,663	£7,315,505	£36,931,355	£24,068,824
Common costs	£554,068	£1,114,757	£1,015,307	£681,095
Allowance for reasonable return	£103,028	£213,074	£655,506	£536,715
Cost Plus	£3,132,759	£8,643,336	£38,602,169	£25,286,634
Implied ROS	3%	2%	2%	2%

5.283 Given that Flynn has submitted that the CMA should have used a ROS analysis to establish a reasonable rate of return for Capsules, the CMA has included the ROS margin that is implied by its ROCE calculation in Table 5.13 (that is, the ROS margin that produces the same level of return as the CMA's ROCE calculation). The implied ROS can be calculated by dividing the allowance for a reasonable return in Table 5.13 by the total Cost Plus for each product.

5.284 From Table 5.13, it can be seen that the ROS implied by the CMA's ROCE analysis is approximately 3% for 25mg capsule strengths, 2% for 50mg capsule strengths, 2% for 100mg capsule strengths and 2% for 300mg capsule strengths. The average ROS across all capsule strengths is approximately 2%.

b. Flynn's representations on the appropriate ROS for Flynn's Products

5.285 In response to the SO, Flynn made the following representations on the conversion of the CMA's ROCE analysis into a ROS output:

5.285.1 Internal ROS comparisons put forward by CRA show that the profitability of Capsules (36% ROS) is in line with the rest of Flynn's portfolio.⁹⁰²

5.285.2 CRA analysis of the profit margins of Wockhardt UK, Teva and Accord-UK in relation to their sale of phenytoin tablets demonstrates that 'there was nothing unusual about the profitability of Flynn's supplies of phenytoin capsules'. Flynn submitted that CRA's analysis showed that the percentage and absolute margins earned by Tablet suppliers were in all cases higher than Flynn's margins on Capsules.⁹⁰³

5.285.3 Analysis by [Flynn Expert Witness 2] shows that the ROS earned by Flynn on Capsules is in line with the ROS rates of other companies in the generics industry (around 25-30%).⁹⁰⁴

5.285.4 Attempts to justify the appropriate ROS by reference to the return on capital are circular.⁹⁰⁵

5.285.5 According to Flynn's expert, [Flynn Expert Witness 2], 'not one of his clients would take on a product if they were only permitted to make a return of 2% ROS'.⁹⁰⁶

5.286 In summary, Flynn submitted that, in light of the available ROS comparators, the 2% ROS implied by the CMA's ROCE analysis was 'entirely disconnected from commercial reality'.⁹⁰⁷

5.287 Flynn submitted that its analysis showed the actual ROS earned by Flynn on its supply of Capsules during the Relevant Period (a ROS of around 36%) was comparable to that earned by other pharmaceutical companies and the returns of Flynn's other products. It further submitted that, had the CMA applied an approach based on profit margins (as the European Commission had done in Aspen), it would not have found that Flynn's prices were excessive.⁹⁰⁸

5.288 In addition to its representations on the appropriate percentage margin for Capsules, Flynn also submitted that an analysis of Flynn's absolute margins (ie pounds per pack) held no basis in economic theory and that:

5.288.1 Relative margins are typically used in finance and economics; and

⁹⁰² PRC03492, Flynn's response to the SO, paragraph 7.30.

⁹⁰³ PRC03492, Flynn's response to the SO, paragraph 7.48. PRC03720, CRA5, paragraphs 74 to 78.

⁹⁰⁴ PRC03492, Flynn's response to the SO, paragraph 7.42.

⁹⁰⁵ PRC03492, Flynn's response to the SO, paragraph 7.26.1.

⁹⁰⁶ PRC03492, Flynn's response to the SO, paragraph 7.25 and PRC03721, [Flynn Expert Witness 2] 5, paragraph 78.

⁹⁰⁷ PRC03492, Flynn's response to the SO, paragraph 1.22.

⁹⁰⁸ PRC03492, Flynn's response to the SO, paragraph 1.12.

5.288.2 Higher volumes should not be a reason to justify lower permissible margins.⁹⁰⁹

c. The CMA's consideration of Flynn's representations

5.289 The CMA sets out its views on the suitability of using the ROS approach to determine a reasonable rate of return for Flynn's Products in paragraphs 5.102 to 5.119. In doing so, the CMA explained why it considers there to be significant conceptual flaws in applying a ROS approach and that these are particularly acute in the specific circumstances of Flynn's Products. In particular, the CMA considers that:

5.289.1 Flynn's standalone ROS analysis is not informative of how returns compare to the investment required by Flynn to supply capsules and the risks assumed in doing so. A standalone ROS analysis therefore provides little insight into the underlying economic profitability of Capsules.

5.289.2 Simple ROS analyses fail to take account of Flynn's arrangements with Pfizer and thereby allow Flynn to rely on its position in the supply chain to hide the true scale of its profitability.⁹¹⁰

5.289.3 The application of the ROS approach introduces a circularity problem in the calculation of Flynn's reasonable rate of return.⁹¹¹

5.289.4 The unusual features in Flynn's supply of Capsules have the consequence that relevant ROS comparators are very difficult to identify.

5.290 The CMA notes that Flynn's representations on the appropriate rate of return are based on the simple computation of the ROS of various other products and companies and do not engage with the overarching issues identified above.

5.291 In the following section, the CMA first explains why it considers that the comparators put forward by Flynn do not provide a sound basis for determining a reasonable rate of return for Capsules.

5.292 Second, given that the CMA is able to reliably estimate Flynn's capital base, it tests the reasonableness of the ROS figures put to it by Flynn by calculating the return on capital that those figures would imply for Capsules (in line with paragraph 5.49 and to address the limitations of looking at ROS in isolation, as described at

⁹⁰⁹ PRC03492, Flynn's response to the SO, paragraphs 1.21 and 7.26.3.

⁹¹⁰ Flynn's cost base is inflated by the high supply price it agreed to pay to Pfizer as part of the arrangements between the Parties. Its inflated cost base means that significant profits earned by Flynn can be associated with a low computed percentage margin.

⁹¹¹ This is the case as the reasonable rate of return is calculated as a mark-up on total costs when applying the ROS approach. In Flynn's case, this means that its reasonable return would be increased by the inclusion of an excessive price (the Pfizer supply price) in its cost stack. In turn, this would increase Flynn's Cost Plus, reduce the scale of its observed profitability and potentially 'hide' the excessiveness of its prices.

paragraphs 5.104 to 5.109). In doing so, the CMA explain why it disagrees with Flynn that this represents 'circular' analysis.

5.293 Third, the CMA assesses absolute measures of profitability, both as they relate to its ROCE calculations and Flynn's ROS submissions. The CMA considers that absolute profitability measures provide a relevant cross-check of the reasonable level of return for Flynn's Products, given that its percentage margins are known to be distorted by the Pfizer supply price. The CMA also explained in paragraphs 5.73 and 5.107.1 that absolute profitability metrics can be used to prevent Type I and Type II errors in assessing excessiveness.

5.294 Finally, the CMA addresses the evidence from Flynn's expert, [Flynn Expert Witness 2], that none of his clients would take on a product at a ROS of 2%.

i. Capsules are an outlier within Flynn's portfolio and Flynn's internal documents confirm that comparisons with its other products are unreliable

5.295 As explained in paragraph 5.285, Flynn has argued that the profitability of Capsules is in line with the rest of its portfolio. Flynn submits this on the basis that it earned an average ROS on Capsules during the Relevant Period of 36%, which was at the median level for Flynn's portfolio.⁹¹²

5.296 The CMA notes that the analysis submitted by Flynn simply calculates the ROS of Flynn's other products and offers this as a reference point for the CMA's assessment of Capsules. However, the analysis ignores the important question of whether Flynn's other products are actually comparable to Capsules and contains no appraisal of those factors which can be expected to affect the ROS of individual products, such as differences in sales volumes and unit costs.⁹¹³

5.297 Similarly, the analysis does not assess the degree of competition faced by each of Flynn's other products, nor the extent to which they might be considered innovative or risky (factors which might be associated with a higher return). The CMA notes, for example, that Circadin (Flynn's second most profitable product during the Relevant Period, after Capsules) is a patented formulation for insomnia treatment⁹¹⁴ and is thus unlikely to represent a good comparator for Capsules, a product for which patent protection has long expired.

5.298 The CMA considers that comparing simple percentage margins across products produces incomplete and misleading comparisons of profitability when relevant product-specific factors are not taken into account.⁹¹⁵ Contrary to Flynn's submissions, the CMA's analysis below demonstrates there are in fact striking

⁹¹² PRC03492, Flynn's response to the SO, paragraph 7.30.

⁹¹³ See also paragraphs 5.46 to 5.48 which explained how various product-specific factors may be expected to affect the observed ROS.

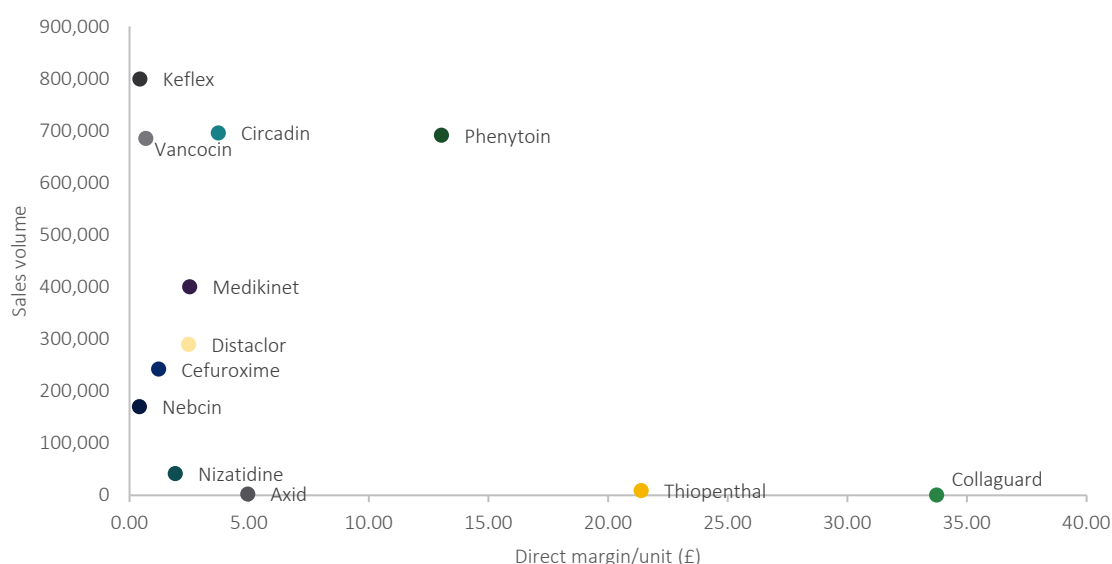
⁹¹⁴ PAD00139, About Circadin I Circadin.

⁹¹⁵ See Table 5.15 which illustrates the limitations in looking at percentage margins alone, by reference to Flynn's own profitability and input costs during the Relevant Period and in subsequent years.

differences in the level of profitability achieved by Capsules when compared to the rest of Flynn's portfolio.

5.299 When the level of sales volumes are properly taken into account, for example, the profitability of phenytoin is shown to be an outlier among Flynn's portfolio. Figure 5.1 shows the relationship between Flynn's margin per pack and sales volumes for each of its products.

Figure 5.1: Flynn's margins per pack and volumes by product (2013-2016)



Source: CMA analysis.

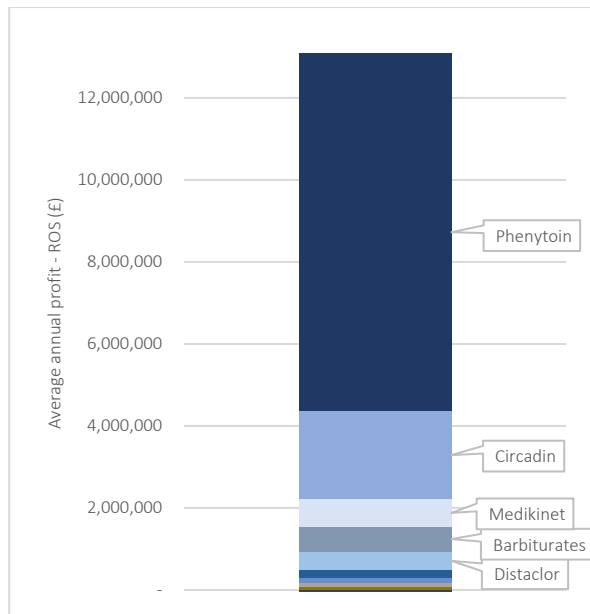
Note: Figure 5.1 excludes Collaguard (2013), Barbiturates and Viperatab as their values distort the axes. Collaguard made a loss in 2013 as a result of expenditure on sales and promotion; the direct margin achieved by Barbiturates and Viperatab were over £100 per pack and over £500 per pack, respectively. Direct margins measure product returns after the deduction of all direct costs and before the allocation of common costs.

5.300 Figure 5.1 shows that two of Flynn's other products achieve similar, or higher, absolute margins per pack than phenytoin but that these products sell in extremely low volumes. This is consistent with the framework set out in paragraph 5.48, where the CMA described how low volume products typically require higher returns.⁹¹⁶

5.301 Similarly, Figure 5.1 shows that all of Flynn's other high volume products earn margins per pack that are materially lower than the level observed for phenytoin. The consequence is that Flynn's returns on phenytoin during the Relevant Period were more than double the total return earned across Flynn's other thirteen products combined. This is illustrated in Figure 5.2 below:

⁹¹⁶ A reasonable return reflects the level of investment and risk incurred in supplying a product. For a given level of investment and risk, a firm that has lower sales volumes will require a higher ROS.

Figure 5.2: Average annual profit (ROS) on Flynn's products (2013-2016)



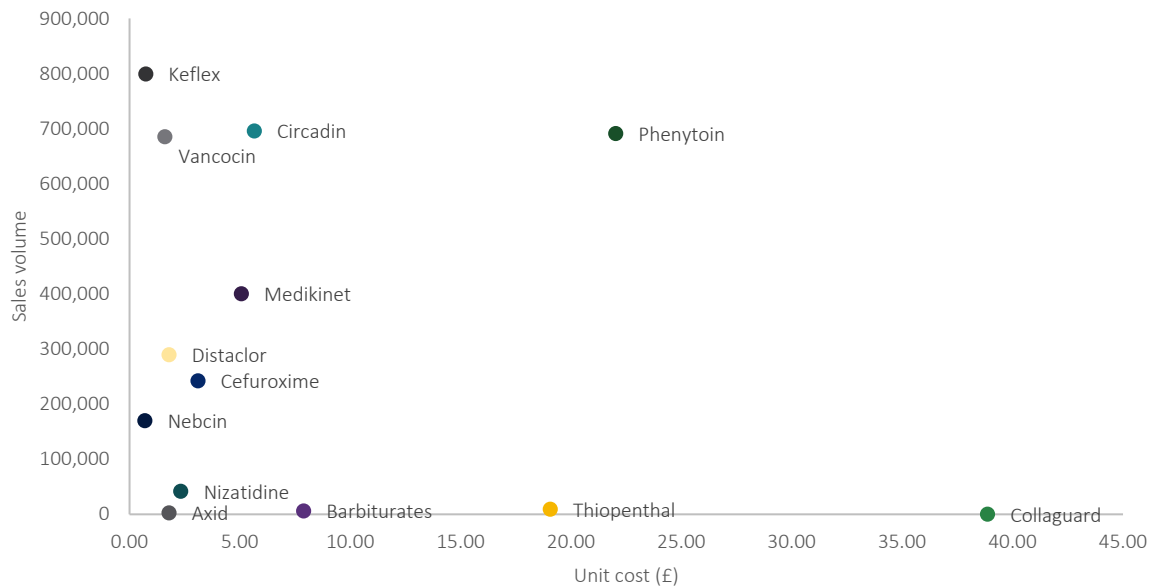
Source: CMA analysis.

Note: The absolute return on each of Flynn's portfolio products is calculated after the deduction of cost of goods sold, distribution costs, sales and promotion costs, depreciation and amortisation and after allocating common costs on the basis of sales volumes (number of packs sold).

- 5.302 Flynn's percentage ROS comparisons mask these stark differences in the level of profitability achieved by Capsules and the remaining products in Flynn's portfolio.
- 5.303 Further, the CMA explained above that input costs are relevant to a consideration of a reasonable ROS.⁹¹⁷ The CMA summarises the differences in unit costs among Flynn's portfolio in Figure 5.3, which shows the relationship between unit costs and sales volumes for each of Flynn's products.

⁹¹⁷ Paragraph 5.48.2.

Figure 5.3: Flynn's unit costs and volumes by product (2013-2016)



Source: CMA analysis.

Note: Figure 5.3 excludes Viperatab as its value distorts the axes. The average unit cost for Viperatab in the years 2013 to 2016 was nearly £900.

5.304 Figure 5.3 shows that phenytoin achieves a unique combination of high unit costs and high sales volumes among Flynn's portfolio (both of which are relevant to a consideration of what is a reasonable ROS for Capsules):

5.304.1 Only Keflex, Circadin and Vancocin sell in comparable volumes to phenytoin. However, phenytoin has significantly higher unit costs than each of these products: an average of over £20 per unit compared to £0.74 for Keflex, £1.61 for Vancocin and £5.66 for Circadin.

5.304.2 Only Thiopental and Collaguard have unit costs comparable to phenytoin. However, Thiopental sold an average of 9,000 units per year between 2013 and 2016. Collaguard sold an average of 147 units. Phenytoin, in comparison, sold an average of around 700,000 units per year over the same period.

5.305 From the above, it can be seen that there are product specific factors that make Flynn's supply of phenytoin very different from the rest of its products. Simple ROS comparisons between products fail to capture these important differences.

5.306 The above analysis demonstrates that Flynn's other products cannot be considered meaningful reference points for a reasonable rate of return for Capsules. Put simply, this is because no other product in Flynn's portfolio has characteristics similar to those of Capsules.

- 5.307 Consistent with the CMA's view above, Flynn's internal documents demonstrate the difficulties in drawing comparisons between Capsules and Flynn's other products.
- 5.308 Flynn itself recognised the considerable differences between its supply of Capsules and the rest of its products, going so far as to produce financial and management reporting that excluded phenytoin from the rest of Flynn's business. Internal emails show that Flynn's director requested that Capsules be excluded from reporting because 'inclusion of phenytoin in the summary ... skews the data far too much to make it useful in assessing the performance of everything else. I guess we need to see the combined summary and a summary excluding phenytoin'.⁹¹⁸
- 5.309 In summary, while Flynn has submitted that the percentage profit margins earned on Capsules are consistent with the rest of its portfolio, that is to ignore the question of whether a comparison with Flynn's other products can be considered meaningful, still less determinative, benchmarks for a reasonable rate of return for Capsules. The CMA's analysis above and Flynn's own treatment of phenytoin in its management reporting demonstrate considerable differences between Capsules and Flynn's other products. The returns of Flynn's other products thus fall some way short of meeting the criteria for relevant comparators.
- 5.310 Consistent with the view that Flynn's other products do not represent good comparators for Capsules, the CAT found in its 2018 judgment that:

*It was not in dispute that any such comparators must be identified on objective, appropriate and verifiable criteria. [CMA Expert Witness 1] [the CMA's expert] was correct to point to some highly unusual features of Flynn's phenytoin business, namely the fact that its supplies were bought at a high price, it had high volumes and the Pfizer-Flynn Capsules did not involve as much commercial risk to Flynn as did some other products. This may have made it difficult to draw reliable comparisons with the remainder of Flynn's portfolio. Phenytoin clearly occupied a very unusual position in Flynn's portfolio, given its absolute level of profitability, its size and its input cost. On this point, we prefer the view of [CMA Expert Witness 1] to that of [Flynn Expert Witness 1] [Flynn's expert].*⁹¹⁹

⁹¹⁸ PHT00376, Email chain of 25 September 2012 between [Flynn Director 3] (Flynn) and [Flynn Director 2], [Flynn Director 4], [Flynn Director 1] (Flynn), RE: Priority Report September 24 (CMA document reference 00145.416), page 1.

⁹¹⁹ *Phenytoin*, paragraph 343.

ii. The margins of Tablet suppliers do not provide a sound benchmark for a reasonable rate of return

5.311 Flynn submitted that the profit margins it earned on Capsules during the Relevant Period were not unusual compared to those of Wockhardt UK, Teva and Accord-UK on their sale of Tablets.⁹²⁰

5.312 The CMA explained in paragraphs 5.40 to 5.49 that the critical issue in using profit margin comparators is the selection of suitable comparators. The selection of comparator companies or products should include that chosen comparators are not distorted by ineffective competition. As Oxera's report for the OFT recognised:

*The aim of the assessment would be to compare the profit margins of an activity with that which would have been achieved in a fully competitive environment... The selection should be based on good reasons to believe that the comparators are subject to some degree of competitive pressure... It would be meaningless to benchmark the profitability of an activity against the profitability of a monopolistic company in another market.*⁹²¹

5.313 The CMA has carried out a detailed assessment of the level and extent of competition in the Tablets market in section 6.C (Unfair when Compared). The CMA finds that a number of factors limited the effectiveness of competition in the Tablets market, including the exercise of market power by Teva, supply issues in the market place and regulatory Guidance recommending Continuity of Supply.⁹²²

5.314 As a result of its findings on the lack of effective competition in the Tablets market, the CMA does not consider the margins earned by Wockhardt UK, Teva and Accord-UK provide suitable comparators for the purposes of estimating a reasonable rate of return for Flynn's Products. It is essential that selected comparators are not distorted by ineffective competition and, for the reasons set out in section 6.C (Unfair when Compared), the CMA considers that this essential criteria is not met in the case of Tablet suppliers.

iii. [Flynn Expert Witness 2]'s comparators do not control for the specific cost structure, risk and investment profile of Capsules

5.315 In addition to the submissions on its own product portfolio, Flynn submitted analysis of the average and median ROS of a set of pharmaceutical companies considered by its expert, [Flynn Expert Witness 2], to be comparable to Flynn. Flynn submitted that [Flynn Expert Witness 2] had refined the companies in his

⁹²⁰ Paragraph 5.285.2.

⁹²¹ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 7.35.

⁹²² Section 6.C (Unfair when Compared).

comparator set from the original Tribunal proceedings and calculated median ROS rates between 25% and 30%.⁹²³

5.316 The CMA has carefully reviewed the comparator analysis provided by [Flynn Expert Witness 2] and finds there to be a number of limitations in the analysis, which prevent it from being a reliable means of establishing a reasonable rate of return for Capsules.

5.317 First, the CMA's analysis in Figure 5.1 and Figure 5.3 showed there to be unusual features in Flynn's supply of Capsules and the CMA explained in paragraph 5.48 how these features can be expected to influence the ROS of a given product.

5.318 Similar to CRA's analysis of Flynn's other products, the comparator analysis presented by [Flynn Expert Witness 2] provides only simplistic percentage margin comparisons, without sufficiently considering the degree of similarity between the comparator set and Flynn's supply of Capsules. As stated by Oxera in its report for the OFT:⁹²⁴

It is essential that the [comparators] have considerable similarity with the company or industry under investigation, since profitability levels can be expected to vary across companies, independently of whether or not profits are excessive. (Emphasis added).

5.319 Specifically, [Flynn Expert Witness 2]'s analysis does not consider how the cost structure, risk, sales volumes and investment profile of Capsules compare against the companies included in his sample and how those factors might be expected to affect the ROS of Capsules. Without assessing these factors, ROS comparisons with other products and companies are rendered unreliable for the purposes of identifying a reasonable rate of return for a specific product: in this case, Capsules.

5.320 The CMA notes that [Flynn Expert Witness 2] acknowledges in his report that specific factors such as those identified above can be expected to influence the ROS of a given product or company. In particular, in setting out the results of his analysis, [Flynn Expert Witness 2] presents weighted average and median ROS figures both including and excluding Sandoz. He states that this is because 'Sandoz has appreciably larger revenues than the other four companies and thus distorts downwards the weighted average calculation'.⁹²⁵ [Flynn Expert Witness 2]'s expert report thereby recognises that high revenues (which can be the result of high costs and high sales volumes) can be expected to result in a lower ROS. The analysis does not, however, comment on the extent to which these factors should be expected to affect the ROS for Capsules and whether certain companies within

⁹²³ PRC03492, Flynn's response to the SO, paragraph 7.45.

⁹²⁴ PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 7.36.

⁹²⁵ PRC03721, [Flynn Expert Witness 2] 5, paragraph 43.

the sample should be considered better comparators than others as a consequence.

5.321 Second, the CMA notes that some of the companies included in [Flynn Expert Witness 2]'s sample engage in activities that prevent them from being reliable comparators for Capsules. Just by way of example:

5.321.1 The portfolio of Alliance Pharma includes patented products, which benefit from a period of exclusivity during which supra-competitive margins may be earned as a reward for innovation.

5.321.2 Some of the proposed comparator companies engage in manufacturing and product development activities. For example:

- (a) Chemidex Pharma states in its annual report that its principal activity is the 'manufacturing and selling of generic medicines' (emphasis added);⁹²⁶
- (b) Essential Pharma states that it is 'investing in the manufacture of specific products' as a means of negating economic risks faced by the company (emphasis added);⁹²⁷ and
- (c) Aspire Pharma states that 'the scientific and regulatory areas of our business continue to be a key strength in helping to deliver innovative and alternative routes for development of products' (emphasis added) and its accounts show that it has capitalised product development costs.⁹²⁸

5.322 Third, the CMA notes that the profit margins of [Flynn Expert Witness 2]'s comparator set fall within a very wide range (from a ROS of 11% to 53%). This in itself suggests that there are significant differences across the selected companies and undermines their usefulness as a benchmark for Capsules.

5.323 The CMA also notes that a review of the same set of companies' returns over a fuller timeframe than that presented by [Flynn Expert Witness 2] produces an even wider range. Sandoz, for example, generated an average ROS in 2016 of 6% and an average ROS in 2017 of 3%.⁹²⁹ Again, this demonstrates that profit margins can be expected to vary significantly across companies and from year to year and undermines the utility of simplistic margin computations as a means of establishing a reasonable rate of return for a particular product.

5.324 Fourth, the CMA considers that the use of average returns across a set of companies is not likely to provide a reasonable benchmark for a specific product,

⁹²⁶ Chemidex Pharma Limited, 2016 annual report and accounts, page 2.

⁹²⁷ Essential Pharma Limited, 2017 annual report and accounts, page 2.

⁹²⁸ Aspire Pharma Limited, 2015 annual report and accounts, pages 4 and 23.

⁹²⁹ Sandoz Limited, 2017 annual report and accounts, page 10.

where that product is known to have specific and unusual features that will affect its ROS (as is the case for Flynn's supply of Capsules).

- 5.325 Fifth, it is unclear to what extent the analysis presented by [Flynn Expert Witness 2] has sought to standardise accounting data. The reported ROS in company financial statements is sensitive to the specific accounting practices of the company. Revenue recognition policies and cost accounting practices may differ considerably between firms and over time and this can affect the reported ROS figures significantly. [Flynn Expert Witness 2]'s report does not comment on whether this has been assessed or whether this may affect the results of the analysis.
- 5.326 For these reasons, the CMA considers that [Flynn Expert Witness 2]'s comparator analysis does not provide a robust and appropriate means of establishing a reasonable rate of return for Flynn's Products.
- 5.327 The CMA recognises that selected comparators do not have to be identical to, or in the same relevant market as, the reference product. Comparators must however be sufficiently similar to the reference product for any comparison to be meaningful and to ensure that the presented figures are really comparable.⁹³⁰ Comparisons must also be made on a consistent basis.⁹³¹ The CMA considers that [Flynn Expert Witness 2]'s comparator analysis does not sufficiently engage with the unusual features of Capsules (namely the combination of a high input price, high sales volumes, low risk and low capital intensity) to ensure that the selected companies are sufficiently similar, nor does the analysis assess whether differences in accounting data make for consistent comparisons.
- 5.328 Flynn has submitted that the CMA should have undertaken further factual enquiries in relation to Flynn's comparator companies.⁹³² It submitted that the CMA has failed to make appropriate enquiries as part of the Remittal and that, inter alia, the CMA should have obtained information from third parties in relation to the profitability and risks taken in relation to potential comparators.⁹³³
- 5.329 The CMA has a duty to evaluate the arguments and evidence advanced by the undertakings fairly and impartially. However, the CMA does not have a duty actively to carry out additional investigative steps in every case or proactively seek additional evidence regarding the comparators put forward.⁹³⁴ The CMA has a margin of manoeuvre or discretion as to how it performs its duty of fair evaluation, including as to the depth and intensity of the inquiry⁹³⁵ and the extent of such duty

⁹³⁰ See for example *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 44-46 and 51; *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin* [2018] CAT 11, paragraph 373.

⁹³¹ *Albion Water II*, paragraphs 252-253; *Latvian Copyright Case*, paragraph 44.

⁹³² PRC03492, Flynn's response to the SO, paragraph 7.34 and PRC03903, Flynn's response to the Letter of Facts, paragraph 2.7.4.

⁹³³ PRC03903, Flynn's response to the Letter of Facts, paragraph 2.7. See also PRC03920, Macfarlanes letter to the CMA dated 10 June 2022, page 3.

⁹³⁴ *Phenytoin CoA*, paragraphs 113, 116 and 270 to 273.

⁹³⁵ *Phenytoin CoA*, paragraphs 113, 116 and 270.

on the CMA will be affected by the quality of the evidence adduced by the defendant undertakings, as there is an important evidential burden upon an undertaking being investigated.⁹³⁶

5.330 Taking these principles into account, the CMA has fairly evaluated those profitability comparators put forward by Flynn and its experts during the Previous Investigation and during the Remittal and it has provided reasons as to why it considers none of these comparators provide a meaningful and reliable basis on which to establish a reasonable rate of return for Flynn's Products (paragraphs 5.295 to 5.327). All of these profitability comparators seek to compare the profitability of Capsules on the basis of percentage profit margins only (whether against Flynn's other products or against the margins earned by third parties). The CMA explained in paragraphs 5.102 to 5.119 that there are a number of significant conceptual problems in applying this type of approach to Flynn's Products. None of Flynn's comparator evidence engages with these overarching issues. Instead, Flynn advances only the simple computation of the profit margins of various other products and companies, without regard to how comparable these products and companies actually are to Capsules and without controlling for the distortion caused by Pfizer's high input price.

5.331 Having fairly and impartially evaluated the comparator evidence submitted by Flynn above, the CMA considers that further investigation would not be necessary or appropriate in circumstances where:

5.331.1 There is information available which allows the CMA to:

- (a) reliably calculate a reasonable return for Flynn's Products based on the specific activities and risks assumed by Flynn in supplying Capsules (ie by adopting the ROCE approach); and
- (b) cross-check and test the reasonableness of the results of a ROCE-based analysis (by reference to the absolute profits earned by Flynn's most comparable products to Capsules).

5.331.2 There are unusual features in Flynn's supply of Capsules which make any comparisons purely based on percentage margins inherently problematic and present significant obstacles in identifying truly comparable products and companies that can be relied upon for the purposes of the CMA's assessment.

5.332 Further, Flynn's submissions suggest that the CMA should have gathered detailed information to appraise the price, cost, volumes, risks, activities and competitive conditions inherent in the supply of hundreds of products across the portfolios of 11 other companies to identify whether there are other products exhibiting similar

⁹³⁶ *Phenytoin CoA*, paragraphs 114.

characteristics to Flynn's supply of Capsules. The CMA considers that the requirement to carry out such an extensive exercise (particularly in the circumstances summarised above and having had regard to (i) the fact that Flynn itself has made no effort to identify any specific drugs that could potentially provide a meaningful comparison for Capsules; and (ii) the fact that the CMA has already taken significant steps to investigate and assess Tablets and the other AEDs which Pfizer's expert considered to be the most comparable to Capsules) would be establishing an approach or a methodology that is so complex and time-consuming that neither the CMA nor any other competition authority would have the time or resources to investigate allegations of unfair pricing.⁹³⁷ Indeed, the complexity of such an analysis was identified by the CAT and recognised by Flynn's expert, [Flynn Expert Witness 3], during the previous court proceedings:

THE CHAIRMAN: What weight do you attach in that sort of analysis to the amount of competition that Flynn and the comparator companies face? Are you factoring that into your analysis or do you take that as a sort of neutral factor which may or may not affect all of them?

[Flynn Expert Witness 3]. I do not know how much the other companies are affected by competition. So I can only assume I have treated it as a neutral factor. I mean, I do know that some companies have less competition on some products and more on others, but to be able to undertake that analysis I would have to have detailed information which I do not have.

THE CHAIRMAN: It would be quite a considerable analysis, almost like a market investigation, dare I say.

*[Flynn Expert Witness 3]. It would be.*⁹³⁸

5.333 For all the reasons set out above, the CMA considers that further investigation would not be necessary or appropriate and that the ROCE methodology, supported by appropriate cross-checks, provides a sufficient evidence base on which to determine a reasonable rate of return for Flynn's Products.

iv. ROS does not measure returns in the context of a risk-return framework and provides an incomplete measure of economic profitability as a result

5.334 Flynn's representations appear to consider that the CMA should assess the excessiveness of Flynn's Prices based purely on profit margins such as ROS. It justifies this by referring to the Commission's analysis in Aspen and considers that

⁹³⁷ *Phenytoin CoA*, paragraph 244.

⁹³⁸ PAD00070, Questions from the Panel to [Flynn Expert Witness 3], day 6 transcript, page 154, lines 7 to 21.

a similar approach should be followed in this case.⁹³⁹ Such an argument, however, misrepresents the Commission's analysis in Aspen.⁹⁴⁰

- 5.335 As explained above, an analysis based solely on ROS does not compare returns with the assets and activities that are necessary to supply Capsules, nor the risks assumed in doing so. A standalone ROS analysis can be misleading for this reason and provides little insight into the underlying economic profitability of Flynn's supply of Capsules. This means that separate analysis may be required to supplement and round out a ROS analysis, in order to understand how returns compare to investment and risk.⁹⁴¹ As explained in paragraph 5.56, the CMA carried out this supplementary analysis when using the ROS approach in its 2016 Infringement Decision.
- 5.336 Similarly, in Aspen, the European Commission explicitly recognised that the 'plus' element should reflect a return on investment or capital employed (to cover the cost of capital). However, in the presence of significant complexity in estimating capital employed, the Commission instead carried out a profit margin analysis to infer a reasonable rate of return and found clear concerns, such that a detailed assessment of the underlying capital employed was not required. In Flynn's case, no such difficulties exist in directly estimating its capital employed and the associated cost of capital.
- 5.337 It is this important element of the assessment that is missing from Flynn's representations, which seek to portray ROS as an appropriate standalone test of excessiveness (and ignores how Flynn's returns on Capsules during the Relevant Period compare to its investment and risk profile).
- 5.338 The CMA considers that an appropriate analysis of Flynn's Prices must be capable of assessing how Flynn's actual returns compare against its activities and risks. The CMA has therefore calculated the return on capital for Capsules that is implied by those ROS figures put to it by Flynn.
- 5.339 Flynn provided data on the appropriate ROS as follows:⁹⁴²
- 5.339.1 Flynn submitted data showing that the average ROS on its products other than phenytoin sodium capsules was 8% in 2013, 10% in 2014 and 18% in 2015.⁹⁴³
- 5.339.2 As part of the CAT appeals, Flynn's experts provided analysis that calculated the average ROS earned across a range of generics

⁹³⁹ PRC03492, Flynn's response to the SO, paragraph 1.12 and 7.43.

⁹⁴⁰ See paragraphs 5.92 to 5.101.

⁹⁴¹ Paragraph 5.49.

⁹⁴² Data was provided during the course of the CMA's Previous Investigation, the CAT appeal and in response to the SO. *Phenytoin* [2018] CAT 11, paragraph 340. See also 2016 Infringement Decision, paragraph 5.187 and 5.193 and PRC03492, Flynn's response to the SO, section 7.

⁹⁴³ 2016 Infringement Decision, paragraph 5.187.

companies and found that the average ROS earned by these companies was 21%.⁹⁴⁴

5.339.3 In response to the SO on remittal, Flynn's expert provided updated analysis of the ROS of several UK-based companies that were judged to be comparable to Flynn.⁹⁴⁵ [Flynn Expert Witness 2] calculated median ROS rates among these companies of 25-30%.⁹⁴⁶

5.340 The CMA disagrees with Flynn that translating these figures to returns on capital represents 'circular' analysis. Rather, this analysis allows the CMA to consider the reasonableness of the returns produced by a range of ROS figures in the context of the capital that is employed by Flynn in supplying Capsules. The CMA has carried out an analysis of returns on capital to supplement the data provided by Flynn and to afford a more complete (and economically meaningful) view of the level of profitability produced by the rates of return put forward by Flynn.

5.341 The results of the CMA's analysis are set out in Table 5.14.

Table 5.14: Returns on capital implied by Flynn's ROS figures

Source	ROS %	Return on capital (implied average)
Flynn internal ROS (low)	8%	43%
Flynn internal ROS (mid)	10%	55%
Flynn internal ROS (high)	18%	108%
Flynn comparators (CAT appeal)	21%	131%
Flynn comparators (SO response: low)	25%	164%
Flynn comparators (SO response: high)	30%	211%

5.342 Table 5.14 shows that the ROS measures put forward by Flynn translate to returns on capital for Capsules which far exceed the WACC used in Jefferies' valuation of Flynn's business (10%), the upper end WACC estimate used in Jefferies' sensitivity analysis (12%), the average cost of capital for pharmaceutical companies identified by KPMG and in the CMA's review of publicly available data (around 8% to 12%)⁹⁴⁷ and any credible benchmark for a reasonable rate of return.

⁹⁴⁴ PRE00711, Second Expert Report of [Flynn Expert Witness 2], Annex 3. Also, PRE00150, First Expert Report of [Flynn Expert Witness 3], page 18.

⁹⁴⁵ PRE00725, Third Expert Report of [Flynn Expert Witness 2], paragraphs 25-48 and paragraph 76. [Flynn Expert Witness 2] explains that the selected companies were considered 'similar' to Flynn in that they operate as sales, marketing and distribution companies (SMDCs) with limited or no manufacturing facilities.

⁹⁴⁶ PRE00725, Third Expert Report of [Flynn Expert Witness 2], paragraph 76.

⁹⁴⁷ Paragraph 5.171.

v. *The returns calculated by the CMA for Flynn's Products are shown to be reasonable when measured in absolute terms*

5.343 Flynn submitted in its response to the SO that an analysis of absolute returns is 'not relevant' because:

5.343.1 relative margins are typically used in finance and economics; and

5.343.2 higher volumes should not be a reason to justify lower permissible margins.⁹⁴⁸

5.344 The CMA disagrees with Flynn on the relevance of absolute measures of profitability. The CMA explained in paragraphs 5.73 and 5.107.1 how this type of analysis can be used to avoid Type I and Type II errors, particularly when assessing allegedly excessive prices for genuinely asset-light businesses.

5.345 The CMA considers that appraising absolute returns as part of its assessment affords a more complete view of a firm's profitability. This can be illustrated by comparing Flynn's own profitability on 100mg capsules during the Relevant Period and in the period since 2017.

5.346 The CMA's analysis shows that, during the Relevant Period, Flynn earned an average ROS on its supply of 100mg capsules of 28%. Data provided by Flynn shows that in the years 2018 and 2019 (ie after it had reduced the prices of Capsules to comply with the Directions) it continued to earn a similar ROS on 100mg capsules, earning a ROS of 30%.⁹⁴⁹

5.347 Flynn has argued that the CMA should place decisive weight on an assessment of Flynn's percentage ROS. On Flynn's case, therefore, there should be little difference in the CMA's consideration of Flynn's Prices and profitability during the Relevant Period and in subsequent years. There are, however, clear and significant differences when absolute measures of profitability are taken into consideration, as Table 5.15 demonstrates.

5.348 Table 5.15 compares Flynn's returns on 100mg capsules during the Relevant Period and in the years 2018 and 2019. It shows that, despite Flynn's ROS remaining broadly stable (indeed, increasing slightly in percentage terms in the later period), Flynn earned returns per pack during the Relevant Period that were over [£] greater than in 2018 and 2019 in absolute terms (over £15 per pack during the Relevant Period compared with [£1-£10.99] per pack in 2018 and 2019).

⁹⁴⁸ PRC03492, Flynn's response to the SO, paragraphs 1.21 and 7.26.3.

⁹⁴⁹ The CMA's calculation of Flynn's average ROS in 2018 and 2019 is based on data provided by Flynn setting out its sales prices and purchase costs throughout these years. In calculating Flynn's ROS, the CMA assumes that Flynn's distribution costs per unit and the proportion of common costs to be allocated to each unit of Flynn's Products remained the same as in the Relevant Period.

Table 5.15: Flynn’s ROS on 100mg capsules during the Relevant Period and in the years 2018-2019

	Relevant Period	2018/2019
Price	54.40	[£1-£10.99]
Total costs	39.17	[£1-£10.99]
<i>Of which: input costs</i>	37.94	[£1-£10.99]
Absolute return	15.23	[£1-£10.99]
ROS	28%	30%

Source: PRC00488, Flynn’s response of 11 September 2020 to the CMA’s s.26 Notice dated 21 August 2020, Annex 1 and CMA analysis.

5.349 Table 5.15 demonstrates that an analysis based only on percentage margins fails to capture significant differences in Flynn’s total absolute returns during the Relevant Period and in subsequent years. It shows clearly that percentage profit margins can be misleading and provide only a partial view of true profitability. Table 5.15 demonstrates why the CMA considers it important to assess absolute levels of profitability in determining the question of excessiveness.

5.350 The relevance of absolute measures of profitability and the limitations in looking at percentage margins in isolation were also confirmed by Flynn’s Director. In his second witness statement to the CAT, [Flynn Director 2] stated that:

*The CMA contends... Flynn’s percentage gross profits for 100mg capsules remained stable over the period of the infringements... but this ignores both the substantial drop in the absolute profit figures per pack and the substantial decline in Flynn’s sales. Taken together, those led to a dramatic reduction in the profitability of phenytoin.*⁹⁵⁰ (Emphasis added)

5.351 Flynn also stated in its response to the CMA’s Letter of Facts that ‘Flynn, like any business, considers absolute returns as well as percentage margins when making business decisions’.⁹⁵¹

5.352 The CMA notes that Flynn had particular regard to absolute measures of profitability when deciding to enter into its agreement with Pfizer. Internal documents show that Flynn focused on absolute profits when modelling the effect of the Parties’ arrangement. For example:

5.352.1 Minutes of a Flynn Board meeting dated 28 March 2012 stated that ‘Phenytoin was budgeted to deliver an additional £2,383k of EBITDA giving a Group EBITDA of £4,691k, almost doubling that of the current year’.⁹⁵²

⁹⁵⁰ PRE00726, [Flynn Director 2] Second Witness Statement, 17 May 2017, paragraph 22.

⁹⁵¹ PRC03903, Flynn’s response to the Letter of Facts, paragraph 4.6.

⁹⁵² PHT00369, Flynn Board Meeting Minutes dated 28 March 2012 (CMA document reference 00145.298), page 3.

5.352.2 Minutes of a Flynn Board meeting dated 19 June 2012 stated that Flynn would ‘only retain a small gross profit of 15.3%’ from the arrangements with Pfizer, but ‘because of the high sales volume, the budgeted additional EBITDA this financial year would be £2,643k’.⁹⁵³

5.352.3 Flynn’s contemporaneous financial modelling and business planning documents, produced in the months prior to entering into the arrangements with Pfizer, focused on the absolute profits that it would earn under different pricing assumptions.⁹⁵⁴

5.353 Flynn’s contemporaneous internal documents contradict its representations that absolute margins are not relevant to an assessment of its returns during the Relevant Period.⁹⁵⁵ Consistent with [Flynn Director 2]’s evidence, they show that Flynn recognised that a given percentage profit margin does not fully reflect the profitability of a particular product. They also show that the absolute level of profitability is fundamental to understanding the attractiveness of supplying a particular product for Flynn. This is consistent with the CMA’s analysis in the following sections, which assess absolute measures of profitability, both as they relate to the CMA’s ROCE calculations (set out in Table 5.12) and Flynn’s ROS submissions.

5.354 The CMA considers that the reasonableness of the returns calculated in Table 5.12 can be demonstrated by comparing this absolute level of return against:

5.354.1 Flynn’s other products (both in total and per pack); and

5.354.2 the reasonable return allocated to Pfizer in the CMA’s assessment.

5.355 In addition, the CMA also compares the results of its Cost Plus analysis in Table 5.13 with Flynn’s contemporaneous price modelling (as referred to in paragraph 5.352.3). The CMA finds that this comparison provides further support for its Cost Plus figures.

Comparison to Flynn’s other products

5.356 The CMA’s Cost Plus analysis includes a reasonable return for Flynn’s Products of around £350,000 per annum.⁹⁵⁶ This level of return means that Flynn’s supply of

⁹⁵³ PHT00372, Flynn Board Meeting Minutes dated 19 June 2012 (draft) (CMA document reference 00145.318), page 4.

⁹⁵⁴ For example, PHT00366, Pfizer Epanutin Financials v2 (CMA document reference 00145.169) (produced in October 2011) and PHT00368, Flynn Pharma Group Business Plan scenario: Base Business + Pending Opportunity (Phenytoin) (CMA document reference 00145.211) (produced in January 2012). See also PHT00402, Schedule of figures re phenytoin prices and volumes with handwritten annotations (taken from [Flynn Director 4]’s green lever arch file) (CMA document reference 00145.991), PHT00384, Bar chart detailing NHS prices with schedule of figures re current NHS Price/current price MSP (CMA document reference 00145.1013), PHT00394, Bar chart detailing NHS prices with schedule of figures re current NHS Price/current price MSP (CMA document reference 00145.1014) and PHT00373, Spreadsheet detailing current NHS price and current price MSP and profits (CMA document reference 00145.336).

⁹⁵⁵ Paragraph 5.288.

⁹⁵⁶ The CMA calculates the annual return under its Cost Plus analysis by dividing the total reasonable return by the number of years in the Relevant Period.

Capsules would have been more profitable than eight of Flynn's other 13 products during 2013-2015.⁹⁵⁷

5.357 At a per unit level, the CMA's Cost Plus analysis includes a reasonable return for Flynn's Products that is equivalent to an average direct margin per pack of £1.52.⁹⁵⁸

5.358 To test the reasonableness of this figure, the CMA has calculated the average direct margin per pack earned across Flynn's other high volume products in 2013, 2014 and 2015.⁹⁵⁹ The CMA finds that Flynn's average direct margin per pack among these products was £1.32 in 2013, £1.52 in 2014, and £1.64 in 2015.⁹⁶⁰

5.359 The returns included in the CMA's Cost Plus analysis are shown to be consistent with those of Flynn's other high volume products, when measured in absolute returns per unit. This demonstrates that the returns calculated in the CMA's Cost Plus analysis are reasonable for Flynn's Products.

5.360 By contrast:

5.360.1 Flynn's low-point internal ROS (8%) translates to an average direct margin per pack for Capsules of £3.06.

5.360.2 Flynn's high-point internal ROS (18%) translates to an average direct margin per pack for Capsules of £6.12.

5.360.3 The comparator ROS put forward by Flynn during the original Tribunal proceedings (21%) translates to an average direct margin per pack for Capsules of £7.19.

5.360.4 Flynn's updated ROS comparator analysis, provided in response to the SO on remittal, translates to:

(a) At 25% ROS: an average direct margin per pack for Capsules of £8.75.

(b) At 30% ROS: an average direct margin per pack for Capsules of £10.95.

⁹⁵⁷ CMA analysis of Flynn data pack received as part of PRC03720, CRA5. See also PAD00031, [Flynn Director 2] Cross Examination, day 4, page 202-203.

⁹⁵⁸ Direct margins are a measure of product returns after the deduction of all direct costs. Direct margins are measured before the allocation of common costs. Returns calculated on this basis are thus higher than the reasonable per pack returns for Flynn's Products presented in Table 5.12.

⁹⁵⁹ For the purposes of this analysis, the CMA excludes those of Flynn's other products which sell fewer than 100,000 units per annum. The CMA considers that these products, which sell significantly fewer units than phenytoin, represent weak comparators for Capsules. This is because, for a given amount of fixed costs, higher volume products require a lower return per pack (since fixed costs can be spread over a greater number of units). The CMA therefore includes the following Flynn products in this analysis only: Circadin, Medikinet, Vancocin, Keflex, Cefuroxime, Distacolor and Nebcin.

⁹⁶⁰ PHT00129, CMA analysis based on Annex 1 of Flynn's response to Section 26 Notice of 9 March 2016 (CMA document reference 01856.2).

5.361 A comparison of these figures against the returns on Flynn's other high volume products (as set out in paragraph 5.358) shows this level of absolute profitability to be too high to represent a reasonable rate of return.

Comparison to Pfizer's reasonable rate of return

5.362 The CMA notes that its Cost Plus analysis produces a total absolute return over the entire Relevant Period for Flynn that is approximately equal to Pfizer's total absolute return (ie a total return of approximately £1.5 million for Flynn). That is, each Party earns broadly the same total absolute return despite marked differences in the underlying ROS for Pfizer (10%) and Flynn (2%).⁹⁶¹

5.363 In the CMA's view, a total absolute return for Flynn that is approximately equal to (or more than) the total return for Pfizer is clearly reasonable for Flynn, if not generous, given the respective activities and risks assumed by each Party in the supply of phenytoin sodium capsules (as described in section 2.D.I.d (Factual Background)).

5.364 This is also demonstrated by the evidence relating to the Parties' own negotiations, during which Pfizer and Flynn discussed a split of the benefit of entering into the arrangements. These discussions suggested that Pfizer should retain the majority share of that benefit.⁹⁶² Therefore, the Parties' own negotiations demonstrate that an outcome whereby Flynn earns the same (or a greater) total return as Pfizer is reasonable, if not generous, to Flynn.

5.365 By contrast:

5.365.1 Flynn's low-point internal ROS (8%) translates to a total return of £6.4 million for Flynn over the Relevant Period, almost five times the reasonable return for Pfizer (on the CMA's calculation of a reasonable level of return).

5.365.2 Flynn's high-point internal ROS (18%) translates to a total return of £16.3 million for Flynn over the Relevant Period, more than twelve times the reasonable return for Pfizer.

5.365.3 The comparator ROS put forward by Flynn during the original Tribunal proceedings (21%) translates to a total return of £19.7 million for Flynn over the Relevant Period, over 14 times the reasonable return for Pfizer.

⁹⁶¹ The fact that the same level of total return translates to a lower ROS for Flynn than for Pfizer is a function of Flynn's inflated cost base. Flynn's Prices are inflated by the input cost it pays to Pfizer and high prices result in a lower observed ROS (given that ROS is calculated as profit divided by price). As explained in paragraph 5.99, significant profits earned by Flynn can be associated with a low computed percentage margin for this reason.

⁹⁶² See section 2.D.I.b (Factual Background). See also PHT00349, Email from [Pfizer Employee 2] to [Pfizer Director 1], [Pfizer Employee 3] and [Pfizer Employer] 'RE: FOR REPLY: Base case numbers' on 7 November 2011 (CMA document reference 00141.146), page 1.

5.365.4 Flynn's updated ROS comparator analysis, provided in response to the SO on remittal, translates to:

- (a) At 25% ROS: a total return of £24.7 million for Flynn over the Relevant Period, over 18 times the reasonable return for Pfizer.
- (b) At 30% ROS: a total return of £31.8 million for Flynn over the Relevant Period, over 23 times the reasonable return for Pfizer.

5.366 In the context of the activities and risks assumed by each Party in supplying phenytoin sodium capsules, the CMA considers this level of return to be unreasonable for Flynn.⁹⁶³

Comparison of CMA Cost Plus to Flynn's contemporaneous price modelling

- 5.367 The CMA notes that contemporaneous documents show that Flynn modelled different prices for Capsules over time, many of which were far lower than the prices that Flynn ultimately charged. In October 2011, for example, Flynn modelled pricing assumptions as follows: 25mg price per pack: £9.18; 50mg price per pack: £9.32; 100mg price per pack: £39.38; and 300mg price per pack: £39.38.⁹⁶⁴
- 5.368 Contemporaneous documents suggest that Flynn continued to plan on the basis of similar pricing assumptions (ie materially lower prices than those which it ultimately charged) through to at least June 2012.⁹⁶⁵
- 5.369 Flynn submitted that these models were 'very early projections'⁹⁶⁶ and reflected 'Flynn's view that the DHSC would negotiate with Flynn to reduce prices'.⁹⁶⁷
- 5.370 Even if the CMA were to accept, quod non, the premise of Flynn's argument (which it does not, consistent with the CAT's definitive findings on countervailing buyer

⁹⁶³ Paragraph 5.274 explained the CMA's view that Flynn assumes limited commercial activity and takes on little risk in supplying phenytoin sodium capsules. This is consistent with the CAT's view in *Phenytoin*, paragraph 346. In contrast, Pfizer remains responsible for the manufacturing process for Capsules and assumes commercial risk in providing a broad set of indemnities to Flynn under the Parties' Exclusive Supply Agreement.

⁹⁶⁴ PHT00366, Pfizer Epanutin Financials v2 (CMA document reference 00145.169), tab 'Normal Trade'. These prices were based on assumed Pfizer supply prices as follows: 25mg: £3; 50mg: £6; 100mg: £36; and 300mg: £36. See also PHT00364, Confidential slide deck prepared for discussion between Pfizer and Flynn at a meeting on 13 October 2011 (CMA document reference 00145.160), page 8. These prices transpired to be very similar to the actual Pfizer supply prices during the Relevant Period, allowing for relevant comparisons to be made with the CMA's Cost Plus figures.

⁹⁶⁵ Flynn's October 2011 modelling assumed that Flynn would retain a gross margin of 12% on its supply of Capsules. Similar assumptions appear to have been adopted in Flynn's 2013-2015 business planning forecasts, produced in January 2012, which assumed a 13% gross margin across Flynn's supply of Capsules. See PHT00368, Flynn Pharma Group Business Plan scenario: Base Business + Pending Opportunity (Phenytoin) (CMA document reference 00145.211), tab 'Phenytoin'. Minutes of a Flynn Board meeting also suggest that it continued to adopt similar pricing assumptions in June 2012. PHT00372, Flynn Board Meeting Minutes dated 19 June 2012 (draft) (CMA document reference 00145.318), page 4 states that 'after paying for the cost of distribution via [X], Flynn will only retain a small gross profit of 15.3%'. The CMA calculates that Flynn actual gross margin during the Relevant Period (36%) was between 2 and 3 times the margins it modelled in 2011 and through to June 2012.

⁹⁶⁶ PRC03903, Flynn's response to the Letter of Facts, paragraph 4.7.

⁹⁶⁷ PRC03903, Flynn's response to the Letter of Facts, paragraph 4.8.

power),⁹⁶⁸ the logic of Flynn's argument suggests that, had it been subjected to constraints on its pricing, Flynn would have expected to charge significantly lower prices than those ultimately charged during the Relevant Period.

5.371 In fact, the prices modelled by Flynn under these circumstances are very similar to the CMA's Cost Plus figures. This is particularly the case for 100mg and 300mg capsules, for which the CMA calculates Cost Plus figures of £39.84 and £38.91 respectively.⁹⁶⁹ The CMA's Cost Plus figure for 50mg capsules is also broadly equivalent to Flynn's initial internal modelling (Flynn modelling: £9.32; CMA Cost Plus: £8.13).⁹⁷⁰

5.372 The CMA considers that this evidence provides further support for its Cost Plus figures. The CMA considers it unlikely that Flynn would carry out business planning and financial modelling based on assumptions it did not believe to be commercially realistic. Indeed, Flynn stated that its early projections reflected its view of the effect of commercial negotiations on its prices. This evidence therefore supports the CMA's view that the results of its Cost Plus analysis, which are consistent with Flynn's internal price modelling, are not 'disconnected from commercial reality'.

vi. *[Flynn Expert Witness 2]'s evidence that a ROS of 2% is too low*

5.373 As above, Flynn's expert, [Flynn Expert Witness 2], considered that a ROS of 2% was too low to represent a reasonable rate of return for Flynn's Products. [Flynn Expert Witness 2] stated in his expert report that 'not one of his clients would take on a product if they were only permitted to make a return of 2% ROS'.⁹⁷¹

5.374 The CMA considers that [Flynn Expert Witness 2]'s evidence in this regard overlooks the specific facts of the case, the specific circumstances of Flynn's supply of Capsules during the Relevant Period and, as the CMA's analysis above demonstrates, the fact that relative profit margin metrics provide only a narrow view of the true profitability of a product or business.

5.375 The CMA explained in paragraph 5.217.2 that Flynn's cost base is distorted by the jointly established arrangement between the Parties and that this means significant profits earned by Flynn can be associated with a low computed percentage margin. The consequence is that simple ROS analyses allow Flynn to rely on its position in

⁹⁶⁸ The CAT found that Flynn's conduct was not constrained by countervailing buyer power on the part of the DHSC: 'We therefore do not think that the DH was, in fact, exercising, or able to exercise, buyer power in a way that effectively constrained Pfizer or Flynn's conduct. Consequently, we do not find that the Pfizer and Flynn were subject to countervailing buyer power from the DH whether in its capacity as purchaser of phenytoin or as an actual or potential regulator of phenytoin capsule prices such as to indicate that they did not hold dominant positions in their respective relevant markets.' *Phenytoin* [2018] CAT 11, paragraph 235.

⁹⁶⁹ The CMA's Cost Plus per pack figures are calculated as the total Cost Plus for each of Flynn's Products in Table 5.13 divided by the sales volumes of each capsule strength during the Relevant Period.

⁹⁷⁰ The CMA's total Cost Plus figure for Flynn in annual absolute terms (across all capsule strengths) is around £17.5 million. Flynn's contemporaneous price modelling equates to total annual revenues of £18.3 million (at actual realised sales volumes).

⁹⁷¹ PRC03492, Flynn's response to the SO, paragraph 7.25 and PRC03721, [Flynn Expert Witness 2] 5, paragraph 78.

the supply chain and its arrangement with Pfizer to obscure the true scale of its profitability during the Relevant Period.

- 5.376 The CMA's analysis in Table 5.15 shows the distortion caused by the high input price paid by Flynn during the Relevant Period. It shows that absolute returns per pack during the Relevant Period were over [X] greater than Flynn's current returns (on its supply of 100mg capsules) but translated to a lower ROS than the ROS that Flynn currently earns, purely as a consequence of the high prices that Flynn agreed to pay Pfizer during the Relevant Period.
- 5.377 Similarly, Flynn's high input costs suppress the ROS that is implied by the CMA's ROCE calculations. Table 5.12 shows that the reasonable return calculated by the CMA translates to a ROS of 2% for Flynn's supply of 100mg capsules during the Relevant Period. However, when applied to Flynn's current (post-Directions) cost structure for 100mg capsules, the same absolute return per pack calculated in Table 5.12 (ie the return calculated by the CMA's ROCE analysis) translates to a considerably higher percentage ROS; a ROS of 10%.⁹⁷²
- 5.378 Again this demonstrates how Flynn's input costs during the Relevant Period distort a consideration of its returns on a percentage basis. [Flynn Expert Witness 2]'s evidence fails to recognise this distortion and ignores the level of absolute profits that would be earned on Flynn's supply of Capsules at low computed percentage margins.
- 5.379 Ultimately, a reasonable rate of return should provide a sufficient financial incentive for engaging in the activity of supplying a good or service. That financial incentive depends not only on the level of percentage profits earned but also on the level of absolute profits. Indeed, Flynn itself submitted that it considers both absolute and relative measures of profitability when making business decisions.⁹⁷³
- 5.380 In the specific circumstances of Flynn's supply of Capsules, a low computed percentage margin produces a level of absolute profitability that was recognised by [Flynn Director 2], a Director of Flynn, as attractive to Flynn. In cross-examination, [Flynn Director 2] accepted that Flynn would remain incentivised to supply Flynn's Products at a far lower ROS than that which its actual prices during the Relevant Period allowed, in view of the absolute profits that would accrue to Flynn.
- 5.381 It was put to [Flynn Director 2] that, at a ROS of 5%, phenytoin would have been the most profitable product in Flynn's portfolio in 2013 and the second most profitable in 2014 and 2015 (in absolute terms).⁹⁷⁴ [Flynn Director 2] accepted that

⁹⁷² To calculate this figure, the CMA has used data provided by Flynn setting out its purchase costs in 2019. The CMA then assumes that Flynn's distribution costs per unit and the proportion of common costs to be allocated to each unit of Flynn's Products remained the same as in the Relevant Period. The CMA sums each of these elements to compute an estimate of Flynn's total costs per pack. It then adds the absolute return per pack from Table 5.12 to Flynn's total costs to calculate a total 'price'. Finally, the CMA computes the ROS by dividing the return per pack by the total 'price'.

⁹⁷³ Paragraph 5.351.

⁹⁷⁴ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 201, lines 9-23.

Flynn would be incentivised to supply Flynn's Products at this level of profitability (which equated to a ROS of 5%):

Q. So it's quite clear that Flynn would have sold Phenytoin if it had been able to obtain a 5 per cent return on sales on it. That's correct, isn't it? It follows from this?

A. If we had, we -- well, would we have made that decision? Probably, yeah.

Q: Well, of course you would. It would have been your second most profitable product. You wouldn't look a gift horse in the mouth, would you, [Flynn Director 2]?

*A: Well, I try not to.*⁹⁷⁵

5.382 [Flynn Director 2] also accepted that at a ROS of 2%, the absolute level of profitability offered by Flynn's Products 'would have been more attractive than just about half [of Flynn's] portfolio' during the Relevant Period.⁹⁷⁶

5.383 [Flynn Expert Witness 2]'s evidence that 'not one of his clients would take on a product if they were only permitted to make a return of 2% ROS'⁹⁷⁷ is therefore inconsistent with the evidence of Flynn's own Director, [Flynn Director 2], and his recognition of the attractiveness to Flynn of supplying Capsules at a ROS of 2% (given the level of absolute profits implied).

d. Conclusion on a reasonable rate of return for Flynn's Products

5.384 In order to determine a reasonable rate of return for Flynn's Products, the CMA has followed the well-established ROCE approach. The CMA calculates a reasonable return for Flynn's Products on this basis in Table 5.12.

5.385 Flynn made various representations on the appropriateness of applying the ROCE approach to Flynn's Products and submitted that the CMA should, instead, have established a reasonable rate of return by reference to comparator profit margins.

5.386 For the reasons explained above, the CMA maintains that the ROCE model is an appropriate method for determining a reasonable rate of return for Flynn's Products.

5.387 The CMA also considers that Flynn's representations place an undue focus on percentage profit margins, which have well-recognised limitations as a means of

⁹⁷⁵ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 201, line 24 to page 202, line 4.

⁹⁷⁶ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 203, line 23 to page 204, line 1. Flynn has 14 products in its portfolio and, at a ROS of 2% in 2013, 2014, 2015, phenytoin sodium capsules would have been more profitable in absolute terms than eight of Flynn's other products.

⁹⁷⁷ PRC03492, Flynn's response to the SO, paragraph 7.25 and PRC03721, [Flynn Expert Witness 2] 5, paragraph 78.

assessing excessive pricing.⁹⁷⁸ The CMA explained in detail above why it considers that the comparators put forward by Flynn do not provide a sound basis for determining a reasonable rate of return for Capsules.

5.388 Further, the CMA carried out cross-checks using absolute measures of profitability to test the reasonableness of its ROCE analysis and Flynn's ROS submissions. The CMA considers that an analysis of a fuller range of profitability metrics demonstrates that:

5.388.1 the returns calculated for Flynn's Products in Table 5.12 are reasonable; and

5.388.2 Flynn's ROS submissions translate to returns on capital and absolute returns that are far above any reasonable rate of return for Flynn's Products.

5.389 For these reasons, the CMA uses the returns calculated in Table 5.12 as the reasonable rate of return for Flynn's Products in its calculation of Cost Plus.

III. Calculation of the reasonable rate of return and Cost Plus for Flynn's Products

5.390 Having assessed what is a reasonable rate of return for Flynn's Products, this section sets out the calculation of Cost Plus for each of Flynn's Products.

5.391 Using the reasonable returns calculated in Table 5.12, Table 5.16 below sets out the resultant Cost Plus figures for each of Flynn's Products on a total revenue and per pack basis for the entire Relevant Period. Table 5.16 is calculated as the sum of Flynn's direct costs in Table 5.9, Flynn's common costs in Table 5.10 and Flynn's allowances for a reasonable rate of return in Table 5.12.

Table 5.16: Cost Plus figures for Flynn's Products (total and per pack), September 2012 to December 2016

Capsule strength	Cost Plus (total)	Cost Plus (per pack)
25mg	£3,132,759	£5.93
50mg	£8,643,336	£8.13
100mg	£38,602,169	£39.84
300mg	£25,286,634	£38.91

IV. Flynn's profit in excess of Cost Plus

5.392 Having established Flynn's Prices, Flynn's costs (both direct and indirect) and a reasonable rate of return for Flynn's Products, this section sets out the CMA's

⁹⁷⁸ A focus only on percentage profit margins would, for example, provide little information on how returns compare to investment and risk, and would not capture that, at a ROS of 2%, Flynn is able to earn the same total absolute return and the same return on capital as Pfizer earns at a ROS of 10%.

findings regarding the amount by which Flynn's Prices exceed Cost Plus. That is, the size of Flynn's excesses.

5.393 The assessment of whether the differential between Prices and Cost Plus is excessive involves the exercise of a proper degree of discretionary judgement by the CMA.⁹⁷⁹ In assessing Flynn's excesses, the CMA considers the size of the excess in both absolute and percentage terms. The CMA considers this to be particularly important in Flynn's case because:

5.393.1 its percentage excesses are suppressed by the high supply prices it paid to Pfizer during the Relevant Period; and

5.393.2 an analysis of absolute returns can be used to avoid Type I errors when assessing allegedly excessive prices for genuinely asset-light businesses, as explained in paragraph 5.73.

5.394 The CMA therefore expresses Flynn's excesses in the following two ways:

5.394.1 as the absolute amount (in pounds sterling) by which Flynn's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Flynn's Prices); and

5.394.2 as the percentage by which Flynn's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Flynn's Prices, then dividing the result by Cost Plus).

5.395 In calculating Cost Plus for each of Flynn's Products, the CMA has adopted an approach which fully allocates costs – both all direct costs and an appropriate allocation of all relevant indirect costs – as well as a reasonable rate of return. As such, the amount by which each of Flynn's Prices exceed Cost Plus reveals the excess that Flynn is earning over and above what would be a reasonable return for its activities in the supply of Flynn's Products.

5.396 The results set out in Table 5.17 below show that Flynn's Prices exceed Cost Plus by 139% for 25mg capsules, 77% for 50mg capsules, 37% for 100mg capsules and 42% for 300mg capsules.

⁹⁷⁹ Section 4.B.II (Legal Framework).

Table 5.17: Flynn's excesses on Flynn's Products, September 2012 to December 2016

	Capsule strength				Total
	25mg	50mg	100mg	300mg	
Revenue	£7,499,989	£15,317,886	£52,700,832	£35,881,444	£111,400,152
Cost Plus	£3,132,759	£8,643,336	£38,602,169	£25,286,634	£75,664,898
Excess (revenue)	£4,367,230	£6,674,550	£14,098,664	£10,594,810	£35,735,253
Excess (per pack)	£8.26	£6.27	£14.55	£16.30	N/A
Excess (%)	139%	77%	37%	42%	47%

- 5.397 Table 5.17 shows that Flynn has lower percentage excesses on 100mg and 300mg capsule strengths than on 25mg and 50mg capsule strengths. However, the full extent of Flynn's excesses on 100mg and 300mg capsule strengths are not evident when considered in percentage terms alone. This is because Flynn's excesses in percentage terms are calculated by reference to Flynn's costs, which are inflated by the supply prices that Flynn pays to Pfizer.
- 5.398 This is particularly true for 100mg and 300mg capsules for which the supply prices that Flynn pays to Pfizer are particularly high. As can be seen from the excess revenue and excess per pack figures in Table 5.17 above, Flynn's excesses on each pack of 100mg and 300mg capsules in absolute terms are in fact much greater than its excesses on 25mg and 50mg capsules, despite the latter having higher excesses in percentage terms. Flynn's excess on each pack of 100mg capsules is £14.55 while its excess on each pack of 300mg capsules is £16.30.
- 5.399 The effect that Pfizer's Prices have in suppressing Flynn's percentage excesses (particularly on 100mg and 300mg capsules) can also be demonstrated by adjusting the analysis accordingly. When the prices that Flynn paid to Pfizer during the Relevant Period are substituted with the prices that it currently pays, for example, Flynn's excesses on 100mg capsules increase from 37% to 724%. Its excesses on 300mg capsules increase from 42% to 715%. Excesses on lower capsule strengths also increase considerably, although to a lesser degree than on 100mg and 300mg capsules. Flynn's excesses on 25mg capsules increase from 139% to 189% and from 77% to 200% for 50mg capsules.⁹⁸⁰

⁹⁸⁰ In calculating these excesses, the CMA has calculated Flynn's Cost Plus for each capsule strength by adding Flynn's 2019 input costs (in place of those it paid to Pfizer during the Relevant Period) to Flynn's distribution costs, its allocation of common costs and its allowance for a reasonable rate of return (the figures for each of which are set out in Table 5.10 and Table 5.12 respectively). The CMA then calculates Flynn's excesses over these revised Cost Plus figures using the same methodology as set out in paragraph 5.394. The CMA adopts a favourable approach to Flynn by maintaining the reasonable rate of return as set out in Table 5.12 in this analysis. Were Flynn's input costs to reduce, the value of its buffer stock would be lower and its capital employed balance would reduce. This would result in a lower reasonable return for each of Flynn's Products and higher levels of excess than presented in paragraph 5.399.

a. Sensitivity analysis and rate of return cross-check

i. Sensitivity analysis – Flynn’s capital employed

5.400 As set out in paragraphs 5.231 to 5.258, the main determinant of Flynn’s capital employed balance is the value of its buffer stock. Flynn’s submissions stated that it considered the value of its buffer stock to be approximately £4-5 million, almost double the value calculated by the CMA.

5.401 In this section, the CMA applies a sensitivity to Flynn’s capital employed balance by including Flynn’s upper estimate for the value of its buffer stock (ie £5 million) in its analysis.

5.402 The CMA considers that Flynn’s stock data suggests that a value of £5 million would be highly generous to Flynn, and that an efficient level of buffer stock is likely to be lower than Flynn’s estimate. Nevertheless, the CMA has tested the robustness of its findings by adopting a generous sensitivity test.

5.403 Table 5.18 sets out the allowance for a reasonable return and the resultant Cost Plus and excess figures for the entire Relevant Period for each of Flynn’s Products on a revenue and per pack basis, adopting Flynn’s upper estimate for the value of its stock (ie £5 million) as part of Flynn’s capital employed.

Table 5.18: Flynn’s allowances for a reasonable rate of return and the resultant Cost Plus and excesses for Flynn’s Products under the CMA’s sensitivity scenario, September 2012 to December 2016

	Capsule strength				Total
	25mg	50mg	100mg	300mg	
Revenue	£7,499,989	£15,317,886	£52,700,832	£35,881,444	£111,400,152
Allowance for reasonable return	£134,724	£314,274	£1,147,807	£848,940	£2,445,744
Cost Plus	£3,164,455	£8,744,536	£39,094,469	£25,598,859	£76,602,319
Excess (revenue)	£4,335,534	£6,573,350	£13,606,364	£10,282,585	£34,797,833
Excess (per pack)	£8.20	£6.18	£14.04	£15.82	N/A
Excess (%)	137%	75%	35%	40%	45%

5.404 Table 5.18 shows that the adoption of Flynn’s upper estimate for the value of its stock leads to a reduction in Flynn’s excesses across each capsule strength. This is because the inclusion of a higher value for stock increases Flynn’s capital employed and, therefore, the reasonable return for each of Flynn’s Products. The increase in the reasonable return for each of Flynn’s Products results in a higher Cost Plus and, therefore, lower levels of excess.

5.405 However, Table 5.18 shows that the reduction in the level of excess across each capsule strength is very limited, in both percentage and absolute terms. The

percentage excess on 25mg capsules falls from 139% to 137%, while the excess on 50mg capsules falls from 77% to 75%. The excess on 100mg capsules falls from 37% to 35% and the excess on 300mg capsules reduces from 42% to 40%.

- 5.406 As explained in paragraphs 5.397 and 5.398, it is particularly relevant to consider absolute returns and absolute excesses for 100mg capsules and 300mg capsules, as the supply prices paid by Flynn to Pfizer for these capsule strengths are particularly high and distort a consideration of Flynn's percentage excesses. Table 5.18 shows that Flynn's absolute excesses on these capsule strengths reduce by only a limited amount under the CMA's sensitivity scenario. Flynn's absolute excess per pack of 100mg capsules reduces from £14.55 to £14.04 and reduces from £16.30 to £15.82 for 300mg capsules.
- 5.407 When Flynn's direct costs are adjusted in the same way as described in paragraph 5.399, Flynn's excesses are shown to be considerable, even under the CMA's sensitivity scenario. Adjusting the analysis in Table 5.18 to include the supply prices that Flynn currently pays to Pfizer (rather than the allegedly excessive prices charged by Pfizer to Flynn during the Relevant Period), Flynn's excesses on 100mg capsules increase from 35% to 665%. Its excesses on 300mg capsules increase from 40% to 661%. Again, excesses on lower capsule strengths increase considerably, but to a lesser degree than on 100mg and 300mg capsules. Flynn's excesses on 25mg capsules increase from 137% to 186% and from 75% to 194% for 50mg capsules.

ii. Rate of return cross-check

- 5.408 In addition to its base case analysis, the CMA has assessed the effect of applying a higher rate of return to Flynn's Products.
- 5.409 The CMA recognises that, in its 2016 Infringement Decision, it attributed a rate of return of 6% ROS to Flynn's Products. In doing so, the CMA always made clear that such level of return was a 'very generous' basis on which to calculate Cost Plus for Flynn's Products⁹⁸¹ and that 'a rate of return well below... [a] ROS of 6% would be reasonable'.⁹⁸² The CMA's analysis above illustrates why that is the case.
- 5.410 Nevertheless, the CMA found in its 2016 Infringement Decision that a ROS of 6% 'should represent an upper bound rate of return for Flynn'.⁹⁸³ The CAT also recognised that there remained some relevance in examining the PPRS ROS figure of 6%.⁹⁸⁴
- 5.411 On remittal, the CMA considered afresh whether a higher ROS could be applied as an upper bound for its analysis. The CMA calculated the returns on capital and the

⁹⁸¹ 2016 Infringement Decision, paragraphs 5.164, 5.186, 5.217, 5.380, 5.473 and 5.523.

⁹⁸² 2016 Infringement Decision, paragraph 5.210.

⁹⁸³ 2016 Infringement Decision, paragraph 5.186.

⁹⁸⁴ *Phenytoin* [2018] CAT 11, paragraph 339.

level of absolute returns produced at various ROS percentages put forward by Flynn during the course of the CMA's Previous Investigation and the Remittal (ranging from 8% to 30%). On the basis of its analysis above, the CMA finds that the level of profitability implied for Flynn's Products at these higher ROS percentages is too high to represent even an upper bound for a reasonable rate of return for Flynn's Products.

5.412 The CMA has therefore carried out a cross-check of its findings by applying a ROS of 6% as the reasonable rate of return for Flynn's Products. This analysis functions as a test of the robustness of the CMA's conclusions. Viewed from a ROCE perspective, the application of a ROS of 6% is equivalent to applying a highly generous WACC of 31% to the CMA's estimate of Flynn's capital employed.⁹⁸⁵

5.413 The CMA's analysis shows that even if it were to adopt a ROS of 6% as part of its Cost Plus analysis, the reduction in the level of excess across each capsule strength would be limited and that Flynn's Prices would remain materially above Cost Plus.

5.414 Table 5.19 sets out the allowance for a reasonable return and the resultant Cost Plus and excess figures for the entire Relevant Period for each of Flynn's Products on a revenue and per pack basis, when a ROS of 6% is applied as the reasonable rate of return.

Table 5.19: Flynn's allowances for a reasonable rate of return and the resultant Cost Plus and excesses for Flynn's Products at a ROS of 6%, September 2012 to December 2016

	Capsule strength				Total
	25mg	50mg	100mg	300mg	
Revenue	£7,499,989	£15,317,886	£52,700,832	£35,881,444	£111,400,152
Allowance for reasonable return	£193,387	£538,102	£2,422,127	£1,579,782	£4,733,398
Cost Plus	£3,223,119	£8,968,364	£40,368,790	£26,329,701	£78,889,973
Excess (revenue)	£4,276,870	£6,349,522	£12,332,043	£9,551,743	£32,510,178
Excess (per pack)	£8.09	£5.97	£12.73	£14.70	N/A
Excess (%)	133%	71%	31%	36%	41%

5.415 Table 5.19 shows that the application of a ROS of 6% leads to a limited reduction in the observed level of excess across each of Flynn's Products. Under these circumstances, Flynn's percentage excess on 25mg capsules would fall from 139% to 133%, while the excess on 50mg capsules falls from 77% to 71%. The excess

⁹⁸⁵ That is, the absolute return produced by applying a WACC of 31% to Flynn's capital employed balance (based on the CMA's estimate of Flynn's capital base) is equivalent to the absolute return given by a 6% ROS.

on 100mg capsules falls from 37% to 31% and the excess on 300mg capsules reduces from 42% to 36%.

- 5.416 As explained in paragraphs 5.397 and 5.398, it is particularly relevant to consider absolute returns and absolute excesses for 100mg capsules and 300mg capsules, as the supply prices paid by Flynn to Pfizer for these capsule strengths are particularly high and distort a consideration of Flynn's percentage excesses. Table 5.19 shows that Flynn's absolute excesses on these capsule strengths reduce by only a limited amount when a ROS of 6% is applied as the reasonable rate of return. Flynn's absolute excess per pack of 100mg capsules reduces from £14.55 to £12.73 and reduces from £16.30 to £14.70 for 300mg capsules.

V. Conclusion on whether Flynn's Prices were excessive

- 5.417 The CMA concludes that each of the excesses set out in Table 5.17 is (in the words of the Albion Water II judgment) 'material' and 'sufficiently large to be deemed excessive' in the context of the Excessive Limb of the United Brands Test.
- 5.418 The CMA's analysis in Annex I provides further support to this conclusion, demonstrating that the excesses on each of Flynn's Products remain excessive under any reasonable approach to common cost allocation.
- 5.419 The CMA considers that Flynn's Prices are clearly materially higher than those that would be required to earn a reasonable rate of return. As the CAT recognised, Pfizer's supply prices provided a price floor below which Flynn would not price but 'Flynn was, in practice, pricing well above this level and could have reduced its prices and still made a material profit'.⁹⁸⁶ The CMA estimates that Flynn's Prices during the Relevant Period allowed it to accrue approximately £36 million in excess profit.
- 5.420 As identified in paragraph 5.267, the CMA considers that a return on capital employed of 10% would be reasonable for Flynn's Products. However, Flynn's Prices over the Relevant Period generate profits which equate to a return on capital employed of 247% on average. This means that, for every £100 that Flynn invested in the supply of phenytoin sodium capsules, it earned an average return of £247 per year. In total, an investor would have earned over £1,000 by the end of the Relevant Period from £100 invested. In contrast, a reasonable return on capital for Flynn's Products, based on its activities and risks, is around 10% per year, equivalent to £45 by the end of the Relevant Period from £100 invested. Flynn's actual returns are clearly not commensurate with its activities, which the CAT found to be 'very limited' and associated with 'very little business risk'.⁹⁸⁷ In this context, it is clear that Flynn's returns far exceed any reasonable rate of return.

⁹⁸⁶ *Phenytoin*, [2018] CAT 11, paragraph 456.

⁹⁸⁷ *Phenytoin* [2018] CAT 11, paragraph 346.

- 5.421 The levels of excess that have been found to be excessive in other cases support a conclusion that Flynn's Prices during the Relevant Period were excessive. In particular, an excess of 25% was found to be excessive in Deutsche Post and an excess of at least 46.8% was found to be excessive in Albion Water II.
- 5.422 While the assessment of excessiveness should be made on a case-by-case basis and the level of excess in earlier cases is not determinative, the CMA considers that a comparison of Flynn's excesses to those established in Deutsche Post and Albion Water II supports the conclusion that each of Flynn's Prices is excessive. Flynn's percentage excesses on each of Flynn's Products throughout the Relevant Period are above the excesses found to have been excessive in Deutsche Post and its percentage excesses for 25mg and 50mg capsules are clearly and significantly above the level of excess found to be excessive in Albion Water II. This remains the case under the CMA's sensitivity scenario.
- 5.423 Moreover, the true scale of Flynn's excesses is suppressed when presented on a percentage basis because of the high supply prices it pays to Pfizer. Were the CMA to adjust for the effect of Flynn's high supply prices on its percentage excesses (for example, by substituting the prices that Flynn paid to Pfizer during the Relevant Period with the prices that it currently pays), the CMA calculates that Flynn's excesses on each of Flynn's Products would be over 180%, and Flynn's excesses on 100mg and 300mg capsules would be over 700%.⁹⁸⁸
- 5.424 The scale of Flynn's excesses is also evident from a comparison of its excess profits with Pfizer's Pre-September 2012 Prices. Flynn's excess profits in themselves amount to several multiples of the historic prices for phenytoin sodium capsules:
- 5.424.1 in respect of 25mg capsules, Flynn's excesses are more than 16 times Pfizer's pre-September 2012 ASPs;
- 5.424.2 in respect of 50mg capsules, Flynn's excesses are more than 12 times Pfizer's pre-September 2012 ASPs;
- 5.424.3 in respect of 100mg capsules, Flynn's excesses are more than six times Pfizer's pre-September 2012 ASPs; and
- 5.424.4 in respect of 300mg capsules, Flynn's excesses are more than seven times Pfizer's pre-September 2012 ASPs.
- 5.425 In addition, the CMA has assessed the effect on Flynn's excesses when a ROS of 6% is applied as the reasonable rate of return. The CMA considers a ROS of 6% represents a generous upper bound for Flynn's rate of return.⁹⁸⁹ The results of this analysis are set out in Table 5.19. The CMA considers that each of the excesses in

⁹⁸⁸ Paragraph 5.399.

⁹⁸⁹ Paragraphs 5.409 to 5.412.

Table 5.19 remain ‘material’ and ‘sufficiently large to be deemed excessive’ in the context of the Excessive Limb of the United Brands Test, thus reinforcing the CMA’s conclusion that Flynn’s Prices were excessive.

- 5.426 Flynn has also been able to maintain the excesses set out above on each of Flynn’s Products for a substantial period of time (over four years). This confirms that each of Flynn’s Prices were excessive, rather than temporary anomalies in an otherwise competitive market.
- 5.427 That Flynn’s Prices for each of Flynn’s Products were excessive continues to hold true if Flynn’s Prices are considered separately before and after some of its prices changed in April 2014. These figures are shown in Annex L.
- 5.428 For these reasons, the CMA concludes that Flynn’s Prices for each of Flynn’s Products were excessive and have been throughout the Relevant Period, thereby satisfying the first stage of the United Brands Test.

6. Unfair

A. Overview and summary of findings

- 6.1 The CMA concludes that Pfizer's Prices for each of Pfizer's Products and Flynn's Prices for each of Flynn's Products throughout the Relevant Period were unfair by reference to the *United Brands* test as further articulated by the Court of Appeal.⁹⁹⁰
- 6.2 First, the CMA finds that Pfizer's Prices and Flynn's Prices were unfair in themselves (see section 6.B).⁹⁹¹
- 6.3 Second, the CMA finds that the comparators relied upon by the Parties do not demonstrate that Pfizer's Prices or Flynn's Prices were fair when compared to competing products or undermine the CMA's conclusion that the Parties' prices were unfair in themselves. In coming to this conclusion, the CMA has evaluated relevant evidence and arguments advanced by Pfizer and Flynn and gathered and evaluated a large body of additional evidence (see section 6.C).⁹⁹²
- 6.4 The CMA has assessed factors relevant to the economic value of Capsules as part of its assessment of whether the Parties' prices were excessive and unfair under the *United Brands* framework.⁹⁹³ Pursuant to the CMA's assessment, the CMA finds that demand side factors in this case do not result in an economic value beyond or additional to the economic value already reflected in the Parties' Cost Plus figures. Based on this, the CMA has concluded that Pfizer's Prices and Flynn's Prices bore no reasonable relationship to the economic value of their products during the Relevant Period (see section 7).

B. Unfair in itself

I. Pfizer's Prices and Flynn's Prices were unfair in themselves

- 6.5 The CMA has concluded that Pfizer's Prices for each of Pfizer's Products and Flynn's Prices for each of Flynn's Products were unfair in themselves during the Relevant Period.

⁹⁹⁰ *Phenytoin CoA* [2020] EWCA Civ 339.

⁹⁹¹ Pfizer submitted that the CMA may only conduct an evaluation by reference to the 'excessive in itself' test in circumstances where there is no sufficiently plausible or *prima facie* reliable evidence adduced by Pfizer in relation to the comparator limb of the unfair test in *United Brands*, citing the reasoning of Green LJ at paragraph 86 of *Phenytoin CoA* [2020] EWCA Civ 339: PRC03488, Pfizer's Response to the SO and DPS, paragraph 38. The Court of Appeal did not say that the CMA may only conduct an unfair in itself analysis where there are no sufficiently plausible or *prima facie* reliable comparators and paragraph 86 of *Phenytoin CoA* [2020] EWCA Civ 339 does not provide authority otherwise. The Court of Appeal clarified that, whilst the two unfair limbs are alternative (paragraphs 97(vii) and 259), the CMA has a duty to evaluate fairly *prima facie* valid evidence or arguments advanced by the Parties whichever alternative it chose to adopt (see paragraphs 86, 97(viii), 259 and 260). This is what the CMA has done in this case: it has found that the Parties' prices were unfair in themselves and then fairly evaluated whether the comparators advanced by the Parties undermined this conclusion.

⁹⁹² *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(viii) and 260.

⁹⁹³ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.

6.6 In coming to this conclusion, the CMA has had regard to the following factors:

6.6.1 The Parties implemented significant price increases⁹⁹⁴ which resulted in very high prices (relative to costs) and went well beyond any level that might have been required to ensure the drug was commercially viable or sustainable:

- (a) Pfizer increased its prices by between 783% and 1,603% and Pfizer's average excess above Cost Plus across all capsule strengths was 416%.
- (b) Flynn's Prices were between 2,366% and 2,682% higher than Pfizer's previous prices. The difference between Flynn's Prices and Pfizer's Prices (ie Flynn's mark-up) was between 662% and 1,800% higher than the prices Pfizer previously charged for Capsules. Flynn's excesses alone (which were on average 47% above Cost Plus across all capsules strengths) were several multiples of the prices that Pfizer previously charged.

6.6.2 The selective nature of Pfizer's price increases. It was only in the UK that Pfizer entered into arrangements of the type agreed with Flynn and significantly increased its prices well above the prices that Pfizer charged for identical Capsules in other European jurisdictions (Capsules supplied in EU Member States were all manufactured by Pfizer in the same German facility as the Capsules supplied to Flynn in the UK).⁹⁹⁵

6.6.3 The Parties' prices reflected their substantial market power. Features of the relevant markets, including the absence of effective constraints and very high barriers to entry meant that those markets were incapable of functioning in a manner likely to produce a reasonable relationship between price and economic value.⁹⁹⁶ The Parties were aware of their market power and exploited this to impose significant overnight price increases on the NHS which they maintained for over four years.⁹⁹⁷ In doing so, the Parties wilfully ignored customer concerns and did not engage constructively to resolve those concerns.

⁹⁹⁴ *Phenytoin* [2018] CAT 11, paragraph 369.

⁹⁹⁵ *Phenytoin* [2018] CAT 11, paragraph 369.

⁹⁹⁶ *Albion Water II* [2008] CAT 31, paragraphs 266 and 268.

⁹⁹⁷ The assessment of whether or not a dominant position has been abused is an objective one, and evidence of anti-competitive intent or motive is not required for a finding of abuse: *C-549/10 P Tomra v European Commission*, EU:C:2012:221, paragraph 21; see also *Hoffmann-La Roche*, EU:C:1979:36, paragraph 91. However, if such evidence exists, while it cannot be sufficient in itself, it may be taken into account in order to determine whether a dominant position has been abused: *C-307/18 Generics (UK) Ltd and others v Competition and Markets Authority*, EU:C:2020:52, paragraph 162; *Royal Mail PLC v OFCOM and Whistl UK Limited* [2019] CAT 27, paragraph 278; *C-549/10 P Tomra v European Commission*, EU:C:2012:221, paragraph 20; and see also *Aspen*, paragraphs 186 to 189. These principles regarding anti-competitive intent or motive apply equally to exploitative abuses as to exclusionary abuses.

- 6.6.4 The features of the products do not provide any justification or legitimate reason for the Parties' prices.⁹⁹⁸ In particular:
- (a) Capsules had long been off-patent and in the third stage of the drug life cycle where competition is expected to drive the prices of generic drugs down and result in ongoing low prices even where they continue to deliver benefits for patients;
 - (b) there was no improvement to the products, or their production or distribution, or any innovation, investment or commercial risk-taking activity which might justify or provide a legitimate reason for the Parties' prices; and
 - (c) the CMA's qualitative assessment demonstrates that Capsules suffer from significant limitations and compare poorly to other AEDs. Reflecting this, Capsules were only recognised as a third-line treatment for patients during the Relevant Period and demand for the products was sustained predominantly by barriers to switching patients to other treatments, not because of the therapeutic benefits of Capsules relative to other AEDs.
- 6.6.5 The evidence on the commercial purpose of the arrangements entered into between the Parties and the approach of the Parties to them⁹⁹⁹ demonstrates that:
- (a) the commercial purpose of the Parties' arrangements was to remove Capsules from the constraints of the PPRS in order to increase prices significantly, thereby generating substantial profits for Pfizer and Flynn; and
 - (b) a key reason for bringing Flynn into the supply chain was to provide reputational protection for Pfizer from the criticism that would arise from the subsequent impact on the NHS, showing that the Parties appreciated the adverse impact of the price increases on the NHS.
- 6.6.6 The Parties' prices had a significant and adverse effect on the end customer and on patient welfare.¹⁰⁰⁰ NHS spending on phenytoin sodium capsules increased significantly after the price increases in September 2012, with no associated benefit and with negative effects on CCGs' ability to provide patient care.

⁹⁹⁸ The CAT noted that whether there is any independent or objective justification could be relevant to weigh in an assessment of unfair in itself: *Phenytoin* [2018] CAT 11, paragraph 369. See also *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v). See further *Aspen*, paragraphs 167 to 176.

⁹⁹⁹ *Phenytoin* [2018] CAT 11, paragraph 369.

¹⁰⁰⁰ *Phenytoin* [2018] CAT 11, paragraphs 369 and 404.

II. The increase in prices

- 6.7 The Parties imposed very significant price increases overnight on the NHS, which resulted in very high prices relative to costs and significantly exceeded any level that might have been required to ensure the commercial viability of the drug. This supports the conclusion that the Parties' prices were unfair in themselves.¹⁰⁰¹
- 6.8 Prior to the arrangements entered into between the Parties, the prices paid by wholesalers and pharmacies for Capsules had been stable for many years before suddenly increasing very significantly in September 2012. As recognised by Sir Geoffrey Vos in his judgment:

*It was quite easy to lose sight of a stark reality, which was that, literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between approximately 7 and 27, when they were in a dominant position in each of their markets. That did not, of course, abrogate the need for a rigorous reasoned approach to the legal and factual questions [...] but it was important to keep in mind.*¹⁰⁰²

a. Pfizer's Prices

- 6.9 The sheer scale of Pfizer's price increases and the resulting very high prices are set out in Table 6.1 below.^{1003, 1004}

¹⁰⁰¹ The CAT held that the increase in price could be a factor which was relevant for the CMA to take into account when considering the application of the 'unfair in itself' test: *Phenytoin* [2018] CAT 11, paragraph 369. See also *British Leyland v Commission*, EU:C:1986:421, paragraph 28, where a significant price increase without an increase in costs was one element contributing to the court's conclusion that a price was unfair and abusive. In commenting on that case, Advocate General Pitruzzella noted that 'a 600% increase in prices without an apparent increase in costs rendered an analysis of the latter unnecessary and focused attention on the difference between present and past prices': Opinion of Advocate General Pitruzzella in C-372/19 *SABAM v Weareone World*, footnote 23. See also *Aspen*, paragraphs 178 to 181.

¹⁰⁰² *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 243.

¹⁰⁰³ Pfizer submitted that the significant price increases are 'largely or wholly irrelevant' and the 'salient point is that the challenged supply price was not excessive by reference to the economic value of the product and the exculpatory comparator products': PRC03488, Pfizer's Response to the SO and DPS, paragraph 39(a). In relation to the first point, the CAT held in *Phenytoin* [2018] CAT 11 at paragraph 369 that the increase in price can be a relevant factor to take into account in an assessment of unfair in itself. As regards the second point, the CMA has considered the appropriateness of the comparator products put forward by the Parties in section 6.C below and whether there was a reasonable relationship between Pfizer's Prices and the economic value of the products in section 7 below.

¹⁰⁰⁴ Pfizer submitted that its pre-September 2012 prices were subject to regulation which is relevant 'since regulation will, all else equal, have a depressing effect on price relative to an unfettered market-based approach': PRC03488, Pfizer's Response to the SO and DPS, paragraph 39(a). The CMA does not, however, use the pre-September 2012 prices as the basis for a finding that Pfizer's Prices were unfair when compared to competing products. A comparison between Pfizer's Prices during the Relevant Period and its pre-September 2012 prices is used to show the scale and significance of Pfizer's price increases, providing support for the finding that Pfizer's Prices were unfair in themselves. In any event, Pfizer's submission that regulation will have a depressing effect on price relative to an unfettered market-based approach is an assertion for which Pfizer provided no supporting evidence.

Table 6.1: Pfizer's Prices compared to its pre-September 2012 prices

	Pre-September 2012 Prices (£)	Pfizer's ASP during the Relevant Period (£)	Multiple	Percentage change
25mg	0.51	4.50	8.8	783%
50mg	0.52	6.71	12.9	1,185%
100mg	2.21	37.56	17.0	1,603%
300mg	2.20	37.01	16.8	1,584%

Source: CMA analysis based on Table 2.3 in section 2.

- 6.10 Furthermore, as a result of the arrangements entered into between the Parties, Pfizer no longer supplied Capsules to wholesalers and pharmacies as it had done previously. Instead, Pfizer brought Flynn into the supply chain and imposed its significant price increases at an upstream level.
- 6.11 As a result of the exclusivity Pfizer provided to Flynn, Flynn was then free to add an additional layer of margin to the prices paid by Pfizer's previous customers above the significant price increases already imposed by Pfizer. Moreover, Pfizer was aware of Flynn's intention to impose a significant additional mark-up as a result of the negotiations between the Parties.¹⁰⁰⁵
- 6.12 Pfizer could have removed Capsules from the PPRS and increased its prices without Flynn's involvement. The evidence shows that a key reason for Flynn's involvement was to shield Pfizer from the reputational harm of imposing such significant price increases.¹⁰⁰⁶
- 6.13 These price increases resulted in very high prices (relative to Pfizer's costs) as shown in Table 6.2 below. Indeed, Pfizer's own expert witness stated before the CAT that: '[c]learly there is a big margin over costs here [for Pfizer]. There is no question about that.'¹⁰⁰⁷

Table 6.2: Pfizer's excesses on Pfizer's Products, September 2012 to December 2016

	Capsule strength			
	25mg	50mg	100mg	300mg
Excess (per pack)	£0.88	£3.20	£32.67	£32.10
Excess (%)	24%	91%	667%	653%

Source: CMA analysis in section 5.

¹⁰⁰⁵ See PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27) and PHT00193, document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹⁰⁰⁶ See paragraphs 6.109 to 6.115.

¹⁰⁰⁷ PAD00030, [Pfizer Expert Witness 2] Cross Examination, day 5, page 225, lines 22 to 23.

- 6.14 Pfizer has submitted that the price increases it imposed in September 2012 were necessary to ensure the continued supply of Capsules to the UK market. In his evidence before the CAT, [Pfizer Director 1] stated that Pfizer's price increases were 'about putting this product back on a fair sustainable basis for the longer term'¹⁰⁰⁸ and 'the only way we could [...] maintain [the product] would be to bring it to a level of profitability that would be sustainable'.¹⁰⁰⁹
- 6.15 However, the evidence shows that this is simply not the case. Pfizer's post-September 2012 prices were not justified by its costs of supply and far exceeded any level that might have been required to ensure the drug would be profitably 'sustainable'.¹⁰¹⁰ Whilst this point is demonstrated simply by looking at Pfizer's excesses above Cost Plus, it is also shown by the following three factors:
- 6.15.1 First, owing to the sheer scale of Pfizer's price increases, any potential historical losses on sales of its Capsules were more than recovered within two months of increasing its prices.¹⁰¹¹
- 6.15.2 Second, Pfizer has submitted that it would put any product with a contribution margin level of 15% and below under review for possible discontinuation.¹⁰¹² Following the price increases, Capsules provided an average contribution margin of 93% - far in excess of the 15% measure.¹⁰¹³
- 6.15.3 Third, Pfizer's Prices during the Relevant Period were between 29% and 699% higher than Pfizer's recent prices for Capsules supplied to Flynn in 2019 ('**Pfizer's Recent Prices**').¹⁰¹⁴ Whilst Pfizer's Recent Prices were set to comply with the Directions, Pfizer was able to decide the appropriate

¹⁰⁰⁸ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 18, lines 16 to 18, and page 59, lines 1 to 3.

¹⁰⁰⁹ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 81, lines 7 to 9.

¹⁰¹⁰ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 81, lines 7 to 9. In *Aspen*, the European Commission noted that if prices were loss-making, 'this allows raising these prices to some extent, but certainly not to a level where the profits and prices become excessive', see paragraph 180.

¹⁰¹¹ Using Pfizer's own measure of contribution, it incurred losses amounting to £3.5 million from January 2007 up to September 2012: PHT00172, Pfizer's Response of 20 November 2015 to the CMA's 2015 Statement of Objections (CMA document reference 01622.2), Table 3. Using the same measure of profitability, Pfizer earned profits of £4.4 million between September 2012 and October 2012 alone, more than covering any losses it claims to have incurred in the preceding five years: PHT00143, UK Sales data update - June 2016: Annex 1 of Pfizer's response of 26 August 2016 to the CMA's s.26 Notice information request of 2 August 2016 (CMA document reference 02115.2).

¹⁰¹² PHT00172, Pfizer's Response of 20 November 2015 to the CMA's 2015 Statement of Objections (CMA document reference 01622.2), paragraph 54. Contribution margin is a measure of profitability after the deduction of direct costs. It assesses profits relative to revenues, with the theoretical maximum being 100% (as profits cannot exceed revenues).

¹⁰¹³ Contribution margin, as defined by Pfizer, is calculated as revenue minus Cost of Goods Sold ('**COGS**'). The CMA has calculated the contribution margin that is implied by Pfizer's price increases by subtracting Pfizer's total COGS over the Relevant Period from its total actual revenues over the Relevant Period. Pfizer's price increases equate to a contribution margin of 80% for 25mg Capsules, 88% for 50mg Capsules, 95% for 100mg Capsules and 94% for 300mg Capsules.

¹⁰¹⁴ PRC00391, Flynn's response of 10 August 2020 to the CMA's s.26 Notice information request of 27 July 2020, Annex 15.

level of pricing.¹⁰¹⁵ At no point has Pfizer submitted that Pfizer's Recent Prices are unsustainable.¹⁰¹⁶

- 6.16 Moreover, at the same time, Pfizer has acknowledged that, in setting its prices, it did not look at its costs at all. Instead, [Pfizer Director 1] explained that Pfizer 'would have had no justification' for its prices unless it is accepted that Pfizer was entitled to impose significant price increases because the NHS was already paying far higher prices for Tablets¹⁰¹⁷:

*So we didn't look at the profitability. We had – we were looking at price, and the reason why this project was able to even be considered was because we had an established benchmark price in the market for the same medicine. If that price benchmark hadn't been there, we couldn't have done this. We would have had no justification.*¹⁰¹⁸

b. Flynn's Prices

- 6.17 As part of the arrangements entered into between Pfizer and Flynn, Flynn willingly agreed to pay Pfizer supply prices which were up to 17 times higher than the prices Pfizer had previously charged to wholesalers and pharmacies. Flynn did this in return for the exclusive rights to supply a product which it knew had very high barriers to entry. Flynn then imposed large price increases on top of the significant price increases already charged by Pfizer, resulting in supply prices to Pfizer's previous customer base that were between 2,366% and 2682% higher than Pfizer's previous prices. As the CAT recognised, whilst Pfizer's supply price was a price floor for Flynn, 'Flynn was, in practice, pricing well above this level and could have reduced its prices and still made a material profit'.¹⁰¹⁹
- 6.18 The scale of the price increases was such that Flynn's mark-up alone (ie the differences between Flynn's Prices and Pfizer's Prices) amounted to several multiples of the prices Pfizer previously charged as shown in Table 6.3 below.

¹⁰¹⁵ When setting revised supply prices, the Directions required Pfizer to have regard to the content of the 2016 Infringement Decision. However, nothing in the Directions precluded the Parties from earning a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing Cost Plus in the 2016 Infringement Decision: 2016 Infringement Decision, CE/9742-13, Annex B, paragraph 1(d).

¹⁰¹⁶ *Phenytoin*, Ruling (Remittal and Permission to Appeal) [2018] CAT 12, paragraph 10.

¹⁰¹⁷ The CMA's assessment of whether Tablets are a meaningful comparator is set out in section 6.C below.

¹⁰¹⁸ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 79, line 24 to page 80, line 5 (emphasis added).

¹⁰¹⁹ *Phenytoin*, [2018] CAT 11, paragraph 456.

Table 6.3: Difference between Pfizer's and Flynn's ASPs per pack (Flynn's mark-up) compared with Pfizer's price per pack before the de-branding of Capsules

	Pre-September 2012 Prices (£)	Flynn's mark-up in the Relevant Period (£)	Difference
25mg	0.51	9.69	1,800%
50mg	0.52	7.69	1,379%
100mg	2.21	16.84	662%
300mg	2.20	18.20	727%

Source: CMA analysis based on Tables 2.3 and 2.5 in section 2.

6.19 The scale of the price increases resulting from Flynn's Prices and the consequent very high prices relative to costs are also shown by a comparison of Flynn's excesses (ie pure profits on top of Flynn's costs plus a reasonable rate of return) against the pre-September 2012 prices in Table 6.4 below.

Table 6.4: Flynn's excesses compared to the pre-September 2012 prices

	Pre-September 2012 Prices (£)	Flynn's excesses (£)	Multiple	Difference
25mg	0.51	8.26	16.2	1,520%
50mg	0.52	6.27	12.1	1,107%
100mg	2.21	14.55	6.6	558%
300mg	2.20	16.30	7.4	641%

Source: CMA analysis based on Flynn's excesses set out in section 5.

6.20 These price increases resulted in very high prices (relative to Flynn's costs) as shown in Table 6.5 below.

Table 6.5: Flynn's excesses on Flynn's Products, September 2012 to December 2016

	Capsule strength			
	25mg	50mg	100mg	300mg
Excess (per pack)	£8.26	£6.27	£14.55	£16.30
Excess (%)	139%	77%	37%	42%

Source: CMA analysis in section 5.

6.21 As set out in section 5, Flynn's excesses above Cost Plus in percentage terms do not reflect the true scale of Flynn's profits in absolute terms, given the distortion caused by the excessive supply prices that Flynn agreed to pay to Pfizer. The CMA demonstrates above in section 5 that it is important also to assess Flynn's absolute returns.¹⁰²⁰

¹⁰²⁰ See section 5.C.

- 6.22 This distortion is particularly true for 100mg and 300mg capsules, which accounted for the vast majority of Flynn's revenues from sales of Capsules during the Relevant Period. In absolute terms, Flynn's excesses for 100mg and 300mg capsules were £14.55 and £16.30 per pack respectively and although the excesses for 25mg and 50mg capsules were comparatively smaller in absolute terms (although very high in percentage terms), these were still significant (£8.26 and £6.27 per pack respectively). Flynn's excesses alone (ie the pure profit it earned above its costs and a reasonable rate of return) were:
- 6.22.1 between 558% and 1,520% higher than Pfizer's pre-September 2012 prices;
 - 6.22.2 between 229% and 569% higher than Flynn's returns from its Capsules prices in 2019;¹⁰²¹ and
 - 6.22.3 between 86% and 245% higher than Pfizer's Recent Prices. Pfizer's Recent Prices provide a reference point for a commercially sustainable price – as set out above, Pfizer has never suggested that these prices were not sustainable.¹⁰²²
- 6.23 Like Pfizer, Flynn also made arguments regarding the price increases being necessary to ensure the financial viability of the product. In his evidence before the CAT, [Flynn Director 2] stated that Flynn had made it clear to the DHSC that 'unless a price rise was implemented, it was not commercially viable to supply the product'.¹⁰²³ [Flynn Director 2] also said that 'unless Flynn generated enough revenue to pay Pfizer's supply costs, it would have been unable to continue operating'.¹⁰²⁴ However, these arguments are somewhat disingenuous. Table 6.5 above shows that Flynn made significant excesses in respect of Capsules and that the product would have been commercially viable at significantly lower prices. As noted above, this was recognised by the CAT which stated that Flynn was pricing well above its costs and could have reduced its prices and still made a material profit.¹⁰²⁵ Flynn's excesses alone were between 229% and 569% higher than

¹⁰²¹ Whilst Flynn's prices in 2019 were set to comply with the Directions, Flynn was able to decide the appropriate level of pricing and at no point has Flynn submitted that its 2019 prices were unsustainable: see paragraph 6.23. Returns from Flynn's 2019 prices have been calculated based on Flynn's sales price data and Pfizer's supply price data provided by Flynn in its response of 10 August 2020 to the CMA's s.26 Notice information request of 27 July 2020, Annex 15, PRC00391. In addition to the supply price charged by Pfizer, the CMA has included distribution costs and an allocation of common costs consistent with its Cost Plus analysis when calculating the returns implied by Flynn's 2019 prices. The CMA has then uplifted the total 2019 return by a factor which reflects the number of years in the Relevant Period.

¹⁰²² The CMA considers that this comparison is informative for assessing the fairness of Flynn's Prices, having taken into account (as covered in this section) that: despite Flynn entering the supply chain, it performed only limited commercial activities and incurred limited risks and Flynn's customer base was to a significant degree guaranteed.

¹⁰²³ PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 36. Flynn also told the DHSC that 'we [Flynn] might have to discontinue the product if we didn't make sufficient margin': PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

¹⁰²⁴ PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 36.

¹⁰²⁵ *Phenytoin*, [2018] CAT 11, paragraph 456. [Flynn Director 2] accepted in his evidence before the CAT that Flynn would have sold Capsules if it had been able to achieve a 5% return on sales and that at a 2% return on sales, Capsules would have been more attractive than about half of Flynn's portfolio during 2013, 2014 and 2015: PAD00031A, [Flynn Director 2] Cross Examination, day 4, page 201, line 11 to page 204, line 3.

Flynn's returns from Capsules in 2019. Whilst Flynn's 2019 prices were set to comply with the Directions, Flynn was able to decide the appropriate level of pricing.¹⁰²⁶ At no point has Flynn submitted that its recent prices are unsustainable.¹⁰²⁷

- 6.24 The prices Flynn imposed were on such a scale they had a significant impact on Flynn's overall profitability (notwithstanding that Flynn undertook only very limited commercial activities, incurred very limited risks, and added very little value).¹⁰²⁸ Flynn made losses in each of the three financial years prior to commencing supply of Capsules.¹⁰²⁹ In the following four financial years (ie those financial years that include the Relevant Period), it earned cumulative profits of over £33 million and distributed approximately £20 million in dividends.¹⁰³⁰
- 6.25 Additionally, [Flynn Director 2]'s evidence regarding the potential commercial viability of the product ignores the fact that Flynn voluntarily entered the supply agreement with Pfizer in the knowledge both that Pfizer was substantially increasing its prices and that Flynn would also be imposing a substantial mark-up of its own.¹⁰³¹
- 6.26 Indeed, the CAT found that the admitted purpose of the arrangements was to price Capsules at a much higher level, thereby generating substantial profits for Pfizer and Flynn.¹⁰³²

III. The selective nature of Pfizer's price increases

- 6.27 During the Relevant Period, Pfizer sold Capsules in several other European jurisdictions under the *Epanutin* brand. The Capsules sold in other European jurisdictions were exactly the same drug as that sold in the UK, manufactured by the same company in the same German facility and with similar direct costs.¹⁰³³

¹⁰²⁶ When setting revised prices, the Directions required Flynn to have regard to the content of the 2016 Infringement Decision. However, nothing in the Directions precluded the Parties from earning a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing Cost Plus in the 2016 Infringement Decision: 2016 Infringement Decision, CE/9742-13, Annex B, paragraph 1(d).

¹⁰²⁷ *Phenytoin*, Ruling (Remittal and Permission to Appeal) [2018] CAT 12, paragraph 11.

¹⁰²⁸ See section 2.D.I.d and Annex E.

¹⁰²⁹ PAD00061, PAD00062, PAD00015, Flynn Pharma (Holdings) Limited financial statements for the years ending 31 March 2010, 31 March 2011 and 31 March 2012.

¹⁰³⁰ PAD00038, PAD00073, PAD00075, PAD00072, Flynn Pharma (Holdings) Limited financial statements for the years ending 31 March 2013, 31 March 2014, 31 March 2015 and 31 March 2016.

¹⁰³¹ See PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27) and PHT00193, document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹⁰³² *Phenytoin* [2018] CAT 11, paragraph 457.

¹⁰³³ Pfizer's corporate COGS/transfer price in financial year 2015 varied across Member States for 100mg capsules between £0.03 to £0.06, and was £0.04 in the UK. Pfizer stated that its corporate COGS are set with reference to the direct costs of Pfizer Manufacturing Deutschland GmbH, with an inter-company adjustment to allow a contribution to unallocated global common costs. See PHT00077, Pfizer's 11 March 2016 response to the CMA's s.26 notice of 11 February 2016 (CMA document reference 01836.2).

- 6.28 Despite these similarities and the fact that Pfizer stated that viability concerns were also relevant in other European jurisdictions,¹⁰³⁴ Pfizer has not sought to enter into any arrangements in any other European jurisdiction equivalent to those it entered into with Flynn in the UK or to implement price increases anywhere near the level of those implemented in the UK. Pfizer's prices for Capsules across other European jurisdictions are set out in Table 2.11 in section 2 above.
- 6.29 The CAT found it 'a significant factor that Pfizer's capsule prices were only increased in the UK and only as a result of the arrangements reached between Pfizer and Flynn'.¹⁰³⁵ Whilst the CAT recognised that some caution must be exercised in comparing prices between countries with differing regulatory regimes,¹⁰³⁶ the CMA considers that the selective nature of Pfizer's price increases supports the conclusion that Pfizer's Prices were unfair in themselves.
- 6.30 In other European jurisdictions, 100mg Capsules were sold in larger packs of 100 x 100mg, whereas in the UK they were sold in packs of 84 x 100mg.¹⁰³⁷
- 6.31 The price of *Epanutin* was subject to regulatory constraints in six out of the seven European jurisdictions in which it was sold outside of the UK, with the exception being Malta.¹⁰³⁸
- 6.32 The ASPs charged by Pfizer to wholesalers across the seven other European jurisdictions for the larger 100 x 100mg Capsules packs ranged between £1.56 and £6.28 during the Relevant Period.¹⁰³⁹ Moreover, this range includes prices charged in Cyprus, Greece and Sweden, where Pfizer had requested and secured price increases specifically for the purpose of securing the commercial viability of the product.¹⁰⁴⁰ This range also includes Pfizer's prices in Malta which were not subject to any regulatory price restraints.
- 6.33 Whilst there are regulatory differences,¹⁰⁴¹ the CMA considers prices in other European jurisdictions to be nonetheless relevant evidence for the purposes of assessing the fairness of (and any potential justifications for) the Parties' prices in the UK.
- 6.34 The price charged by Pfizer in Sweden is at the top end of the range of prices. At around the same time that it entered into the arrangements with Flynn, Pfizer

¹⁰³⁴ PRE00627, Pfizer's Closing Submissions, paragraph 248.

¹⁰³⁵ *Phenytoin* [2018] CAT 11, paragraph 402.

¹⁰³⁶ *Phenytoin* [2018] CAT 11, paragraph 402.

¹⁰³⁷ PRC00564, Pfizer's 23 September 2020 response to Question 3 of the CMA's s.26 notice of 12 August 2020.

¹⁰³⁸ PHT00077, Pfizer's response of 11 March 2016 to the CMA's s.26 Notice information request of 11 February 2016 (CMA document reference 01836.2), question 3.

¹⁰³⁹ See Table 2.11.

¹⁰⁴⁰ PHT00077, Pfizer's 11 March 2016 response to the CMA's s.26 notice of 11 February 2016 (CMA document reference 01836.2) and PRC00564, Pfizer's response to question 3 of the CMA's s.26 Notice dated 12 August 2020. See further Table 2.10.

¹⁰⁴¹ PRC03488, Pfizer's Response to the SO and DPS, paragraph 39(c).

secured a price increase of around 230% for *Epanutin* in Sweden.¹⁰⁴² The CMA understands that the price increase was specifically permitted to ensure the drug's long-term commercial viability and its ongoing availability for existing patients.¹⁰⁴³ The approval increased the price that Pfizer was able to charge to pharmacies in Sweden (downstream from the wholesale prices in paragraph 6.32 above) for a *larger* pack of 100 x 100mg capsules to SEK 79.50 (approximately £7.41).¹⁰⁴⁴

- 6.35 In relation to Malta, where the CMA understands Pfizer was not subject to any regulatory restrictions on pricing, Pfizer has not explained why it did not increase its supply prices if they were either loss-making or only marginally profitable. By contrast, Pfizer applied for price increases in Sweden, Cyprus, and Belgium/Luxembourg where the average monthly volumes were approximately only half of those sold in Malta.¹⁰⁴⁵
- 6.36 Pfizer has submitted that the arrangements entered into with Flynn in the UK and the subsequent price increases were designed to secure the commercial viability of the product.¹⁰⁴⁶ However, Pfizer's ASP of £37.56 for a *smaller* pack of 84 x 100mg Capsules in the UK was nearly six times higher than its highest wholesale ASP in other European jurisdictions during the Relevant Period (even where these had been increased specifically for the purposes of ensuring continued supply by Pfizer).¹⁰⁴⁷
- 6.37 The significant differences in price between the UK and these seven other European jurisdictions illustrate the true scale of the price increases imposed in the UK, as well as the resulting very high prices. They also illustrate further how the price increases in the UK went beyond any level that might have been necessary to ensure commercial viability, given that this is exactly the same drug, manufactured by the same company, in the same facility in Germany, and with similar direct costs.

IV. The Parties' prices reflected their substantial market power

- 6.38 It has been established that there were features of the relevant markets which provided Pfizer and Flynn with substantial market power during the Relevant Period. The evidence also demonstrates that the Parties were aware of their market power and exploited this by imposing significant price increases and

¹⁰⁴² See section 2.D.II.i and Decision published by the Swedish Dental Care and Medicines Benefit Agency (TLV) in respect of application by Pfizer AB for a price increase for *Epanutin*. Dated 5 November 2012. Decision Ref: 2670/2012. Swedish language version available at PAD00042. English language translation prepared by the CMA, PAD00043.

¹⁰⁴³ See section 2.D.II.i.

¹⁰⁴⁴ The pharmacy price has been converted to GBP using the 2012 average exchange rate from the Bank of England. The increased price level in Sweden of approximately £7.41 was considerably higher than the 15% contribution margin level in the UK below which Pfizer said it would put a product under review, which equates to a price of £2.41 for 100mg capsules. The authority also approved a price increase in the final customer price (ie the price at which the drug is reimbursed by the national authority) to SEK 126 (approximately £11.74): see section 2.D.II.i. In Sweden during the Relevant Period, Pfizer's actual ASP to wholesalers was £6.28, whilst its ASP to pharmacies was £7.08: see Table 2.11.

¹⁰⁴⁵ See Tables 2.10 and 2.11.

¹⁰⁴⁶ See paragraph 6.14.

¹⁰⁴⁷ See Table 2.11.

sustaining these for over four years.¹⁰⁴⁸ The Parties' price increases forced the NHS to spend an additional £169 million¹⁰⁴⁹ on Capsules during the Relevant Period, without any additional benefits for patients.

a. Features of the relevant markets provided the Parties with substantial market power

6.39 The absence of effective constraints from competitors or purchasers, and very high barriers to entry ensured that Pfizer and Flynn were 'shielded from effective competitive pressure' which enabled the Parties 'to fulfil [their] pricing ambitions'.¹⁰⁵⁰ The evidence clearly demonstrates that, during the Relevant Period, the relevant markets were not 'capable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value'.¹⁰⁵¹

6.40 The CAT in *Phenytoin* found that the Parties each held dominant positions in their respective markets.¹⁰⁵² The CAT noted the 'high barriers to entry' and found 'little sign of Pfizer's or Flynn's prices being constrained by competition either from within the relevant market, or from outside it'.¹⁰⁵³

6.41 Potential competitors faced very high and permanent barriers to entry to the relevant markets during the Relevant Period:

6.41.1 At the manufacturing level, only Pfizer can manufacture Capsules. Pfizer had a market share of 100% and benefitted from absolute barriers to entry by other manufacturers.¹⁰⁵⁴

6.41.2 At the distribution level, the Exclusive Supply Agreement meant that Pfizer could only supply Capsules to Flynn in the UK.¹⁰⁵⁵

¹⁰⁴⁸ See paragraphs 6.50 to 6.56.

¹⁰⁴⁹ The CMA has calculated the NHS's annual spend on Capsules using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices. The CMA has calculated the NHS spend on Capsules over the Relevant Period at pre-2012 Drug Tariff prices and also at post-2012 Drug Tariff prices (taking into account the reduction of the Drug Tariff price in 2014) to calculate the additional spend as a result of the price increases.

¹⁰⁵⁰ See *Albion Water II* [2008] CAT 31, in particular paragraphs 213, and 266 to 268, where the CAT held that features of the relevant market(s) may be relevant to establishing abuse in excessive pricing cases. At paragraph 213, the CAT held that 'factors that establish a dominant position, notably barriers to entry, may well be relevant to determining whether a price is so high as to amount to an abuse [...]. This is particularly true in excessive pricing cases, in which it is important to distinguish excessive prices shielded from effective competitive pressure from temporarily high prices that are the subject of normal market forces in a competitive market'. The CAT in *Phenytoin* also stated that 'provided only objective facts are relied on, then they may be relevant to establishing the existence of dominance as well as having to be examined to see if they contribute to a finding of abuse': *Phenytoin* [2018] CAT 11, paragraph 241. Accordingly, the CMA has taken account of features of the relevant markets and finds that these support its conclusion that Pfizer's Prices and Flynn's Prices were unfair in themselves.

¹⁰⁵¹ *Albion Water II* [2008] CAT 31, paragraphs 268 and 270.

¹⁰⁵² *Phenytoin* [2018] CAT 11, paragraphs 198 and 253.

¹⁰⁵³ *Phenytoin* [2018] CAT 11, paragraphs 250 and 251.

¹⁰⁵⁴ See also *Albion Water II* [2008] CAT 31, paragraph 269.

¹⁰⁵⁵ PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.280), clause 2.2.

- 6.42 Demand for Capsules was to a significant degree inelastic.¹⁰⁵⁶ The guidance on Continuity of Supply had a significant impact, in practice, on pharmacists' dispensing practice and meant that Flynn's customer base in the UK was to a significant degree guaranteed.¹⁰⁵⁷ Continuity of Supply therefore operated as a significant barrier to entry.¹⁰⁵⁸
- 6.43 The only competition to Flynn in the relevant market was parallel imports of Capsules from abroad. However, the supply of the product available to parallel importers was limited and not sufficiently reliable to provide effective competitive pressure on Pfizer or Flynn.¹⁰⁵⁹
- 6.44 Consistent with the barriers to entry, there was no competitive entry during the Relevant Period which was able to constrain sufficiently either Pfizer's Prices or Flynn's Prices. The CAT found that following the launch of NRIM's 100mg phenytoin sodium capsules product from April 2013, whilst there were considerable volume fluctuations, there was 'little price effect',¹⁰⁶⁰ and price interaction was relatively limited over the Relevant Period between NRIM's product and Flynn's product.¹⁰⁶¹ The CAT concluded 'that there was not sufficiently effective competition between [Flynn's product and NRIM's product] for NRIM to be in the same relevant market and there was clear evidence that NRIM offered only limited competition'.¹⁰⁶²
- 6.45 The CAT also concluded that the Parties were not subject to countervailing buyer power from the DHSC in a way that effectively constrained either Pfizer's or Flynn's conduct.¹⁰⁶³ Both Parties were able to impose very high prices without the DHSC's approval and to sustain them despite clear dissatisfaction from the DHSC and CCGs.¹⁰⁶⁴
- 6.46 Pfizer's and Flynn's dominance was not temporary, nor were their prices merely 'temporarily high'.¹⁰⁶⁵ In fact, the Parties continued to charge excessive prices for

¹⁰⁵⁶ Pfizer submitted that '[i]t is well established that price inelasticity may be a feature of pharmaceutical markets [...] and [it] cannot provide a foundation for market power [...] non-price competition in the form of therapeutic substitution [is] the critical issue in pharmaceutical markets': PRC03488, Pfizer's response to the SO and DPS, paragraph 39(e). First, as regards therapeutic substitution relating to Capsules, this was impacted by the guidance on Continuity of Supply as set out in paragraph 6.42 above. Second, the CMA considers that Continuity of Supply is relevant as a barrier to entry and expansion which supports the CMA's finding that the relevant markets were incapable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value. The CAT also referred to Continuity of Supply when noting that high barriers to entry were supportive of a finding that Pfizer and Flynn were dominant: *Phenytoin* [2018] CAT 11, paragraph 250.

¹⁰⁵⁷ *Phenytoin* [2018] CAT 11, paragraphs 150 and 346.

¹⁰⁵⁸ *Phenytoin* [2018] CAT 11, paragraph 151.

¹⁰⁵⁹ [Flynn Director 1] of Flynn noted that the supply of Capsules available to parallel importers was limited and 'spasmodic': see PAD00031, [Flynn Director 2] Cross Examination, day 4, page 109, lines 4 to 12 and see also *Phenytoin* [2018] CAT 11, paragraphs 248 and 249.

¹⁰⁶⁰ *Phenytoin* [2018] CAT 11, paragraph 160.

¹⁰⁶¹ *Phenytoin* [2018] CAT 11, paragraph 183, where the CAT also noted that 'NRIM's launch price was well below Flynn's, but Flynn did not respond until nearly a year later; and only once. We have already found that this price reduction was, at best, only in part a response to competition from NRIM'.

¹⁰⁶² *Phenytoin* [2018] CAT 11, paragraph 247.

¹⁰⁶³ *Phenytoin* [2018] CAT 11, paragraph 235.

¹⁰⁶⁴ See further Annexes B and C.

¹⁰⁶⁵ *Albion Water II* [2008], CAT 31, paragraph 213.

over four years until they were required to lower them to comply with the Directions issued with the 2016 Infringement Decision because the CAT refused Flynn's application for interim relief.¹⁰⁶⁶

- 6.47 The Parties also took steps to raise barriers to competition further and to protect their significant price increases.
- 6.48 As described in section 2, in designing the arrangements, Flynn presented to Pfizer what it had described as 'strategic options in preventing parallel imports into the UK'.¹⁰⁶⁷ The 'strategic option' adopted was to make Flynn the MA holder in the UK and Ireland and to change the name to 'Phenytoin Sodium Flynn Hard Capsules'. As a result, parallel importers of *Epanutin* were no longer able to compete to fulfil closed prescriptions for existing patients treated with Capsules.¹⁰⁶⁸
- 6.49 As found by the CAT, Flynn also actively relied upon Continuity of Supply to try to protect its own sales.¹⁰⁶⁹ In late 2013 and early 2014, Flynn made considerable efforts to persuade Boots and Lloyds to observe Continuity of Supply and warned of the risks of switching patients away from Flynn's Products.¹⁰⁷⁰

b. The Parties were aware of their market power and exploited it

- 6.50 The evidence shows that the Parties were aware of their market power and exploited this to impose significant price increases on the NHS.¹⁰⁷¹ They saw an opportunity and they took it.
- 6.51 The Parties were aware that they did not face any effective constraint from competing suppliers. There were no other manufacturers of phenytoin sodium

¹⁰⁶⁶ Other than monthly fluctuations, the Parties only reduced their prices once during the Relevant Period: see section 2.D.II and see also *Phenytoin* [2018] CAT 11, paragraphs 175 and 183. See also *Flynn v CMA*, Judgment on Interim Relief [2017] CAT 1.

¹⁰⁶⁷ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27). In the final version of these slides, the options presented were headed as 'strategic options which Pfizer could adopt to help prevent stock-out situations in lower-priced markets', see section 2.D.I. See also PHT00194, document entitled 'Flynn Pharma Epanutin Proposal October 2010 – FAQs': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.66).

¹⁰⁶⁸ Flynn was also subsequently successful in enforcing its trade mark rights against parallel importers in the UK courts. See *Flynn Pharma Limited v Druggsrus Limited* [2015] EWHC 2759 and *Flynn Pharma Limited v Druggsrus Limited* [2017] EWCA Civ 226.

¹⁰⁶⁹ *Phenytoin* [2018] CAT 11, paragraphs 127 to 128.

¹⁰⁷⁰ PHT00108, Correspondence dated 8 October 2013 to 10 March 2014 with Boots/Alliance regarding Phenytoin switching: Annex 16a of Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.20); and PHT00170, Correspondence dated 8 October 2013 to 10 March 2014 with Celesio regarding Phenytoin switching: Annex 15 of Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.19).

¹⁰⁷¹ The assessment of whether or not a dominant position has been abused is an objective one, and evidence of anti-competitive intent or motive is not required for a finding of abuse: *C-549/10 P Tomra v European Commission*, EU:C:2012:221, paragraph 21; see also *Hoffmann-La Roche*, EU:C:1979:36, paragraph 91. However, if such evidence exists, while it cannot be sufficient in itself, it may be taken into account in order to determine whether a dominant position has been abused: *C-307/18 Generics (UK) Ltd and others v Competition and Markets Authority*, EU:C:2020:52, paragraph 162; *Royal Mail PLC v OFCOM and Whistl UK Limited* [2019] CAT 27, paragraph 278; *C-549/10 P Tomra v European Commission*, EU:C:2012:221, paragraph 20; and see also *Aspen*, paragraphs 186 to 189. These principles regarding anti-competitive intent or motive apply equally to exploitative abuses as to exclusionary abuses.

capsules at the time they began negotiating the arrangements¹⁰⁷² and the Parties were aware that different manufacturers' phenytoin sodium products (including capsules and Tablets) were not interchangeable to a significant degree.¹⁰⁷³

- 6.52 Illustrating an awareness of the market power that this gave the Parties, shortly after the price increases, [Pfizer Employee] of Pfizer said in an email regarding the '24x drug price hike' that:

If I remember correctly: [...] A price increase is only possible (from a commercial perspective) if there is no other manufacturer selling the same molecule (otherwise they would be undercut on price) and/or physicians are slow to switch from the brand

¹⁰⁷² Prior to entering into the agreements, Pfizer's internal regulatory team estimated 'it would take a competitor a minimum of 2 years to bring a competitor phenytoin capsules to the market and trigger price reductions': PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 44 and PHT00200, Document of 1 August 2011 entitled 'Briefing for [Pfizer President 1] about the Epanutin divestment': Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.154). A document prepared by Flynn for Pfizer noted that '[t]here have been no generic competitors to date': PHT00194, document entitled 'Flynn Pharma Epanutin Proposal October 2010 – FAQs': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.66). NRIM began supplying 100mg phenytoin sodium capsules in April 2013 and whilst the Parties became aware of NRIM's potential entry prior to the price increases being implemented, upon learning that NRIM had been granted an MA, Pfizer expected that Flynn would be able to retain two-thirds of the market: PHT00221, Email of 23 October 2011 from [Pfizer Director 1] Pfizer to [Pfizer President 2] J A Finance and [Pfizer Employee] Pfizer re Epanutin Update detailing the agreement with Flynn and the appearance of NRIM and its Marketing Authority: Pfizer's response of 18 June to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.191). [Pfizer Director 1] noted that Pfizer later revised its revenue forecast as a result of NRIM's expected entry: PRE00156, Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 74. However, this revision did not lead to the Parties revising the prices they planned to impose, indicating that they considered the significant price increases to be sustainable. In respect of Flynn, as [Flynn Director 2] explained in the CAT, Flynn was not 'particularly concerned about NRIM' as it anticipated that NRIM's strategy was 'not [...] to start a "race to the bottom" on price but rather to build up a 30-50% share of the market': see PAD00031, [Flynn Director 2] Cross Examination, day 4, page 127, line 25 to page 128, line 4 and PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 52.

¹⁰⁷³ Flynn's initial proposal to Pfizer dated 1 July 2010 records that '[t]ablets & capsules are not easily interchangeable': PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27); [Flynn Director 2] noted that 'the tablets and capsules are recognised as NOT being readily interchangeable, so doctors and patients would be reluctant to switch': PHT00363, Email of 16 March 2010 from [Flynn Director 2] Flynn to [Flynn Non-executive Director 1] [X] re Correction – Capsules not Tablets: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.12); Flynn also noted that 'Epanutin capsules & tablets are not interchangeable': PHT00197, Minutes of Flynn Pharma Board Meeting of 15 December 2010: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.80); a Pfizer internal email noted that '[i]ndustry has, rightly, made a big deal of epilepsy drugs being one of the key medicines where you shouldn't mess with the presentation that a patient is stabilised on – with a great deal of expert medical and pharmacy support': PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31); PHT00185, Email chain of 17 September 2009 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re the Epanutin Proposal put forward by Tor: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference of 00141.28); and PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 30. See also *Phenytoin* [2018] CAT 11, paragraphs 124 to 126. This understanding was further emphasised by the correspondence sent to the Parties shortly after they imposed their price increases which made it clear that CCGs considered that patients currently prescribed Capsules could not be switched to an alternative formulation for the majority of indications: PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.527).

*As this is an Epilepsy product, physicians are slow to switch patients to generic alternatives and so Flynn have been able to increase price.*¹⁰⁷⁴

- 6.53 The Parties' awareness of their market power and their intention to exploit it is starkly illustrated by a presentation Flynn gave to Pfizer in July 2010 in which Flynn observed:

*Even if 50% of sales of 100mg were lost to [parallel imports] the upside would still be > £20m*¹⁰⁷⁵

- 6.54 Accordingly, such was Flynn's confidence in its market power that it informed Pfizer that, even if they lost 50% of their market share as a result of their price increases, they would still make very significantly increased revenues.
- 6.55 The Parties also knew that the NHS would have little option but to pay the very high prices they imposed because patients taking Capsules were to a significant degree captive. Flynn's proposal briefing document sent to Pfizer stated that, if Capsules were discontinued, switching patients to Tablets would cost the NHS 'in excess of £100M' and '[m]ore importantly, there is a possibility that [the] welfare of the patient might be impacted, as the capsules and tablets are not readily interchangeable'.¹⁰⁷⁶
- 6.56 Further, as set out in section 5, Flynn's contemporaneous documents show that it modelled different prices for Capsules before implementing its price increases, many of which were far lower than the prices Flynn ultimately charged.¹⁰⁷⁷ Flynn submitted that these lower prices reflected its view that it would be subject to competitive constraints.¹⁰⁷⁸ Given Flynn imposed and maintained for over four years significantly higher prices than those modelled (reflecting the absence of such constraints), this further demonstrates Flynn's awareness of its market power.

¹⁰⁷⁴ PHT00353, Email of 15 October 2012 from [Pfizer Employee] Pfizer to [Pfizer Employee and others] Pfizer (CMA document reference 00141.469). Pfizer submitted that this document identifies the rationale for the price increase as being to keep the product on the market as it was not commercially viable, and the price was cheaper to the NHS than Tablets: PRC03901, Pfizer's Response to the Letter of Facts, paragraph 31. Pfizer does not appear to contest that this document supports the CMA's finding that the Parties were aware of their market power. The CMA finds above at paragraph 6.15 that Pfizer's price increases went well beyond any level that may have been necessary to ensure the drug's commercial viability. In respect of Tablets, the CMA finds below in section 6.C that these were not a meaningful comparator for Capsules. As set out in Annex C, there were numerous events which should have made the Parties reconsider whether their pricing and use of Tablets as a benchmark was appropriate.

¹⁰⁷⁵ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27), page 11.

¹⁰⁷⁶ PHT00193, Document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹⁰⁷⁷ See section 5.C.II.c.

¹⁰⁷⁸ Flynn submitted that these were very early projections and reflected its view 'that the DHSC would negotiate with Flynn to reduce the prices. The NRIM MA for Phenytoin Sodium 100mg capsules was granted in September 2011, and so Flynn would have been aware at the time it was setting its prices of the likelihood of further generic entry from NRIM and others, as well as the uncertainty around the impact on pricing and volumes that parallel imports would have in the UK': PRC03903, Flynn's Response to the Letter of Facts, paragraph 4.8.

c. The Parties wilfully ignored customer concerns and did not engage constructively

- 6.57 As set out above, the Parties were aware that they did not face any effective constraint from competitors or customers. The Parties exploited this to impose and maintain significant price increases whilst disregarding significant concerns from the DHSC and CCGs. In Flynn's words, following the launch of its Capsules, it 'took a lot of criticism from payers and healthcare professionals regarding the price increase'.¹⁰⁷⁹ This section addresses this evidence but should be read in conjunction with Annexes B and C of this decision.
- 6.58 There were many events and occasions where end customers raised strong concerns about the Parties' prices, which should have made the Parties pause and reconsider whether their pricing and reliance on Tablets as a benchmark was appropriate.¹⁰⁸⁰ Consequently, it is not plausible for the Parties to have maintained their prices on the basis that the DHSC was willing to pay these prices, did not have 'any serious objection' to them and considered the price increases to be 'justifiable'.¹⁰⁸¹
- 6.59 Any price increase may have a detrimental impact on customers with finite budgets.¹⁰⁸² However, the sheer scale and tone of end customer complaints would have made it unambiguously clear to the Parties that their end customers were neither willingly paying the prices they had imposed nor considered them to reflect the value of the drug. Instead, they were only paying under protest. The complaints made clear, amongst other things, that the scale of the price increases were 'completely unjustifiable' given 'the product is unchanged' and there was 'no additional health benefit for patients'.¹⁰⁸³ The complaints also warned about the impact on the NHS given the scale of the price increases.¹⁰⁸⁴
- 6.60 As set out comprehensively in Annexes B and C, this substantial volume of evidence shows that the Parties knew that the DHSC and end customers objected to the scale of the price increases and did not consider the benchmarking against the Drug Tariff was justified, and these concerns were communicated unambiguously to the Parties.

¹⁰⁷⁹ PHT00401, Flynn, *Phenytoin* (2) (CMA document reference 00145.827).

¹⁰⁸⁰ See Annexes B and C. This responds to PRC03903, Flynn's Response to the Letter of Facts, paragraphs 1.9 and 3.14.

¹⁰⁸¹ PRC03488, Pfizer's Response to the SO and DPS, paragraph 15; PRC03492, Flynn's Response to the SO, paragraph 2.22; and see also PRC03903, Flynn's Response to the Letter of Facts, paragraph 3.7.3.

¹⁰⁸² PRC03901, Pfizer's Response to the Letter of Facts, paragraph 30.

¹⁰⁸³ PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes; Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.527) and PHT00210, Letters published in the British Medical Journal on 22 January 2013, (CMA document reference 00020.2).

¹⁰⁸⁴ See Annex B.

- 6.61 Prior to implementing the price increases, the DHSC had made it clear to Flynn that it was not happy with the level of Flynn's proposed prices for Capsules, as set out further in Annex C.¹⁰⁸⁵
- 6.62 The DHSC again raised its concerns directly with Flynn in a meeting on 6 November 2012 shortly after Flynn imposed its very high prices notwithstanding the DHSC's previously articulated concerns.
- 6.63 Flynn's notes of the meeting record that the DHSC informed Flynn that it was 'struggling and trying to understand the justification' for the price increases which were 'hitting hard NHS pockets'.¹⁰⁸⁶ The DHSC expressly rejected the Parties' proposal to benchmark the prices of Capsules against the prices of Tablets. The DHSC made it clear to Flynn that:
- 6.63.1 it was not happy with the prices for Capsules;
 - 6.63.2 it 'needed to be able to justify the large increase as value for money';
 - 6.63.3 the significantly greater volumes of Capsules dispensed than Tablets meant the related impact on NHS costs was 'very difficult';
 - 6.63.4 it was not happy with the price of Tablets; and
 - 6.63.5 it did not consider comparisons with Tablets to be relevant for phenytoin sodium capsules.¹⁰⁸⁷
- 6.64 [Flynn Director 2] later accepted that the DHSC at this meeting was very unhappy with the price increases¹⁰⁸⁸ and was not happy with the use of Tablets as a benchmark for Capsules.¹⁰⁸⁹
- 6.65 The DHSC also raised its concerns directly with Pfizer in a meeting in January 2013.¹⁰⁹⁰
- 6.66 Despite this evidence showing that the DHSC and other key stakeholders did not accept the scale of the price increases, and the availability of a more reasonable course of action (by reducing their prices and engaging constructively with the

¹⁰⁸⁵ See also *Phenytoin* [2018] CAT 11, paragraph 232.

¹⁰⁸⁶ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

¹⁰⁸⁷ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.16); PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585); and see also *Phenytoin* [2018] CAT 11, paragraph 232.

¹⁰⁸⁸ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 167, lines 13 to 14.

¹⁰⁸⁹ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 158, lines 16 to 20.

¹⁰⁹⁰ See Annex C and section 2.D.III.c.

DHSC¹⁰⁹¹), the Parties continued to impose their high prices and did not engage constructively or sufficiently with the DHSC to resolve what Flynn conceded were 'legitimate concerns' regarding the prices it was imposing.¹⁰⁹² The evidence clearly shows that Flynn's conduct was not, as it submits, transparent, cooperative and constructive¹⁰⁹³ and did not reflect a 'negotiation'.¹⁰⁹⁴

- 6.67 Flynn informed the DHSC that the prices it had imposed were necessary to ensure 'the continued commercially viable supply'¹⁰⁹⁵ and Flynn 'might have to discontinue the product if [it] didn't make sufficient margin'.¹⁰⁹⁶ However, this explanation was somewhat disingenuous as it disregarded the fact that Flynn (and Pfizer) were making very substantial margins on their sales of Capsules. Indeed, as the CAT found in *Phenytoin*, Flynn could have reduced its prices and still made a material profit.¹⁰⁹⁷ Similarly, the CMA has established above that Pfizer's prices went well beyond the level that would have been necessary to ensure that it remained financially viable for them to continue to produce Capsules.¹⁰⁹⁸ Accordingly, it is difficult to reconcile Flynn's behaviour with its claim that it was 'transparent,' 'cooperative' and 'constructive' in its dealings with DHSC.
- 6.68 By contrast, the evidence shows that DHSC approached its discussions with the Parties in good faith and with the aim of understanding the reasons for the price increases proposed.¹⁰⁹⁹ It accepted, based on Flynn's submissions, that a price increase might be justified and sought to gain an understanding of the issue by reference to Flynn's costs of supply.¹¹⁰⁰ However, neither Pfizer nor Flynn provided Pfizer's supply price to the DHSC.¹¹⁰¹ Again, this behaviour was not 'transparent', 'cooperative' or 'constructive' and also demonstrates the Parties understood the DHSC was in a weak position. They were, on the one hand, informing the DHSC that their very high prices were necessary to ensure the financial viability of Capsules, but on the other would not provide the DHSC with material information regarding their costs – in the knowledge that DHSC was powerless to demand it.

¹⁰⁹¹ This possibility had been raised by the GMMMG in its letter to the Parties on 10 October 2012. The letter from the GMMMG set out that '[t]he only credible alternative is that the companies must make a case for a **modest** price increase, but this must stand up to economical and clinical justification'. See further Annex C.

¹⁰⁹² PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18).

¹⁰⁹³ PRC03492, Flynn's Response to the SO, paragraphs 1.5 and 2.5 and PRC03903, Flynn's Response to the Letter of Facts, paragraph 3.7.

¹⁰⁹⁴ PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 32; and see also PRC03492, Flynn's Response to the SO, paragraphs 2.13 and 2.15 and PRC03903, Flynn's Response to the Letter of Facts, paragraph 3.7.1.

¹⁰⁹⁵ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18).

¹⁰⁹⁶ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

¹⁰⁹⁷ *Phenytoin* [2018] CAT 11, paragraph 456.

¹⁰⁹⁸ See paragraph 6.15.

¹⁰⁹⁹ See Annex C and section 2.D.III.

¹¹⁰⁰ See Annex C and section 2.D.III.

¹¹⁰¹ See Annex C and section 2.D.III.

- 6.69 At the November 2012 meeting, Flynn agreed to the DHSC's request for Flynn to contact Pfizer to establish whether it was possible for Flynn to negotiate a reduction in Pfizer's supply price, after which Flynn would reduce its prices to the NHS.¹¹⁰² Flynn later told the DHSC that, in light of 'legitimate concerns as to (NHS) cost', it was continuing to discuss supply pricing with Pfizer.¹¹⁰³ Flynn also explained to certain CCGs who raised concerns that it was seeking to reduce its cost of goods with a view to moderating its prices.¹¹⁰⁴ However, there is no evidence that Flynn ever discussed the possibility of any price reduction with Pfizer in light of the statements it made to the DHSC and CCGs.¹¹⁰⁵ Moreover, in any event, Flynn did not need to reach an agreement to Pfizer to reduce its own prices, as it could have made unilateral reductions and still made strong returns.¹¹⁰⁶
- 6.70 It is also notable that the Parties did not re-engage in discussions with the DHSC when the OFT opened its investigation in May 2013 or at any stage of the subsequent OFT and CMA investigation, when it would have been evident to the Parties that the DHSC and various stakeholders had brought the concerns they had regarding the level of the Parties' prices to the OFT's attention.
- 6.71 The failure of the Parties to re-engage with the DHSC further undermines the claim that they engaged with the DHSC in a 'constructive' manner. Given the obvious discrepancy between the Parties' understanding of the DHSC's views on Tablets and the position the DHSC took in practice, if the Parties genuinely wished to address the DHSC's concerns, the Parties would have been expected to have contacted the DHSC to seek its views on (and potentially its support for) the position they were taking. Instead, the Parties made no contact with the DHSC after January 2013 and maintained their excessive prices until January 2017, when they were required to bring them down in line with the CMA's Directions.
- 6.72 Indeed, the CAT found in relation to the interaction between the Parties and the DHSC that it was 'very difficult to conclude from these events that by early 2013 Pfizer or Flynn's conduct was in practice constrained either by intervention from the DH, or anticipation of that intervention'.¹¹⁰⁷

¹¹⁰² PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.16).

¹¹⁰³ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18).

¹¹⁰⁴ PHT00386, Email of 23 October 2012 from [Flynn Director 2] Flynn to [X] (CMA document reference 00145.522); PHT00380, Email of 12 October 2012 from [Flynn Director 2] Flynn to [X] (CMA document reference 00145.478); and PHT00382, Email of 10 October 2012 from [Flynn Director 2] to [X] (CMA document reference 00145.494).

¹¹⁰⁵ See section 2.D.III.b.iv and see also *Phenytoin* [2018] CAT 11, paragraph 234.

¹¹⁰⁶ *Phenytoin* [2018] CAT 11, paragraph 456.

¹¹⁰⁷ *Phenytoin* [2018] CAT 11, paragraph 234 (emphasis added).

V. The features of the products do not provide any justification or legitimate reason for the Parties' prices

6.73 The assessment above demonstrates that the Parties' prices were excessive and resulted in returns significantly above any level which might have been required to ensure the commercial viability and ongoing supply of the product. The CMA has considered below whether there are other factors which might otherwise serve to justify the Parties' prices as fair and not abusive.¹¹⁰⁸

6.74 Based on an evaluation of the features of the product and its supply by the Parties, the CMA has concluded that there are no relevant factors which justify the magnitude of the Parties' price increases and the resulting prices charged by the Parties during the Relevant Period. The evidence demonstrates that the Parties' prices were, instead, a result of the exploitation of their substantial market power, power which ultimately arose from the drug's clinical limitations rather than its benefits.¹¹⁰⁹

a. The drug had long been in the third stage of the drug life cycle during which competition typically drives down prices

6.75 There was no justification for the Parties' very high prices based on the drug's position within the drug life cycle.

6.76 Phenytoin sodium capsules have been off patent since before Pfizer's acquisition of *Epanutin* in 2000.^{1110, 1111} The drug had therefore long been in the third stage of the drug life cycle, where competition between generic suppliers is expected to result in significant price falls and ongoing low prices.¹¹¹² This is the case even where a drug continues to deliver significant benefits to patients.

6.77 As noted in an internal Pfizer presentation, the 'UK is [a] commodity driven market with aggressive pricing of [g]enerics'.¹¹¹³ This is the case even for life-saving

¹¹⁰⁸ See *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).

¹¹⁰⁹ As set out in section 2, various factors which all arise from the drug's clinical limitations mean that Capsules are a niche generic. These features mean that it had a relatively small target patient population and was a declining market due to the lack of new patients being prescribed the drug. It is also a relatively difficult drug to manufacture, which arises from the drug's clinical features, including its NTI. Further, the recommendation on Continuity of Supply which acted as a barrier to entry arose as a result of phenytoin sodium's therapeutic limitations, in particular its NTI and non-linear pharmacokinetics: PRE00499, Second Expert Report of [Pfizer Expert Witness 1], 19 May 2017, paragraph 2.10. In respect of Flynn, its dominant position was also secured by the exclusive nature of the arrangements between the Parties, see paragraph 6.41.2.

¹¹¹⁰ Phenytoin sodium capsules were first marketed in 1938: see section 2.A.I.

¹¹¹¹ Pfizer submitted that the age of Capsules is irrelevant to their value and the salient issue is their value today: PRC03488, Pfizer's Response to the SO and DPS, paragraph 39(d). The CMA considers that the fact that Capsules were long in the third stage of the drug life cycle is relevant to the price that would be expected for a generic drug as set out at paragraphs 6.76 to 6.77. As a relevant feature of the products, the CMA considers that this is relevant to its assessment of whether the prices of Capsules were unfair in themselves. Further, the CMA considers that the relevant issue for its assessment of the fairness of the Parties' prices is the value of the products during the Relevant Period.

¹¹¹² See section 2.B.

¹¹¹³ PHT00362, Pfizer Presentation slides setting out 2009 Financials, 1 January 2009, (CMA document reference 00141.9), page 3. This statement is the first bullet point in a slide titled 'Price Assumptions Factored into [Pfizer's EPBU 2009-2013 Operating Plan]' and therefore is a key pricing assumption within the operating plan of a business with

medicines. In these circumstances, sales are typically driven by the prices offered to wholesalers and pharmacies. This competition causes the average drug price to fall gradually towards the cost level. As the DHSC noted in a meeting with the CMA, 'it would expect the price of a generic, off patent, product to approach marginal cost'.¹¹¹⁴ Accordingly, the primary driver of price for a product in the third stage of the drug life cycle is the degree of competition faced by the suppliers, rather than the therapeutic value of a product.

6.78 The Parties would have understood from their interactions with the DHSC that, in order to determine whether the Parties' prices might be justified given their stage in the drug lifecycle, the DHSC wanted to understand their costs of production and supply.¹¹¹⁵ The evidence demonstrates that there were at least two occasions when the DHSC was approached regarding price levels or increases for either Tablets or Capsules.¹¹¹⁶ On both occasions, the DHSC raised explicit concerns regarding the price levels proposed and sought costs information (which was not provided), including when seeking to understand the basis for the very high prices that Pfizer and Flynn imposed in September 2012.¹¹¹⁷

6.79 In contrast to what is expected during the third stage of the drug life cycle, the ASPs of Capsules increased significantly in September 2012 and were maintained at a very high level for over four years.

b. There was no improvement, innovation, investment or commercial risk-taking activity which justifies the Parties' prices

6.80 The Parties' prices cannot be justified on the basis of any improvement, innovation or investment in the product or any commercial risk-taking activity by the Parties.

6.81 Neither of the Parties conducted any innovation related to the products, or developed or improved the products. Pfizer's and Flynn's Capsules during the Relevant Period were identical to *Epanutin*: there was no change to their formulation.¹¹¹⁸ As Flynn noted, post-de-branding, the products remained 'qualitatively and quantitatively identical in all but product name'.^{1119, 1120} Pfizer's

significant experience in the sale of generic drugs. It supports the position that typically, provided market features do not shield a generic drug from competition, competition amongst suppliers of homogenous generic drugs leads to more intense price competition.

¹¹¹⁴ PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1). Pfizer submitted that it is not possible to generalise that competition in generics markets necessarily leads to commodity pricing: PRC03488, Pfizer's Response to the SO and DPS, paragraph 35. However, as set out section 2.B, typically, provided market features do not shield a generic drug from competition, competition leads to more intense price competition and, as the DHSC expected, this causes the average drug price to fall towards cost.

¹¹¹⁵ See Annex C.

¹¹¹⁶ In respect of Capsules, see sections 2.D.II and 2.D.III. In respect of Tablets, see paragraphs 6.260 to 6.264.

¹¹¹⁷ See Annex C.

¹¹¹⁸ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 13, lines 11 to 24.

¹¹¹⁹ PHT00212, Flynn Draft Communication Plan of August 2012 for the Introduction of Phenytoin Sodium Flynn Hard Capsules: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.581), page 2.

¹¹²⁰ Pfizer submitted that the products being packaged, produced and delivered exactly as before reflects Pfizer's concern to maintain customer confidence in the products and changes were not necessary for Pfizer's revised supply

Prices and Flynn's Prices during the Relevant Period therefore do not reflect any additional benefits having been created for patients by the Parties.

- 6.82 There was no other relevant improvement, such as any production efficiency (eg resulting from any improvement to manufacturing facilities) or improvement to the distribution and supply of the products.
- 6.83 There was no change in the manufacturing arrangements.¹¹²¹ Pfizer's and Flynn's Capsules after September 2012 continued to be manufactured from the same Pfizer plant in Germany in which *Epanutin* had been produced for many years.
- 6.84 The route to market remained largely identical.¹¹²² The Capsules continued to be delivered to the same pre-wholesaler used by Pfizer prior to September 2012, [X]. [X] then stored the Capsules and delivered them to Flynn's customers. Flynn had no warehousing or delivery facilities and it did not at any point take receipt of, or dispatch, the products. The only change was that Flynn was inserted into the supply chain and placed orders for the products with Pfizer on a weekly basis.¹¹²³
- 6.85 For the purposes of justifying its prices, Flynn made a number of representations regarding its activities. Flynn submitted that it should be allowed to make additional revenues and charge far higher prices to account for, amongst other things:
- 6.85.1 steps it took to put into effect the arrangements with Pfizer and to maintain the existing position for patients, including ensuring continuity of supply, and its risks and responsibilities as an MA holder following the transfer of the MA from Pfizer to Flynn;
 - 6.85.2 the costs that it would have incurred had it taken certain steps which it did not in practice take to establish an alternative sources of API to Pfizer;
 - 6.85.3 its expenditure on buffer stocks;
 - 6.85.4 risks it argues were inherent in the high price it had proposed and subsequently paid to Pfizer as part of the arrangements between the Parties; and
 - 6.85.5 its activities in relation to products unrelated to Capsules.¹¹²⁴

prices to be lawful: PRC03901, Pfizer's Response to the Letter of Facts, paragraph 29. Irrespective of the Parties' motivations for maintaining the products exactly as before, the CMA considers that there was no improvement to the products, their production or their distribution which might justify the Parties' very high prices.

¹¹²¹ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 13, lines 8 to 21. See also PHT00350, Various emails, Email of 1 December 2011 from [Pfizer Employee 2] (Pfizer) to [Pfizer Employee] (Pfizer) (CMA document reference 00141.209): [Pfizer Employee 2] of Pfizer states '[w]e want to source the product exactly as now – similar volumes, same packaging, different artwork on packaging' and in response [Pfizer Employee] of Pfizer queries 'I need to understand how if today you break even; if you keep buying the product at the same price, you will manage to increment E20'.

¹¹²² See section 2.D.I.d.

¹¹²³ See section 2.D.I.d.

¹¹²⁴ See Annex E.

6.86 The CMA does not accept that these justify Flynn's Prices. Where the factors referred to by Flynn resulted in it incurring any costs, these have been fully accounted for (including allowing a reasonable rate of return) in the CMA's assessment at Limb 1 (excessive). Moreover, Flynn's reliance on factors such as maintaining buffer stocks also needs to be considered in the context that Flynn was selling Capsules to an assured base at a very high price. The CMA does not consider that these factors resulted in additional economic value for end customers or patients, or resulted in significant risk-taking by the Parties. Having considered the representations made by Flynn, the CMA's view is that Flynn undertook only limited commercial activities and its level of risk was low.¹¹²⁵ The CMA has addressed the Parties' representations and provided further reasons for its conclusions in Annex E.

c. The patient benefit provided by the drug does not justify the Parties' prices

6.87 Given that Capsules had long been off patent prior to the Relevant Period, and that the price increases imposed did not reflect any improvement to the product, its supply or additional benefits for patients, the Parties' price increases were only made possible because of the absence of effective competition in the supply of Capsules.

6.88 Notwithstanding this, the CMA has also considered whether the features of Capsules resulted in 'additional benefits'¹¹²⁶ or any 'particular enhanced value'¹¹²⁷ for customers and might nevertheless explain or justify the significant price increases and the resulting very high prices.

6.89 Any drug which continues to be prescribed to patients should provide a benefit to those patients. The existence of some patient benefit is, therefore, a pre-requisite to the continued supply of any drug. This is also the case for Capsules. However, the CMA finds that the therapeutic benefit of Capsules does not justify the Parties' very high prices for the reasons set out below.

6.90 First, as a treatment for epilepsy, Capsules have long been superseded by other AEDs as a first-line treatment (and had been prior to the Relevant Period). These other AEDs were preferred to Capsules due to their greater overall benefits for patients. This was recognised in NICE guidance published in 2012 which identified phenytoin as a third-line treatment.¹¹²⁸ This reflects an assessment of the drug's therapeutic benefits by an expert body¹¹²⁹ based on a significant volume of

¹¹²⁵ See section 2.D.I.d, section 5.C.II and Annex E.

¹¹²⁶ *Albion Water II* [2008] CAT 31, paragraph 7.

¹¹²⁷ *Albion Water II* [2008] CAT 31, paragraph 222.

¹¹²⁸ PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13) (this Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022).

¹¹²⁹ See PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13), pages 69 to 75 (this

evidence, and which categorises AEDs based on the benefits they provide to patients. Phenytoin's categorisation by NICE as a third-line treatment reflects the fact that other AEDs have greater efficacy, fewer side effects, fewer adverse drug interactions, and/or greater ease of clinical use.¹¹³⁰

- 6.91 The drug's marginalisation due to therapeutically superior alternatives is also reflected in the Parties' internal documents.
- 6.92 [Flynn Director 1] told the DHSC that the 'drug is no longer first-line or even recognised as adjunctive therapy in the treatment or management of any specific epilepsy seizure type. Indeed current advice (NICE CG137, January 2012) specifically discourages its use in certain circumstances.' [Flynn Director 1] also noted Flynn's view that 'the declining usage observed in the current year (10-15% decrease over 2011) will continue in light of current treatment advice and the emergence of newer more effective, and albeit more expensive,¹¹³¹ drug treatment options'.¹¹³² Pfizer explained that phenytoin-based products have 'been superseded in many clinical situations by newer medicines which have a better safety and tolerability profile; a wider therapeutic index; no requirement for blood monitoring and fewer drug interactions'.¹¹³³ Pfizer's internal documents also describe Capsules as being a 'last resort' treatment option.¹¹³⁴
- 6.93 The drug's marginalisation is also reflected in the fact that it was only very rarely prescribed to new patients during the Relevant Period. [Pfizer Expert Witness 1]'s evidence stated that when prescribing an AED, clinicians will have regard, amongst other things, to clinical guidelines and the balance of efficacy against side effects.¹¹³⁵ Pursuant to this balancing exercise, the evidence indicates that Capsules were only very rarely prescribed to new patients during the Relevant Period.¹¹³⁶

Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022).

¹¹³⁰ PAD00017, National Clinical Guideline Centre, Pharmacological Update of Clinical Guideline 20, *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care, methods, evidence and recommendations* (as last updated in October 2019), for example, pages 212, 220, 317, 382 and 388; and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 19.

¹¹³¹ First-line treatment options were more expensive than *Epanutin* at the prices charged by Pfizer prior to September 2012. However, the prices of generic versions of first-line AEDs were significantly below the Parties' prices for Capsules during the Relevant Period: see paragraph 6.99.

¹¹³² PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18).

¹¹³³ PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice information request of 8 May 2013 (CMA document reference 00086.1), question 1(i).

¹¹³⁴ PHT00185, Email chain of 17 September 2009 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re the Epanutin Proposal put forward by Tor: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.28).

¹¹³⁵ PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 4.10. Other factors that clinicians will have regard to include the drug's licensed indications, the type of epilepsy, ease of use of the drug (ie how well it interacts with other drugs and how easy it is to regulate the dose) and experience with the drug.

¹¹³⁶ Prescription to new patients during the Relevant Period would have been in circumstances where patients have not responded to other preferred treatments or after patients have experienced status epilepticus. See section 2.A.VI.

- 6.94 Second, evidence gathered by the CMA on remittal from [Professor of Neurology], a clinical expert, does not suggest that Capsules had previously been hugely undervalued, or that the drug has ‘additional benefits’¹¹³⁷ or any ‘particular enhanced value’¹¹³⁸ related to any therapeutic advantages of the product.¹¹³⁹ Instead, [Professor of Neurology]’s view is that phenytoin sodium exhibits a combination of unique therapeutic disadvantages¹¹⁴⁰ which do not benefit patients or customers or enhance the value of the product for them. These include:
- 6.94.1 its NTI and non-linear pharmacokinetics. It is the only AED in use which has both these characteristics.¹¹⁴¹ The combination of them makes it difficult for practitioners to regulate the dose,¹¹⁴² and can lead to toxicity and irreversible problems for patients;¹¹⁴³
 - 6.94.2 potential serious side effects.¹¹⁴⁴ It is an enzyme-inducing drug, which are recognised as having potential serious side effects which are not a concern for non-enzyme-inducing AEDs.^{1145, 1146} It is also the worst enzyme-inducing AED currently in use in terms of side effects;¹¹⁴⁷ and

¹¹³⁷ *Albion Water II* [2008] CAT 31, paragraph 7.

¹¹³⁸ *Albion Water II* [2008] CAT 31, paragraph 222.

¹¹³⁹ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 6.

¹¹⁴⁰ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 6.

¹¹⁴¹ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 9.

¹¹⁴² Small increases in dose can result in toxicity and small decreases in dose can result in falls in the plasma concentration below a therapeutic level. See PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, paragraphs 5.4 and 6.5 and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 8. Phenytoin is the only AED where drug blood level monitoring is indicated by NICE when adjusting the dose: PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13), paragraph 1.9.17.9 (this Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022) and PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 19.

¹¹⁴³ Toxicity can cause patients to be ataxic and unsteady, rendering automatic movements and actions much more difficult (for example, patients needing to consciously think about how to walk): PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 8.

¹¹⁴⁴ See section 2.A.IV. See also PRC03488, Pfizer’s Response to the SO and DPS, paragraph 24(a): ‘[Pfizer Expert Witness 1] was always clear that there are other AEDs which are generally better tolerated than phenytoin sodium.’

¹¹⁴⁵ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 18 and PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 5.5. As phenytoin is a strong enzyme inducer, patients taking it are likely to have a lower life expectancy: PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 11 and PAD00041, EMC, *Phenytoin Sodium Flynn Hard Capsules 100mg SmPC*.

¹¹⁴⁶ Pfizer submitted that ‘to the extent that the CMA has concluded that phenytoin is distinctively difficult to administer because of its enzyme inducing nature, that is a simplistic and flawed view’: PRC03488, Pfizer’s Response to the SO and DPS, paragraph 26. However, as set out above at paragraph 6.94.1, the CMA finds that phenytoin sodium is distinctively difficult to administer due to its NTI and non-linear pharmacokinetics. Pfizer also submitted that some other AEDs are also enzyme-inducing drugs: PRC03488, Pfizer’s Response to the SO and DPS, paragraph 26. However, the issues caused by phenytoin sodium’s enzyme-inducing nature are just one of the drug’s disadvantages identified above at paragraph 6.94. Further, phenytoin is a strong enzyme inducer and also has side effects linked to its non-linear pharmacokinetics, which means it is the worst enzyme-inducing AED currently in use in terms of side effects (see paragraph 6.94.2). Pfizer also noted that cenobamate is an enzyme-inducing drug which [Professor of Neurology] ‘rates highly’. [Professor of Neurology] explained that cenobamate is a new AED which may be more effective than other current third-line treatment options: PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraph 2.

¹¹⁴⁷ Pfizer submitted that phenytoin sodium’s side effects are ‘comparable to many of the drugs that are used first/second line’: PRC03488, Pfizer’s Response to the SO and DPS, paragraph 24(d). The CMA does not agree. [Professor of Neurology]’s evidence indicates that: (i) phenytoin sodium’s side effects are potentially severe and, in light of these, ‘you would not use [phenytoin sodium] if there were other options’ and (ii) phenytoin sodium is the worst AED in use currently in terms of side effects – ‘it has more side effects and is the only [enzyme-inducing AED] which has issues caused by

- 6.94.3 potential drug interactions, which make phenytoin sodium very difficult to use as a third-line treatment.¹¹⁴⁸ It is the most problematic AED currently in use in terms of adverse drug interactions.¹¹⁴⁹
- 6.95 As a result of these clinical limitations (in particular the NTI and non-linear pharmacokinetics), Capsules are subject to regulatory guidance recommending Continuity of Supply for patients stabilised on the drug.¹¹⁵⁰ This is the ultimate reason that Pfizer and Flynn were able to impose significant price increases on customers, rather than anything related to the therapeutic benefits associated with the drug.
- 6.96 Third, the vast majority of patients treated with Capsules during the Relevant Period were legacy patients¹¹⁵¹ and there were significant barriers to switching these legacy patients to alternative treatment options:
- 6.96.1 First, there were significant barriers to switching these patients to other AEDs (that are not phenytoin sodium) or withdrawing treatment.¹¹⁵²
- 6.96.2 Second, Continuity of Supply provided a significant barrier in practice to the switching of patients by pharmacists between phenytoin sodium products.¹¹⁵³
- 6.97 [Professor of Neurology]'s view is that these legacy patients would have been treated with a different AED due to the therapeutic limitations of Capsules if there were no barriers to switching, or if they were to have been first diagnosed during the Relevant Period.¹¹⁵⁴ This indicates that these patients continue to be treated with Capsules not because of their therapeutic benefits relative to other AEDs, but because of concerns around switching patients away from the drug.
- 6.98 This does not mean that Capsules have zero therapeutic benefit for patients being treated with the drug. However, this evidence shows that demand for Capsules

non-linear pharmacokinetics': PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraphs 14 and 18. This evidence is consistent with NICE guidelines which highlight the tolerability issues with phenytoin sodium: PAD00017, National Clinical Guideline Centre, Pharmacological Update of Clinical Guideline 20, *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care, methods, evidence and recommendations* (as last updated in October 2019), for example, pages 212, 220, 317, 382 and 388.

¹¹⁴⁸ PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 5.4 and see also paragraph 6.6.

¹¹⁴⁹ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 11.

¹¹⁵⁰ See section 2.A.V.

¹¹⁵¹ See section 2.A.VI.

¹¹⁵² See section 2.A.VI and PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 6.17.

¹¹⁵³ See section 2.A.V and *Phenytoin* [2018] CAT 11, paragraph 150. This is also reflected in the decision of the Swedish authority, the TLV, to approve a price increase for Pfizer (see section 2.D.II.i). The price increase was granted for the purposes of securing the commercial viability of the drug only for existing patients. Reflecting that demand is sustained through concerns around switching (rather than ongoing prescription to new patients), the TLV explicitly excluded new prescriptions from its decision to allow a price increase.

¹¹⁵⁴ PRC01816, Note of call with [Professor of Neurology] on 7 January 2021, paragraph 5. [Professor of Neurology] noted that these patients, if first treated today, would be given a current first- or second-line treatment rather than Capsules. This applies equally to the Relevant Period during which Capsules were only recommended as a third-line treatment.

during the Relevant Period was sustained predominantly by barriers to switching patients to superior treatments, not because of the therapeutic benefits of Capsules relative to other AEDs.

6.99 Fourth, the evidence put forward by Pfizer relating to the supply prices of other AEDs does not suggest that Capsules should command a significant price premium based on an assessment of therapeutic benefits.¹¹⁵⁵ Instead, the evidence demonstrates that generic competition has resulted in low prices for four of these other AEDs, irrespective of their therapeutic benefits.¹¹⁵⁶ The CMA does not consider that these AEDs are sufficiently similar to Capsules to provide a meaningful comparison for the Parties' prices for Capsules.¹¹⁵⁷ However, to the extent that the prices of these other generic AEDs might provide any indication of the economic value of patient benefit, the evidence shows that the prices of other generic AEDs which are recommended by NICE as first-line treatments for focal seizures¹¹⁵⁸ (and which continue to be prescribed to new patients due to their clinical benefits for patients)¹¹⁵⁹ are supplied at prices far below the Parties' prices during the Relevant Period.¹¹⁶⁰

6.100 Pfizer made a number of representations regarding the CMA's assessment of the patient benefit provided by Capsules. These are set out along with the CMA's response in Annex E.

VI. The commercial purpose of the arrangements and the approach of the Parties to them

6.101 In *Phenytoin* the CAT held that the commercial purpose of the arrangements and the approach of the Parties to them could be relevant factors to take account of when considering the application of the 'unfair in itself' test.¹¹⁶¹

6.102 The following further support the CMA's conclusion that the Parties' prices were unfair in themselves:

6.102.1 the commercial purpose of the arrangements was to remove Capsules from the PPRS in order to increase prices significantly, thereby generating substantial profits for Pfizer and Flynn; and

¹¹⁵⁵ See Green LJ at paragraph 172 of *Phenytoin CoA* [2020] EWCA Civ 339: 'if there is evidence of the prices being charged in relevant, comparator, markets which were effectively competitive then those prices could be capable of acting as proxy evidence of the economic value of patient benefit'.

¹¹⁵⁶ See section 6.C.III.

¹¹⁵⁷ See section 6.C.III.

¹¹⁵⁸ This is the seizure type for which Capsules are prescribed.

¹¹⁵⁹ Reflecting the NICE guidance, [Professor of Neurology] explained that, typically, lamotrigine or levetiracetam (both of which were selected as comparators by Pfizer) will be prescribed in the first instance, with around 50% of patients becoming seizure free on the first AED prescribed. See PRC01815, Note of call with [Professor of Neurology] on 26 November 2020, paragraph 9, and see also PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 4.6.

¹¹⁶⁰ See section 6.C.III.

¹¹⁶¹ *Phenytoin* [2018] CAT 11, paragraph 369.

6.102.2 a key reason for bringing Flynn into the supply chain was to provide reputational protection for Pfizer from the criticism that would arise from the impact on the NHS, showing that the Parties appreciated the adverse impact on the NHS.

a. The commercial purpose was to remove Capsules from the PPRS to increase prices significantly

6.103 As also found by the CAT,¹¹⁶² the commercial purpose of the arrangements was to remove Capsules from the PPRS in order to price them at a much higher level, thereby generating substantial profits for Pfizer and Flynn.¹¹⁶³

6.104 [Pfizer Director 1] had referred internally within Pfizer to 'an attractive commercial opportunity to increase revenues significantly due to an anomaly in the Drug Tariff'.¹¹⁶⁴ An internal Pfizer email regarding the arrangements with Flynn stated that '[t]he incremental revenue will be approximately £20M / year – and as nothing else changes significantly, this goes straight through to the bottom line'.¹¹⁶⁵

6.105 Similarly, Flynn's presentation to Pfizer in July 2010 highlighted that Tablets were 'sold at ~30x the price' of Capsules.¹¹⁶⁶ Internally, Flynn referred to the Drug Tariff price of Tablets as resulting in 'tremendous scope to increase the price of the capsules, which can only be done by [de-branding] the product'.¹¹⁶⁷

6.106 However, the Parties were fully aware that the DHSC would not approve a price increase under the PPRS based on prices benchmarked against the Drug Tariff

¹¹⁶² *Phenytoin* [2018] CAT 11, paragraph 457.

¹¹⁶³ 'Pfizer is unable to change the price of this branded product due to PPRS': Presentation slides entitled 'A Specialty Care Pharma Company': PHT00164, Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27); 'PPRS restrictions prevent Pfizer achieving a price increase for the brand without modulating the price of other products': PHT00193, Document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹¹⁶⁴ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31). This email was regarding Tor's earlier proposal for Capsules, where the key elements were the same as Flynn's proposal, ie genericising the products and implementing significant price increases. Tor proposed to increase the Drug Tariff price to £76.50 for 84 x 100mg Capsules (similar to the Drug Tariff price of Capsules from October 2012 to April 2014 of £67.50): PHT00184, Document entitled 'Epanutin/Phenytoin generic switch': Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.636). [Pfizer Director 1] later said that he and his team had been long aware that there was a disparity between the reimbursement price of Capsules and the reimbursement price of Tablets which was 'much higher': PRE00156, Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 19.

¹¹⁶⁵ PHT00350, Email of 1 December 2011 from [Pfizer Employee 2] (Pfizer) to [Pfizer Employee] (Pfizer) (CMA document reference 00141.209). See also PHT00213, Email of 7 June 2011 from [Pfizer Director 1] to [Pfizer President 2] and [Pfizer Employee 6], (CMA document reference 00141.136): '[t]here is a significant commercial upside for EPUK - approx £25m per annum in revenues, practically all of which goes straight through to IBT [income before taxes]'. See further PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 81, lines 4 to 6.

¹¹⁶⁶ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27). A briefing document prepared by Flynn for Pfizer on the proposed commercial arrangements noted that '[t]he potential increased revenues to Pfizer are approximately £26M p.a.': PHT00193, document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹¹⁶⁷ PHT00363, Email of 16 March 2010 from [Flynn Director 2] (Flynn) to [Flynn Non-executive Director 1] ([X]) re Correction – Capsules not Tablets: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.12).

price of Tablets. Indeed, [Pfizer Director 1] confirmed in his evidence before the CAT that Pfizer's finance team had advised that the DHSC 'would not entertain any exceptional price rise or reset' of Capsules on this basis.¹¹⁶⁸ Flynn was also fully aware that the DHSC would not approve a PPRS price increase on this basis: in a meeting with Flynn in July 2012, the DHSC noted the 'difficulties in agreeing to a [PPRS] launch price that was significantly higher than Epanutin'.¹¹⁶⁹ Flynn was also told in July 2012 that the PPRS pricing committee had rejected its informal proposal to re-brand Capsules within the PPRS at prices benchmarked against the Drug Tariff price of Tablets.¹¹⁷⁰

- 6.107 The Parties disregarded the DHSC's opposition to their attempts to increase the price of Capsules within the PPRS using the Drug Tariff price of Tablets as a benchmark. Flynn proceeded to de-brand Capsules, thereby removing the drug from any regulatory constraints, and the Parties imposed significant price increases for Capsules.
- 6.108 The Parties used the Drug Tariff price of Tablets as their justification for the price increases to the exclusion of all other factors (for example, any assessment of patient benefit or the level of profitability required for continuity of supply). As confirmed by [Pfizer Director 1] before the CAT, when Pfizer set its prices, 'we didn't look at the profitability' and absent the Drug Tariff price of Tablets, 'we couldn't have done this...[w]e would have had no justification'.¹¹⁷¹ In relation to the Parties' use of Tablets as their justification, as set out in Annex C, there were numerous events that should have made the Parties reconsider their approach. The CMA has found in section 6.C that the Drug Tariff price of Tablets was not a meaningful comparator for Capsules.

b. Flynn's involvement was to provide reputational protection for Pfizer

- 6.109 The Parties had anticipated significant criticism prior to imposing their price increases and a key reason for introducing Flynn into the supply chain via the Parties' commercial arrangements was to manage the reputational risk for Pfizer arising from the price increases and the adverse impact on the NHS budget.¹¹⁷²

¹¹⁶⁸ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 43, lines 14 to 23.

¹¹⁶⁹ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.9).

¹¹⁷⁰ See section 2.D.II.b.

¹¹⁷¹ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 79, line 24 to page 80, line 5.

¹¹⁷² The ability to divert reputational risk onto Flynn was one of the key elements of the arrangements highlighted by Flynn in its initial presentation to Pfizer: PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27), pages 7 and 8. See also: PHT00193, Document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65), page 4; PHT00194, Document entitled 'Flynn Pharma Epanutin Proposal October 2010 – FAQs': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.66); [Pfizer Director 1] noted that '[t]here are some potentially significant pharmaco-political and reputational consequences which would rule out Pfizer doing this on our own, rather than through a third party', PHT00213, Email of 7 June 2011 from [Pfizer Director

6.110 Reflecting an awareness that the impact on the NHS would be likely to generate criticism, in an email sent on 2 February 2010, [Pfizer Director 1] said regarding the positioning of a significant price increase that:

*We need to work out how we can position this as “no change” with patients & physicians; and at the same time “change” with [the DHSC] and payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in [a] time of funding crisis.*¹¹⁷³

6.111 The Parties' plan was for Pfizer to rely on the divestiture to Flynn, leaving Flynn (as the MA holder for Capsules) to publicly defend the price increases, shielding Pfizer from 'pharmacopolitical damage'.¹¹⁷⁴

6.112 During the Previous Investigation, Pfizer told the OFT that it involved Flynn in de-branding Capsules as it did not have the necessary regulatory expertise which Flynn had.¹¹⁷⁵ However, the evidence indicates that Flynn's expertise was not as strong as Pfizer suggested. First, Flynn itself engaged consultants, [X], to handle the regulatory process.¹¹⁷⁶ Second, in June 2012, [Pfizer Director 1] questioned Flynn's expertise in an internal Pfizer email, following a report of Flynn's discussions with the MHRA.¹¹⁷⁷

1] to [Pfizer President 2] and [Pfizer Employee 6], (CMA document reference 00141.136); Flynn told the OFT that 'Pfizer had indicated that it did not want to genericise Epanutin itself due to potential reputational damage risks': PHT00249, Final note of meeting of 16 July 2013 between the OFT and Flynn CMA document reference 00413.1), paragraph 9; and PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 61, line 18 to page 62, line 1.

¹¹⁷³ PHT00187, Internal Pfizer e-mail chain of 2 February 2010 [from [Pfizer Employee] to [Pfizer Director 1]] re Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.57). [Pfizer Director 1]'s evidence before the CAT was that, while he believed the price increases to be 'justifiable and appropriate', he raised concerns internally in anticipation of a negative response from 'ill-informed' industry critics who would likely fail to consider the full context of the arrangements: PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraphs 33 to 34 and PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 59, line 17, to page 60, line 17. Irrespective of [Pfizer Director 1]'s views on the justification for the price increases, the CMA considers that the evidence nevertheless demonstrates that he and other individuals within Pfizer were aware of the significant and adverse impact that the price increases would have on the NHS and were concerned that there would be a negative response.

¹¹⁷⁴ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27). In relation to pharmacopolitical issues, Flynn stated that 'Pfizer UK's position would be simple: Pfizer has divested the product to Flynn Pharma Ltd': PHT00193, Document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹¹⁷⁵ PHT00171, Draft note of meeting of 20 August 2013 between the OFT and Pfizer (CMA document reference 00412.1), paragraphs 22 to 23. See also PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 58.

¹¹⁷⁶ PHT00245, Email chain between [MHRA Employee] and [MHRA Employee] MHRA and others dated 15 - 21 June 2012 re Validated Type IB variation - Epanutin - Flynn Pharma - out of stock situation: MHRA's email of 20 August 2013 to the OFT providing its chronology of events concerning its interactions with Flynn with supporting documents (CMA document reference 00380.20); PHT00244, MHRA's email of 20 August 2013 to the OFT providing its chronology of events concerning its interactions with Flynn with supporting documents (CMA document reference 00380.35); and PHT00104, Note of teleconference between MHRA, Flynn Pharma and [X] held on 25 June 2012: MHRA's email of 20 August 2013 to the OFT providing its chronology of events concerning its interactions with Flynn with supporting documents (CMA document reference 00380.23).

¹¹⁷⁷ 'What is your view in how Flynn are handling this? – I thought they viewed this opportunity as a way of demonstrating their expertise to us with a view to us doing further deals with them; however I'm rapidly losing faith in them, so they have an enlarging credibility gap to close with me, and quickly': PHT00246, Internal Pfizer email chain of 22 June 2012 [from [Pfizer Employee 3] to [Pfizer Director 1] and Pfizer Employee 2] re chain discussing problems with the regulator/assessor granting the generic license due to patient safety concerns: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.359).

- 6.113 In fact, as recognised by Pfizer employees,¹¹⁷⁸ Pfizer could have de-branded *Epanutin* itself. Likewise, [Flynn Director 2] told Pfizer there were no ‘PPRS issues’ with Pfizer de-branding *Epanutin* itself but proceeding with Flynn was ‘ALL about reputation’, noting ‘would Pfizer execs want the Daily Mail camped on their doorstep[?]’¹¹⁷⁹
- 6.114 A Flynn internal document further shows that it recognised its role in shielding Pfizer from reputational risks. Flynn noted that if the arrangements between the Parties were terminated and the MA returned to Pfizer:
- Pfizer would need [...] in effect, [to] publicly acknowledge through its actions, that the original sale was an opaque arrangement to conveniently enhance their returns in the interim period. [...] The reputational risks, adverse publicity and damage to governmental relations in the UK would render a ‘return’ untenable...*¹¹⁸⁰
- 6.115 Before the CAT, [Pfizer Director 1] said he did not personally think that a strategy of diverting reputational risk on to Flynn would succeed (although that does not mean that it was not Pfizer’s aspiration).¹¹⁸¹ [Pfizer Director 1] did confirm that some of his Pfizer colleagues believed that the arrangements with Flynn would provide Pfizer with reputational protection.¹¹⁸²
- 6.116 In practice, when questioned about the price increases by the DHSC, Pfizer simply referred the DHSC to Flynn.¹¹⁸³

¹¹⁷⁸ [Pfizer Employee 1] of Pfizer said that Tor’s ‘proposal is that we do it via Tor to distance ourselves from the price increase. Clearly, we do not need Tor to do this and could just try to go down this route ourselves’: PHT00183, Internal Pfizer email chain of 23 July 2009 [from [Pfizer Employee 1] to [Pfizer Employee 2] and [Pfizer Employee]] re Tor Generics Proposed Project: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00141.21); and PHT00198, Internal Pfizer e-mail [from [Pfizer Employee 3] to [Pfizer Director 1] and [Pfizer Employee 2]] of 17 June 2011 re Flynn and the possible advantages of going with Flynn re divestment: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00141.137).

¹¹⁷⁹ PHT00198, Internal Pfizer e-mail [from [Pfizer Employee 3] to [Pfizer Director 1] and [Pfizer Employee 2]] of 17 June 2011 re Flynn and the possible advantages of going with Flynn re divestment: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00141.137).

¹¹⁸⁰ PHT00401, Flynn, *Phenytoin* (2) (CMA document reference 00145.827). Flynn submitted that this document reflects the fact that the success of the product was not inevitable and the possibility that Flynn might have to cease the relationship with Pfizer depending upon the price that could be achieved, and that risks that Flynn faced included potential competition: PRC03903, Flynn’s Response to the Letter of Facts, paragraph 3.18. As to termination of the agreement, whilst this Flynn internal document identifies that ‘Pfizer were seeking a get out if Flynn’s plan was not sustainable’, the document also contains Flynn’s view that, in practice, a return of the MA to Pfizer would be ‘untenable’ for Pfizer and ‘there is no going back’. As to the commercial risks that Flynn faced, the CMA finds that these were limited (see paragraph 6.86 and Annex E). As to the risks of potential competition, the main potential constraint foreseen by the Parties was from parallel imports which they did not anticipate would be sufficient to restrict their ability to sustain very high prices relative to costs: PHT00164, Presentation slides entitled ‘A Specialty Care Pharma Company’: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27).

¹¹⁸¹ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 62, line 18 to page 63, line 16.

¹¹⁸² PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 62, line 18 to page 63, line 9.

¹¹⁸³ ‘Since Pfizer no longer holds the UK marketing authorisation it would not be appropriate for us to comment on Flynn Pharma’s marketed product nor it’s [sic] pricing strategy’: PHT00060, Email of 27 February 2013 between Department of Health Staff [[DHSC Employee 5], [DHSC Employee 1], [DHSC Employee 3] and [DHSC Employee 8] (DH)] forwarding on redacted email from Pfizer - re Outstanding actions from the Meeting with DH on 10 January 2013: Enclosed with Department of Health’s response of 15 August 2013 to the OFT’s s.26 Notice information request of 26 June 2013 (CMA document reference 00367.22).

6.117 The Parties' appreciation of the likely criticism of the price increases shows that they appreciated the repercussions they would cause for the NHS, as well as the absence of any justification based on benefits to patients or the NHS.

VII. The Parties' prices had a significant and adverse effect on the end customer

6.118 The significant and adverse effect that the Parties' prices had on the end customer and on patient welfare further supports the CMA's conclusion that the Parties' prices were unfair in themselves.

6.119 As described in section 4 (legal framework) above, 'the primary interest to be protected under the Chapter II prohibition is that of the consumer'.¹¹⁸⁴ It is, therefore, relevant to look beyond the immediate customer and take the interests of end customers, as well as consumers, into account when assessing whether a price is unfair.¹¹⁸⁵

6.120 The end customer in this case is the NHS, in the form of CCGs and equivalent purchasers in Scotland, Wales and Northern Ireland which pay for Capsules.

6.121 The NHS budget is finite and legitimate demands for healthcare will always exceed available funding. Accordingly, the NHS's funds need to be prioritised. In the period 2010 to 2015, NHS efficiency policy tasked the NHS with making £20 billion of efficiency savings in order to make more funds available to treat patients.¹¹⁸⁶ Budgetary constraints and efficiency savings continued to pose a challenge to the NHS, with a funding gap of £30 billion needing to be covered in the period 2015/16 to 2020/21.¹¹⁸⁷

6.122 Similarly, CCG budgets are tightly managed: there is a significant amount of expenditure that is unavoidable; demand for discretionary spending far outpaces the funds available; and CCGs have legal responsibilities to balance their budgets.¹¹⁸⁸

6.123 CCGs exercise no direct control over the prescribing process.¹¹⁸⁹ Once the prescriber takes the decision to prescribe a drug, CCGs have no option but to fund the product dispensed, which in this case is an essential treatment.¹¹⁹⁰ Therefore it is not possible to infer from the fact that CCGs paid for Capsules after September

¹¹⁸⁴ *Albion Water II* [2008] CAT 31, paragraphs 218 and 271. See also *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 215.

¹¹⁸⁵ Pfizer submitted that the fact that the price increases led to increased costs within the NHS budget does not lead to the result that Pfizer's Prices were unfair in themselves: PRC03488, Pfizer's response to the SO and DPS, paragraph 39(g). However, the CAT found that the impact on the end customer could be a relevant factor for an assessment of unfair in itself in both *Phenytoin* [2018] CAT 11 at paragraphs 369 and 404, and *Albion Water II* [2008] CAT 31 at paragraph 271. The CMA considers that the significant and adverse impact that the Parties' prices had on the end customer and on patient welfare supports its conclusion that the Parties' prices were unfair in themselves.

¹¹⁸⁶ See section 2.C.I.c.

¹¹⁸⁷ PAD00025, NHS England, *NHS Five Year Forward View: Recap briefing for the Health Select Committee on technical modelling and scenarios*, page 4.

¹¹⁸⁸ PRE00001, First Witness Statement of [REDACTED], 10 January 2017, paragraph 26.

¹¹⁸⁹ PRE00001, First Witness Statement of [REDACTED], 10 January 2017, paragraph 23.

¹¹⁹⁰ See section 2.C.I.c.

2012 that they were willing to pay the prices imposed or that this reflected any economic value over and above Cost Plus.¹¹⁹¹

6.124 Furthermore, CCGs do not derive any economic benefit from onward sale of the product to downstream customers.¹¹⁹² In contrast to the situation in *Scandlines* and *Attheraces*, CCGs do not (indeed cannot) derive any downstream revenues from the onward supply of the product or service. Instead, CCGs have had to find the additional funds required to pay the Parties' prices from within their already constrained budgets.

6.125 As a result of the Parties' price rises, the NHS's annual spend on phenytoin sodium capsules increased from £2.3 million prior to September 2012 to approximately £50 million in 2013, an increase of 2,073%. This was at a time when the NHS budget was increasing by only around 1.5% a year.¹¹⁹³

6.126 Table 6.6 below sets out the NHS's annual spend on phenytoin sodium capsules during the Relevant Period and immediately before.¹¹⁹⁴

Table 6.6: NHS annual spend on phenytoin sodium capsules

	Prior to September 2012 (£m)	2013 (£m)	2014 (£m)	2015 (£m)	2016 (£m)
NHS annual spend on phenytoin sodium capsules*	2.3	50	42	37	35

* The NHS's annual spend on phenytoin sodium capsules has been calculated using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices for phenytoin sodium capsules that were in effect at the time.

6.127 The Parties' price increases forced the NHS to spend an additional £169 million¹¹⁹⁵ on Capsules during the Relevant Period.

6.128 The increased cost to certain CCGs is summarised in Table 6.7 below.

¹¹⁹¹ Opinion of Advocate General Wahl in *Latvian Copyright*, paragraph 63.

¹¹⁹² Opinion of Advocate General Wahl in *Latvian Copyright*, paragraph 63.

¹¹⁹³ See section 2.D.II.g.

¹¹⁹⁴ Of the NHS annual expenditure on phenytoin sodium capsules in Table 6.6, Pfizer accounted for £25.2 million of the 2013 figure, £13.3 million of the 2014 figure, £12 million of the 2015 figure and £12.5 million of the 2016 figure. Flynn accounted for £8.6 million of the 2013 figure, £11.1 million of the 2014 figure, £9.1 million of the 2015 figure, and £7.2 million of the 2016 figure. Pfizer's and Flynn's revenues from Capsules have been calculated using data provided by Pfizer and Flynn. Flynn's revenue is net of Pfizer's revenue to avoid double counting.

¹¹⁹⁵ The CMA has calculated the NHS's annual spend on Capsules using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices. The CMA has calculated the NHS spend on Capsules over the Relevant Period at pre-2012 Drug Tariff prices and also at post-2012 Drug Tariff prices (taking into account the reduction of the Drug Tariff price in 2014) to calculate the additional spend as a result of the price increases.

Table 6.7: CCG annual expenditure on phenytoin sodium capsules

CCG	Pre-2012 expenses (£)	Post-2012 expenses (£)
Gloucestershire CCG	24,000	400,000
Coastal West Sussex CCG	20,000	320,000
Somerset CCG	20,000	440,000
GMMMG (12 CCGs in the Greater Manchester area)	48,000	2,000,000

Source: PRE00004, First Witness Statement of [X], 10 January 2017, PRE00002, First Witness Statement of [X], 10 January 2017, PRE00003, First Witness Statement of [X], 10 January 2017, and PRE00001, First Witness Statement of [X], 10 January 2017.

6.129 There is clear harm arising to the NHS from the scale of the Parties' price increases.¹¹⁹⁶ The direct consequence was that CCGs had to commit extra money from their constrained budgets to continue to fund the supply of Capsules, with no associated benefit. The redirection of these funds inevitably impacted CCGs' ability to fund other patient services, to the general detriment of patient care.¹¹⁹⁷

6.130 [X] of the GMMMG in a witness statement to the Tribunal explained the adverse impact of the Parties' price increases as follows:

Like all unforeseen cost increases, this will have impacted on the range of services the [Greater Manchester] CCGs could provide to patients and money which was earmarked for different treatments would have been diverted to cover the additional costs for [Capsules]. Other patients will have had their treatments delayed, stopped or changed as a result.

*This also created a substantial burden; the work that had to be done by GP practices and [PCTs'] [...] staff and clinicians to address this new cost distracted from and reduced the opportunities arising from other programmes being undertaken.*¹¹⁹⁸

6.131 Similarly, [X] of Somerset CCG explained the impact as follows:

The approximate additional £1.2 million spent on phenytoin capsules over the period from September 2012 to date has meant that Somerset CCG has been unable to spend that money on commissioning other elements of patient care and at a time of growing demand on the NHS, the additional

¹¹⁹⁶ Pfizer submitted that it rejects the suggestion that the price increases had an adverse effect on patient welfare and there is no suggestion that patients were removed from phenytoin sodium following the price increases: PRC03488, Pfizer's Response to the SO and DPS, paragraph 39(g). However, as set out at paragraph 6.129 above, the CMA finds that the harm to patients from the Parties' price increases did not arise from switching patients from phenytoin sodium to other treatments, but rather from the redirection of funds impacting CCGs' ability to fund other patient services.

¹¹⁹⁷ PRE00004, First Witness Statement of [X], 10 January 2017, paragraphs 11 and 13; PRE00002, First Witness Statement of [X], 10 January 2017, paragraph 11; PRE00003, First Witness Statement of [X], 10 January 2017, paragraph 16; and PRE00001, First Witness Statement of [X], 10 January 2017, paragraph 34.

¹¹⁹⁸ PRE00004, First Witness Statement of [X], 10 January 2017, paragraphs 11 and 12.

*cost has contributed to the Somerset CCG now having a forecast deficit on its budget, which places additional pressures on the CCG and healthcare staff within Somerset.*¹¹⁹⁹

- 6.132 As set out further at Annex B, contemporaneous complaints from CCGs and clinicians demonstrate strong concerns regarding the harm to the NHS and patients resulting from the scale of the Parties' price increases.
- 6.133 This impact on end customers had been anticipated by the Parties. Internal documents relating to Tor's similar proposal to increase significantly the prices of Capsules show Pfizer employees raising ethical concerns about the impact it would have on the NHS.¹²⁰⁰ Similarly, shortly after Flynn's very high prices were imposed, Flynn's [X] told directors of Flynn that 'I still have reservations about the price level agreed with DH. I am not prepared to get into discussion and debate with customers about this.'¹²⁰¹ Flynn's [X] expressed these concerns *notwithstanding* that he was mistakenly under the impression that Flynn's Prices had been agreed with the DHSC.¹²⁰² In fact, as set out in Annex C, the DHSC had made clear its strong concerns regarding Flynn's Prices.

VIII. Conclusion

- 6.134 In light of the matters set out above, the CMA concludes that Pfizer's Prices and Flynn's Prices were unfair in themselves.

C. Unfair when compared

I. Introduction

- 6.135 The Unfair Limb is an alternative rather than a cumulative test.¹²⁰³ Accordingly, it is sufficient to demonstrate that one of the unfairness alternatives ('unfair in itself' or 'unfair when compared to competing products') is satisfied to establish an infringement.

¹¹⁹⁹ PRE00003, First Witness Statement of [X], 10 January 2017, paragraph 16.

¹²⁰⁰ [Pfizer Director 1] said that '[t]his could generate significant upside, but whilst legal, would increase the price of phenytoin capsules to the NHS significantly. How does that fit with [our] Trust initiative?': PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31); [Pfizer Employee 2] of Pfizer said that an ethical concern 'needs careful onward consideration': PHT00214, Email from [Pfizer Director 1] to [Pfizer Employee 2], [Pfizer Employee 3] and [Pfizer Employee] copying [Pfizer Employee] (document 00141.23); and see also PHT00183, Internal Pfizer email chain of 23 July 2009 [from [Pfizer Employee 1] to [Pfizer Employee 2] and [Pfizer Employee]] re Tor Generics Proposed Project: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.21).

¹²⁰¹ PHT00379, Email of 12 October 2012 from [Flynn Employee 1] (Flynn) to [Flynn Director 2] (Flynn), (CMA document reference 00145.477). Reservations 'about the price level', in the context of receiving a complaint from a customer regarding Flynn's Prices, demonstrates concerns were raised within Flynn about the level of its prices.

¹²⁰² The author of this email did not attend the meetings between Flynn and the DHSC in July or November 2012.

¹²⁰³ C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255; and *Phenytoin CoA*, paragraph 259.

- 6.136 Based on the assessment set out in section 6.B above, the CMA has concluded that the Parties' prices during the Relevant Period were unfair in themselves. The CMA is not required to demonstrate that the Parties' prices during the Relevant Period were also unfair when compared to competing products.
- 6.137 However, the CMA has fairly evaluated relevant evidence put forward by the Parties in their defence, including any *prima facie* valid comparators.¹²⁰⁴ The Parties have advanced the following as being meaningful comparators for the purposes of assessing the fairness of their prices for Capsules during the Relevant Period:
- 6.137.1 Tablets; and
- 6.137.2 Certain other AEDS.
- 6.138 The CMA has considered whether the evidence relating to these comparators undermines the CMA's conclusion that the Parties' prices were unfair in themselves during the Relevant Period.¹²⁰⁵
- 6.139 As described in section 4 (Legal Framework), for the purposes of determining whether a price is unfair when compared to competing products, a comparator does not need to be identical¹²⁰⁶ or in the same relevant market,¹²⁰⁷ but it does need to be sufficiently similar to the product concerned to allow for a 'meaningful' comparison based on objective, verifiable and appropriate criteria.¹²⁰⁸ This means that a comparison of the prices must be made on a consistent basis and it must be ensured that the figures are really comparable.¹²⁰⁹
- 6.140 Reflecting the view of the Court of Appeal that, '[i]n broad terms a price will be unfair when the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of "normal and sufficiently effective competition"',¹²¹⁰ the competitiveness of the market from which a comparator is taken is an important and relevant factor.¹²¹¹ Prices that are not set in conditions of effective competition are highly unlikely to be meaningful comparators. A comparator cannot be considered meaningful and reflective of economic value simply on the basis that the customer has accepted and is paying the price.¹²¹²

¹²⁰⁴ *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(viii) and 260.

¹²⁰⁵ See *Phenytoin* [2018] CAT 11, paragraph 367.

¹²⁰⁶ C-372-19 *SABAM v Weareone.World, Wecandance*, EU:C:2020:959, paragraph 32 and *Albion Water II* [2008] CAT 31, paragraph 252.

¹²⁰⁷ C-372-19 *SABAM v Weareone.World, Wecandance*, EU:C:2020:959, paragraph 32 and *Phenytoin* [2018] CAT 11, paragraph 373.

¹²⁰⁸ *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 41, 44-46 and 51. See also *Phenytoin* [2018] CAT 11, paragraphs 392 and 444.

¹²⁰⁹ See for example *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 44-46 and 51; *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin* [2018] CAT 11, paragraph 373.

¹²¹⁰ *Phenytoin CoA*, paragraph 97(i); and *United Brands*, EU:C:1978:22, paragraph 249. See also *Phenytoin CoA*, paragraph 249.

¹²¹¹ For further support for this point, see also *Scandlines*, paragraphs 172 and 173; *Phenytoin* [2018] CAT 11, paragraph 390; *Phenytoin CoA*, paragraphs 155 and 172; and *Aspen*, paragraph 199.

¹²¹² See for example *Albion Water I* [2006] CAT 23, paragraphs 754 to 756.

Comparisons should also not be drawn with products the price of which may have been inflated by the exercise of significant market power.¹²¹³

- 6.141 Based on the totality of the evidence examined, the CMA has concluded that the comparator evidence does not undermine the CMA's conclusion that Pfizer's and Flynn's prices during the Relevant Period were unfair in themselves.
- 6.142 The remainder of this section contains the CMA's assessment of the evidence relevant to the two comparators advanced by the Parties: Part A addresses Tablets and Part B addresses other AEDs.

II. Phenytoin Sodium Tablets

a. Introduction

- 6.143 Prior to the exclusive supply arrangements entered into between the Parties and the subsequent de-branding of Capsules and the significant price increases, there was a large difference between the reimbursement price paid by the NHS for Capsules and the reimbursement price paid by the NHS for Tablets. The reimbursement price for 84 x 100mg Capsules was £2.83. The reimbursement price for 28 x 100mg Tablets was £30.
- 6.144 The Parties identified this sizeable difference and the potential to significantly increase revenues by de-branding Capsules and increasing the price closer to the reimbursement price for Tablets. Pfizer's internal documents refer to the 'attractive commercial opportunity to increase revenues significantly due to an anomaly in the Drug Tariff'.¹²¹⁴ Flynn's [REDACTED] [Flynn Director 2] explained to another shareholder that, as a result of the price of Tablets being 'approx 10x the price of the capsules' 'there is tremendous scope to increase the price of the capsules, which can only be done by [de-branding] the product'.¹²¹⁵
- 6.145 Subsequently, without any increase in the underlying costs of production or any additional investment, innovation or improvement in the drug, its production or distribution, the Parties significantly increased their prices using the higher Drug Tariff price of Tablets as their justification for doing so.¹²¹⁶

¹²¹³ This is consistent with the CAT's findings in *Albion Water I* [2006] CAT 23, paragraph 757 and *Albion Water II* [2008] CAT 31, paragraph 257. See also *Phenytoin CoA*, paragraphs 154 and 155. This is also consistent with the submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, paragraphs 49 and 50.

¹²¹⁴ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to Pfizer Employee 2] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31).

¹²¹⁵ PHT00363, Email from [Flynn Director 2] (Flynn) to [Flynn Non-executive Director 1] dated 16 March 2010, Subject: 'Correction – capsules not tablets' (CMA document reference 00145.12).

¹²¹⁶ In evidence previously provided to the CAT, [Pfizer Director 1] set out that Pfizer 'didn't look at the profitability. We had – we were looking at price, and the reason why this project was able to even be considered was because we had an established benchmark price in the market for the same medicine. If that price benchmark hadn't been there, we couldn't have done this. We would have had no justification'. See PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 79, line 24 to page 80, line 5.

- 6.146 Packs of 100mg Capsules contain 84 Capsules. For the purposes of comparing the £30 Drug Tariff price of 28 x 100mg Tablets to 84 x 100mg Capsules (as sold by the Parties), the CMA has multiplied £30 by three (to an effective Drug Tariff price of £90 for 84 x 100mg Tablets). This was also the approach adopted by the Parties in practice for the purposes of benchmarking against the Tablets Drug Tariff price.
- 6.147 The Parties argue that the £30 Drug Tariff price for a pack of 28 x 100mg Tablets reflected the value of Tablets to the DHSC and was what the DHSC was willing to pay. The Parties' view is that this makes £30 an appropriate benchmark for their own prices for Capsules. The Parties argue that their prices, which were set below £30 (or the equivalent of £90 for 84 x 100mg Capsules) were, therefore, fair by comparison.¹²¹⁷
- 6.148 Notably, in respect of Flynn, notwithstanding its primary case that the economic value of Capsules was £30, Flynn has at the same time conceded that it priced above this level for its 50mg and 25mg Capsules: for the 50mg strength, Flynn priced 'very slightly (6.53%) above the tablet price'; and for the 25mg strength, 'if pro-rated to strength this translates to a price 110% above the tablet price'.¹²¹⁸

b. The CMA's investigation on Remittal

- 6.149 The CMA has gathered and evaluated additional evidence for the purposes of assessing Tablets as a potential comparator. In doing so, the CMA has considered prices at two different levels of the supply chain:
- 6.149.1 The £30 Drug Tariff price: this was not a like-for-like comparison for either of the Parties' prices. The Drug Tariff price is the downstream price paid by CCGs (ie, the NHS) to pharmacists for dispensing a drug.
- 6.149.2 Supplier ASPs: these are the market prices actually charged by suppliers of Tablets to direct customers (ie wholesalers and pharmacies) at the comparable level of the supply chain to Flynn (but still downstream from Pfizer's level of the supply chain).
- 6.150 The CMA has sought to determine whether either of these prices was a meaningful comparator for the purposes of assessing the fairness of the Parties' prices for Capsules during the Relevant Period.
- 6.151 The remainder of this section sets out:
- 6.151.1 an overview of the relevant factual background to the CMA's assessment of Tablets;

¹²¹⁷ PRC03492, Flynn's response to the SO, paragraph 1.17 and PRC03488, Pfizer's response to the SO and DPS, paragraph 12.

¹²¹⁸ PRE00709, Flynn's Skeleton Argument, paragraph 218 and footnote 310 (emphasis added).

6.151.2 the CMA's assessment of the £30 Drug Tariff price of Tablets as a potential comparator; and

6.151.3 the CMA's assessment of the ASPs of Tablets suppliers as a potential comparator.

c. Relevant Factual Background to Tablets

6.152 This part describes the factual background relevant to the CMA's assessment of Tablets as a potential comparator, including:

6.152.1 product characteristics and usage of Tablets;

6.152.2 the regulatory regime for Tablets;

6.152.3 the evolution of the Drug Tariff price of Tablets; and

6.152.4 market entry and upstream supply prices of Tablets.

i. Product Characteristics and Usage

6.153 Tablets and Capsules have the same active ingredient and are both prescribed to patients with epilepsy in the UK for the purposes of controlling focal seizures.

6.154 During the Relevant Period, both Tablets and Capsules were in the third stage of the drug life cycle. Owing to the product characteristics of phenytoin sodium common to Tablets and Capsules, Tablets are (and were during the Relevant Period) a third-line AED which are very rarely prescribed to new patients. As a result, the number of patients taking Tablets is also declining – the CMA has calculated that there were approximately 6,000 patients taking Tablets in 2019 compared to 10,000 in 2012.¹²¹⁹

6.155 During the Relevant Period, Tablets were subject to the same clinical guidance as Capsules which recommended that patients were not switched between different manufacturers' products. In *Phenytoin*, in relation to Capsules, the CAT found that this guidance 'as a matter of fact, inhibited (even if it did not always preclude) switching and, to an extent, locked in patients to the existing supplier'.¹²²⁰

6.156 However, there were also differences between Capsules and Tablets during the Relevant Period.

6.157 First, there was a significant difference between the prescribed volumes of Capsules and Tablets during the Relevant Period. Tablets were prescribed to a

¹²¹⁹ Based on PCA data, the total volume of Tablets dispensed in 2012 and 2019 in DDD terms was 3,577,403 and 2,140,697 respectively. Dividing these figures by 365 days gives an estimate of 9,801 patients in 2012 and 5,865 patients in 2019. See PAD00082, PAD00083, PAD00098, PAD00113, PAD00121, PAD00088, PAD00089, PAD00104, PAD00119, and PAD00123.

¹²²⁰ *Phenytoin*, CAT [11] 2018, paragraph 196.

substantially smaller set of patients in the UK than Capsules. Between 2012 and 2016, the NHS dispensed approximately four times the number of 100mg Capsules (196 million) as 100mg Tablets. The total cost to the NHS of 100mg Tablets over the Relevant Period was approximately £41.1 million.¹²²¹ Over the same period, following the Parties' price increases, the NHS spent approximately £177.5 million on Capsules.¹²²²

- 6.158 Second, as described above, during the Relevant Period, Capsules were sold at strengths of 25mg (28 Capsules), 50mg (28 Capsules), 100mg (84 Capsules) and 300mg (28 Capsules). However, Tablets were only sold at a dosage strength of 100mg in packs of 28 Tablets for the duration of the Relevant Period.

ii. The Regulatory Regime

- 6.159 The NHS was responsible for funding the supply of both Capsules and Tablets to epilepsy patients in the UK during the Relevant Period.

- 6.160 Since April 2005, Tablets have been in category M of the Drug Tariff.

- 6.161 During the Relevant Period, category M reimbursement prices were set on a quarterly basis using volume-weighted ASPs based on retrospective sales and volume data supplied to the DHSC by manufacturers and suppliers who were members of scheme M. Further details relating to scheme M are set out in section 2 (Factual Background).

- 6.162 The margin earned by pharmacies on category M drugs was the principal mechanism used by the DHSC to ensure that the £800 million funding target, agreed under the community pharmacy contractual framework, was delivered to pharmacies. For this reason, as explained by the PSNC in its published guidance, the DHSC often sets category M reimbursement prices at levels substantially above the upstream supply prices.¹²²³

- 6.163 The DHSC did not use scheme M to regulate the supply prices of generic drugs. The DHSC's policy across all generic products was to rely on competition to determine prices.¹²²⁴ Scheme M accordingly allowed its members to alter the price

¹²²¹ Between 2012 and 2015 the prevailing Drug Tariff price of £30 per pack has been used. For 2016, a weighted average has been calculated based on the Drug Tariff being between £24.50 and £30.

¹²²² For 100mg capsules: for 2012, a weighted average has been calculated using the Drug Tariff prices of 66p and £67.50; for 2013, the prevailing Drug Tariff price of £67.50 per pack has been used; for 2014, a weighted average has been calculated using the Drug Tariff prices of £54 and £67.50; and between 2015 and 2016, the prevailing Drug Tariff price of £54 per pack has been used. The same methodology has been used for the other strengths.

¹²²³ PAD00020, PSNC, *Retained margin (category M)*. The [Former Teva Director] also described the reimbursement prices for category M drugs as being 'significantly higher' than suppliers' selling prices, with at one stage category M Drug Tariff prices being 'two or three times higher than the prices that were being provided by generics companies', PAD00030, [Former Teva Director] Cross Examination, day 5, page 15, lines 9-13. A report by Oxera found that the retained margin uplift to category M Drug Tariff prices is on average in the region of 100%: PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 2.27.

¹²²⁴ PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), pages 3 to 4, paragraph 13.

at which a medicine was sold without any requirement to discuss such changes with the DHSC in advance.¹²²⁵

iii. The evolution of the Drug Tariff price of Tablets

6.164 In *Phenytoin*, the CAT's view was that, as part of any subsequent investigation, the CMA should develop 'a better understanding of the evolution of the tablet market and tablet pricing'.¹²²⁶ The CAT found that 'the price behaviour of tablets over time seems to us to be more relevant than the 2007 price for comparison purposes'.¹²²⁷

6.165 For these purposes, the CMA has gathered and considered evidence relating to:

6.165.1 the significant price increases imposed by Teva between March 2005 and October 2007;

6.165.2 the meeting between the DHSC and Teva in October 2007; and

6.165.3 the Drug Tariff price since October 2007.

6.166 This evidence is described below.

The significant price increases imposed by Teva between March 2005 and October 2007

6.167 During this period, price increases imposed by Teva as the monopoly supplier of Tablets drove the Drug Tariff price upwards from £3.87 in April 2005 to £113.62 in October 2007.¹²²⁸

6.168 Before the introduction of scheme M, the Drug Tariff price for a pack of 28 x 100mg Tablets rose gradually from £0.20 in 1991 to £1.70 in March 2005.¹²²⁹

6.169 Scheme M was introduced in April 2005. The Drug Tariff price at the beginning of scheme M increased to £3.87. Under scheme M, suppliers were free to set their prices without any restrictions.

6.170 Following the introduction of scheme M, because Teva was the sole supplier of Tablets, the Drug Tariff price of Tablets was determined exclusively by Teva's supply prices. Teva's adopted strategy at this time was 'to set [its] prices by reference to the reimbursement price'.¹²³⁰ An increase in Teva's supply price therefore led to a consequential increase in the Drug Tariff price for the next

¹²²⁵ See further section 2 (Factual Background).

¹²²⁶ *Phenytoin* [2018] CAT 11, paragraphs 7 and 467.

¹²²⁷ *Phenytoin* [2018] CAT 11, paragraph 380.

¹²²⁸ PHT00040, Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.2), pages 14 to 15.

¹²²⁹ PHT00040, Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.2), pages 14 to 15.

¹²³⁰ PHT00222, Teva UK's response of 4 June 2013 to the OFT's s.26 Notice information request of 8 May 2013 (CMA document reference 00100.1), page 2.

quarter.¹²³¹ Teva's price increases had the effect of pushing up the Drug Tariff price, which it then followed with further increases in its own prices. [Former Teva Director] ([REDACTED]) confirmed that, during this period, Teva continued to 'nudge' its selling price upwards by reference to the Drug Tariff price.¹²³²

- 6.171 By October 2007, Teva had increased its ASPs to over £50.¹²³³ This process resulted in a very significant increase in the Drug Tariff price of Tablets. The Drug Tariff price rose from £3.87 in April 2005 to £113.62 in October 2007 (an increase of 2,836%).¹²³⁴

The meeting between the DHSC and Teva in October 2007

- 6.172 According to the DHSC, Teva and its senior managers received a lot of criticism about the price of Tablets at the time.¹²³⁵ On 16 October 2007, the DHSC and Teva met to discuss concerns the DHSC had raised regarding Teva's price increases.
- 6.173 For the purposes of bringing down the cost of Tablets to the NHS, at the meeting, it was agreed that there would be a phased reduction in the Drug Tariff price of Tablets to £40 from 1 January 2008, to £35 from 1 April 2008 and to £30 from 1 July 2008.
- 6.174 The meeting between the DHSC and Teva was attended by [Former Teva Director] and [Teva Employee 1] ([REDACTED]).¹²³⁶ The two DHSC officials in attendance at the meeting were [DHSC Employee 1] and [DHSC Employee 2]. Both DHSC attendees have since retired.¹²³⁷
- 6.175 Neither the DHSC nor Teva have a note of the meeting.¹²³⁸ The CMA's understanding of the discussion between the DHSC and Teva has been informed by the following:

6.175.1 contemporaneous email correspondence between the DHSC and Teva from 17 and 18 October 2007;¹²³⁹

¹²³¹ *Phenytoin* [2018] CAT 11, paragraph 211.

¹²³² *Phenytoin* [2018] CAT 11, paragraph 211.

¹²³³ PHT00222, Teva UK's response of 4 June 2013 to the OFT's s.26 Notice information request of 8 May 2013 (CMA document reference 00100.1), page 3.

¹²³⁴ PHT00040, Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.2), pages 14 to 15.

¹²³⁵ PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), page 7, paragraph 36.

¹²³⁶ PAD00030, [Former Teva Director] Cross Examination, day 5, page 17, lines 12-21; and PRC00458, emails between [DHSC Employee 1] (DHSC) and [Former Teva Director] (Teva) dated 17 October 2007 and 18 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020.

¹²³⁷ PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice dated 22 December 2020, question 4(g).

¹²³⁸ PRC01234, Email from [DHSC Employee 1] to DHSC colleagues on 24 July 2013 (DHSC009.795) and Teva's response dated 4 September 2020 to the CMA's s.26 Notice dated 31 July 2020.

¹²³⁹ PRC00458, emails between [DHSC Employee 1] (DHSC) and [Former Teva Director] (Teva) dated 17 October 2007 and 18 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020.

6.175.2 Teva's internal documents reporting on the outcome of the meeting from November 2007 and January 2008;¹²⁴⁰

6.175.3 an internal DHSC email from July 2013 in which one of the DHSC attendees sets out his recollection of the events leading to the meeting with Teva;¹²⁴¹

6.175.4 witness evidence provided by one of the attendees, [Former Teva Director], who was Flynn's factual witness during the appeal to the CAT in 2017;¹²⁴² and

6.175.5 responses by the DHSC to the CMA's information requests.

6.176 Aspects of this evidence are summarised in Annex M.

The Drug Tariff price since October 2007

6.177 Following the meeting between Teva and the DHSC on 16 October 2007, the DHSC reduced the Drug Tariff price of Tablets in line with the discussion with Teva. The Drug Tariff price reduced to £40 from 1 January 2008, to £35 from 1 April 2008 and to £30 from 1 October 2008.¹²⁴³

6.178 Teva's supply price decreased from an ASP of £51.25 per pack in October 2007¹²⁴⁴ to a list price of £29.50 per pack in October 2008.¹²⁴⁵

6.179 Following the meeting between Teva and the DHSC, Tablets were removed from the quarterly adjustment mechanism which determined the Drug Tariff price for category M drugs. The Drug Tariff price instead remained at £30 without the potential for quarterly revisions between October 2008 and April 2016.¹²⁴⁶

6.180 There is no evidence that the DHSC and Teva discussed the period of time for which the Drug Tariff price would remain fixed at £30 – although the emails sent by the DHSC to Teva immediately after the meeting in October 2007 refer to the DHSC's anticipation of 'further reductions thereafter'.¹²⁴⁷ The DHSC has also not

¹²⁴⁰ PRC00461, Internal briefing note Phenytoin Sodium 100mg, 27 November 2007: Teva's response of 4 November 2020 to the CMA's s.26 Notice dated 31 July 2020. See also PRC00461, Internal briefing note Phenytoin Sodium 100mg, 27 November 2007: Teva's response of 4 November 2020 to the CMA's s.26 Notice dated 31 July 2020.

¹²⁴¹ PRC01233, Email from [DHSC Employee 1] (DHSC) to DHSC colleagues dated 16 July 2013 (DHSC009.253), DHSC response of 22 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹²⁴² PRE00625, First Witness Statement of [Former Teva Director], 6 February 2017. See also PAD00030, [Former Teva Director] Cross Examination, day 5.

¹²⁴³ This is reflected in the email exchange between the DHSC and Teva immediately following the meeting. See PRC00458, emails between [DHSC Employee 1] (DHSC) and [Former Teva Director] (Teva) dated 17 October 2007 and 18 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020.

¹²⁴⁴ PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1.

¹²⁴⁵ PHT00222, Teva UK's response of 4 June 2013 to the OFT's s.26 Notice information request of 8 May 2013 (CMA document reference 00100.1).

¹²⁴⁶ PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice dated 22 December 2020, questions 6 to 8.

¹²⁴⁷ PRC00458, emails between [DHSC Employee 1] (DHSC) and [Former Teva Director] (Teva) dated 17 October 2007 and 18 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020.

been able to identify internally any information regarding '[redacted]'.¹²⁴⁸ Whilst the DHSC staff who attended the meeting in 2007 have retired, the DHSC provided its view that 'we assume the intention was for the reimbursement price of phenytoin sodium to drop below £30 in line with average market prices'.¹²⁴⁹

6.181 The DHSC has also explained that '[redacted]'.¹²⁵⁰

6.182 For category M products, the ordinary consequence of reducing supply prices for scheme M members would be a downward adjustment to the Drug Tariff price (which would be calculated based on the pricing data being submitted by scheme M members to the DHSC).¹²⁵¹ As described further below, upstream prices (at the equivalent level of the supply chain to Flynn) were significantly below £30 during the Relevant Period. However, following the meeting between the DHSC and Teva, the Drug Tariff price of Tablets was no longer subject to quarterly adjustments under scheme M. As a result, the Drug Tariff price remained at £30 even once supply prices began to fall.

6.183 The DHSC has explained that the difference between the £30 reimbursement price it was paying to pharmacies for Tablets and the lower upstream supply prices (ie the profit being made by pharmacies) contributed to delivering the profit margin agreed as part of the community pharmacy contractual framework.¹²⁵² However, the fact that the Drug Tariff price remained at £30 for as long as it did was described by the DHSC as an 'oversight'. The DHSC has explained that:

[redacted].¹²⁵³

6.184 The DHSC has explained that '[redacted]'.¹²⁵⁴ In response, having calculated what the Drug Tariff price of Tablets would have been had Tablets been in the usual category M calculation process, the DHSC gradually reduced the Drug Tariff price over a series of quarters from April 2016, before placing Tablets back into the usual price setting process for category M Drug Tariff prices from April 2017.¹²⁵⁵

¹²⁴⁸ PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice dated 22 December 2020, questions 6(b), 7(a) and 7(b).

¹²⁴⁹ PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice dated 22 December 2020, question 4(a)(i).

¹²⁵⁰ The DHSC told the CMA that '[redacted]'. See PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice dated 22 December 2020, question 6(a).

¹²⁵¹ PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice dated 22 December 2020, question 3.

¹²⁵² PRC00350, DHSC response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020, questions 5(b) and 10(c).

¹²⁵³ PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice of 22 December 2020, question 7(a).

¹²⁵⁴ [redacted]: PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice of 22 December 2020, question 7(b). The CMA spoke to a DHSC official on 11 February 2016 regarding the fact that the CMA would seek further documents from the DHSC regarding the price of Tablets, noting that the Parties had submitted that the price of Tablets was a reasonable benchmark for phenytoin sodium capsules: PHT00225, File note of telephone conversation with [DHSC Employee 7] of DH, 10.30am on 11 February 2016 (CMA document reference 01719A). That DHSC official later had a conversation with a DHSC analyst regarding Tablets: PRC01157, Email from [DHSC Employee] to [DHSC Employee 7] on 16 February 2016 (DHSC010.295), DHSC response of 11 December 2021 to the CMA's s.26 Notice of 7 July 2020.

¹²⁵⁵ PRC01322, DHSC response dated 19 January 2021 to the CMA's s.26 Notice of 22 December 2020, question 8(a).

6.185 Since April 2017, the Drug Tariff price of Tablets has been calculated in the same way as that of all category M drugs.

6.186 As a result of falling supply prices, the Drug Tariff price of Tablets has reduced from £15.21 in April 2017, when Tablets were placed back into the usual category M calculation mechanism, to £6.42 in June 2022.¹²⁵⁶

iv. Market entry and the evolution of the supply prices of Tablets

6.187 The £30 Drug Tariff price was downstream from the supply prices charged by Tablets suppliers at the equivalent level of the supply chain to Flynn (and was even further downstream from Pfizer's supply prices). Therefore, the like-for-like comparison would be to compare Flynn's prices for Capsules with the supply prices charged by Tablets suppliers to wholesalers and pharmacies.

6.188 The CMA has gathered evidence regarding market entry in Tablets and the evolution of supply prices. This evidence shows that, during the Relevant Period, Teva was no longer a monopoly supplier and ASPs (at the equivalent level of the supply chain to Flynn's sales of Capsules) were significantly below the £30 Drug Tariff price.

6.189 The CMA's assessment of whether Tablets ASPs might themselves be a meaningful benchmark for assessing the fairness of the Parties' supply prices for Capsules is set out in section 6.C.II.e below.

d. The CMA's assessment of the £30 Drug Tariff price of Tablets as a potential comparator

i. Introduction and summary of the CMA's assessment

6.190 In assessing whether the £30 Drug Tariff price of Tablets represented a meaningful comparator for the purposes of assessing the fairness of the Parties' prices for Capsules, the CMA has considered the evidence previously gathered by the CMA and adduced by the Parties. The CMA has also collected and evaluated a large body of additional evidence as part of its investigation on Remittal.

6.191 In particular, the CMA has considered whether the £30 Drug Tariff price is capable of allowing for a consistent comparison with the Parties' supply prices in circumstances where it is set at a different level of the supply chain and is subject to a different reimbursement framework. As part of this, the CMA has assessed whether the £30 Drug Tariff price reflected effective competition. The CMA has also considered whether CCGs (which were the end customers paying for the

¹²⁵⁶ In June 2018, the DHSC announced that it would discontinue scheme M and the scheme terminated in June 2019. From January 2020, Drug Tariff prices for all category M products have been calculated based on data submitted by all suppliers of each category M drug, rather than just those suppliers who were members of scheme M. See further section 2.

products) and the DHSC were willing to pay £30 and saw this as reflective of the value of the drug.

6.192 Taken together, and having considered the Parties' representations on the evidence, the CMA has concluded that £30 Drug Tariff price of Tablets is not a meaningful comparator. The CMA has reached this conclusion based on the following factors:

6.192.1 First, the £30 Drug Tariff price was not a like-for-like comparison with the Parties' prices, which were at different levels of the supply chain. Critically, the £30 Drug Tariff price was significantly above the upstream selling prices charged by Tablets suppliers during the Relevant Period (which would be the like-for-like comparison with Flynn's Prices). This makes any comparison between the £30 Drug Tariff price and Flynn's upstream supply prices inconsistent and not meaningful. This inconsistency has an even greater impact for any comparison against Pfizer's Prices, which are even further upstream from the Drug Tariff price. In Phenytoin, the CAT saw the possibility of lower upstream supply prices for Tablets as 'a potentially very important point indeed'.¹²⁵⁷

6.192.2 Second, the £30 Drug Tariff was not a price set in conditions of effective competition and the evidence shows that the price continued to reflect Teva's substantial market power and significant price increases:

- (a) At the time of the meeting with the DHSC in 2007, at which the £30 Drug Tariff price was agreed, Teva was the monopoly supplier of Tablets. The DHSC had no alternative sources of supply and, due to the nature of the product, patients could not be switched to alternative treatments.
- (b) Reflecting Teva's market power, the £30 Drug Tariff price was substantially higher than it had been prior to a series of significant price increases imposed by Teva between 2005 and 2007. The Drug Tariff price of £30 was almost eight times higher than the Drug Tariff price of £3.87 (paid by the DHSC in April 2005 at the beginning of scheme M) and almost 18 times higher than the Drug Tariff price of £1.70 (paid by the DHSC in March 2005).

6.192.3 Third, the Parties' justification for increasing their prices by reference to the Drug Tariff price of Tablets is based on the contention that £30 reflected what the DHSC had accepted to be the value of Tablets and was willing to pay.¹²⁵⁸ However, there is a significant body of contemporaneous

¹²⁵⁷ *Phenytoin* [2018] CAT 11, paragraph 386.

¹²⁵⁸ See, for example, PRC03492, Flynn's response to the SO, paragraphs 1.17, 1.30, 8.4, 8.7, 8.8; see also PRC03903, Flynn's response to the Letter of Facts, paragraphs 5.4 to 5.6 and PRC03488, Pfizer's response to the SO and DPS, paragraphs 6(a), and 10 to 17.

evidence (which the Parties were aware of when imposing and maintaining their prices) which explicitly contradicts this view. The evidence shows that:

- (a) The DHSC had refused to allow both Pfizer and Flynn to increase their prices in the PPRS by reference to the Drug Tariff price of Tablets.
- (b) The DHSC explicitly told Flynn (both before and after it imposed its high prices) that it objected to Flynn's Prices and could not understand the justification for the significant price increases.
- (c) The DHSC expressly rejected the proposal to benchmark the price of Capsules against the price of Tablets and explicitly told Flynn that it should not assume that the DHSC or the NHS was happy with the £30 Drug Tariff price of Tablets. At the same time, the DHSC warned Flynn that the proposal to benchmark its price against the Tablets Drug Tariff price would make the cost of Capsules very difficult for the NHS and would have a material impact on CCG budgets.¹²⁵⁹
- (d) Numerous key NHS stakeholders, including clinicians and CCGs (which bore the financial cost of the Parties' prices), complained directly to the Parties at the time of the price increases. These complaints explicitly and strongly contested the scale of the significant price increases, highlighted the absence of any therapeutic justification and raised concerns about harm to CCG budgets and the impact on patient care.¹²⁶⁰
- (e) In 2013, the DHSC considered and rejected a separate request by Teva to re-brand its own generic Tablets and to price these at £30 in the PPRS. The DHSC's consideration and rejection of Teva's request is another indication that the DHSC had not determined £30 to be the value of Tablets to the NHS and what it was willing to pay.

6.193 The remainder of this section provides further explanations and reasoning for the CMA's conclusions described above.

6.194 The section also includes the CMA's evaluation of the Parties' representations regarding the meeting between the DHSC and Teva in 2007, and the reasons why the CMA disagrees with the Parties' interpretation of the significance of that meeting to the CMA's assessment.

¹²⁵⁹ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

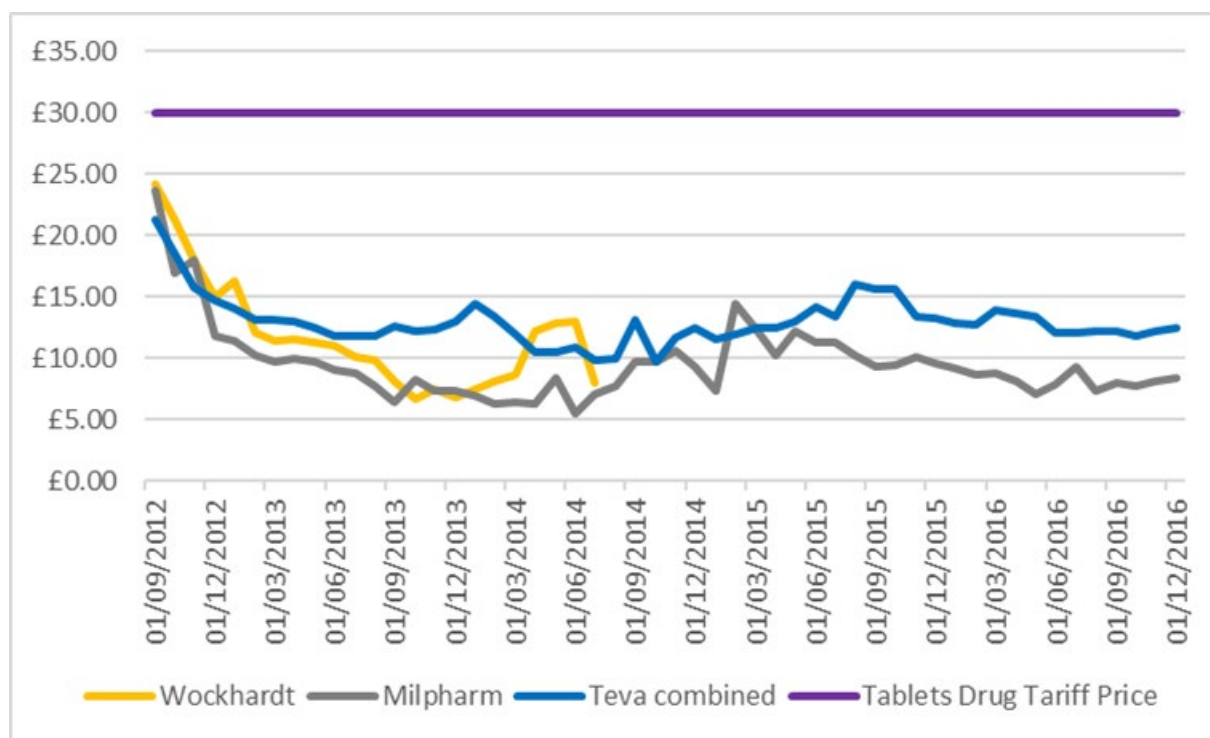
¹²⁶⁰ See Annex B for a summary of CCG complaints following the Parties' price increases.

ii. The £30 Drug Tariff price is not the like-for-like comparison and was significantly above actual supply prices during the Relevant Period

- 6.195 Where price comparators are used to assess the fairness of potentially abusive prices, such comparisons must be made on a consistent basis and the figures must be comparable.¹²⁶¹
- 6.196 A comparison between the Parties' supply prices for Capsules and the Drug Tariff price of Tablets is not a like-for-like comparison. The Drug Tariff price of Tablets is the price paid by the NHS (and, specifically, CCGs) as the final customer in the supply chain. This price is downstream compared to Flynn's supply prices and further downstream when compared to Pfizer's supply prices.
- 6.197 In this case, the evidence shows that the £30 Drug Tariff price for Tablets was significantly above upstream selling prices.
- 6.198 As part of the Remittal, the CMA has gathered a significant body of evidence regarding supply prices and competitive conditions in the supply of Tablets. This evidence (described in section 6.C.II.e below), demonstrates that there were significant limitations on competition between suppliers.
- 6.199 However, notwithstanding the limitations on competition in respect of the supply of Tablets, Figure 6.1 shows that the supply prices for the three suppliers of Tablets during the Relevant Period (Teva, Milpharm and Wockhardt) were all significantly below £30 during the Relevant Period. The large difference between market supply prices for Tablets (charged at the equivalent level of the supply chain to Flynn to largely the same set of customers) and £30 illustrates the deficiencies in the £30 Drug Tariff as a comparator for Flynn's Prices (and even more so for Pfizer's Prices).

¹²⁶¹ See for example *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 44-46 and 51; *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin* [2018] CAT 11, paragraph 373.

Figure 6.1: Tablets suppliers' average selling prices during the Relevant Period



Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1, PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1, PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2, PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK, PRC00326, Milpharm's response dated 22 July 2020 to the CMA's s.26 Notice of 29 June 2020, Milpharm Data Sheet Final, PRE00274, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, BK, CMA Case 50908-Annex 2 - Data Feb'17toAug'20- Compl. 20Oct'20, and PRC01415, Milpharm's response of 5 February 2021 to the CMA's s.26 Notice of 29 January 2021, Annex 2. Notes: The Tablets Drug Tariff price was fixed at £30 for the period October 2008 to April 2016, however, the CMA has fixed the Drug Tariff price at £30 until December 2016 to enable a comparison between the Tablets suppliers' ASPs and the £30 Drug Tariff price for the duration of the Relevant Period.

6.200 In order to be meaningful, any comparison must be made on a consistent basis.¹²⁶²

The evidence clearly demonstrates that the Drug Tariff price was significantly higher than supply prices at Flynn's level of the supply chain and is not, therefore, a consistent or reliable benchmark for upstream supply prices during the Relevant Period.

iii. The £30 Drug Tariff price was not set in conditions of effective competition and was distorted by the significant price increases imposed by Teva

6.201 Consistent with the evidence showing that actual market supply prices for Tablets were significantly below £30 during the Relevant Period, other evidence demonstrates that the £30 Drug Tariff price was, itself, heavily distorted by Teva's market power.

¹²⁶² See for example *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; *Phenytoin* [2018] CAT 11, paragraph 443; and *Latvian Copyright*, EU:C:2017:689, paragraphs 44-46 and 51.

- 6.202 Prices set in conditions of effective competition will be of the most value as comparators for the purposes of the *unfair when compared* assessment. Conversely, prices which themselves have been inflated by the exercise of market power will not be meaningful comparators.¹²⁶³
- 6.203 The Drug Tariff price of Tablets had historically been well below £30 until shortly before 2007. In March 2005, the Drug Tariff price of Tablets was £1.70. At the beginning of scheme M in April 2005, the Drug Tariff price rose to £3.87.
- 6.204 At this point, Teva was the monopoly supplier of Tablets to the NHS and used the absence of any competition to significantly increase its prices. From mid-2005, Teva imposed a series of significant price increases to over £50, which pushed the Drug Tariff price up from £3.87 in April 2005 to £113.62 in October 2007 (an increase of 2,836%).¹²⁶⁴
- 6.205 The increases in the Drug Tariff price of Tablets between 2005 and 2007 are set out below in Table 6.8.

Table 6.8: Drug Tariff price of Tablets from 1 March 2005 to 1 October 2007

Date	Category	Drug Tariff price
1 March 2005	A	£1.70
1 April 2005	M	£3.87
1 July 2005	M	£3.23
1 October 2005	M	£8.56
1 January 2006	M	£9.82
1 April 2006	M	£24.73
1 July 2006	M	£13.85
1 October 2006	M	£52.25
1 January 2007	M	£48.58
1 April 2007	M	£62.29
1 July 2007	M	£53.51
1 October 2007	M	£113.62

- 6.206 Teva's price increases were not the result of any significant change to its costs or product improvement. Instead, by its own acceptance, they were the result of its position as the sole supplier of Tablets in the market.
- 6.207 [Former Teva Director] explained to the Tribunal how, following the commencement of scheme M in April 2005, Teva used the opportunity each quarter to 'nudge' its price upwards by reference to the Drug Tariff price. As Teva

¹²⁶³ This is consistent with the CAT's findings in *Albion Water I* [2006] CAT 23, paragraph 757 and *Albion Water II* [2008] CAT 31, paragraph 257. See also *Phenytoin CoA*, paragraphs 154 and 155. This is also consistent with the submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, paragraphs 49 and 50.

¹²⁶⁴ PHT00040, Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.2), pages 14 to 15.

was a monopoly supplier, the DHSC had no alternative sources of supply and, due to the nature of the product, there were significant barriers to switching patients to alternative treatments.¹²⁶⁵ [Former Teva Director] explained that Teva was able to do this because it was 'the only company making this product'.¹²⁶⁶

- 6.208 Teva was able to impose these significant and highly profitable price increases because of its dominant position. A Teva internal document from 2007 corroborates the point. The document reported that 'Phenytoin (epilepsy) is the star in our generic portfolio and as we are the only supplier in the market we have been able to maintain high prices. We estimate to make an additional margin of £19.6m vs the initial WP. Sales are estimated to have gone up from an initial estimate of £5.8m to £25.4m by the year end'.¹²⁶⁷ This reflects that Teva's price increases were not driven by increases in cost. The document records that all of this additional revenue would be profit, with an additional margin of £19.6 million being projected when compared to its previous projections.¹²⁶⁸ One of the DHSC attendees at the 2007 meeting with Teva stated that Teva 'was quite open about the process, it saw an opportunity and exploited it'.¹²⁶⁹
- 6.209 The £30 Drug Tariff price adopted following the meeting between the DHSC and Teva in October 2007 represented a reduction from the Drug Tariff price in the previous quarter of £113.62. However, the context surrounding the Drug Tariff price being set at £30 is highly significant to determining its suitability as a benchmark. The CAT highlighted the need to understand 'the evolution of the tablet market and tablet pricing'¹²⁷⁰ and provided its view that 'the price behaviour of tablets over time seems to us to be more relevant than the 2007 price for comparison purposes'.¹²⁷¹ The CMA has considered whether Teva had been able to preserve the price increases imposed since the beginning of 2005.
- 6.210 In his oral evidence provided to the CAT, [Pfizer Director 1] confirmed that Pfizer had not had any discussions with the DHSC regarding its views on the £30 Drug Tariff price of Tablets or its use as a benchmark by the Parties.¹²⁷² Instead, [Pfizer Director 1] confirmed that Pfizer 'inferred' that the DHSC was content with the Drug Tariff price¹²⁷³ based on '[Pfizer's] interpretation of what happened in the market'.¹²⁷⁴ [Pfizer Director 1] explained that Pfizer 'couldn't think of any other

¹²⁶⁵ See paragraphs 6.155 and Section 2.A.

¹²⁶⁶ PAD00030, [Former Teva Director] Cross Examination, day 5, page 41, line 21, to page 42, line 17 (emphasis added).

¹²⁶⁷ PRE00496, Teva internal presentation, Staff Briefing Q2 2007, page 19 (emphasis added).

¹²⁶⁸ Teva confirmed that in the period between 2003 and 2013, 'Teva's base cost of goods per pack (excluding fixed overhead costs, distribution costs, etc) fluctuated between [£] and [£]. See PRC00450, Teva's response of 28 August 2020 to the CMA's section 26 notice dated 31 July 2020, question 1.

¹²⁶⁹ PRC01233, Email from [DHSC Employee 1] (DHSC) to DHSC colleagues dated 16 July 2013 (DHSC009.253), DHSC response of 22 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹²⁷⁰ *Phenytoin* [2018] CAT 11, paragraphs 7 and 467.

¹²⁷¹ *Phenytoin* [2018] CAT 11, paragraph 380.

¹²⁷² PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 35, lines 8-13 and page 46, lines 16-19.

¹²⁷³ PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraph 67 and PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 3, lines 3-15.

¹²⁷⁴ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 37 lines 24-25 and page 47, lines 11-12.

credible reason why Teva would treble their price and then, within a month or two, bring it back down to the price it was at before'.¹²⁷⁵ [Pfizer Director 1] made the same point about the DHSC having intervened to reduce the Drug Tariff price back to the level it had been prior to Teva's price increases on a number of occasions. For instance:¹²⁷⁶

the tablets had been at this price previously. They then suddenly increased in price and were then very quickly reduced back to the price that they were at before [...] So our inference, our conclusion, was that the Department of Health had found the trebling of the price unacceptable, had intervened with Teva to bring the price down to where it was before [...] our inference was that the Department of Health was happy with the price that they were at previously [...]. (emphasis added)

- 6.211 However, the evidence shows Pfizer's interpretation of what had 'happened in the market' to have been incorrect. The DHSC had not been able to bring prices back down to the level they had been prior to Teva's significant price increases. If this had been the case, this would be a relevant factor for the CMA's assessment. However, [Pfizer Director 1]'s evidence was mistaken: £30 was not the prevailing Drug Tariff price prior to 'the trebling of the price by Teva'. Instead, the Drug Tariff price of Tablets had been far lower. In evidence provided to the CAT, [Former Teva Director] identified that the 'original price' of Tablets was significantly lower, describing it as being 'around the same price as Phenytoin capsules, historically. So I think about £3'.¹²⁷⁷
- 6.212 The Parties rely on the reduction in price and the resulting cost saving for the NHS to support their use of the £30 Drug Tariff price as their price benchmark.¹²⁷⁸ However, the quantum of the saving made by the NHS (and the impact on Teva's revenues¹²⁷⁹) is a direct reflection of the extent of the price increases previously imposed by Teva. At £30, the Drug Tariff price remained significantly higher than historical prices and continued to be distorted by Teva's exercise of its substantial market power. The outcome of the 2007 meeting was that the DHSC would continue to pay a price almost eight times greater than the Drug Tariff price of £3.87 in April 2005 (at the beginning of scheme M) and almost 18 times greater than the Drug Tariff price of £1.70 in March 2005 (immediately prior to the introduction of scheme M).
- 6.213 In describing the '[g]eneral framework for excessive pricing', Flynn has submitted that 'any approach should be premised on a comparison with prices likely to have

¹²⁷⁵ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 37, line 25 and page 38, lines 1-3.

¹²⁷⁶ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 39, lines 3-15.

¹²⁷⁷ PAD00030, [Former Teva Director] Cross Examination, day 5, page 44, lines 7-9.

¹²⁷⁸ PRC03488, Pfizer's response to the SO and DPS, paragraph 13(b).

¹²⁷⁹ In support of its case regarding the significance of the 2007 meeting, Pfizer has referred to the impact on Teva's revenues resulting from the reduction in the Drug Tariff price following the 2007 meeting. See PRC03488, Pfizer's response to the SO and DPS, paragraph 13(b).

pertained in normal and sufficiently effective competition'.¹²⁸⁰ Plainly, the level of price increase Teva was able to retain based on the Drug Tariff price of £30, without any increase in supply costs or product improvement, is not consistent with an outcome that would be expected in a generic drug market with effective competition. The CMA does not consider that a price which has been subject to such a significant increase, over such a short period, and without any increase in the underlying costs of supply, or any product improvement, is likely to be a meaningful comparator for the purposes of assessing the fairness of other prices.¹²⁸¹

6.214 This highlights the circularity of the Parties' reliance on the £30 Drug Tariff price to justify their significant price increases for Capsules. In order for a price to be a meaningful comparator, it should not itself be inflated by the exercise of market power.¹²⁸² Instead, as recognised by the Court, 'a proxy [for economic value] might be what consumers are prepared to pay for the good or service in an effectively competitive market'.¹²⁸³ However, the evidence clearly demonstrates that the £30 Drug Tariff price of Tablets was not the outcome of a competitive process (whether effective competition or otherwise). Instead, it still reflected the exercise of substantial market power by Teva prior to the 2007 meeting.

iv. Contemporaneous evidence shows that key NHS stakeholders did not accept or agree to the significant price increases and were not 'willing' purchasers

6.215 As recognised by the Court of Appeal, in broad terms the economic value of a good or service is what a consumer is willing to pay for it.¹²⁸⁴ However, the Court also recognised that 'this cannot serve as an adequate definition in an abuse case since otherwise true value would be equated with anything which a dominant supplier exploiting its position could get away with' and 'the simple fact that a consumer will or must pay the price that a dominant undertaking demands is not therefore an indication it reflects a reasonable relationship with economic value'.¹²⁸⁵

6.216 As set out above, the CMA has gathered evidence which demonstrates that the £30 Drug Tariff price was: significantly above actual market supply prices for Tablets during the Relevant Period; was not to any degree a competitive price; and

¹²⁸⁰ PRC03492, Flynn's response to the SO, paragraph 5.6.

¹²⁸¹ Pfizer has submitted that that the relevant question for the purposes of determining whether the £30 Drug Tariff price of Tablets is a meaningful benchmark is whether there is a good basis to suppose that £30 was an unfair and/or unlawful price (see PRC03488, Pfizer's response to the SO and DPS, paragraph 6(a), 14, 17(a) and 17(c)). Pfizer has also submitted that there is nothing in the CMA's SO or Letter of Facts which suggests that it was an unlawful price (see PRC03901, Pfizer's response to the Letter of Facts, paragraphs 15 and 16). The CMA does not accept these representations. In order to conclude that a price is not a meaningful comparator for the purposes of the *United Brands* test, there is no requirement for that price to itself be unlawful.

¹²⁸² This is consistent with the CAT's findings in *Albion Water I* [2006] CAT 23, paragraph 757 and *Albion Water II* [2008] CAT 31, paragraph 257. See also *Phenytoin CoA*, paragraphs 154 and 155. This is also consistent with the submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, paragraphs 49 and 50.

¹²⁸³ *Phenytoin CoA*, paragraph 154.

¹²⁸⁴ *Phenytoin CoA*, paragraph 155.

¹²⁸⁵ The Court of Appeal also confirmed that, instead, 'a proxy might be what consumers are prepared to pay for the good or service in an effectively competitive market': *Phenytoin CoA*, paragraph 155.

was a price which still reflected and continued to be distorted by Teva's market power and significant price increases between 2005 and 2007. Furthermore, CCGs had no choice but to continue to fund the purchase of Capsules in order to ensure that they remained available to legacy patients. As set out above, there were substantial barriers to switching these legacy patients to other treatments, including between suppliers of phenytoin sodium products.

- 6.217 In these circumstances (and consistent with the views of the Court of Appeal set out above), the fact that the NHS continued to pay the £30 Drug Tariff price cannot be seen as evidence of the product's economic value.
- 6.218 This is enough to dismiss any arguments based on customers' willingness to pay in this case (even absent evidence of the NHS and CCGs being overtly unwilling to pay the Parties' prices).
- 6.219 However, in this case there is also a significant body of contemporaneous evidence which demonstrates that the DHSC and CCGs were, in practice, very clearly not willing to pay the Parties' increased prices and paid them under protest.
- 6.220 This evidence is particularly relevant in this case, given the Parties have submitted that the economic value of Capsules should be determined by what they consider to be the purchaser's willingness to pay and acceptance of the higher price of £30.¹²⁸⁶ The Parties adopted this view without having participated in or having any direct knowledge of the meeting between Teva and the DHSC five years earlier on which they rely to support their view. Before the CAT, [Pfizer Director 1] explained that 'this was the conclusion I drew from what we [sic] actions we saw in the marketplace'.¹²⁸⁷
- 6.221 However, the Parties have ignored a significant body of contemporaneous evidence which contradicts their submissions, demonstrates that the purchaser in this case was not willing to pay, did not agree to and did not accept the Parties' significantly increased supply prices. Moreover, it is evident that the Parties were fully aware of the DHSC's concerns. The evidence includes:
- 6.221.1 The DHSC's clear and unequivocal opposition to the Parties' price increases and the proposal to use the £30 Drug Tariff price of Tablets as a price benchmark.
- 6.221.2 The significant number of complaints made by CCGs and clinicians to the Parties regarding the scale of their price increases and the absence of any justification.

¹²⁸⁶ See, for example, PRC03492, Flynn's response to the SO, paragraphs 1.17, 1.30, 8.4, 8.7, 8.8; see also PRC03903, Flynn's response to the Letter of Facts, paragraphs 5.4 to 5.6 and PRC03488, Pfizer's response to the SO and DPS, paragraphs 6(a), and 10 to 17.

¹²⁸⁷ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 47, lines 11-12.

6.221.3 The DHSC's consideration and rejection of a request from Teva in 2013 to re-brand its own generic Tablets and to price these at £30 in the PPRS.¹²⁸⁸

The DHSC's unequivocal opposition to the Parties' prices and the use of Tablets as a justification

- 6.222 The Parties have submitted that the Drug Tariff price of Tablets reflected the DHSC's assessment of the value of the drug and was what the DHSC had determined it was willing to pay.¹²⁸⁹
- 6.223 Pfizer submits that it 'inferred that the Teva tablet price was a price that the NHS were content with'¹²⁹⁰ and had understood the DHSC to have been 'happy' with this price.¹²⁹¹
- 6.224 Flynn submits that £30 was 'what the DHSC was in fact willing to pay for phenytoin sodium 100mg'¹²⁹² and that it was 'entitled to rely on the assumption that the tablet price was a fair price'.¹²⁹³
- 6.225 The Parties' interactions with the DHSC are summarised below. These interactions are also comprehensively set out in Annex C. In light of these events, the Parties cannot reasonably have been of the view that the DHSC and CCGs were willing to pay their prices and did not have 'any serious objection'¹²⁹⁴ to them. The DHSC raised clear and unequivocal objections directly with the Parties regarding their price increases and their reliance on the Drug Tariff price of Tablets. Both Pfizer and Flynn were aware that the DHSC did not consider that the Drug Tariff price of Tablets justified a significant price increase. Moreover, when the DHSC sought information on costs to gain an understanding of the rationale for the price increases it was rebuffed.¹²⁹⁵
- 6.226 The evidence adduced by Pfizer demonstrates that the DHSC had made it clear to Pfizer that Capsules did not warrant any exceptional price increase within the PPRS based on the higher Drug Tariff price of Tablets. As [Pfizer Director 1] explained before the Tribunal:

So on the one hand, it was very clear to us that from [the DHSC's] initial intervention and then subsequent acceptance of the tablet price, that that represented the value that they believed that medicine gave to the NHS.

¹²⁸⁸ Teva's request was not public. The Parties would not, therefore, have been aware of this.

¹²⁸⁹ See, for example, PRC03492, Flynn's response to the SO, paragraphs 1.17, 1.30, 8.4, 8.7, 8.8; see also PRC03903, Flynn's response to the Letter of Facts, paragraphs 5.4 to 5.6 and PRC03488, Pfizer's response to the SO and DPS, paragraphs 6(a), and 10 to 17.

¹²⁹⁰ PAD00031, [Pfizer Director 1] Cross Examination, lines 20-21, page 38.

¹²⁹¹ PRC03488, Pfizer's response to the SO and DPS, paragraph 44.

¹²⁹² PRC03903, Flynn's response to the Letter of Facts, paragraph 8.8

¹²⁹³ PRC03631, Transcript of Flynn's Oral Hearing, page 56, line 9.

¹²⁹⁴ PRC03488, Pfizer's response to the SO and DPS, paragraph 15.

¹²⁹⁵ See further paragraph 6.68.

*Yet at the same time, the advice I was getting from our finance team, who'd raised this subject in previous discussions with the Department, was that they would not entertain any exceptional price rise or price reset of the capsules accordingly.*¹²⁹⁶

6.227 [Pfizer Director 1]'s evidence shows that Pfizer knew that the DHSC 'would not entertain' a Capsules price increase by reference to the Drug Tariff price of Tablets before it used another mechanism to implement an increase on exactly this basis. Accordingly, Pfizer was aware that the 'inference' it had drawn regarding the DHSC's views did not reflect the DHSC's position in practice, or what the DHSC was telling Pfizer at the time.

6.228 Flynn also engaged in dialogue with the DHSC prior to the implementation of the price increases. On 18 July 2012 Flynn met with the DHSC to discuss its proposals to increase the price of Capsules. At the meeting, the DHSC expressed its immediate reservations regarding Flynn's proposal to significantly increase its supply prices:

*Whilst DH acknowledged the need for this product to remain on the market, DH expressed the difficulties in agreeing to a launch price that was significantly higher than [the prevailing price of] Epanutin.*¹²⁹⁷

6.229 A further clear signal that the DHSC did not approve of a substantial increase in the price of Capsules is provided by Flynn's engagement with the PPRS Pricing Committee. Flynn submitted a request to the Committee to increase the price of Capsules within the PPRS, to a price around 25% to 30% below the £30 Drug Tariff price of Tablets. The DHSC wrote to Flynn on 26 July 2012 to inform the company that its request had been rejected.¹²⁹⁸

6.230 As such, Flynn would also have clearly understood that the DHSC did not consider the Drug Tariff price of Tablets to be an appropriate reference point for an increase in the price of Capsules. Notwithstanding the DHSC's views, Pfizer and Flynn proceeded to impose price increases based upon the Drug Tariff price of Tablets.

6.231 At a further meeting between Flynn and the DHSC in November 2012, following the imposition of the price increases, the DHSC again raised concerns over Flynn's Prices. Having been informed by Flynn that it increased its prices by reference to the Drug Tariff price of Tablets, the DHSC told Flynn that it 'had never confirmed

¹²⁹⁶ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 43, lines 14 – 23.

¹²⁹⁷ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.9), page 1, paragraph 5.

¹²⁹⁸ PHT00051, Email of 26 July 2012 from [DHSC Employee] Department of Health to [Flynn Director 4] Flynn re Epanutin Capsules: Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.13).

that it was content with the price of the tablets'.¹²⁹⁹ Flynn's note of the meeting confirms that the DHSC expressed clear reservations about the use of the Tablets Drug Tariff price as a benchmark:

*We [Flynn] should not (in [redacted] [DHSC Employee 6]) view; assume that the DH and NHS are happy with the price of the tablets.*¹³⁰⁰

6.232 The DHSC reiterated to Flynn that it did not consider comparisons with Tablets to be relevant:

*Further, it [the DH] did not consider comparisons with the table [sic] relevant, as the products are not interchangeable. They were different formulations, which may incur different costs, and the tablets had significantly less of the market so had less economies of scale. Although a price increase might have been justified for Flynn's product, the scale of it was the concern.*¹³⁰¹

6.233 Flynn's note also records the DHSC pointing to the significant differences in prescribed volumes between Capsules and Tablets and the related impact on the total cost to the NHS as a further reason for not drawing a comparison with the price of Tablets:

*DH ([redacted]) [DHSC Employee 4] had commented that the much larger market share of the capsules made the total cost very difficult for them, more visible and hitting hard NHS pockets. The DH were struggling and trying to understand the justification.*¹³⁰²

6.234 [DHSC Employee 4]'s comment, recorded in the Flynn meeting note, clearly demonstrates that, far from thinking that the Drug Tariff price of Tablets was an appropriate reference point for the price of Capsules, the 'DHSC were struggling and trying to understand the justification' and, additionally, saw the larger market for Capsules as an important reason why Tablets were not an appropriate benchmark.

6.235 In practice, the significant difference in volumes between Tablets and Capsules meant that there was a material difference in the comparable costs of Tablets and Capsules to the NHS. Reflecting the objections raised directly by the DHSC,

¹²⁹⁹ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.16).

¹³⁰⁰ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

¹³⁰¹ PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.16).

¹³⁰² PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

following the imposition of the Parties' price increases, the annual cost of Capsules to the NHS increased to £50 million in 2013. In the same year the NHS spent around £11.1 million on Tablets (approximately one fifth of its spend on Capsules). During the Relevant Period, the DHSC spent around £41.1 million on Tablets compared to around £177.5 million on Capsules.¹³⁰³ Of this, an additional approximately £169 million¹³⁰⁴ was a direct result of the Parties' price increases.

- 6.236 At the meeting in November 2012, the DHSC also requested Flynn's costs of goods information in order to assess whether the price increases could be justified.¹³⁰⁵ Flynn told the DHSC that it could not provide this information because it was confidential under its agreement with Pfizer.
- 6.237 Following the meeting with Flynn in November 2012, the DHSC continued to seek costs information from Flynn and Pfizer. The DHSC also raised the issue of pricing directly with Pfizer and sought comments on the significant price increase.¹³⁰⁶ However, Pfizer wrote to the DHSC declining to comment on the increased price of Capsules.¹³⁰⁷ It would have been obvious to the Parties from the DHSC's enquiries (which the Parties evaded) that the DHSC had ongoing reservations about the price increases they had imposed and the benchmark they had relied upon.
- 6.238 [Flynn Director 2] (one of Flynn's [redacted]) who had attended the November 2012 meeting with DHSC, later confirmed that DHSC had made it clear they were 'very unhappy' with the increased prices. [Flynn Director 2] also confirmed that, following this meeting, he understood that the DHSC was not happy with the use of the Tablets Drug Tariff price as a benchmark.¹³⁰⁸ The CAT also concluded that Flynn was aware of the DHSC's opposition to the price increases: '[w]hen it was suggested by the MHRA that Flynn should approach the DH to discuss pricing, it

¹³⁰³ For 100mg capsules: for 2012, a weighted average has been calculated using the Drug Tariff prices of 66p and £67.50; for 2013, the prevailing Drug Tariff price of £67.50 per pack has been used; for 2014, a weighted average has been calculated using the Drug Tariff prices of £54 and £67.50; and between 2015 and 2016, the prevailing Drug Tariff price of £54 per pack has been used. The same methodology has been used for the other strengths.

¹³⁰⁴ The CMA has calculated the NHS's annual spend on Capsules using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices. The CMA has calculated the NHS spend on Capsules over the Relevant Period at pre-2012 Drug Tariff prices and also at post-2012 Drug Tariff prices (taking into account the reduction of the Drug Tariff price in 2014) to calculate the additional spend as a result of the price increases.

¹³⁰⁵ PHT00053, Email of 24 October 2012 between [DHSC Employee 3] (DH) and [DHSC Employee 7] (DH) et al re Flynn stating that the agreement with Pfizer is a simple 3rd party manufacturing supply contract for Epanutin/Phenytoin: Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.15); PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585); and PHT00054, Note of a meeting between the Department of Health and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.16).

¹³⁰⁶ PHT00057, Redacted note of meeting of 10 January 2013 between Pfizer and DH at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.19).

¹³⁰⁷ PHT00060, Email of 27 February 2013 between Department of Health Staff [[DHSC Employee 5], [DHSC Employee 1], [DHSC Employee 3] and [DHSC Employee 8] (DH)] forwarding on redacted email from Pfizer - re Outstanding actions from the Meeting with DH on 10 January 2013: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.22).

¹³⁰⁸ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 158, lines 16 to 20 and page 167, lines 8 to 14.

was made clear to Flynn by the DH that it was not happy either with the Tablet price or with Flynn's increased capsule prices.'¹³⁰⁹

- 6.239 It is simply not sustainable that, having had an application for a price increase under the PPRS rejected and after having been explicitly told by the DHSC that (i) it was not happy with Flynn's prices and (ii) Flynn should not use the £30 Drug Tariff price of Tablets as a benchmark, Flynn was somehow (as it has submitted) 'entitled to rely on the assumption' that, in fact, the exact opposite was true and, based on this, charge excessive prices for over four years.
- 6.240 Instead of engaging with the DHSC's clear concerns regarding their prices and the use of Tablets as a benchmark, the Parties instead proceeded to rely on an obvious fiction - that the DHSC did not have any 'serious objection' to their prices and that the Drug Tariff price of Tablets represented a price the DHSC was, in fact, 'happy' with and willing to pay. The Parties never provided their costs information to the DHSC following its request, never re-engaged with the DHSC to understand the reasons for the DHSC's clearly contrary views (both on the Parties' prices and the Tablet benchmark) and never pursued any other course of action to address the DHSC's concerns.
- 6.241 Flynn's view is that the evidence described above, 'does not have any influence on the economic value and clear evidence of what the DHSC was in fact willing to pay for phenytoin sodium 100mg' because 'it was clearly in the DHSC's interests at this stage, as the purchaser, not to accept that it was content with the price of phenytoin tablets.'¹³¹⁰
- 6.242 The CMA disagrees with this submission. The positions taken by the Parties on the importance of the DHSC to the CMA's assessment are incongruous.
- 6.243 Both Parties put the DHSC's conduct in 2007 relating to the price of a different drug at a different point in time – Tablets – at the heart of their case, arguing that the fact the DHSC initially agreed to a reduction of the Drug Tariff to £30 is representative of the value they placed on phenytoin sodium. However, this submission takes events entirely out of their context. The Parties were not directly involved in the discussions between Teva and the DHSC and therefore cannot be certain of how the matter was resolved. However, there is a significant body of evidence unambiguously demonstrating that the Parties would have been aware of the DHSC's opposition to its use of the £30 Drug Tariff as a benchmark both before and after their price increases were implemented. Moreover, rather than engaging with the DHSC's attempts to understand the rationale for the price increase, the Parties disengaged and proceeded with their strategy. The gist of the Parties' position on the £30 Drug Tariff price is that the CMA's assessment should take

¹³⁰⁹ *Phenytoin* [2018] CAT 11, paragraph 232.

¹³¹⁰ PRC03492, Flynn's response to the SO, paragraph 8.8

place in a vacuum, divorced from the DHSC's conduct and explicit views on their *own* prices just before and at the beginning of the Relevant Period.

Key customer stakeholders, including CCGs and clinicians, raised strong concerns with the Parties in large numbers

- 6.244 In addition to the concerns raised directly with the Parties by the DHSC, there is also a significant body of contemporaneous evidence showing that other key NHS stakeholders made the Parties aware that this was not a price that they considered to be justifiable, accepted, or were willing to pay.
- 6.245 These included complaints from CCGs (which the Parties recognise in their internal documents as being the relevant NHS 'payer'¹³¹¹) and clinicians. These complaints explicitly and strongly contested the significant price increases, highlighted the absence of any therapeutic or other justification and raised concerns about the resulting harm to CCG budgets and the impact on patient care. This evidence is described in Annex B.
- 6.246 Contemporaneous evidence also shows that staff at Pfizer and Flynn recognised the impact of their price increases on CCGs and raised reservations internally about the scale of the prices being imposed.¹³¹²
- 6.247 As described above, the Parties' case on Tablets relies on an inference that the customer was willing to pay far higher prices for their product. However, consistent with the evidence described above relating to the Parties' engagement with the DHSC, there is a significant body of evidence of large numbers of purchasing bodies and healthcare professionals expressing strong and reasoned objections to their prices and which directly contradict the Parties' submissions on the customer's willingness to pay.

The DHSC rejected a request by Teva to benchmark the price of its Tablets against the £30 Drug Tariff price

- 6.248 Further contemporaneous evidence of the DHSC not considering that a reimbursement price of £30 for Tablets was justified is provided by a proposal Teva made to the DHSC to place a branded version of its generic Tablet product, 'Pentran', in the PPRS.¹³¹³ The product would be identical to Teva's unbranded Tablets product then on the market in the UK.
- 6.249 Prior to inclusion in the PPRS, Teva had to seek agreement from the PPRS Pricing Committee (part of the DHSC) on its proposed price. On 28 October 2013, Teva sent a pricing application to the DHSC proposing a list price of £30 for 28 Tablets,

¹³¹¹ PHT00187, Internal Pfizer e-mail chain of 2 February 2010 [from [Pfizer Employee] to [Pfizer Director 1]] re Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.57). PHT00401, Flynn internal document titled 'Phenytoin (2)' (CMA document reference 00145.827).

¹³¹² See paragraph 6.133.

¹³¹³ [REDACTED].

based on the prevailing Drug Tariff price of Tablets.¹³¹⁴ This was the price agreed between Teva and the DHSC in the meeting in October 2007.

- 6.250 The Parties have submitted that, despite evidence to the contrary, £30 was what the DHSC had accepted as being a fair price for Teva's Tablet and one that it was willing and prepared to pay between 2012 and 2016. In these circumstances, the DHSC's consideration of Teva's proposed list price of £30 in 2013 is relevant to the CMA's assessment of the Parties' case.
- 6.251 However, contrary to what might have been expected based on the Parties' submissions regarding what the DHSC was willing to pay for Tablets, the DHSC rejected Teva's proposal – because they did not believe the price was justified.¹³¹⁵
- 6.252 Moreover, when considering Teva's request the DHSC focused, amongst other things, on getting an understanding of Teva's costs as the starting point in any analysis it conducted to assess the appropriate price.
- 6.253 In considering Teva's requested list price of £30, the DHSC raised concerns that the Tablets Drug Tariff price might not reflect Teva's actual supply prices¹³¹⁶ and believed that there was likely to be a gap between Teva's actual supply prices and the Drug Tariff price paid by the DHSC. The DHSC referred to the impact resulting from the inclusion of the pharmacy margin in the Drug Tariff price of category M drugs, noting that 'there is probably considerable margin being pumped into the reimbursement price over their selling price'.¹³¹⁷
- 6.254 Instead of approving Teva's proposed price of £30, for the purposes of assessing Teva's request, the DHSC instead asked Teva to provide:
- 6.254.1 its actual selling price;¹³¹⁸ and
- 6.254.2 a full costs breakdown, including manufacturing costs for its Tablets product.¹³¹⁹

¹³¹⁴ PRC01175, Email from [Teva Employee] (Teva) to [DHSC Employee 8] (DHSC) on 28 October 2013 (DHSC004.851), DHSC response of 15 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹³¹⁵ The DHSC wrote to Teva on 15 November 2013 confirming that the PPRS Pricing Committee had refused its request: PRC01174, Email from [DHSC Employee 8] (DHSC) to [Teva Employee] and [Teva Employee] (Teva), Teva - Pentran 100 mg Tablets DH non agreement to proposed launch price (DHSC004.848), 15 November 2013, DHSC response of 15 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹³¹⁶ PRC01169, Internal DHSC email from [DHSC Employee 6] to [DHSC Employee 8] and others, FW: Teva: PL - Pentran (PC decision). Phenytoin (DHSC004.408), 15 November 2013, DHSC response of 15 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹³¹⁷ PRC01169, Internal DHSC email from [DHSC Employee 6] to [DHSC Employee 8] and others, FW: Teva: PL - Pentran (PC decision). Phenytoin (DHSC004.408), 15 November 2013, DHSC response of 15 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹³¹⁸ PRC01174, Email from [DHSC Employee 8] (DHSC) to [Teva Employee] and [Teva Employee] (Teva), RE: Teva - Pentran 100 mg Tablets DH non agreement to proposed launch price (DHSC004.848), 15 November 2013, DHSC response of 15 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹³¹⁹ PRC01176, Email from [DHSC Employee 8] (DHSC) to [Teva Employee] (Teva), FW: Teva - Pentran 100 mg Tablets - Additional information request (DHSC004.852), 28 November 2013, DHSC response of 15 December 2020 to the CMA's s.26 Notice of 7 July 2020.

- 6.255 After receiving the DHSC's requests, Teva decided not to pursue its application and did not provide this data to the DHSC.¹³²⁰
- 6.256 The DHSC's approach to Teva's pricing proposal is consistent with the approach it adopted with Flynn and Pfizer in 2012. In each case, the DHSC refused to accept the £30 Drug Tariff price as the appropriate price benchmark. Instead, the DHSC asked for additional pricing and costs information. In each case, Teva, Flynn and Pfizer withheld the requested information from the DHSC.
- 6.257 The difference from the NHS's perspective is that Teva required approval from the PPRS Pricing Committee and, in the absence of any data from Teva on its costs of supply, the DHSC was able to refuse to approve Teva's price. For Capsules, the DHSC also refused Flynn's request for a price increase within the PPRS to a price around 25% to 30% below the £30 Drug Tariff price of Tablets. However, following this refusal, Flynn de-branded Capsules, removed them from the PPRS and imposed significantly higher prices without ever providing its costs information to the DHSC.
- 6.258 Flynn's representations on the relevance of this evidence focus on whether the DHSC saw the price of Capsules as a potential price benchmark for Teva's proposed PPRS list price for Tablets. Flynn submits that the evidence relating to Teva's application shows that the DHSC saw Capsules as a potentially appropriate comparator.¹³²¹ Pfizer submits that all the evidence relating to Teva's application and the DHSC's consideration of its proposed list price of £30 is irrelevant.¹³²²
- 6.259 However, the Parties' representations miss the key point. They benchmarked the price of Capsules against the £30 Drug Tariff price of Tablets and submitted that the DHSC had considered £30 to be an appropriate price for Capsules and Tablets.
- 6.260 Teva's Pentran application provides further, contemporaneous evidence, that the DHSC did not consider that £30 was an appropriate list price for Tablets (ie the very same drug, manufactured by the same supplier, that had formed the basis of the discussions between the DHSC and Teva at the 2007 meeting).
- 6.261 Moreover, the Parties' representations fail to address the following points, which are inconsistent with their submissions that £30 reflected the value of Tablets to the DHSC and that the DHSC was continuing to pay £30 on this basis.
- 6.262 In considering Teva's request, the DHSC makes no reference to £30 being any reflection of its assessment of the value of the product in 2007 or subsequently. In

¹³²⁰ PRC01176, Email from [Teva Employee] (Teva) to [DHSC Employee 8] (DHSC), RE: Teva - Pentran 100 mg Tablets - Additional information request (DHSC004.852), 30 January 2014, DHSC response of 15 December 2020 to the CMA's s.26 Notice of 7 July 2020.

¹³²¹ PRC03492, Flynn's response to the SO, paragraph 8.15.2.

¹³²² PRC03488, Pfizer's response to the SO and DPS, paragraph 17(b).

fact (and consistent with the CMA's conclusions), the DHSC raised concerns that the £30 Drug Tariff price was at the wrong level of the supply chain for the purposes of Teva's proposal and might be significantly above Teva's actual upstream selling prices.¹³²³

- 6.263 As a result, instead of accepting the proposed price of £30 (ie the price which the Parties argue represented what the DHSC was willing to pay for this very product), the DHSC rejected Teva's proposal based on this price.¹³²⁴
- 6.264 The DHSC considered that an assessment of Teva's proposal would require knowledge of Teva's actual upstream supply prices and an understanding of its costs of supply. This was also the DHSC's approach to trying to understand the justification for the Parties' price increases for Capsules and shows that the starting point for the DHSC's consideration of whether a price could be justified was gaining an understanding of the supplier's costs. The DHSC did not have Teva's costs information for the purposes of the discussions at the meeting in 2007. This is consistent with the DHSC's view that the discussion between the DHSC and Teva at that meeting would not have been by reference to the 'value' of the drug and that the Parties were incorrect to say that it had attached a specific 'value' to phenytoin sodium.¹³²⁵
- 6.265 In contrast with the approach adopted by the Parties, Teva (including [Teva Employee 1] – who had attended the 2007 meeting with the DHSC on behalf of Teva) did not try to use the outcome of the 2007 meeting to justify its proposed list price of £30 or argue that, notwithstanding the DHSC's objections, the DHSC had previously determined that £30 was a fair price reflecting its assessment of the value of this very drug. Instead, Teva (and [Teva Employee 1]) agreed with the recommendation to 'back away' from the Pentran proposal in light of the level of detail the DHSC was requesting.¹³²⁶ The implication of Teva's internal decision to 'back away' following the DHSC's request for costs information was that it was not confident that the DHSC would then approve £30 as an appropriate list price.
- 6.266 This is consistent with and supports the CMA's conclusions that the outcome of the meeting between the DHSC and Teva in 2007 did not reflect a 'value assessment'

¹³²³ See paragraph 6.253.

¹³²⁴ Flynn has submitted that the fact that the DHSC did not approve Teva's proposal to benchmark its price against the £30 Drug Tariff price and instead requested actual pricing and costs information 'suggests that the DHSC considered the Drug Tariff price to be relevant to the determination of Teva's application otherwise they would not have engaged at all with Teva's proposal' (PRC03492, Flynn's response to the SO, paragraph 8.15.2). Whilst the DHSC's requests do reflect that it saw Teva's supply prices for Tablets and its costs of supply to be relevant to the determination, it is not clear how Flynn draws the conclusion that the DHSC's refusal to approve Teva's proposed price of £30 is evidence that, in fact, it saw £30 to be relevant.

¹³²⁵ PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), paragraphs 33 and 39.

¹³²⁶ PRE00568, Email from [Teva Employee 1] (Teva) to [Teva Employee], [Teva Employee] and [Teva Employee] (Teva) on 28 November 2013, RE: Teva - Pentran 100 mg Tablets - Additional information request - H55535-0021-001705, Teva's response of 20 April 2021 to the CMA's s.26 Notice of 25 January 2021.

by the DHSC and that the DHSC was not willing to pay £30 for Tablets (or Capsules) during the Relevant Period.

v. The CMA's conclusion on the £30 Drug Tariff price

6.267 As described at paragraph 6.191 above, to determine whether the £30 Drug Tariff price of Tablets is a meaningful comparator for the purposes of assessing the fairness of the Parties' prices for Capsules, the CMA has considered above: (i) whether the £30 Drug Tariff price allows for a consistent comparison with the Parties' supply prices; (ii) whether the £30 Drug Tariff price was reflective of effective competition; and (iii) whether the NHS saw £30 as reflective of the value of Capsules and were willing to pay this price.

6.268 Based on this assessment, the CMA has concluded that:

6.268.1 The £30 Drug Tariff price was not a like-for-like comparison with the Parties' prices, which were at a different level of the supply chain. The Drug Tariff price was significantly higher than actual supply prices charged at the equivalent level of the supply chain to Flynn during the Relevant Period. This makes any comparison against Flynn's Prices (and even more so against Pfizer's Prices) inconsistent.¹³²⁷

6.268.2 The £30 Drug Tariff price was not a price reflective of any degree of competition and remained highly inflated by Teva's exercise of its market power and significant price increases between 2005 and 2007. Reflecting this, the Drug Tariff price of £30 was almost eight times greater than the Drug Tariff price of £3.87 at the beginning of scheme M and almost 18 times greater than the Drug Tariff price of £1.70 in March 2005.

6.268.3 The DHSC and CCGs did not consider £30 to be the value of Capsules, or Tablets, and were not willing to pay this price during the Relevant Period.

6.269 Accordingly, the £30 Drug Tariff price of Tablets is not a meaningful benchmark for the purposes of assessing the fairness of the Parties' prices for Capsules. In reaching this conclusion, the CMA has also considered and taken account of the Parties' representations regarding the significance of the 2007 meeting between

¹³²⁷ The Parties have submitted that they both, in any event, set their prices below the £30 Drug Tariff price. Flynn has submitted that, whilst it 'benchmarked its launch price of phenytoin capsules against the Drug Tariff price of tablets it did not sell it at this price – and instead sold the tablets at considerably below this level'. See PRC03492, Flynn's response to the SO, paragraph 8.15.2. Pfizer has submitted that 'Pfizer's capsule price – set at around half of the £30 DT price for the identical tablet product – cannot have been unfair'. See PRC03488, Pfizer's response to the SO and DPS, paragraph 6(a), see also paragraphs 12, 14, 16, 17(a), 17(c), 41(a), and 44. The CMA has concluded that the £30 Drug Tariff price was not a meaningful comparator for the purposes of assessing the fairness of the Parties' prices. It follows naturally from this that pricing below £30 does not necessarily make the Parties' prices fair. However, if there is evidence that the Parties' prices were fair when compared to another appropriate and meaningful benchmark then that would be relevant to the CMA's overall assessment. The CMA has assessed below whether the ASPs of Tablets suppliers or the prices of certain other AEDs might indicate that the Parties' prices were fair.

the DHSC and Teva. The CMA's assessment of the Parties' representations is set out below.

vi. *The Parties' representations regarding the 2007 meeting between the DHSC and Teva*

Introduction

- 6.270 The Parties argue that the CMA should determine the fairness of their prices for Capsules between 2012 and 2016 exclusively by reference to what they submit was the DHSC's acceptance of £30 as the value of Tablets at the meeting between the DHSC and Teva in October 2007.¹³²⁸
- 6.271 The Parties have submitted that the £30 Drug Tariff price was a fair price which resulted from the DHSC 'intervening' and 'negotiating' a reduced price with Teva and that £30, therefore, reflected the value of the drug to the DHSC and was what it was willing to pay. The Parties also rely on the fact that the DHSC then paid the £30 Drug Tariff price for a number of years.¹³²⁹ The Parties' view is that they were then entitled to rely on this (and did so in good faith) as a legitimate and meaningful benchmark to justify significantly increasing the prices paid by the NHS for Capsules.
- 6.272 The CMA does not accept the Parties' submissions on the significance of the 2007 meeting. The CMA likewise does not consider the Parties' arguments that they understood the DHSC to have been willing to pay the £30 Drug Tariff price and relied on this in good faith to be sustainable in the face of the evidence gathered.
- 6.273 First, this ignores the evidence described above surrounding the Drug Tariff price being fixed at £30. Following the DHSC's discussions with Teva and the subsequent price reduction, the DHSC was still paying a price significantly higher than it had done prior to Teva's very significant Tablet price increases in the period between 2005 and 2007.
- 6.274 Second, this ignores the financial impact of the Parties' pricing decisions. The Tablets market is significantly smaller than the Capsules market, meaning that a high Drug Tariff price for Tablets would have much lower impact on CCG budgets than the same Drug Tariff price for Capsules. This point was made explicitly by the DHSC to Flynn when contesting the Parties' use of the £30 Drug Tariff price in 2012. The DHSC saw the larger market for Capsules as an important reason why Tablets were not an appropriate benchmark.¹³³⁰ Reflecting this concern, during the Relevant Period, the DHSC spent around £41.1 million on Tablets compared to

¹³²⁸ Pfizer has described the 2007 meeting as 'the single most important factual issue in this case'. See PRE00627, Pfizer's written closing submission, paragraph 14.

¹³²⁹ See, for example, PRC03492, Flynn's response to the SO, paragraphs 1.17, 1.30, 8.4, 8.7, 8.8; see also PRC03903, Flynn's response to the Letter of Facts, paragraphs 5.4 to 5.6 and PRC03488, Pfizer's response to the SO and DPS, paragraphs 6(a), and 10 to 17.

¹³³⁰ See Annex C.

around £177.5 million on Capsules.¹³³¹ [Former Teva Director], Teva's [X] and its representative in discussions with the DHSC in respect of Tablets pricing, confirmed that the DHSC's focus would have been on 'overall cost' rather than the specific price.¹³³²

- 6.275 Third, the Parties reliance on the Tablets Drug Tariff price was based solely upon an inference as to the DHSC's views on the £30 Drug Tariff price following the meeting between the DHSC and Teva. However, this inference needs to be balanced against the substantial volume of evidence which shows that the Parties knew that the DHSC (and many CCGs and other stakeholders) objected to their prices and did not consider that the benchmarking against the Tablets Drug Tariff price was justified and that these reservations were communicated unambiguously to the Parties. This evidence included the DHSC having previously rejected explicit requests for price increases by reference to the Drug Tariff price of Tablets. This evidence is comprehensively set out in Annexes B and C to this Decision.
- 6.276 However, notwithstanding these clear objections, and the possibility of taking a more reasonable course of action (at the very least, by engaging with DHSC to understand why its position starkly contrasted with the Parties' assumptions on the Tablets Drug Tariff price¹³³³), the Parties essentially disengaged from discussions with the DHSC and CCGs on pricing. If the Parties were confident in their reliance on the Tablets Drug Tariff price as a benchmark, given the obvious discrepancy between their understanding of the DHSC's views on Tablets and the position the DHSC took in practice, they would have been expected to have contacted the DHSC to gain its views, and potentially its support, on this point. Instead, the Parties refused to provide cost price information when the DHSC requested it (knowing that the DHSC did not have the power to compel its production) and related the price levels they had imposed to the financial viability of the product (an argument not supported by the excesses they earned).¹³³⁴
- 6.277 The evidence the CMA has gathered demonstrates that the DHSC (and CCGs) did **not** consider the benchmark to be appropriate and communicated that to the Parties. Indeed, [Flynn Director 2] conceded that he knew that the DHSC objected to the use of the benchmark.¹³³⁵ The DHSC's discontent with the Parties' prices would also have been clear to the Parties through the OFT and CMA investigation. However, at no stage following the commencement of the investigation did the Parties seek dialogue with the DHSC to resolve the issue.

¹³³¹ See paragraph 6.157.

¹³³² PAD00030, [Former Teva Director] Cross Examination, day 5, page 37, lines 14-16.

¹³³³ This possibility had been raised by the GMMMG in its letter to the Parties on 10 October 2012. The letter from the GMMMG set out that '[t]he only credible alternative is that the companies must make a case for a **modest** price increase, but this must stand up to economical and clinical justification'. See further Annex B.

¹³³⁴ See section 6.B.II.

¹³³⁵ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 158, lines 16 to 20 and page 167, lines 8 to 14.

- 6.278 Instead, the Parties continued to impose their very high prices based on an inference drawn from what happened to the Tablets Drug Tariff price following the meeting between Teva and the DHSC in October 2007. Neither Party attended the meeting between Teva and the DHSC and no formal announcement was made as to its outcome which they could have relied upon. Further, [Pfizer Director 1] of Pfizer confirmed that Pfizer did not speak to anyone from Teva or the DHSC about what happened at the meeting and that Pfizer relied purely on an inference relating to the outcome of the meeting between Teva and the DHSC.¹³³⁶
- 6.279 Given the scale of the evidence showing both Pfizer and Flynn were made aware of the DHSC's objections (and those of CCGs and other stakeholders), the inferences drawn by the Parties were clearly not justified in practice.
- 6.280 The CMA has addressed below some of the specific representations made by the Parties on the evidence gathered regarding the 2007 meeting.

The Parties' reliance on the email chain between the DHSC and Teva from October 2007¹³³⁷

- 6.281 To support their case that the £30 Drug Tariff price of Tablets was a meaningful comparator for a fair price for Capsules, the Parties rely on extracts from an email exchange between the DHSC and Teva immediately following the meeting in October 2007.
- 6.282 The email exchange records the outcome of the discussion between Teva and the DHSC at the meeting. Flynn's view is that 'this email is very important because it is showing not just that there was some sort of passive acceptance. It clearly shows an agreement.'¹³³⁸ The Parties also rely on a reference made by one of the DHSC attendees in the email chain to the outcome of the 2007 meeting being 'of value to NHS patients'.
- 6.283 In the same email, the DHSC official also refers to the Drug Tariff price reducing to £30 on 1 July 2008 'with a view to a further reduction'. In a subsequent email in the same chain, the DHSC official sets out that 'the reimbursement price will fall to £30 from 1 October 2008 and we will anticipate further reductions thereafter'.
- 6.284 The CMA does not consider that this email chain elevates the significance of the 2007 meeting or indicates that the £30 Drug Tariff price was a meaningful benchmark. Given the Tablets Drug Tariff price in the previous quarter had been £113.62, a reduction to £30 would of course be 'of value' to the NHS. However, this does not make the resulting per pack price of £30 a meaningful comparator.

¹³³⁶ See PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 37 lines 24 and 25 and page 38, lines 1-3.

¹³³⁷ PRC00458, emails between [DHSC Employee 1] (DHSC) and [Former Teva Director] (Teva) dated 17 October 2007 and 18 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020. Also described further in Annex M.

¹³³⁸ PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 51, lines 9 – 11.

Following the meeting, the £30 Drug Tariff price remained significantly above historical supply prices and continued to be distorted by Teva's substantial market power and significant price increases between 2005 and 2007. Additionally, the evidence shows that the DHSC and CCGs did not agree to or accept the Parties' prices or their use of the Tablets Drug tariff price as a price benchmark for Capsules.

The Parties' reliance on the DHSC internal email from 2013¹³³⁹

- 6.285 The Parties rely on an internal DHSC email chain from July 2013 in which one of the DHSC attendees from the 2007 meeting, in describing the events leading into that meeting, comments that:

The alternative of ejecting the company from membership of Scheme M and then enforcing a maximum price by direction of the Secretary of State was considered a less attractive option.

*On reflection, the classification of phenytoin as a generic and its subsequent inclusion in category M was not a good idea. The company was quite open about the process, it saw an opportunity and exploited it. It could have done the same under the previous category A process, but did not notice until the introduction of category M.*¹³⁴⁰

- 6.286 Pfizer has submitted that this evidence shows that the DHSC 'considered, and rejected, the use of more draconian regulatory powers (including enforcing a maximum price)' which suggests the DHSC considered it had negotiated a fair price for Tablets with Teva.¹³⁴¹ Pfizer has also submitted that this evidence shows that the DHSC 'had the power to reduce and fix the price of phenytoin sodium capsules, should it have wanted to do so' and that 'the DH (and others in the market) at least considered that it had those powers at the time of the 2007 meeting'.¹³⁴²
- 6.287 Flynn has submitted that this 'reflects the fact that the DHSC not only had alternative powers, it considered those powers and chose not to use them' and that the DHSC believed it had other options to reduce the price of Tablets if it was not happy with the £30 Drug Tariff price.¹³⁴³

¹³³⁹ PRC01233, Email from [DHSC Employee 1] (DHSC) to DHSC colleagues dated 16 July 2013 (DHSC009.253), DHSC response of 22 December 2020 to the CMA's 26 Notice of 7 July 2020.

¹³⁴⁰ PRC01233, Email from [DHSC Employee 1] (DHSC) to DHSC colleagues dated 16 July 2013 (DHSC009.253), DHSC response of 22 December 2020 to the CMA's 26 Notice of 7 July 2020.

¹³⁴¹ PRC03488, Pfizer's response to the SO and DPS, paragraph 14.

¹³⁴² PRC03488, Pfizer's response to the SO and DPS, paragraph 15.

¹³⁴³ PRC03492, Flynn's response to the SO, paragraph 1.16.

- 6.288 The CMA does not consider that this email from 2013 alters the CMA's conclusions regarding the significance of the 2007 meeting for the purposes of assessing the Parties' prices.
- 6.289 Consistent with the findings of the CAT regarding the relevance of the DHSC's powers in this case¹³⁴⁴, the question of whether the £30 Drug Tariff price of Tablets is a meaningful benchmark does not turn on the precise scope of the DHSC's powers.
- 6.290 In particular, an internal DHSC email (which was created some time after the meeting between Teva and the DHSC and after the Parties had imposed their price increases) does not provide a basis for rebutting the substantial body of direct evidence that demonstrated to the Parties that the DHSC (and CCGs) did not consider that the Drug Tariff price of Tablets provided an appropriate benchmark for their prices.
- 6.291 Moreover, the email does not contain the DHSC's formal or considered view of the powers it had at the time, nor does it reflect an objective legal assessment of those powers. It is the opinion of one DHSC employee. The Parties knew the DHSC had limited powers to intervene – demonstrated by the fact they did not provide the DHSC with their costs information when it was requested and that they were able to impose their price increases despite obvious objections from the DHSC.
- 6.292 The evidence also shows that, for the DHSC, the outcome of the meeting was that it would continue to pay a far higher price for Tablets than it had prior to Teva's imposition of a number of significant price increases as a monopoly supplier.¹³⁴⁵ The CMA does not consider that a price which has been subject to such a significant increase, over such a short period, and without any increase in the underlying costs of supply or any product improvement, is likely to be a meaningful comparator for the purposes of assessing the fairness of other prices.
- 6.293 In *Phenytoin*, the CAT considered the question of the DHSC's regulatory powers and concluded:

The question is whether the DH was, as a matter of fact, able to exercise buyer power in the form of regulatory power materially to influence Pfizer and Flynn's pricing. With regard to the extent of the DH's legal powers, and without deciding the point, we simply observe that Pfizer itself acknowledged in its skeleton argument that the DH was unclear about the scope of its powers, and that the amendment to the NHS Act 2006 introduced by the 2017 Act suggests to us that the DH considered it did not

¹³⁴⁴ *Phenytoin* [2018] CAT 11, paragraph 207.

¹³⁴⁵ At £30, the Drug Tariff price was almost eight times greater than the Drug Tariff price of £3.87 in April 2005 (at the beginning of scheme M) and almost 18 times greater than the Drug Tariff price of £1.70 in March 2005 (immediately prior to the introduction of scheme M).

already have the necessary powers in this area. It is also clear that, as a matter of fact, the DH did not seek to exercise any legal powers.^{1346 1347}

- 6.294 Pfizer applied to the Court of Appeal to appeal the CAT's conclusion on this point. The Court of Appeal refused to grant permission, giving the following reasons:

*[T]he CAT was clearly entitled to conclude that it did not need to decide the precise extent of the Department of Health's powers and to find that the Department had no effective means to limiting the appellants' prices. Both the case law and common sense show that the focus should be on whether there is an effective constraint rather than the theoretical position, and Case C-280/08 Deutsche Telekom v Commission confirms that the failure of the Department to exercise any powers it may have had could not have absolved the appellants from their "special responsibility not to allow their conduct to impair genuine undistorted competition".*¹³⁴⁸

- 6.295 Consistent with this, the CMA has conducted its evaluation of the £30 Drug Tariff price based on a far wider body of evidence.
- 6.296 The CMA, in any event, rejects the Parties' submissions that this extract shows that the DHSC had the regulatory powers to allow it to reduce and fix the prices of generic drugs supplied by members of a voluntary scheme. As recognised by the CAT and in Teva's internal documents reporting on the 2007 meeting,¹³⁴⁹ the DHSC did not in fact use any formal powers to seek to regulate or require a reduction in Teva's price. Furthermore, as set out further in section 2, the DHSC did not have effective powers to require a price reduction in these circumstances:
- 6.296.1 The DHSC could not use the Reserve Power under the NHS Act to require Teva to reduce its price for Tablets or impose a fixed price.¹³⁵⁰ Prior to 7 August 2017, the DHSC's Reserve Power to limit the prices charged for a health service medicine could not be exercised in relation to a member of a voluntary scheme.¹³⁵¹ Teva was a member of both the voluntary PPRS (which applied to Teva's branded drugs) and scheme M. Accordingly, in order to use the Reserve Power, the DHSC would have needed to eject Teva from both scheme M and the PPRS. In addition, there were legal and

¹³⁴⁶ *Phenytoin* [2018] CAT 11, paragraph 207.

¹³⁴⁷ There were no relevant changes to the powers of the DHSC between the 2007 meeting with Teva and the DHSC's engagement with Flynn and Pfizer in 2012.

¹³⁴⁸ *Flynn Pharma Limited & Ors v CMA*, Order made by the Rt. Hon. Lord Justice Newey, dated 12 December 2018 (emphasis in original).

¹³⁴⁹ See PRC00461, Internal briefing note Phenytoin Sodium 100mg, 27 November 2007: Teva's response of 4 November 2020 to the CMA's s.26 Notice dated 31 July 2020.

¹³⁵⁰ See section 2.C.II.h.

¹³⁵¹ Section 262(2) of the NHS Act. See also Section 2.C and PHT00040, Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.2).

practical challenges for the DHSC to use the Reserve Power, even for suppliers who were not members of voluntary schemes.¹³⁵²

6.296.2 The DHSC was not able to (and has never sought to) use the scheme M arrangements to regulate generic drug prices. The scheme M arrangements did not provide an effective mechanism for doing so and the DHSC lacked the capability to determine whether a price charged for an individual generic drug was fair or reasonable for these purposes.¹³⁵³

The Parties' reliance on the DHSC 'fixing' the Drug Tariff price and the absence of further intervention by the DHSC

6.297 The Parties have relied on the circumstances surrounding the fixing of the Drug Tariff price at £30, as well as the absence of further intervention by the DHSC after October 2007, to argue that the DHSC must have seen £30 as a fair price for Tablets.¹³⁵⁴

6.298 The CMA does not consider that the DHSC's explanations regarding the precise mechanism by which the outcome of the 2007 meeting was implemented add to the relevance of the meeting for the purposes of the CMA's assessment.¹³⁵⁵ The fact that Tablets were removed from the category M quarterly price adjustment process simply reflects the outcome of the 2007 meeting. The explanations the DHSC has been able to provide on this are set out at paragraphs 6.179 to 6.186 above.

6.299 The CMA also does not agree that the absence of efforts by the DHSC to secure further reductions in the Tablets Drug Tariff price is evidence that it was willing to

¹³⁵² First, there was no enforcement regime to compel the provision of information (such as costs data) under section 264 of the NHS Act for non-branded drugs. Whilst scheme M had provisions in relation to the provision of data, ultimately, as the scheme was voluntary, a member could withdraw from the scheme at any time. Second, even if it had costs data, the DHSC lacked the capability to analyse such data on an individual product level to determine whether a price charged was fair or reasonable (see PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), paragraph 9). Instead, the DHSC's policy was to rely on competition to control prices of unbranded generic drugs (see PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), paragraph 13). Third, the Reserve Power was only exercisable after consultation with the BGMA (section 262(1) of the NHS Act).

¹³⁵³ Flynn submitted that it was not credible that the DHSC lacked the capability and capacity to determine the fair and reasonable price of a drug: PRC03492, Flynn's Response to the SO, paragraph 6.10 and PRC03631, Transcript of Flynn's Oral Hearing, 6 December 2021, page 33, line 13 to page 34, line 9. The CMA does not agree. Whilst the DHSC was resourced to develop, operate and maintain its schemes, it did not have the resources or appropriate infrastructure and implementing framework in place to determine the fair and reasonable price of an individual generic drug: PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), in particular paragraphs 9 and 10. In respect of the PPRS, the method the DHSC used to evaluate a price increase application was to look at the sales and costs of a company's overall portfolio of licensed branded medicines, rather than at the product level: PHT00082, Final version of the note of the CMA's meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), paragraph 9.

¹³⁵⁴ PRC03488, Pfizer's response to the SO and DPS, paragraphs 6(a) and 13(a).

¹³⁵⁵ Pfizer has submitted that '[X]'. The DH has also confirmed that this model clearly flagged phenytoin sodium tablets as the only product with a fixed price.' Pfizer's view is that this 'strongly reinforces Pfizer's case that the DH, as the ultimate customer/payor, considered £30 to be a fair price for phenytoin sodium'. See PRC03488, Pfizer's response to the SO and DPS, paragraph 6(a).

pay £30 or saw this as the value of the product.¹³⁵⁶ ¹³⁵⁷ This was a point also previously accepted by the CAT in concluding that it ‘cannot say whether the DH ‘accepted’ the tablet price in the sense of regarding it as a fair price for the purpose of an Article 102 test. All we can say is that the price appears to have been accepted in practice and that no further direct intervention occurred.’¹³⁵⁸

6.300 The DHSC explained to the CMA that the Drug Tariff price remained at £30 for as long as it did due to an oversight.¹³⁵⁹ In 2016, [✂], they took action to put Tablets back into the usual category M calculation process in order to benefit from lower prices for Tablets.¹³⁶⁰

6.301 The following factors support the CMA’s view that the absence of subsequent intervention does not indicate that the DHSC was happy with and willing to pay the £30 Drug Tariff price:

6.301.1 First, in 2012, the DHSC explicitly rejected the use of the Tablets Drug Tariff price as a benchmark for the Parties’ prices and told them not to assume that it was happy with the price of Tablets.¹³⁶¹

6.301.2 Second, in 2013, the DHSC considered a request by Teva to list its own Tablets product (ie the very product subject to the discussions at the 2007 meeting) in the PPRS at a list price of £30. The DHSC rejected the request and, instead, sought to understand Teva’s costs of supply.

6.301.3 Third, as described at paragraphs 6.296.1 to 6.296.2 above, the DHSC did not have sufficient powers to require Teva to make further reductions. In September 2012, the DHSC was unable to exert any material buyer power on the Parties, as confirmed by the CAT.¹³⁶² Consistent with this, the DHSC told the CMA in 2016 that ‘there was nothing more (besides the discussion it held with Teva) that it could have done to achieve a further reduction to Teva’s tablet price’.¹³⁶³

6.301.4 Fourth, the potential for further efforts at intervention by the DHSC must be considered in the light of the overall cost of Tablets to the DHSC. As highlighted by the DHSC to Flynn when contesting the Parties’ use of the £30 Drug Tariff price in 2012, the DHSC’s overall spend on Tablets was

¹³⁵⁶ As recognised by the Court of Appeal, ‘[t]he simple fact that a consumer will or must pay the price that a dominant undertaking demands is not [...] an indication it reflects a reasonable relationship with economic value’: *Phenytoin CoA*, paragraphs 154-155.

¹³⁵⁷ PRC03492, Flynn’s response to the SO, paragraphs 6.25 to 6.28; and PRC03488, Pfizer’s response to the SO and DPS, paragraph 14.

¹³⁵⁸ *Phenytoin* [2018] CAT 11, paragraphs 230 and 231.

¹³⁵⁹ PRC01322, DHSC response dated 19 January 2021 to the CMA’s s.26 Notice of 22 December 2020, question 7(a).

¹³⁶⁰ PRC01322, DHSC response dated 19 January 2021 to the CMA’s s.26 Notice of 22 December 2020, question 8(a).

¹³⁶¹ See further Annex C.

¹³⁶² *Phenytoin* [2018] CAT 11, paragraph 235.

¹³⁶³ PHT00082, Final version of the note of the CMA’s meeting of 23 February 2016 with the Department of Health (CMA document reference 02032.1), paragraph 35, and at paragraph 34 the DHSC also told the CMA that, it would have liked to have seen further decreases, but had not actively sought further reductions due to ‘the DH’s limited resources, lack of capability [...], and the fact that the tablets market was relatively small’.

far smaller than Capsules. [Former Teva Director] also previously explained to the CAT that the overall cost of a drug to the NHS would have to be 'pretty eye watering' to attract any sort of regulatory intervention.¹³⁶⁴ During the Relevant Period, the DHSC spent around £41.1 million on Tablets compared to around £177.5 million on Capsules.¹³⁶⁵ Given the more limited volumes and resultant overall cost of Tablets to the NHS, subsequent intervention was less likely.

Conclusion on the evidence relating to the 2007 meeting

- 6.302 The CMA has considered the evidence previously submitted by the Parties, including that of [Former Teva Director], as well as the new evidence gathered on Remittal on which the Parties have relied.
- 6.303 For the reasons set out above, the CMA does not consider that the outcome of the 2007 meeting and the evidence relating to it support the conclusion that the £30 Drug Tariff price of Tablets was a meaningful benchmark for the fairness of the Parties' prices for Capsules years later.¹³⁶⁶

e. The CMA's assessment of Tablets ASPs as a potential comparator

i. Introduction

- 6.304 In *Phenytoin*, the CAT identified the importance of considering ASPs in the upstream market for the supply of Tablets.¹³⁶⁷ The CAT's view was that the CMA should have conducted an investigation into the competitive conditions in the market for the supply of Tablets to assess whether their ASPs were set in conditions of effective competition and might therefore be a useful comparator to assess whether the Parties' prices for Capsules were fair.¹³⁶⁸ Of particular relevance was the possibility that the Tablets market may have experienced competitive entry¹³⁶⁹ which may have resulted in price competition leading to a decline in ASPs:

[I]f it is indeed the case that new entrants have entered the tablet sector and that as a result price competition has reduced the tablet ASP, a matter on which we can make no finding on the evidence before us, this would suggest that one of the material reasons given in the Decision by the CMA for disregarding the tablet as a meaningful comparator, namely that it was

¹³⁶⁴ PAD00030, [Former Teva Director] Cross Examination, day 5, page 37, lines 14-16.

¹³⁶⁵ See paragraph 6.157.

¹³⁶⁶ The CMA has also addressed a small number of the Parties' representations relating to the meaningfulness of the £30 Drug Tariff price as a comparator in Annex F.

¹³⁶⁷ *Phenytoin*, CAT [11] 2018, paragraphs 7, 384 to 391 and 467.

¹³⁶⁸ *Phenytoin*, CAT [11] 2018, paragraphs 384 to 391.

¹³⁶⁹ The CAT noted that, according to information submitted by the solicitors for Pfizer, several Tablet suppliers had entered the market since 2009, suggesting that competitive conditions may have changed. The list incorrectly included Hillcross and Actavis as manufacturers of Tablets, *Phenytoin*, CAT [11] 2018, paragraph 380 and footnote 75. There were in fact only two entrants to the Tablets market: Wockhardt and Milpharm.

*subject to the same restrictions on competition as the capsule, would be wrong. However, that process would also be highly germane to seeking to establish the benchmark price in conditions of sufficient competition, as well as being informative on the question of unfairness.*¹³⁷⁰

- 6.305 The Parties' view is that the evidence referred to by the CAT and evaluated by the CMA below relating to Tablets ASPs and competitive conditions is irrelevant and that the CMA should determine whether their prices for Capsules were fair exclusively by reference to what they argue was the DHSC's acceptance of the £30 Drug Tariff price of Tablets. Both Pfizer and Flynn have submitted that they had no knowledge of the prices charged by suppliers of Tablets to wholesalers as such information is not publicly available, and that is why they relied upon the Drug Tariff price as a reference point for their prices of Capsules.¹³⁷¹
- 6.306 The CMA does not agree that the Parties' lack of awareness of ASPs makes them irrelevant or affects the objective assessment of whether Tablet ASPs are a suitable comparator. On the contrary, in the CMA's view, the Parties' lack of awareness of ASPs, giving them a partial picture of what was happening in the supply of tablets, demonstrates the inappropriateness of relying on the Drug Tariff price as an appropriate reference point for capsules. Furthermore, the Parties were, in fact, aware of a significant number of factors which undermined the Drug Tariff price as a potential benchmark.¹³⁷² Consistent with the conclusions of the CAT, as well as the importance of the competitiveness of proposed comparators emphasised in the case law,¹³⁷³ the CMA has analysed the competitive conditions in the Tablets market since 2005. The purpose of this analysis is to assess whether Tablets ASPs might provide a meaningful comparator against which to consider whether Pfizer's Prices and Flynn's Prices were fair. This analysis is set out below.

ii. The CMA's findings

- 6.307 The CMA finds that the Tablets market did not exhibit sufficiently effective competition during the period January 2005 to December 2021 for Tablets ASPs to provide a meaningful comparator for assessing the fairness of the Parties' prices for Capsules.
- 6.308 For the majority of that period, Teva was either a monopolist (January 2005 to September 2009) or there was a duopoly with Teva and one other supplier (first Wockhardt (October 2009 to August 2012) then Milpharm (August 2014 to December 2021)).

¹³⁷⁰ *Phenytoin*, CAT [11] 2018, paragraph 390.

¹³⁷¹ PRC03488, Pfizer's response to the SO and DPS, paragraph 18; PRC03492, Flynn's response to the SO, paragraph 8.40; and PRC03493, Fifth Expert Report of CRA, paragraphs 82 to 83.

¹³⁷² See section 6.C.II.

¹³⁷³ See, for example, *Scandlines*, paragraphs 172 and 173; *Phenytoin* [2018] CAT 11, paragraph 390; *Phenytoin CoA*, paragraphs 155 and 172; and *Aspen*, paragraph 199.

- 6.309 There was a relatively brief period (22 months) of some increased competition when there were three Tablet suppliers in the market (Teva, Milpharm and Wockhardt) between September 2012 and July 2014. However, even though prices reduced during this period there were a number of factors which limited the effectiveness of competition, with the evidence demonstrating that Teva maintained a significant majority share of supply while also charging the highest prices for most of the period assessed. The entrants, Wockhardt and Milpharm, while gaining share of supply when they entered, were unable to grow their sales volumes despite the clear financial incentive on pharmacies to switch to their products. This shows that Teva maintained a substantial degree of market power at all times.
- 6.310 Notwithstanding the CMA's conclusion that Tablets ASPs do not provide a meaningful comparator, the CMA has nevertheless considered the Parties' supply prices during the Relevant Period alongside the ASPs of the Tablet suppliers (and the entrants into the Tablets market (Wockhardt and Milpharm) in particular) during the period of three player supply. The comparison shows that the Parties' ASPs were significantly higher than the ASPs of Wockhardt and Milpharm and were even higher than Teva's ASPs despite Teva's position of market power following the initial price falls following Milpharm's entry. To the extent that any weight should be given to such a comparison as being informative on the question of fairness, the comparison does not indicate that the Parties' prices during the Relevant Period were fair or undermine the CMA's conclusion that the Parties' prices were unfair in themselves. If anything, it supports this conclusion.
- 6.311 Accordingly, the CMA's analysis of Tablets ASPs does not undermine or justify departing from the conclusion that Pfizer's Prices and Flynn's Prices were unfair in themselves.¹³⁷⁴

iii. Competition within the Tablets market from January 2005 to December 2021

- 6.312 The following section assesses competition within the Tablets market between January 2005 and December 2021.
- 6.313 It should be noted when reading the CMA's analysis that Tablets are sold in packs of 28, whereas 100mg Capsules are sold in packs of 84.¹³⁷⁵ When referring to Teva, Wockhardt and Milpharm's ASPs below, the CMA has referred to their prices for a pack of 28 Tablets and, therefore, the Tablet ASPs presented cannot be

¹³⁷⁴ Pfizer has submitted that the CMA has changed its case and is 'pursuing the third iteration of its case in relation to the tablet', referring to the CMA 'having previously identified the tablet ASPs as a potential answer'. See, for instance, PRC03901, Pfizer's response to the Letter of Facts, paragraph 10 and PRC03488, Pfizer's response to the SO and DPS, paragraph 41. This misrepresents the CMA's previous position. Consistent with the position taken by the CMA on remittal, the CMA previously found that the Tablets Drug Tariff price was not a like-for-like comparison and did not allow for a consistent comparison with the Parties' upstream prices. The CMA's view was that the consistent comparison would be with Tablets supply prices at the equivalent level of the supply chain to the Parties. However, the CMA did not conclude on the competitiveness of Tablets ASPs or on whether Tablets ASPs were a meaningful comparator. On remittal, the CMA has assessed whether Tablets ASPs (at the equivalent level of the supply chain to Flynn) could in practice be a meaningful comparator. This is not a change of the CMA's position.

¹³⁷⁵ 25mg, 50mg and 300mg Capsules are sold in packs of 28 Capsules.

directly compared with the Parties prices. It is necessary to multiply Teva, Wockhardt and Milpharm's ASPs by three to provide a like for like price comparison with the Parties' prices.¹³⁷⁶

6.314 The CMA has assessed the pricing behaviour of Tablet suppliers during the following time periods, based on changes to the number of suppliers in the market as set out in Table 6.9 below.

Table 6.9: Tablet products available from January 2005 to December 2021 (by manufacturer)

Period	Dates	Tablet products available in the UK
1	January 2005 - September 2009	Teva
2	October 2009 – August 2012	Teva, Wockhardt
3	September 2012 – July 2014	Teva, Wockhardt, Milpharm
4	August 2014 – December 2021	Teva, Milpharm

Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1, PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1, PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2, PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK; PRC00326, Milpharm's response dated 22 July 2020 to the CMA's s.26 Notice of 29 June 2020, Milpharm Data Sheet Final, PRE00274, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, BK, CMA Case 50908-Annex 2 - Data Feb'17toAug'20- Compl. 2Oct'20, and PRC01415, Milpharm's response of 5 February 2021 to the CMA's s.26 Notice of 29 January 2021, Annex 2.

Period 1: January 2005 to September 2009 – Teva is a monopolist

6.315 Teva was the monopoly supplier of Tablets in the UK between January 2005 and September 2009. Accordingly, by definition, Teva's ASPs during this period were set in conditions where it was not exposed to any level of competition, let alone effective competition.

6.316 The Tablets market was also characterised by barriers to entry in the form of requiring an MA to launch a product and uncertainties around securing patient demand due to the regulatory guidance.¹³⁷⁷ The DHSC also lacked sufficient buyer power to act as a material constraint.¹³⁷⁸ Collectively, these factors provided Teva with a substantial level of market power.

6.317 Between April 2005 (when Scheme M was introduced) and October 2007, Teva exercised its substantial market power by significantly increasing its prices such that its ASP rose from £2.67 per pack in 2005 to a peak of £51.25 in October 2007 (an increase of over 1,800%).

¹³⁷⁶ 100mg Capsules are sold in packs of 84 capsules and Tablets are sold in packs of 28 tablets. As such, the Tablet ASPs need to be multiplied by three to provide a like for like comparison.

¹³⁷⁷ NICE guidance published in October 2004 advised against changing the formulation or brand of AED.

¹³⁷⁸ See section 6.C.II.d. above.

- 6.318 These price increases were highly profitable and not the result of cost price pressures. A Teva Staff Briefing for Q2 in 2007 highlighted the strong financial performance of Tablets. The briefing noted that Teva was ‘the only supplier of phenytoin’ and that ‘the price has gone up very much over the past year or so’. ¹³⁷⁹
- 6.319 Indeed, by the end of Q2 2007 Teva’s ASP had increased to £43.72 per pack (an increase of over 1,500% compared to its ASP in 2005). The absence of any cost price pressure is shown by Teva internal documents estimating that the value of its sales would increase more than four-fold from an initial estimate of £5.8 million to £25.4 million by the year end as a result of its price increases, with all of the additional £19.6 million generated being profit. ¹³⁸⁰
- 6.320 Teva’s increased prices meant Tablets, a 70 year old drug, with a declining patient base and which had not been subject to any innovation, was seen as ‘the star in [its] generic portfolio’ in terms of financial performance. ¹³⁸¹
- 6.321 It is notable that this document also attributed Teva’s ability ‘to maintain high prices’ to being ‘the only supplier in the market’. ¹³⁸² In other words, Teva considered it was the lack of any competitive constraint that provided it with the ability to impose these price increases. There is no suggestion from the document that the increases were justifiable on the basis of the value of the drug to the NHS. [Former Teva Director] ([REDACTED]) also confirmed to the CAT in 2016 that Teva was able to do this because it was ‘the only company making this product’. ¹³⁸³
- 6.322 As explained in section 6.C.II.c.iii above and shown in Figure 6.2 below, the Drug Tariff price was fixed at £30 from October 2008 following a meeting between Teva and the DHSC in October 2007. Teva reduced its supply price in November 2008 to ensure that it was pricing under the £30 Drug Tariff price. Following this reduction, Teva’s ASP stabilised at approximately £26 from November 2008. Teva’s ASP remained at this level until around April 2012.

¹³⁷⁹ PRE00496, Teva internal presentation, Staff Briefing Q2 2007, page 4.

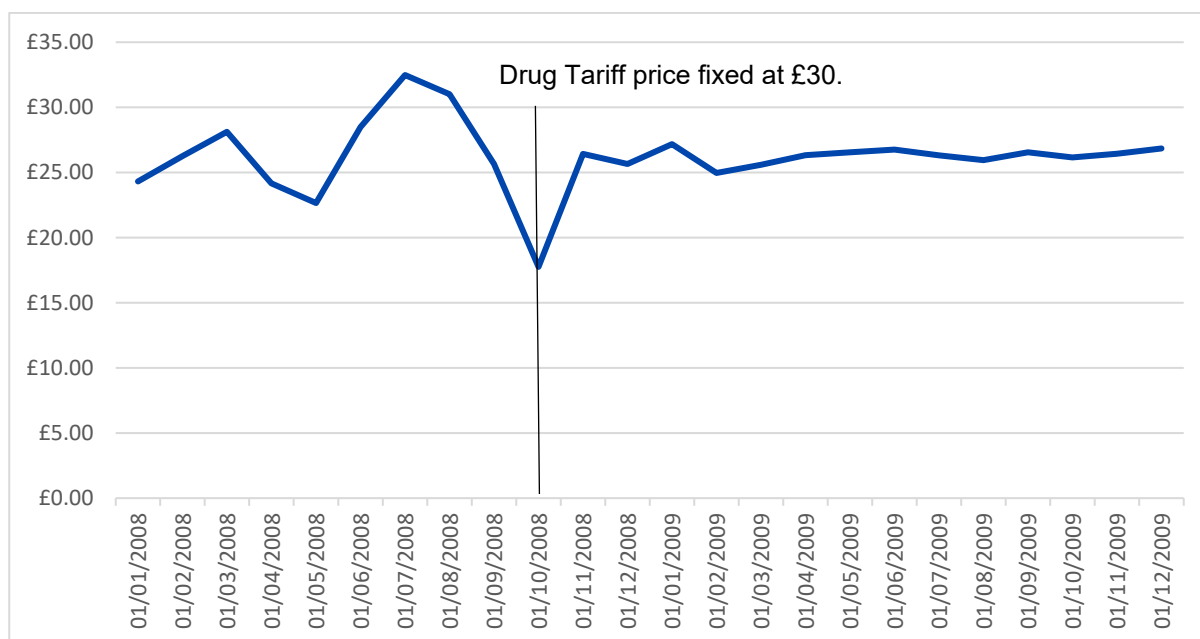
¹³⁸⁰ PRE00496, Teva internal presentation, Staff Briefing Q2 2007, page 19.

¹³⁸¹ PRE00496, Teva internal presentation, Staff Briefing Q2 2007, page 19.

¹³⁸² PRE00496, Teva internal presentation, Staff Briefing Q2 2007, page 19.

¹³⁸³ PAD00030, [Former Teva Director] Cross Examination, day 5, page 41, line 21, to page 42, line 17.

Figure 6.2: Teva's average selling price for a pack of 100mg phenytoin sodium Tablets, January 2008 to December 2009



Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1; PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1; and PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2.

6.323 The ASP of approximately £26 does not represent a reasonable price benchmark for assessing whether Flynn's and Pfizer's prices were fair. The revised price did not result from competition. Instead, Teva remained a monopolist and was not subject to an effective level of constraint.¹³⁸⁴ Teva's ASP, at approximately £26, remained around 870% higher than it had been in 2005 (which was £2.67), reflecting the continued exercise of its substantial market power.

6.324 The CMA's conclusion that Teva's ASP does not provide a meaningful benchmark for what an effectively competitive price might look like is strongly supported by what happened to prices in the market in Period 3 – when, briefly, there were three Tablet suppliers in the market and ASPs declined significantly.

Conclusion on Period 1

6.325 Teva was a monopolist during this period and, following the introduction of Scheme M, it exercised its monopoly power to impose and maintain substantial price increases for its Tablets. A contemporaneous Teva document confirms that the reason it had been able to impose its price increases was because it was not subject to competition. This point was later confirmed by [Former Teva Director] ([X]). Even after Teva had reduced its prices to approximately £26, it was still

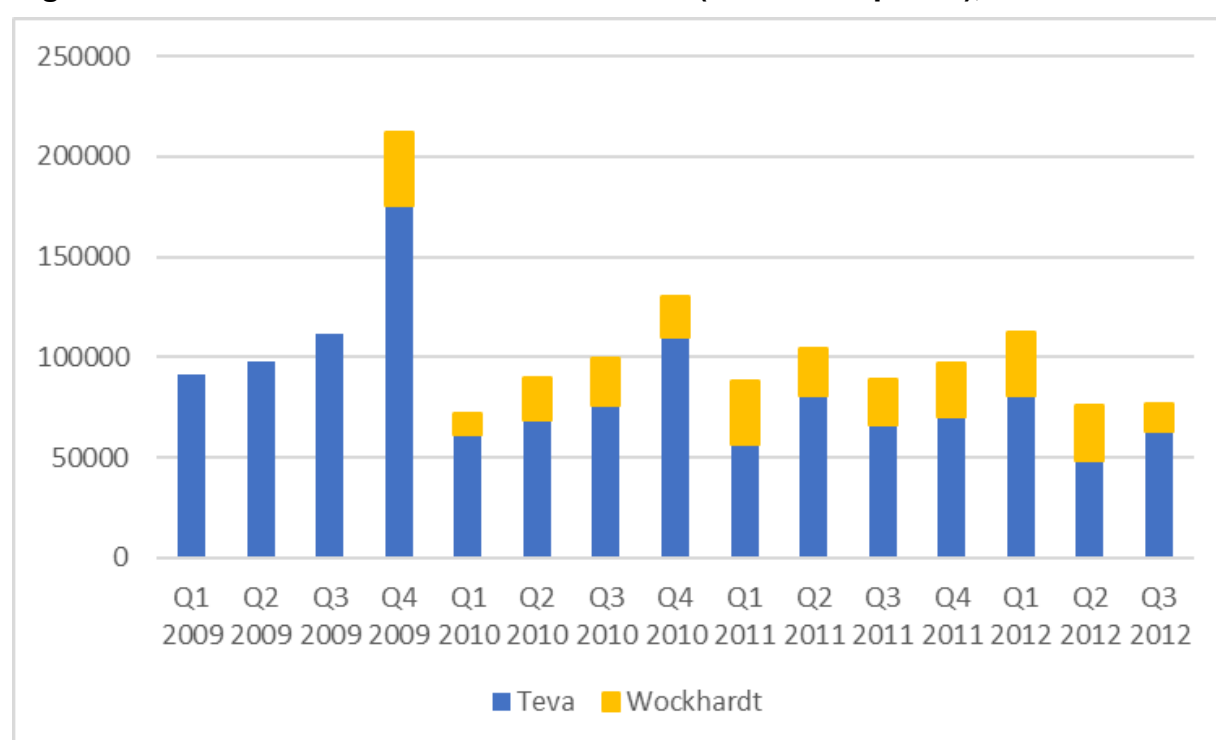
¹³⁸⁴ Regarding the potential constraint from regulation, as explained above. [Former Teva Director] of Teva confirmed in his response to questions in the CAT that the overall cost to the NHS would have to be 'pretty eye watering' to attract regulatory intervention. See also section 6.C.II.d. above.

pricing approximately 870% higher than its ASP in 2005. The CMA does not consider that Teva's ASPs during this period of monopoly supply provide a meaningful comparator for assessing whether Pfizer's Prices and Flynn's Prices were fair.

Period 2: October 2009 to August 2012 – Wockhardt enters the market

6.326 Wockhardt launched its Tablet in October 2009. Figure 6.3 presents quarterly data on the number of packs sold by Teva and Wockhardt for the period Q1 2009 to Q3 2012. It demonstrates there was a competitive interaction between Wockhardt's and Teva's Tablets, with Wockhardt successfully gaining sales. Wockhardt's share of supply was 23% across the period, while Teva's was 77%.

Figure 6.3: Teva's and Wockhardt's volumes (number of packs), Q1 2009 to Q3 2012

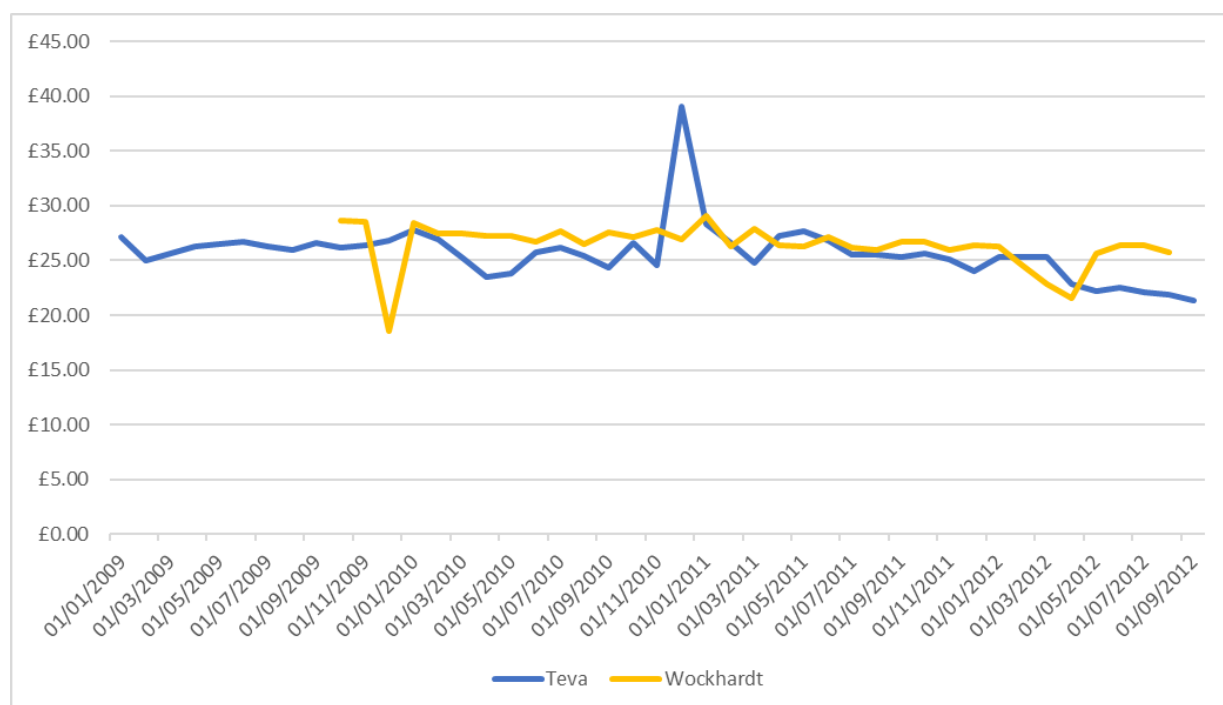


Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1; PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1; PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2; and PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK.

6.327 Figure 6.4 below presents Teva and Wockhardt's monthly ASPs for a pack of 100mg Tablets for the period January 2009 to September 2012. It shows that, although there were fluctuations in price, Teva and Wockhardt's ASPs generally remained high, stable and very similar in level to each other throughout this period. Although Teva's ASP fell from £25.34 in March 2012 to £21.90 in August 2012 (this may have been the result of a strategy to gain market share before the MHRA

Guidance was introduced¹³⁸⁵) its ASP during Period 2 as a whole was nevertheless £25.94 (with a range between £21.90 - £28.31).¹³⁸⁶ Wockhardt's ASP was £25.82 and varied between £18.53 and £29.05. Accordingly, for most of the period, both Teva and Wockhardt were achieving ASPs that were only marginally less than the ASP maintained by Teva prior to Wockhardt's entry. Teva's and Wockhardt's ASPs were 872% and 867% than Teva's ASP of £2.67 in 2005, respectively.

Figure 6.4: Teva and Wockhardt's monthly average selling prices for a pack of 100mg phenytoin sodium Tablets, January 2009 to September 2012



Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1; PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1; PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2; and PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK.

6.328 Accordingly, the CMA does not consider that the Tablets market exhibited an effective level of competition during this period. Instead, Teva and Wockhardt were able to profitably co-exist in the market without having to compete aggressively. This co-existence was facilitated by the substantial price increases Teva had imposed in Period 1 which enabled both firms to charge high ASPs and not need to compete strongly for market share. This is very similar to what occurred in the

¹³⁸⁵ As explained in paragraph 6.354 below, Teva was aware of the consultation on the MHRA Guidance from at least June 2012 and adopted a more competitive pricing strategy in anticipation of the Guidance being published.

¹³⁸⁶ With the exception of December 2010 when Teva's ASP was £39.06, which appears to be an anomaly.

Capsules market following NIRM's entry – a dynamic that the CAT found did not represent effective competition.¹³⁸⁷

- 6.329 Wockhardt confirmed to the CMA that its entry strategy was, indeed, to gain market share whilst at the same time trying to maintain price stability and avoid a price war with Teva. Referring to the fact that selling prices were high (in the £20s range) when it entered, Wockhardt stated that there was 'never any reason or intention to move on pricing at this point'.¹³⁸⁸ Wockhardt explained that the high level of the Drug Tariff price and the fact there were only two suppliers in the market facilitated this strategy, adding that 'prices would only have moved if another player came to the market'.¹³⁸⁹
- 6.330 Teva also did not wish to engage in robust price competition with Wockhardt, and believed that Wockhardt was unlikely to compete aggressively. This is demonstrated by contemporaneous internal Teva documents. For example, in an email dated 15 October 2008, a Teva national account manager observed that he did not expect Wockhardt would be aggressive on price:

*...think Wockhardt will be sensible with this as they hardly have any value lines, and from what [X] was saying their stability has not been too great so I think they are having to destroy a few batches on the way which will no doubt increase their cost.*¹³⁹⁰ (emphasis added)

- 6.331 Further, an email from Teva's [X], dated 14 November 2009, (the month after Wockhardt had entered the market), shows that Teva offered at least one, one-off (rather than permanent) price reduction to a customer to meet Wockhardt's competitive threat, however it also makes clear that senior Teva staff were not concerned about the overall threat that Wockhardt posed:

*ok [to price match] but a 1 off only and not [a] permanent price – believe no pharmacy will switch to Wockhardt so stock will stay in SL [short-line] and not pull out, therefore not a price threat*¹³⁹¹ (emphasis added)

- 6.332 In addition to its commercial strategy, Wockhardt's ability to constrain Teva was further limited by technical difficulties it experienced with the manufacture of its Tablets. These technical difficulties (which ultimately led to Wockhardt's exit from the market in July 2014) meant that it chose not to scale up its production and

¹³⁸⁷ The CAT found that NIRM's commercial strategy was not to threaten Flynn's position beyond a certain point and that NIRM appeared to have accepted a degree of pricing parity and stability. The CAT's view was that the NIRM capsule was better regarded as outside the relevant market, *Phenytoin* [2018] CAT 11, paragraph 196.

¹³⁸⁸ PRC01144a, Note of call with Wockhardt of 17 November 2020, page 1.

¹³⁸⁹ PRC01144a, Note of call with Wockhardt of 17 November 2020, page 1.

¹³⁹⁰ PRE00278, Email of 15 October 2008, Re: [X] boost order. - H55535-0015-001728, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

¹³⁹¹ PRE00468, Email chain of 14 November 2009, Re: Phenytoin and [X] - H55535-0023-003110, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020.

instead focused on maintaining the quality of the product it was able to produce and not risk creating further problems.¹³⁹²

- 6.333 Teva was aware of Wockhardt's difficulties. A note of a meeting between Teva and [X], dated 13 November 2009, recorded that [X] had expressed concerns regarding the 'continuity of availability' of Wockhardt's Tablet because Wockhardt was unable 'at this time to produce any significant volume'.¹³⁹³ The fact that this information was disclosed to Teva would have supported internal views that Wockhardt would not compete aggressively.¹³⁹⁴
- 6.334 As has been stated, Capsules and Tablets were both subject to guidance on Continuity of Supply, which had an impact on the level of switching between suppliers in the market (and therefore limited the likelihood of effective competition). Period 2 pre-dated the MHRA Guidance (which was published in November 2013) – and which created a strong barrier to switching. However, NICE had also published guidance recommending Continuity of Supply in 2004, which was updated in 2012, and this would have been a reference point for pharmacies and wholesalers during this Period.
- 6.335 The data shows that some customers purchased Tablets from Wockhardt – indicating that they may not have followed Continuity of Supply. However, it is also clear that Teva retained the majority of the share of the supply and was not required to reduce its prices in order to do so. The qualitative evidence does not provide an indication of whether and, if so, to what extent the NICE guidance influenced purchasing decisions. However, it is not necessary to reach a conclusion on this point because it is clear from the data that the market was not subject to effective competition during this Period.

Conclusion on Period 2

- 6.336 The CMA does not consider that ASPs during this period of duopoly supply provide a meaningful comparator for assessing whether Pfizer's Prices and Flynn's Prices were fair.¹³⁹⁵ Although there was a competitive interaction between Teva and Wockhardt, the dynamic was one of profitable co-existence rather than effective competition, this facilitated by the very high prices in the market following Teva's exercise of its market power. Teva's inflated ASPs were barely impacted by

¹³⁹² PRC03714, Note of call with Wockhardt of 25 January 2022, paragraph 22.

¹³⁹³ PRE00355, Note of meeting between Teva and [X] on 13 November 2009, Contact Report 13-11-09.doc - H55535-0023-008310.doc, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020.

¹³⁹⁴ There is further evidence that Teva was aware of Wockhardt's stability issues before Wockhardt entered the market in the form of an internal email dated 15 October 2008 and stating: 'from what [X] was saying their stability has not been too great so I think they are having to destroy a few batches on the way', PRE00278, Email of 15 October 2008, Re: [X] boost order. - H55535-0015-001728, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

¹³⁹⁵ In its response to the SO, Flynn submitted that the competition between Wockhardt and Teva in this period was normal compared to what is typically expected following first generic entry, ie where there are two generic competitors. (see PRC03492, Flynn's response to the SO, paragraphs 8.21 and 8.22). However, regardless of whether this is an accurate or reasonable description or not, it ignores the key question of *whether the market itself was effectively competitive?* The analysis in this section demonstrates that the market was not effectively competitive.

Wockhardt's entry and remained high and stable and close to the level they stood at prior to Wockhardt's entry. Teva also retained a share of supply of 77% during this period.

- 6.337 This appraisal of the competitive situation in Period 2 is confirmed by what happened in Period 3 when Milpharm entered the market and more substantial price competition initially occurred during a relatively brief period of three player supply.

Period 3: September 2012 to July 2014. Milpharm enters the market. Temporarily there are three players.

Analysis of price and volume data

- 6.338 Milpharm entered the market in September 2012. This started a period of 22 months where there were three Tablet suppliers in the market, before Wockhart exited the market in July 2014. However, as will be seen, this period of three player competition was effectively just 16 months in duration, with Wockhardt winding down its market position from January 2014, after which it functioned with very limited supply until its market exit.
- 6.339 Figure 6.5 shows the ASPs of all three Tablet suppliers during this period and that Milpharm's entry prompted greater price competition than had existed during Period 2.
- 6.340 At launch, Milpharm was more expensive than Teva. Its ASP in September 2012 was £23.63, compared with Teva's ASP of £21.35 and Wockhardt's ASP of £24.23. However, Milpharm then reduced its prices and remained cheaper than both Teva and Wockhardt for the significant majority of Period 3.
- 6.341 Figure 6.5 shows that, in the period September to December 2012, all three Tablet suppliers experienced significant falls in their ASPs, upsetting the broadly flat trend in ASPs that had occurred from November 2008 to September 2012.
- 6.342 By the end of December 2012, Milpharm's ASP had fallen by 50% to £11.77, Teva's ASP had fallen by 31% to £14.69, and Wockhardt's ASP had fallen by 38% to £15.00.
- 6.343 The ASPs for all three Tablet suppliers initially continued to fall in 2013, albeit not as steeply as they had done in the final three months of 2012. There are distinctly different pricing patterns between Wockhardt and Milpharm on the one side, and Teva on the other.
- 6.344 Wockhardt's and Milpharm's ASPs fell throughout 2013:
- 6.344.1 In respect of Milpharm, Figure 6.5 shows that Milpharm's ASPs fell throughout 2013 and the first half of 2014. Milpharm's ASPs fell below £10

a pack from March 2013 and between March 2013 and October 2014, its ASP was £7.56, reaching a low of £5.51 in June 2014 (some 77% lower than its ASP when it entered the market in September 2012). Milpharm's price only recovered to £10 a pack in November 2014, four months after Wockhardt had exited and prices increased in the market.

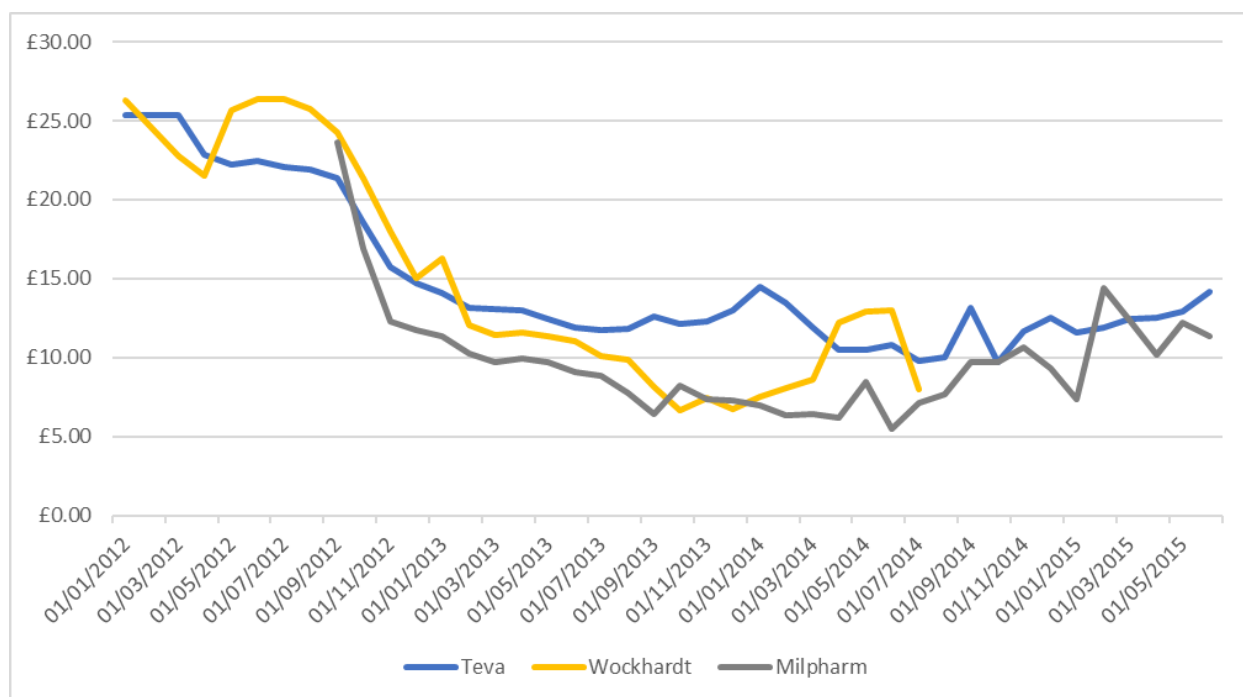
6.344.2 In respect of Wockhardt, Figure 6.5 shows that its ASP also fell throughout 2013 but began to increase in 2014. Wockhardt's ASP fell below £10 from August 2013 (later than Milpharm). Between August 2013 and March 2014, Wockhardt's ASP was £7.79. At its lowest (in October 2013) it was £6.66, 73% lower than its ASP in September 2012 when Milpharm entered. Wockhardt's ASP began to increase in January 2014 and rose above £10 in April 2014, two months before it exited the market. This increase could be because it had limited stock and prioritised fulfilling hospital tenders, which may have been agreed at higher prices than prevailing ASPs.¹³⁹⁶

6.345 By contrast, Teva's ASP only fell until August 2013 when it reached £11.79, before increasing for the remainder of the year and into January 2014 (reaching £14.49 in January 2014). Teva's ASP then fell again from February 2014 to July 2014. However, its ASP only fell slightly below £10 for one month during this period - when it reached £9.82 in July 2014 (this was 54% lower than its ASP in September 2012 when Milpharm entered).

6.346 The data demonstrates that Teva was able to maintain a significant price differential over Wockhardt and Milpharm during 2013. Teva's ASP for 2013 was £12.57, compared to £9.82 for Wockhardt and £8.78 for Milpharm. As such, Teva's ASP was 28% and 43% higher than Wockhardt and Milpharm's respectively. As a result of the increases in Teva's ASPs towards the end of 2013, the price differential grew. Between September and December 2013, Teva's ASP was 71% and 74% higher than Wockhardt's and Milpharm's ASPs respectively.

¹³⁹⁶ PRE00017, Wockhardt internal email chain of 14 March 2014, Subject: 'RE: Wockhardt Phenytoin 100mg', page 1; and PRE00331, Internal chain dated 2 June 2014, Fw: Phenytoin – H55535-0028-003317.pdf, enclosed in Teva's response to the CMA's s.26 Notice of 18 September 2020, page 2.

Figure 6.5: Teva's, Wockhardt's and Milpharm's average selling prices for a pack of 100mg phenytoin sodium Tablets, January 2012 to June 2015



Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1, PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1, PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2, PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK, PRC00326, Milpharm's response dated 22 July 2020 to the CMA's s.26 Notice of 29 June 2020, Milpharm Data Sheet Final, PRE00274, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, BK, CMA Case 50908-Annex 2 - Data Feb'17toAug'20- Compl. 2Oct'20, and PRC01415, Milpharm's response of 5 February 2021 to the CMA's s.26 Notice of 29 January 2021, Annex 2.

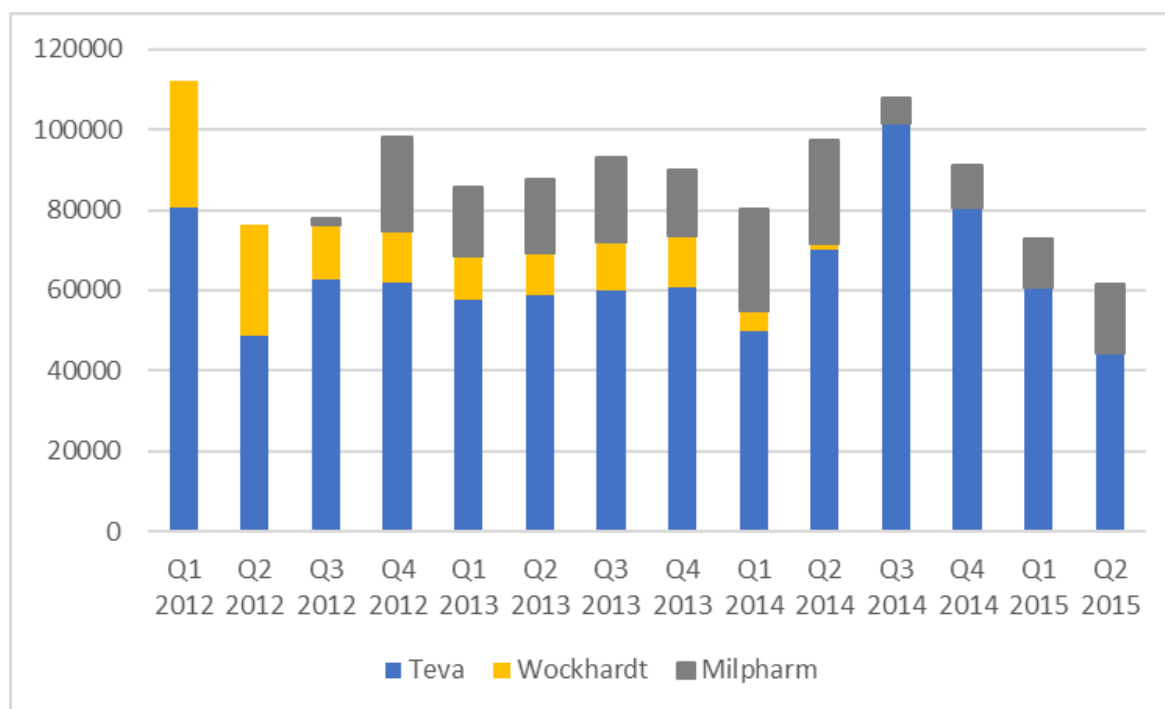
6.347 Figure 6.6 shows the sales volumes of Teva, Milpharm and Wockhardt from January 2012 to June 2015. It shows that Milpharm successfully gained sales from both Teva and Wockhardt following its entry, with Wockhardt, in particular, being squeezed.

6.348 In 2012, Teva's average monthly sales of Tablets was approximately 21,100 packs per month and Wockhardt's was approximately 7,100 packs.

6.349 In 2013, following Milpharm's entry, Teva's average monthly sales reduced to 19,800 packs (a fall of 7%) whereas Wockhardt's monthly sales reduced significantly to approximately 3,900 packs (a fall of 46%). Milpharm's average monthly sales in 2013 was approximately 6,000 packs.

6.350 Accordingly, Teva maintained by far the largest share of the market and double the level of Wockhardt and Milpharm's combined sales. Moreover, as shown above, Teva achieved this share of supply whilst maintaining a significant positive price differential to its competitors.

Figure 6.6: Volume of 100mg Tablets (number of packs) supplied in the UK by Teva, Wockhardt and Milpharm, Q1 2012 to Q2 2015



Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1. PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1, PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2, PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK, PRC00326, Milpharm's response dated 22 July 2020 to the CMA's s.26 Notice of 29 June 2020, Milpharm Data Sheet Final, PRE00274, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, BK, CMA Case 50908-Annex 2 - Data Feb'17toAug'20- Compl. 2Oct'20, and PRC01415, Milpharm's response of 5 February 2021 to the CMA's s.26 Notice of 29 January 2021, Annex 2.

6.351 As stated above, Wockhardt exited the Tablets market in July 2014. Figure 6.6 shows that Wockhardt experienced a significant decline in its sales volumes in the months before it exited, declining from approximately 3,900 packs per month during 2013 to just 900 packs per month in 2014 up until its exit in July.

6.352 Most of the sales volumes Wockhardt lost in the period leading up to its exit switched to Teva: Teva's monthly volumes increased from approximately 19,800 packs per month in 2013 to approximately 23,900 packs per month in the period January to July 2014. In comparison, Milpharm's sales volumes increased more modestly in absolute terms (from approximately 6,000 packs per month in 2013 to approximately 7,800 packs per months from January to July 2014). Again, Teva made these gains despite being significantly more expensive than Milpharm.

Analysis of documentary evidence for the period September to December 2012

- 6.353 The qualitative evidence is consistent with the conclusions the CMA has drawn from the price and volume data and indicates that there are two key reasons why price competition was initially more intense in this period.
- 6.354 First, Teva adopted a 'defence plan' to strengthen its market position in anticipation of the MHRA Guidance, which Teva believed would reduce switching between different Tablet suppliers. This plan preceded Milpharm's entry and was clearly a more aggressive strategy than Teva had initially adopted when Wockhardt entered the market.¹³⁹⁷
- 6.355 The premise of the 'defence plan' was set out in an internal Teva email, dated 16 August 2012, from Teva's [X]. The plan would see Teva seeking to not only retain its existing customer base, but also gain further customers (in the belief that any customers would be less likely to switch to a competitor once the MHRA Guidance came into force):

In summary we need to:-

Ensure we keep the customers we have. *The consultation will advise that either a brand name be given to the product or that patients cannot be switched from their existing generic. Therefore all customers we have now will be protected to us, and will have to keep their patients on Teva Phenytoin.*

Capture more share now. *Any new accounts we switch over to Teva Phenytoin from now until the consultation drops will also be protected to us in the near future. Therefore we should be actively looking to increase customer penetration on this product now.*¹³⁹⁸ *(emphasis added)*

- 6.356 The second reason competition was initially more intense in this period is because of Milpharm's entry strategy. Milpharm initially competed more intensely on price and, as such, its entry strategy was more disruptive than Wockhardt's had been. Milpharm informed the CMA that its strategy was to 'sell to as many customers as possible' in order 'to "break into" Teva's position and get market share quickly'.¹³⁹⁹ In order to do this it used its regular meetings with customers to try to establish Teva's selling price and would then offer to undercut it to try to win sales.¹⁴⁰⁰

¹³⁹⁷ Internal documents provided to the CMA by Teva show that Teva was aware of the MHRA consultation on the Guidance from at least June 2012. See PRE00292, Re: MHRA consultation on branded prescribing: COMMENTS REQUIRED BY CLOSE OF PLAY WEDNESDAY 27 JUNE PLEASE – H55535-00190992758, Teva's response to the CMA's s.26 Notice of 18 September 2020.

¹³⁹⁸ PRE00293, Email chain of 16 August 2012, RE: Phenytoin - defence plan - H55535-0015-001817, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 2.

¹³⁹⁹ PRC01796, Note of call between CMA, [X] and Milpharm, 25 February 2021, page 1.

¹⁴⁰⁰ PRC01796, Note of call between CMA, [X] and Milpharm, 25 February 2021, page 1

- 6.357 Contemporaneous documentary evidence from Teva confirms that Milpharm's entry resulted in a period of more intense competition, particularly in the period September to December 2012:
- 6.357.1 A Teva Commercial Generics Report for September 2012 stated that Teva was 'finding prices declining at a fast rate with Aurobindo [Milpharm] striving to pick up business at almost any price'.¹⁴⁰¹
- 6.357.2 A Teva Europe Monthly Report, also for September 2012, stated that Aurobindo [Milpharm] had started supplying Tablets and were 'being very aggressive on price in order to gain business before the DH advise that patients do not switch their medication'.¹⁴⁰²
- 6.357.3 A number of 'Contact Reports' containing notes of meetings Teva held with its customers during September 2012 provide further evidence that Milpharm offered Teva's customers lower prices to win sales. For example, a contact report of a meeting between Teva and [X] on 14 September 2012 states '[p]henytoin offered 25.00 but Milpharm have offered 21.00'.¹⁴⁰³
- 6.357.4 An internal Teva email dated 20 September 2012 refers to a price challenge from [X] which required it to reduce its prices and notes '[a]s you'll see (and as discussed) they've challenged us on Phenytoin @ £22.25. I've spoken to [X] about this — its [sic] not Wockhardt, it's the new entrant to the market (presume you know who this is as he didn't actually tell me). We don't have to match this price, but [X] says he's [sic] needs us to reduce the price to some extent as he can't ignore it.'¹⁴⁰⁴
- 6.358 In October 2012, Teva implemented a £1 price reduction across all of its customers as part of its 'defence strategy' 'to maintain [its] retail volume' because it was 'out on price in the market now'.¹⁴⁰⁵
- 6.359 However, it is apparent Teva became concerned about the level of price falls that were taking place in the market and consequently its 'defence strategy' appears to have evolved into a more nuanced approach with it focusing on retaining its larger accounts. Teva produced a priority list of the customers it wished to focus on

¹⁴⁰¹ PRE00495, Commercial Generics Report September 2012.docx - H55535-0030-012062.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 5.

¹⁴⁰² PRE00423, Europe Monthly Report - UK Sep 2012.xlsm - H55535-0035-003385.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 11.

¹⁴⁰³ PRE00481, Note of meeting between Teva and [X] on 14 September 2012, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1. Other examples include, PRE00482, a note of a meeting with [X] on 24 September 2012, which notes '[p]henytoin 12.00 offer from Millpharm [sic] 18.00 from Wokhardt [sic]', page 1; and PRE00483, a note of a meeting between Teva and [X] on 28 September 2012, which states 'Phenytoin – Aurobindo [Milpharm] have also now offered at £17 / pack', page 2.

¹⁴⁰⁴ PRE00299, Email chain of 20 September 2012, Re: [X] Sept Price challenges - H55535-0015-001849.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

¹⁴⁰⁵ PRE00301, Email chain of 11 October 2012, RE: Phenytoin for retail - H55535-0015-001835.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

retaining, with the implication being it was prepared to lose lower volume customers (to both provide competitors with space in the market and also to manage the substantial decline that had taken place in respect of prices in the market).¹⁴⁰⁶ This strategy essentially marked an evolution of the profitable co-existence that had existed in Period 2.

- 6.360 Consistent with this strategy, Teva internal documents from October 2012 show it made substantial price reductions to [X] and [X], who were both priority customers, to retain their business.¹⁴⁰⁷ However, also in October 2012, Teva chose not to compete with Wockhardt for [X]'s business, with Teva employees stating that they needed 'to give Wockhardt some share'.¹⁴⁰⁸ Similarly, Teva chose not to compete with Wockhardt in November 2012 in respect of Tablet sales to [X]. An internal Teva email discussing the [X] situation shows Teva believed it had been 'a bit too successful' with its 'defence plan' and that it needed 'to give Wockhardt some room' and also 'try and manage the price decline somewhat in the short term'.¹⁴⁰⁹
- 6.361 An internal Teva email chain of 16 November 2012 shows Teva considering whether or not to compete for sales of Tablets to [X]. The email again shows that Teva considered it had been 'too successful getting business' and so it had 'pared back to the customers who have always been loyal on this product else there will be no value left in the product and the current hit to profit is already excessive'.¹⁴¹⁰
- 6.362 The strategy of providing Wockhardt with 'some share' or 'some room' to arrest the price decline continued into 2013. A Teva internal email chain, dated 7 January 2013, discussed whether Teva should compete on price with Wockhardt for sales to [X] (a wholesaler). The email stated 'Phenytoin; already have required MS%, don't wish to compete with Wockhardt in this account, current price is best offer'.¹⁴¹¹ In other words, Teva did not wish to gain further sales at the risk of pushing market prices down further.
- 6.363 It is also clear that some of Teva's larger customers used the presence of competition in the market to negotiate lower prices from Teva. An internal Teva document, dated 21 October 2013, showed that it was considering whether to respond to a price challenge by Milpharm for [X]'s purchases ('[X] are talking to

¹⁴⁰⁶ PRE00303, Email chain of 16 October 2012, Re: Phenytoin – H55535-0020-004777.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

¹⁴⁰⁷ PRE00423, Europe Monthly Report - UK Sep 2012.xlsm - H55535-0035-003385.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 11; PRE00305, Email chain of 29 October 2012, Re: Phenytoin [X] - H55535-0030-013396.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

¹⁴⁰⁸ PRE00304, Internal email chain of 22 October 2012, Re: Phenytoin for [X] – Feedback - H55535-0030-013377.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

¹⁴⁰⁹ PRE00310, Email chain of 8 November 2012, RE: [X] tentative price list with order- H55535-0030-013532.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

¹⁴¹⁰ PRE00470, Email chain of 16 November 2012, RE: Price approval ([X]) [X] prices – H55535-0030-001083.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 2.

¹⁴¹¹ PRE00319, Email chain of 7 January 2013, RE: [X] tentative price list - H55535-0030-013656.pdf, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020, page 1.

me about a phenytoin challenge which they would like us to respond to. Current price is £9.00. [X] are being offered £7.00 for spotbuys— Aurobindo [Milpharm]’.)¹⁴¹² [X] confirmed to the CMA that it used the availability of Milpharm and Wockhardt’s Tablets ‘to negotiate a lower [Tablet] supply cost from Teva’.¹⁴¹³

- 6.364 In a similar manner to Teva, Wockhardt also sought to reduce the intensity of price competition in the market by not competing with Milpharm for certain customers. Wockhardt officials informed the CMA that it ‘might defend accounts to retain volume or **give some share to Milpharm to try to keep the price stable**’ (emphasis added).¹⁴¹⁴

Limitations on the effectiveness of competition in Period 3

- 6.365 Although Period 3 saw more intense price competition than Period 2, with prices being competed down, there were nevertheless limitations on the competition that occurred. This is demonstrated by a high-level assessment of the market positions of Teva and Milpharm.
- 6.366 Teva retained the majority share of supply whilst maintaining a significant price gap compared to its competitors, this included gaining most of Wockhardt’s share of supply when the latter was preparing to exit the market.¹⁴¹⁵ By contrast, Milpharm only achieved a share of supply of 20% during 2013, despite being significantly cheaper than its competitors for virtually the entire year. The lack of switching away from Teva, and Milpharm’s inability to grow its share of supply, despite the clear financial incentives to do so, is not indicative of effective competition. It is also consistent with Teva possessing substantial market power.
- 6.367 There are a number of factors which impacted on the effectiveness of price competition during Period 3.
- 6.368 As with Period 2, competition started from an inflated price level as a result of Teva’s previous exercise of its substantial market power and the limited price competition that occurred following Wockhardt’s entry. At the point Milpharm entered the market in September 2012, Teva’s ASP was £21.35, this was still 700% above its price for 2005 (which was £2.67).
- 6.369 Although Milpharm’s entry strategy was more disruptive than Wockhardt’s had been and price competition was initially more intense, where prices start from such an inflated position, the competitive process might take time to produce conditions of sufficiently effective competition. This is all the more so where there are a relatively small number of suppliers in the market and the market size is small (as

¹⁴¹² PRE00699, Email chain of 21 October 2013, RE: PHENYTOIN challenge AB – 25_H55535-0020-005495, enclosed with Teva’s response to the CMA’s s.26 Notice of 25 January 2021, page 1.

¹⁴¹³ PRC00304, [X] response dated 17 July 2020 to the CMA’s section 26 Notice dated 17 June 2020, question 1(ii).

¹⁴¹⁴ PRC01144a, Note of call between the CMA and Wockhardt on 17 November 2020, page 4.

¹⁴¹⁵ The CAT, in *Phenytoin*, explained that there was a clear financial incentive to substitute the cheaper for the more expensive and this would lead one to expect high levels of switching. *Phenytoin* [2018] CAT 11, paragraph 189.

was the case with Tablets¹⁴¹⁶).¹⁴¹⁷ Flynn's own expert confirmed that, where there are three competitors in the market, in the unbranded generic sector, '[i]f no further suppliers enter the market, the three companies will not usually seek to compete further on price because the increase in volume will be offset by reductions in the price or will otherwise eventually result in a race to the bottom'.¹⁴¹⁸

6.370 In the case of Tablets, the competitive process did not have sufficient time to produce an effectively competitive outcome as Wockhardt faced supply issues and prepared to exit the market from January 2014. In effect, this limited the period of three player supply to approximately 16 months.

6.371 Moreover, even in this 16 month period, the scope of competition was limited by a number of other factors which significantly reduced its effectiveness.

Teva and Wockhardt's commercial strategies

6.372 First, as shown by their contemporaneous documents, Teva and Wockhardt took steps to manage the price decline that was taking place in the market by prioritising certain customers, and sacrificing others in an effort to ensure prices stabilised. This strategy itself was facilitated by the relatively high prices that prevailed in the market and the relatively small number of suppliers.

Wockhardt and Milpharm's supply issues

6.373 Second, competition between the three players was also inhibited as a result of Wockhardt and Milpharm experiencing supply issues, which were known in the market place.

6.374 In respect of Wockhardt, the analysis in Period 2 demonstrated that it had issues with the quality of its product and, as a result, did not increase production (and instead focused on ensuring quality rather than quantity of its Tablet and risking creating further problems).¹⁴¹⁹

¹⁴¹⁶ As explained in the *Relevant Factual Background to Tablets* above, Tablets were prescribed to a substantially smaller set of patients in the UK than Capsules. Between 2012 and 2016, the NHS dispensed approximately four times the number of 100mg Capsules (196 million) as 100mg Tablets.

¹⁴¹⁷ The European Commission noted in its *Aspen* Decision that empirical data suggests that sufficiently effective generic price competition may require more than one or two entrants, citing the European Commission's 2009 Pharmaceutical Sector Inquiry Report, Annexes to Chapter B – Part II of the Report, pages 556-598 and a study from the US suggesting that up to six or seven generics entrants may be required to compete down high prices, see <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>. The European Commission also noted that the empirical data suggests that small market sizes may delay the emergence of effective generic competition, and that it may take a significant amount of time in small markets for prices to drop to levels likely reflecting effective competition, see *Aspen*, paragraph 199.

¹⁴¹⁸ PRE00150, Expert Report of [Flynn Expert Witness 3], 4 February 2017, paragraph 36(b). In response to cross examination, [Flynn Expert Witness 3] confirmed that he was explaining that three companies in the market will not usually be enough to provoke intense price competition, PAD00070, [Flynn Expert Witness 3] Cross Examination, day 6, page 112, line 11 to page 114, line 18.

¹⁴¹⁹ PRC03714, Note of call with Wockhardt of 25 January 2022, paragraph 22.

- 6.375 Wockhardt confirmed to the CMA that it had issues with the stability and dissolution of its Tablet¹⁴²⁰ throughout its time on the market.¹⁴²¹ In Period 3 it tried to resolve these issues by reformulating its Tablet¹⁴²² but was unable to get MHRA approval for it and decided to exit the market rather than continue to supply its existing product.¹⁴²³
- 6.376 In January 2014 Wockhardt ‘blocked’ all bar one of its batches of its 100mg Tablets from sale as a result of stability issues, leaving it with just over two months’ stock to supply.¹⁴²⁴ By June 2014 Wockhardt was informing customers that it could not supply them and it finally exited the market in July.¹⁴²⁵ The fact Wockhardt had such limited supply from January 2014 means, in effect, its presence in the market for much of 2014 was somewhat illusory and meant that the period of three player competition was, in fact, 16 months rather than 22 months.
- 6.377 Milpharm’s ability to compete was also limited by supply issues. Milpharm relied on supply from its parent company, Aurobindo, for the stock it supplied to the UK market. Milpharm described its supply chain as being ‘hit and miss’ at the time of its entry in September 2012 explaining that ‘it could sell all of its stock and then be waiting for its next shipment’ during which time it was unable to make further sales to existing customers or try to gain new customers.¹⁴²⁶
- 6.378 Milpharm explained that it was also initially difficult for it to establish how stable its supply to the market would be.¹⁴²⁷ As a result, Milpharm was not always able to order sufficient product to meet demand or might not be provided with all of the stock that it had ordered.¹⁴²⁸
- 6.379 These issues meant that Milpharm focused on supplying Tablets on a transactional rather than contractual basis, ie Milpharm would see how much stock it had at a given time and offer this to customers rather than agree contractually to continuous

¹⁴²⁰ Dissolution is the amount of the active ingredient dissolved in a given time.

¹⁴²¹ These issues were due to gelatine cross-linking with the Tablets’ sugar coating, creating problems in releasing the core of the Tablet, PRC03714, Note of call with Wockhardt of 25 January 2022, paragraphs 5, 7 and 9; PRE00010, Timelines for Manufacture of Phenytoin 100mg Tablets at Custom Pharmaceuticals, dated 21 October 2021, page 1-2; PRE00006, Pharmaceutical-development.pdf, enclosed with Wockhardt’s response to the CMA’s s.26 Notice of 18 September 2020, page 1. The report states ‘[d]issolution testing of phenytoin tablets has occasionally been problematic with erratic results. The disintegration time of tablets when tested very similar but considerable variability was seen in dissolution. Examination of tablets during the dissolution test showed that in some tablets a skin-like structure can be observed, which with time erupts allowing the core to dissolve. It is known that gelatin can undergo cross-linking and it is suspected that this is the case with this sugar coat’.

¹⁴²² The reformulation involved not using gelatine in the sugar coat of the tablet so that it did not have the same issues as the original product. See PRC03714, Note of call with Wockhardt of 25 January 2022, paragraph 8.

¹⁴²³ PRC03714, Note of call with Wockhardt of 25 January 2022, paragraphs 14 and 21. The difficulty in obtaining MHRA approval arose because the original product batches, to which Wockhardt had to show equivalence, were not stable (that is, the batches used for testing had different dissolution profiles and Wockhardt was unable to show equivalence to both dissolution profiles with its reformulated product). PRC03714, Note of call with Wockhardt of 25 January 2022, paragraphs 11 and 12.

¹⁴²⁴ PRE00020, Email of 9 January 2014, Phenytoin 100mg tablets FP3456, enclosed with Wockhardt’s response to the CMA’s s.26 Notice of 18 September 2020; PRC00314, Wockhardt response to the CMA’s s.26 Notice dated 29 June 2020, page 1.

¹⁴²⁵ PRE00028, Email chain of 23 June 2014 between Wockhardt and [X], Subject: ‘phenytoin tabs 100mg (28)’.

¹⁴²⁶ PRC01796, Note of call between CMA, [X] and Milpharm, 25 February 2021, paragraph 9.

¹⁴²⁷ PRC03676, Note of call with Milpharm of 20 January 2022, paragraph 35.

¹⁴²⁸ PRC03676, Note of call with Milpharm of 20 January 2022, paragraph 36.

supply until it improved its supply chain in 2016.¹⁴²⁹ Longer-term contractual arrangements were avoided as Milpharm could not guarantee consistent supply.¹⁴³⁰

6.380 Milpharm's and Wockhardt's supply issues were known to the Tablet suppliers. The evidence set out in Period 2 showed that Teva was aware of Wockhardt's production issues. Milpharm confirmed that it was also aware of Wockhardt's difficulties, with commercial staff involved in sales of Tablets informing the CMA that they believed 'Wockhardt did not seem serious on the product since it was in and out of stock with quite poor supply chain reliability' in the period 2013/14.¹⁴³¹ Milpharm believed both its customers and competitors were aware of its supply issues.¹⁴³²

Guidance recommending Continuity of Supply

6.381 Third, competition in the market place was also limited by the regulatory Guidance recommending Continuity of Supply. For much of Period 3, the applicable Guidance was that which had been issued by NICE¹⁴³³ with the MHRA Guidance being published on 13 November 2013.

6.382 In *Phenytoin*, the CAT made a number of findings in relation to the MHRA Guidance and Continuity of Supply in relation to Capsules:

6.382.1 Continuity of Supply had a significant impact, in practice, on pharmacists' dispensing practice, with pharmacists tending to favour the existing supplier of products on which patients were already stabilised. However, the MHRA Guidance did not prevent all switching and a limited degree still occurred.¹⁴³⁴

6.382.2 There was a clear financial incentive for pharmacies and wholesalers to substitute the cheaper for the more expensive, and one would expect very high levels of switching if the clinical guidance did not inhibit it.¹⁴³⁵ By inhibiting (even if it did not always preclude) switching, Continuity of

¹⁴²⁹ PRC03676, Note of call with Milpharm of 20 January 2022, paragraph 37.

¹⁴³⁰ Flynn claimed that a review of the sales data shows that there was nothing unusual about changes in Milpharm's monthly volumes of Tablets during the period 2012 – 2013 compared with later periods and so this does not support the contention that supply issues occurred (PRC03492, Flynn's response to the SO, paragraph 8.31). The CMA does not agree that it would necessarily be clear from sales data that there were supply issues, especially as these issues were present from the point of Milpharm's entry.

¹⁴³¹ PRC01796, Note of call between CMA, [X] and Milpharm, 25 February 2021, paragraph 16.

¹⁴³² PRC03676, Note of call with Milpharm of 20 January 2022, paragraph 39. An example of Teva's awareness of Milpharm's supply status is an internal Teva report from August 2014 which queried 'how much stock have Aurobindo [Milpharm] got and have they also got issues', PRE00402, Teva spreadsheet, Products to be discussed.xls – H55535-0028-013339.xls, enclosed with Teva's response to the CMA's s.26 Notice of 18 September 2020.

¹⁴³³ See section 2.V above.

¹⁴³⁴ *Phenytoin* [2018] CAT 11, paragraph 150.

¹⁴³⁵ *Phenytoin* [2018] CAT 11, paragraph 189.

Supply locked in patients to the existing supplier.¹⁴³⁶ Each supplier would have a 'captive body of patients'.¹⁴³⁷

6.382.3 Continuity of Supply meant that Flynn's customer base in the UK was to a significant degree guaranteed.¹⁴³⁸

6.383 Evidence gathered by the CMA in relation to Tablets is consistent with the CAT's conclusions in respect of Capsules, and supports the conclusion that both the NICE and MHRA Guidance on Continuity of Supply limited switching and, as *such*, limited the level of competition that took place in the market.

6.384 Milpharm explained that, from its experience, the guidance on Continuity of Supply acted as a barrier to its expansion within the market place stating that while some pharmacies and wholesalers were prepared to switch based on price, others 'follow[ed] [the] guidance more rigidly'.¹⁴³⁹ Milpharm cited [X] as an example of a pharmacy who '...would not switch no matter what the commercial offering, not even if the product was offered at £1, because the superintendent pharmacist would not agree'.¹⁴⁴⁰

6.385 Milpharm confirmed that it had been unable to grow its customer base after its initial entry stating that its 'customers have been established since launch and that numbers are relatively stable',¹⁴⁴¹ which is broadly confirmed by its data. For example, Milpharm was not able to grow its sales following the publication of the MHRA Guidance (with its sales actually declining). In the 12 months prior to the publication of the MHRA Guidance, Milpharm's¹⁴⁴² average monthly sales volume was 6,598 packs, compared to 5,850 packs in the 12 months following publication.¹⁴⁴³ This failure to gain sales is in spite of the fact that Milpharm was significantly cheaper than Teva for the overwhelming majority of this period and is consistent with both the NICE and MHRA Guidance impacting on competition.

6.386 Wockhardt's experience was also that the guidance on Continuity of Supply impacted on sales with some customers willing to switch based on price, and with

¹⁴³⁶ *Phenytoin* [2018] CAT 11, paragraph 196.

¹⁴³⁷ *Phenytoin* [2018] CAT 11, paragraph 151.

¹⁴³⁸ *Phenytoin* [2018] CAT 11, paragraph 346.

¹⁴³⁹ PRC01796, Note of call between CMA, [X] and Milpharm, 25 February 2021, paragraph 13.

¹⁴⁴⁰ This is corroborated by an internal Milpharm email discussion dated 4 August 2015 which discusses that [X] would not switch to Milpharm's product '*purely on a commercial offering as their superintendent had the final call on all AED's*', PRE00249, Email chain, FW: Phenytoin 100mg – Laxmico, 4 August 2015, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, page 2.

¹⁴⁴¹ PRC01623A, Final note of call between CMA and Milpharm, 9 February 2021, paragraph 10.

¹⁴⁴² Given Wockhardt's sales reduced significantly from January 2014 prior to exiting the market, the CMA considers that it is not instructive to assess its sales volumes before and after the publication of the MHRA Guidance.

¹⁴⁴³ Milpharm's response dated 22 July 2020 to the CMA's s.26 Notice of 29 June 2020, Milpharm Data Sheet Final, PRE00274, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, BK, CMA Case 50908-Annex 2 - Data Feb'17toAug'20- Compl. 2Oct'20, and PRC01415, Milpharm's response of 5 February 2021 to the CMA's s.26 Notice of 29 January 2021, Annex 2.

other customers being 'more "ethical" and [taking] account of the guidance and therapeutic area of Tablets'.¹⁴⁴⁴

6.387 Indeed, Pfizer agreed with the CMA that the guidance on Continuity of Supply limited competition between Tablet suppliers stating that it was 'clear' that 'the comparative lack of switching in the market was exacerbated by the MHRA's 2013 Guidance'.¹⁴⁴⁵

6.388 The role of the MHRA Guidance in limiting competition between Tablet suppliers is further demonstrated by the impact it had on Wockhardt's and Milpharm's commercial strategies. Wockhardt informed the CMA that a reason why it decided not to continue to reformulate its product and re-enter the Tablets market was because the MHRA Guidance made it 'harder for it [Wockhardt] to come back into the market and win back its share'.¹⁴⁴⁶

6.389 Further, Milpharm decided not to launch a 50mg strength Tablet because it believed it would not be able to get a foothold with the product as a result of the MHRA Guidance.¹⁴⁴⁷

Conclusion on Period 3

6.390 Although competition in Period 3 was initially more intense than had previously occurred and resulted in significant price reductions for all Tablet suppliers, the CMA does not consider that competition was sufficiently effective for ASPs during this period to be considered as an appropriate benchmark for assessing the fairness of the Parties' prices during the Relevant Period.

6.391 There were a number of factors that limited the effectiveness of competition during this period.

6.392 At the point of Milpharm's entry, the Tablets market continued to be distorted by the price increases imposed by Teva during a period of monopoly supply and maintained during a subsequent period of duopoly supply.

6.393 The period of three player competition was, in reality, limited to just 16 months following Milpharm's entry. It is likely that a longer period of more intense

¹⁴⁴⁴ PRC01144a, Note of call with Wockhardt of 17 November 2020, paragraphs 8-10.

¹⁴⁴⁵ PRC03901, Pfizer's response to the Letter of Facts, paragraph 19(a), referring to PRC03676 Final Note of call between CMA and Milpharm, 20 January 2022.

¹⁴⁴⁶ PRC03714, Note of call with Wockhardt of 25 January 2022, paragraph 27.

¹⁴⁴⁷ PRC01623A, Final Note of call between CMA and Milpharm, 9 February 2021, paragraph 8. In addition, an internal Milpharm presentation from 2015 included an action for Milpharm to 'Build [a] business plan for entering capsules market' (PRE00181, Milpharm internal document, UK Top 20 INN - Planning (sent to [X]) 260115.pptx, page 8). Pfizer submitted that this suggests Milpharm considered (i) there could and would be switching in the capsule market; and (ii) that Milpharm had a realistic chance of capturing market share (PRC03901, Pfizer's response to the Letter of Facts, paragraph 19(d)). The CMA does not consider that the evidence supports these propositions given that Milpharm never ultimately entered the capsules market - particularly in light of the evidence showing that Milpharm did not proceed to launch a different strength of the Tablet product which it already produced.

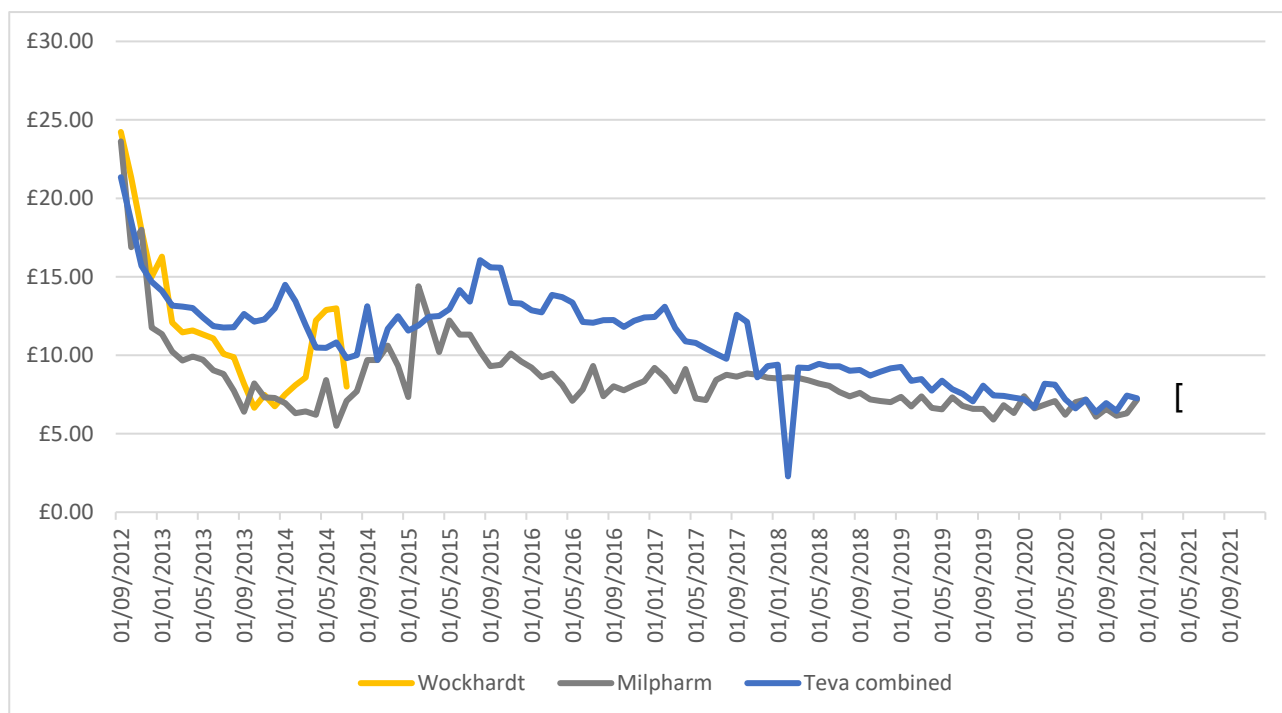
competition, typically with further entrants, would have been needed to erode prices, previously distorted by market power, to competitive levels.

- 6.394 However, there were a range of factors that also significantly limited the scope and effect of competition even during this 16 month period.
- 6.395 First, both Teva and Wockhardt adopted strategies of ceding some customer volumes to avoid competition on price and stabilise their ASPs.
- 6.396 Second, Milpharm and Wockhardt both experienced supply constraints which impacted on their ability to compete effectively and this was known by other suppliers.
- 6.397 Third, the regulatory guidance recommending Continuity of Supply provided further barriers to expansion, particularly after the publication of the MHRA Guidance in November 2013 (just over a year after Milpharm's entry).

Period 4: August 2014 to December 2021 – Wockhardt exits the market, leaving Teva and Milpharm as a duopoly

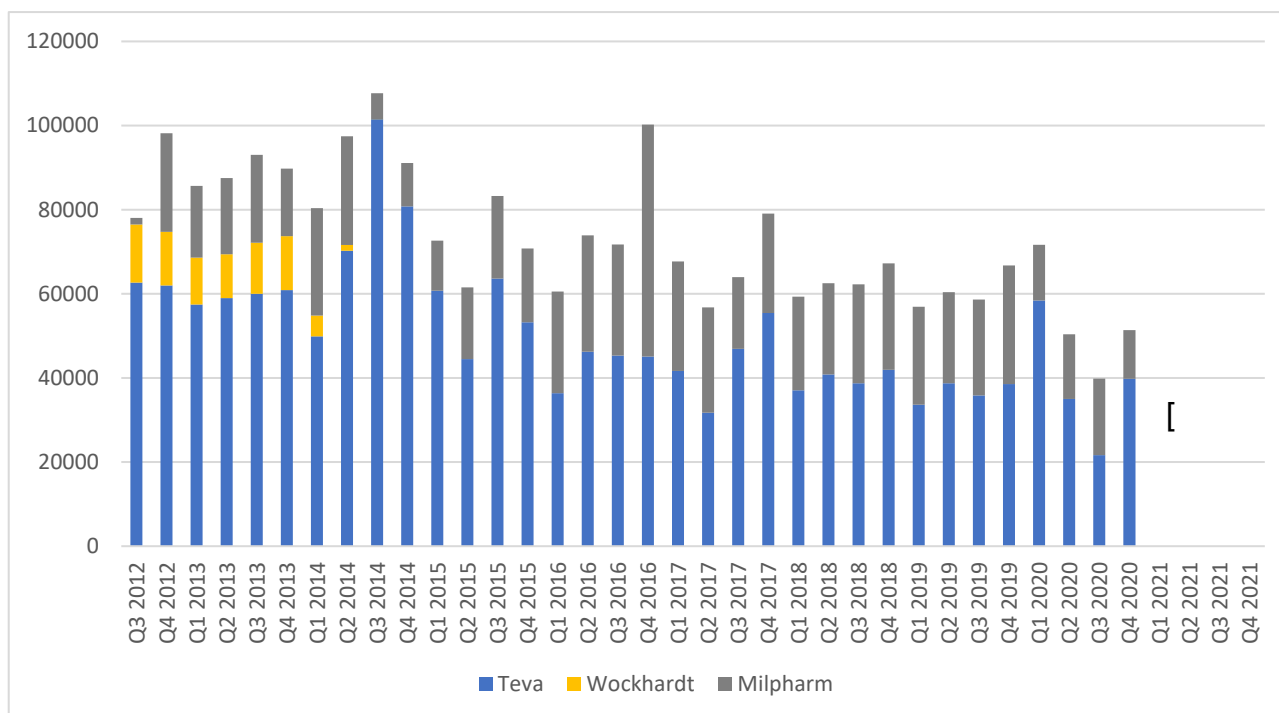
- 6.398 Wockhardt exited the market in July 2014, leaving Teva and Milpharm in a duopoly.

Figure 6.7: Teva's, Wockhardt's and Milpharm's average selling prices for a pack of 100mg phenytoin sodium Tablets, September 2012 to December 2021



Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1, PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1, PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2, PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK, PRC00326, Milpharm's response dated 22 July 2020 to the CMA's s.26 Notice of 29 June 2020, Milpharm Data Sheet Final, PRE00274, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, BK, CMA Case 50908-Annex 2 - Data Feb'17toAug'20- Compl. 2Oct'20, and PRC01415, Milpharm's response of 5 February 2021 to the CMA's s.26 Notice of 29 January 2021, Annex 2, PRC03614, Milpharm's response of 18 January 2022 to the CMA's s.26 Notice of 5 January 2022, Annex 2, and PRC03620, Teva's response of 19 January 2022 to the CMA's s.26 Notice of 5 January 2022, Annex 2.

Figure 6.8: Teva's, Milpharm's and Wockhardt's sales volumes, Q3 2012 to Q4 2021



Source: PRC00457, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, Annex 1, PRC00636, Teva's response of 2 October 2020 to the CMA's s.26 Notice of 18 September 2020, Annex 1, PRC01516, Teva's response of 12 February 2021 to the CMA's s.26 Notice of 25 January 2021, Annex 2, PRC00315, Wockhardt's response of 20 July 2020 to the CMA's s.26 Notice of 29 June 2020, CMA Data Template WUK, PRC00326, Milpharm's response dated 22 July 2020 to the CMA's s.26 Notice of 29 June 2020, Milpharm Data Sheet Final, PRE00274, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020, BK, CMA Case 50908-Annex 2 - Data Feb'17toAug'20- Compl. 2Oct'20, and PRC01415, Milpharm's response of 5 February 2021 to the CMA's s.26 Notice of 29 January 2021, Annex 2, PRC03614, Milpharm's response of 18 January 2022 to the CMA's s.26 Notice of 5 January 2022, Annex 2, and PRC03620, Teva's response of 19 January 2022 to the CMA's s.26 Notice of 5 January 2022, Annex 2.

6.399 Figure 6.7 shows that, both Teva and Milpharm initially charged and sustained higher ASPs than they had charged prior to Wockhardt's exit.

6.400 Teva's ASP increased from £9.82 in July 2014 to a peak of £16.06 in August 2015 and did not fall below its July 2014 level for three years. Milpharm's ASP increased from £7.09 in July 2014 to a peak of £14.39 in February 2015 and did not fall below its July 2014 level for over four years. There is no suggestion that these price increases were the result of any increase in costs. The fact that Teva and Milpharm were able to implement and sustain price increases is not demonstrative of an effectively competitive market.

6.401 Milpharm's prices began to fall from March 2015, while Teva's prices also began to decline from September 2015. By December 2021 (the latest data the CMA holds), Teva and Milpharm's ASPs had both fallen to [£1-£10.99]. This was Teva's lowest

price ([REDACTED]). The CMA has been unable to establish why prices have declined in the way that they have.¹⁴⁴⁸

6.402 However, notwithstanding these price reductions, competition between Teva and Milpharm was not intense. Table 6.10 below compares the annual ASPs of Teva and Milpharm from 2015 to 2021. For the period 2015 to 2020, it shows Teva's ASP was comfortably above Milpharm's ASP, with the gap being particularly significant from 2015 to 2017. This price differential should have created a clear financial incentive for pharmacists and wholesalers to switch from Teva to Milpharm. However, as Figure 6.8 shows, Teva was able to maintain this price difference, while still maintaining a majority share of supply of 64% for the period 2015 to 2020 (varying between 56% and 77% in each year).

6.403 Table 6.10 also shows that [REDACTED] in 2021. [REDACTED].¹⁴⁴⁹ [REDACTED], Milpharm's ASP began to fall and reached [£1 – £10.99] by December 2021.

Table 6.10: Annual ASPs for Teva and Milpharm for the Period 2015 to 2021

	2015	2016	2017	2018	2019	2020	2021
Teva's ASP	£13.53	£12.62	£10.95	£8.63	£7.86	£7.22	[£1-£10.99]
Milpharm's ASP	£10.59	£8.13	£8.30	£7.81	£6.73	£6.68	[£1-£10.99]
Difference (£)	£2.94	£4.49	£2.65	£0.82	£1.13	£0.54	[REDACTED]
Difference (%)	28%	55%	32%	10%	17%	8%	[REDACTED]

Notes:

1. For 2015 to 2020, Teva's ASP was higher than Milpharm's. As such, the rows showing the difference between the ASPs shows by how much, in percentage and absolute terms, Teva's ASP was higher than Milpharm's.
2. For 2021, [REDACTED].

6.404 Evidence gathered from Teva and Milpharm confirms that the degree of competition was limited during this period.

6.405 Milpharm explained to the CMA that its 'customers have been established since launch and that numbers are relatively stable' and went on to note that:

phenytoin sodium tablets were fairly different than other generic products in that the price of the product is generally static with very little price change, as if there wasn't any other competing product ... the product is

¹⁴⁴⁸ CMA officials asked Milpharm during a call whether they could explain the steadily falling prices. Milpharm explained 'that there are price fluctuations but stated that it was not clear what was causing it. He [Milpharm] explained that it may be buyers doing their job by asking for price reductions for Tablets or within the basket of deals, such as reducing the price of one drug in return for a high price or more volumes of another. [REDACTED] [Milpharm] explained that there is not a 'competition factor' in the market for phenytoin sodium tablets which would drive the price down'. PRC01623A, Final Note of call between CMA and Milpharm, 9 February 2021, page 2. From January 2020 the manner in which the Drug Tariff was calculated was adjusted such that it would have included Milpharm's ASPs and this would have placed downward pressure on the Tariff and therefore reduced the benchmark against which both firms are likely to have set their prices.

¹⁴⁴⁹ PRC03676, Final Note of call between CMA and Milpharm, 20 January 2022, page 2.

*given out [dispensed by pharmacists] as either Teva or Milpharm and so the products do not compete in the way that other generics compete.*¹⁴⁵⁰

- 6.406 Milpharm reiterated the lack of competition in the market in a later call with the CMA explaining that the Tablets market ‘was unlike other generic drug markets because there was little competitive interaction between Teva and Milpharm for the supply of Tablets and it was extremely difficult to win more sales’.¹⁴⁵¹
- 6.407 Milpharm went on to note that, given the difficulties in increasing sales, it had adopted strategies designed to capture new patients who were not stabilised on a particular manufacturer’s product.¹⁴⁵² Figure 6.8 demonstrates that Milpharm has not been able to increase its sales of Tablets using this strategy.¹⁴⁵³
- 6.408 Teva also confirmed that its experience was that competition in the Tablets market had been limited with prices being relatively stable and there being no major price challenges from Tablets customers.¹⁴⁵⁴
- 6.409 As has been demonstrated in Period 3 above, the MHRA Guidance limited the scope and effect of competition between Tablet suppliers and it continued to do so during Period 4.
- 6.410 Contemporaneous Milpharm documents demonstrate that the Guidance continued to act as a barrier to expansion during Period 4. In an email, dated 3 August 2015, Milpharm’s National Account Manager identified the MHRA Guidance as a reason why pharmacists might not be prepared to switch between Tablet suppliers. The email referred to the fact that [X] would not switch to the Milpharm Tablet ‘purely on a commercial offering’ because their superintendent pharmacist ‘had the final call on AED’s’. This clearly suggests that the decision as to whose Tablet would be stocked would be influenced by non-commercial factors, Continuity of Supply in particular. Indeed, the email also states that the MHRA Guidance ‘may shine further light on why Teva hold such a majority market share’.¹⁴⁵⁵
- 6.411 Milpharm has confirmed that the Guidance has acted as an ongoing barrier to it increasing its sales. A Milpharm employee informed CMA officials that since he joined Milpharm in 2017 Milpharm had struggled to increase its sales as a result of the Guidance. He explained that ‘Milpharm would always try to sell to new customers, but there was always resistance from certain customers who responded that they were supplied by Teva and did not want to switch their

¹⁴⁵⁰ PRC01623A, Final Note of call between CMA and Milpharm, 9 February 2021, paragraph 11.

¹⁴⁵¹ PRC03676, Final Note of call between CMA and Milpharm, 20 January 2022, paragraph 6.

¹⁴⁵² PRC03676, Final Note of call between CMA and Milpharm, 20 January 2022, pages 3-4.

¹⁴⁵³ Contrary to Flynn’s representation that Milpharm was able to ‘overcome’ what Flynn accepts were ‘limitations in customer switching in the more recent periods’ by adopting a strategy of proposing dual supply to win new customers (PRC03903, Flynn’s response to the Letter of Facts, paragraph 5.12.3).

¹⁴⁵⁴ Teva provided this description in response to a question about market dynamics ‘over the last 18 months’, ie since September 2020, PRC03750, Note of call between CMA and Teva, 4 March 2022, paragraphs 8 to 10.

¹⁴⁵⁵ PRE00249, Email chain, FW: Phenytoin 100mg – Laxmico, 4 August 2015, enclosed with Milpharm’s response to the CMA’s s.26 Notice of 18 September 2020.

patients' and this meant that 'it had been difficult to win new volumes in the Tablets market'.¹⁴⁵⁶

- 6.412 Teva was more reserved in its description of how Continuity of Supply impacted the market. During a call, it informed the CMA that it did not have a view on the impact of the MHRA Guidance on prescribers or dispensers as Teva 'just supplies into the market', but it would expect that the MHRA Guidance would be adhered to.¹⁴⁵⁷ However, this submission must be considered in the context of evidence of Teva's previous conduct which is less passive than it suggested – in particular - that it sought to increase its market share prior to the Guidance coming into force on the basis that it thought switching would be made more difficult.
- 6.413 Milpharm's ability to compete with Teva during this Period continued to be impacted by supply chain issues.¹⁴⁵⁸ It was not until at least 2016 that Milpharm's parent company improved its supply chain which enabled Milpharm to move to supplying customers on a contractual volumes basis, rather than a transactional one.¹⁴⁵⁹ This allowed Milpharm to establish a regular supply to existing customers based on a more robust supply chain'. However, Milpharm also explained to the CMA that it 'had stuck to those [existing] customers,'¹⁴⁶⁰ meaning that it was not growing its sales by selling to new customers.
- 6.414 What is also significant in this period are internal Milpharm documents which show that, despite the fact that Milpharm's prices were significantly lower than they had been when it entered the market, it nonetheless was making strong returns, showing the ongoing distortive effect of Teva's exercise of its market power.
- 6.415 An internal Milpharm presentation dated January 2015 (when Milpharm's ASP was £7.34, 69% lower than its ASP when it entered) referred to Tablets as being a 'highly profitable product' for Milpharm.¹⁴⁶¹
- 6.416 Further, an internal Milpharm email dated 9 March 2015 (at which point Milpharm's ASP was £12.37, 48% lower than when it entered) described the prices as being 'handsome' and 'at a good price'.¹⁴⁶² Indeed, the email describes that 'Phenytoin 100mg is our profit driver for 2015/16'.

¹⁴⁵⁶ PRC03676, Final Note of call between CMA and Milpharm, 20 January 2022, paragraph 20.

¹⁴⁵⁷ PRC03750, Note of call between CMA and Teva, 4 March 2022, paragraph 9.

¹⁴⁵⁸ Although Milpharm informed the CMA that the reliability of its supply chain had improved from around 2016, it provided the example of [REDACTED] – see PRC03676, Final Note of call between CMA and Milpharm, 20 January 2022, paragraphs 8-13.

¹⁴⁵⁹ PRC03676, Note of call with Milpharm of 20 January 2022, paragraphs 38 to 39.

¹⁴⁶⁰ PRC01796, Note of call between CMA, [REDACTED] and Milpharm, 25 February 2021, paragraph 25.

¹⁴⁶¹ PRE00181, Milpharm internal document, UK Top 20 INN - Planning (sent to [REDACTED]) 260115.pptx, page 8.

¹⁴⁶² PRE00229, Email chain, Phenytoin, 9 March 2015, enclosed with Milpharm's response to the CMA's s.26 Notice of 18 September 2020. The email states 'I notice that in Jan and Feb 2015, the biggest customers are [REDACTED] (1,388 packs at a handsome price), [REDACTED] (1,440 pack, thanks for sharing information regarding Profit Share), [REDACTED] (900 packs, again at a good price)'.

6.417 The evidence provided by Milpharm shows that despite significant price reductions (compared to Milpharm's ASP when it entered), Milpharm considered that Tablets were a highly profitable product (suggesting there was a generous margin being achieved on its sales). This is supportive of the CMA's finding that competition in the Tablets market during Period 4 was not sufficiently effective and also that Teva's previously very high prices had an ongoing, distortive effect on competition in the market. Despite a very significant discount relative to its entry price, it is clear Tablets continued to be a strong performer in Milpharm's portfolio, so strong that it was seen as its 'profit driver'.

Conclusion on Period 4

- 6.418 The CMA does not consider that ASPs during this period of duopoly supply provide a meaningful comparator for assessing whether Pfizer's Prices and Flynn's Prices were fair.
- 6.419 The evidence shows that there was very limited competition in the market at this time. In particular Teva's ASP was comfortably above Milpharm's ASP in the period 2015 to 2020 and yet it maintained a majority share of supply of 64% over the same period despite the obvious financial incentive to switch.
- 6.420 Contemporaneous documentary evidence, together with oral evidence provided by Milpharm, confirms that there was limited competition between Milpharm and Teva, with the MHRA Guidance seeming to play an important role in dampening competition.

iv. Comparison of Tablets ASPs and Flynn and Pfizer's ASPs

- 6.421 The CMA has concluded that the Tablets market did not exhibit sufficiently effective competition during the period January 2005 to December 2021. Although there was a short period of more intense competition in Period 3, it was limited by several factors (as set out in the conclusion for Period 3). Therefore, at no stage do Tablets ASPs provide a meaningful comparator to establish whether the Parties' supply prices for Capsules were fair.
- 6.422 Without prejudice to this conclusion, the CMA has, nevertheless, conducted a comparison of the Parties' prices for Capsules during the Relevant Period (September 2012 to December 2016) against the Tablets ASPs in Period 3 to consider if it could be informative for the assessment of whether or not the Parties' prices for Capsules were fair.
- 6.423 This comparison has been conducted by reference to the ASPs of Tablets and the Parties ASPs' for 100mg Capsules only. This is because Tablets are only available in the UK in 100mg strength, meaning a comparison cannot be made between the ASPs of Tablets and the 25mg, 50mg and 300mg strength Capsules. The Parties have not challenged this approach in their representations.

- 6.424 In conducting this assessment, the CMA has multiplied the Tablets ASP by three to ensure a like for like comparison due to the pack size differences between 100mg Capsules and Tablets.¹⁴⁶³
- 6.425 Period 3 was chosen for the comparison because it clearly represents the period where competition was most intense. Additionally, although the CMA has concluded to the contrary, both Parties have submitted that ASPs during this period were the result of effective competition.¹⁴⁶⁴
- 6.426 Given the factors identified by the CMA as limiting competition between Tablet suppliers during Period 3, the CMA considers that ASPs achieved during this period are significantly higher than would have been the case in conditions of sufficiently effective competition. As such, the CMA has compared each of the Parties' ASPs during the Relevant Period with the lowest ASPs of the entrants to the Tablets market during Period 3.
- 6.427 The CMA has selected Milpharm's and Wockhardt's lowest monthly ASPs of £16.53 and £19.98 for 84 Tablets for the comparison given the CMA's conclusion that, even at their lowest, these prices still reflected the limitations on competition present in the market, the short period of time in which three players were present and the history of the significant price increases imposed by Teva.¹⁴⁶⁵
- 6.428 The CMA has excluded Teva's ASPs from the comparison on the basis that its prices reflect its substantial market power and therefore it is appropriate for them to be excluded.¹⁴⁶⁶
- 6.429 As set out in Period 4 above, the prices of Tablets have steadily fallen in recent years. Both Teva's and Milpharm's ASPs were [£11-£20.99] in December 2021 (for 84 Tablets).¹⁴⁶⁷ Across 2021 as a whole, Teva's and Milpharm's ASPs were [£11-£20.99] and [£11-£20.99] respectively for 84 tablets. These ASPs are [£]. The evidence demonstrates that the Guidance remains a significant barrier to competition between Milpharm and Teva and that there is limited competitive interaction between their Tablets.¹⁴⁶⁸ However, current prices are [£].¹⁴⁶⁹
- 6.430 The CMA first sets out the comparison between Milpharm and Wockhardt's lowest Monthly ASPs during Period 3 and Flynn's ASPs before considering the same comparison for Pfizer.

¹⁴⁶³ 100mg Capsules are sold in packs of 84 capsules and Tablets are sold in packs of 28 tablets.

¹⁴⁶⁴ PRC03492, Flynn's response to the SO, paragraph 8.29. PRC03488, Pfizer's response to the SO and DPS, paragraph 6(b) and 21(b).

¹⁴⁶⁵ In addition, as shown by Figure 6.7, ASPs have continued to fall over time, which supports the CMA's use of Milpharm and Wockhardt's lowest ASP.

¹⁴⁶⁶ See paragraph 6.140 above.

¹⁴⁶⁷ This is the latest data the CMA has received from the Tablet suppliers.

¹⁴⁶⁸ See the conclusion for Period 4 above.

¹⁴⁶⁹ Moreover, the June 2022 Drug Tariff shows that the Drug Tariff price of Tablets in June 2022 was £6.42. Given that ASPs are typically lower than the Drug Tariff price, this implies that the ASPs of Tablets [£].

Comparison between Milpharm and Wockhardt's lowest ASPs and Flynn's ASPs during the Relevant Period

- 6.431 Flynn operates at the same level of the supply chain as the Tablet suppliers, accordingly a comparison of Milpharm and Wockhardt's ASPs represents a like for like comparison with Flynn's ASPs.
- 6.432 Table 6.11 below compares Milpharm and Wockhardt's lowest monthly ASP charged during the period of three player supply with Flynn's ASPs during the Relevant Period. The comparison shows that the prices charged by Flynn for 100mg Capsules during the Relevant Period are significantly higher than the lowest ASPs of Milpharm and Wockhardt.
- 6.433 As such, this comparison does not undermine the CMA's finding that Flynn's prices were unfair in themselves. If anything, it supports this conclusion.

Table 6.11: Comparison between the Tablets ASPs during the period of three Tablets Suppliers and Flynn's ASPs during the Relevant Period

	Percentage difference between Milpharm's lowest ASP (£16.53 for 84 Tablets) and Capsule ASPs	Percentage difference between Wockhardt's lowest ASP (£19.98 for 84 Tablets) and Capsule ASPs
Flynn's ASP during the Relevant Period (£54.40)	229%	172%
Flynn's ASP – September 2012 to March 2014 (£59.53)	260%	198%
Flynn's ASP – May 2014 to 7 December 2016 (£48.93)	196%	145%

Notes:

The tablets ASPs are based on Milpharm's and Wockhardt's lowest ASPs during the period September 2012 and July 2014. Milpharm's lowest ASP was £5.51 per pack of 28 Tablets in June 2014 and Wockhardt's lowest ASP was £6.66 in October 2013. The Tablet ASPs have been multiplied by three to give an ASP for 84 Tablets.

Comparison between Milpharm and Wockhardt's lowest ASPs and Pfizer's ASPs during the Relevant Period

- 6.434 Pfizer's supply price is at an upstream level of the supply chain compared to the Tablets ASPs used for the comparison. The result is that any comparison between Pfizer's prices and those of the Tablet suppliers is not like for like and, everything being equal, Pfizer's Prices would be expected to be lower than Milpharm and Wockhardt's ASPs. This approach is consistent with the views articulated by the CAT in its Phenytoin judgment, in which it recognised that comparing Pfizer's

Prices with Tablet ASPs would be ‘comparing prices at different points in the distribution chain’ and observed that ‘Pfizer’s ASPs were not significantly below Teva’s ASPs even though Pfizer’s prices were at an upstream level of the supply chain when compared to Teva’.¹⁴⁷⁰

6.435 Table 6.12 below compares Milpharm and Wockhardt’s lowest monthly ASP charged during the period of three player supply (September 2012 to July 2014) with Pfizer’s prices during the Relevant Period.¹⁴⁷¹ The comparison shows that the lowest ASPs of Milpharm and Wockhardt are significantly below the prices charged by Pfizer for 100mg Capsules during the Relevant Period. Given that Pfizer operates at an upstream level of the supply chain, where one would expect lower ASPs compared with the Tablets ASPs to account for the additional margin in the supply chain, the figures in Table 6.12 understate the comparative difference.

6.436 As such, this comparison does not undermine the CMA’s finding that Pfizer’s Prices were unfair in themselves. If anything, it supports this conclusion.

Table 6.12: Comparison between the Tablets ASPs during the period of three Tablets Suppliers and Pfizer’s ASPs during the Relevant Period

	Percentage difference between Milpharm’s lowest ASP (£16.53 for 84 Tablets) and Capsule ASPs	Percentage difference between Wockhardt’s lowest ASP (£19.98 for 84 Tablets) and Capsule ASPs
Pfizer’s ASP during the Relevant Period (£37.56)	127%	88%
Pfizer’s ASP – September 2012 to December 2013 (£40.94)	148%	105%
Pfizer’s ASP – March 2014 to 7 December 2016 (£34.21)	107%	71%

Notes:

The tablets ASPs are based on Milpharm’s and Wockhardt’s lowest ASPs during the period September 2012 and July 2014. Milpharm’s lowest ASP was £5.51 per pack of 28 Tablets in June 2014 and Wockhardt’s lowest ASP was £6.66 in October 2013. The Tablet ASPs have been multiplied by three to give an ASP for 84 Tablets.

The Parties’ Representations on the CMA’s comparison

6.437 Both Pfizer and Flynn made representations on the comparison made by the CMA in response to the CMA’s Remittal SO.

¹⁴⁷⁰ See *Phenytoin* [2018] CAT 11, paragraphs 385 and 387.

¹⁴⁷¹ See paragraph 6.426 above for an explanation of the reasons why the CMA has selected Milpharm and Wockhardt’s lowest monthly ASP.

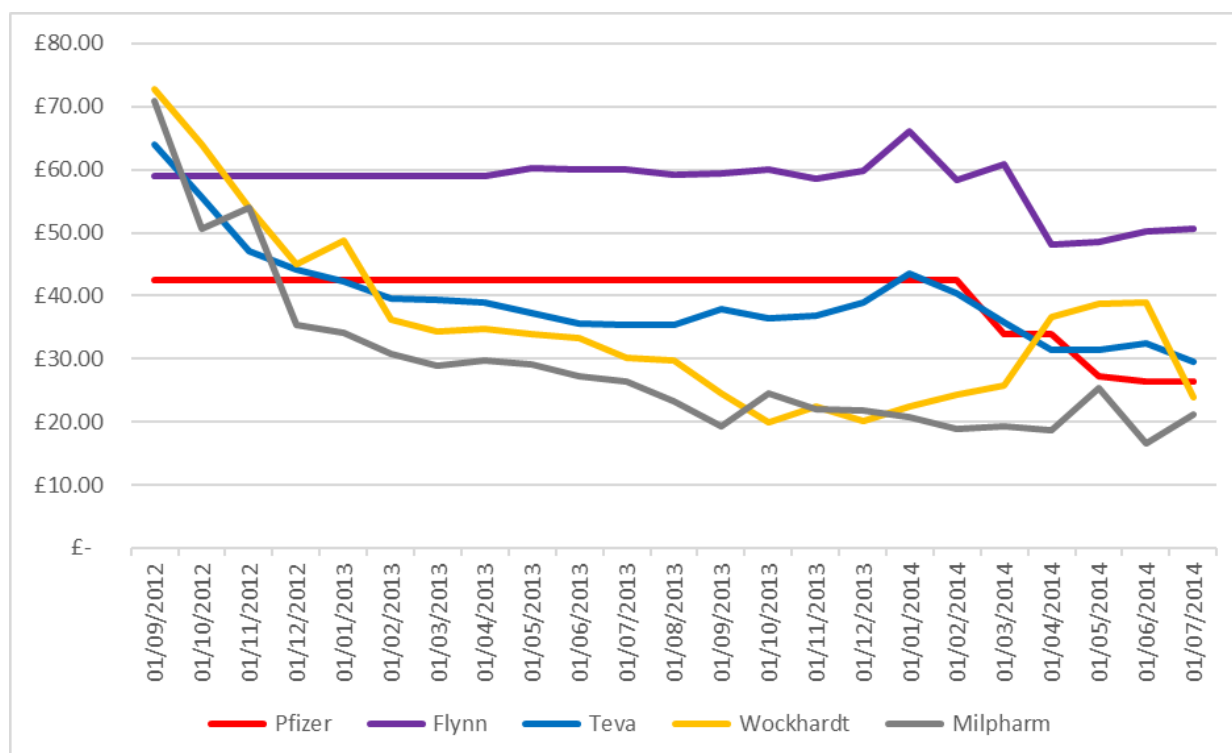
Flynn's representations

- 6.438 Flynn stated that the CMA has not adequately justified why it thinks it is appropriate to only take into account Wockhardt and Milpharm's lowest prices in the comparison presented.¹⁴⁷²
- 6.439 This is incorrect, the CMA has fully justified its approach. The Tablets market was not, at any stage, effectively competitive. Accordingly, the CMA considers that it would not be appropriate to use a higher price in Table 6.11 as the CMA finds that even the lowest prices are higher than would be expected under conditions of sufficiently effective competition for the reasons set out above in Period 3.
- 6.440 However, even if the CMA were to consider a broader range of ASPs in its comparison – thereby addressing Flynn's concerns¹⁴⁷³ – Figure 6.9 below shows that Flynn's ASP would still be significantly above *all* of the Tablet suppliers' ASPs during the *whole* period of three player supply *following* the initial price reductions that took place in the period September to December 2012. For instance, there was a significant difference between Flynn's ASPs during the Relevant Period and all of Milpharm, Wockhardt and Teva's ASPs in the period December 2012 to July 2014. This difference exists notwithstanding the highly inflated price base that competition started from in the Tablet market and Teva's own substantial market power, both of which continued to distort competition. Indeed, as the CMA has established, Milpharm considered its Tablet to be a 'highly profitable product' when it was priced at £7.34 (the equivalent of £22.02 for 84 Tablets, and some 69% lower than its ASP when it entered).
- 6.441 Accordingly, again, these comparisons do not undermine the CMA's finding that Flynn's Prices were unfair in themselves. If anything, the comparisons further support this conclusion. Flynn has not put forward any comparisons against the ASPs of Tablet suppliers during Period 3 (which Flynn described as being subject to 'healthy competition') which would suggest that its supply prices for Capsules were fair.

¹⁴⁷² PRC03492, Flynn's response to the SO, paragraph 8.44.2.

¹⁴⁷³ See, for instance, PRC03551, Flynn's written response to the CMA's Oral Hearing questions, dated 14 December 2021. Flynn submitted that 'Flynn's concern is that there are clearly inappropriate adjustments in the CMA's calculations of ASPs. In particular, the CMA's approach only takes into account the lowest monthly averages of Wockhardt and Milpharm's ASPs and does not include Teva's ASP at all.'

Figure 6.9: Comparison between the Tablets ASPs and Pfizer's and Flynn's ASPs (for 84 Capsules/Tablets) during Period 3 (September 2012 to July 2014)



6.442 Flynn has submitted that '[f]ocusing solely on ASPs ignores input costs' and that the CMA should instead compare the margins made by Flynn and those made by Tablet suppliers during this period, which Flynn sees as 'more appropriate, than a simple comparison of ASPs.'¹⁴⁷⁴

6.443 The CMA rejects this submission. The purpose of price comparators at Limb 2 of the *United Brands* test is to establish what customers might be prepared to pay for the product or service in an effectively competitive market (in order to ultimately evaluate the economic value of the product).¹⁴⁷⁵ To the extent that any comparison between Capsules and Tablets is meaningful, the appropriate comparison would be between Flynn's prices and the prices charged by Tablet suppliers at the equivalent level of the supply chain to Flynn.

6.444 Flynn's argument has similar features and would have similar consequences to the arguments previously put forward by Pfizer as part of its appeal Ground 4.¹⁴⁷⁶ Like Pfizer's appeal Ground 4, this representation tries to distinguish Flynn's Prices from Pfizer's Prices. However, this distinction is entirely artificial and ignores the fact that

¹⁴⁷⁴ PRC03551, Flynn's written response to the CMA's Oral Hearing questions, dated 14 December 2021.

¹⁴⁷⁵ See *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 155 and 172. See also *Scandlines*, paragraphs 169 to 175 and *Albion Water II*, paragraphs 252 and 253. This approach is also consistent with Flynn's submissions on the 'General framework for excessive pricing' (see Flynn SO response paragraphs 5.5 to 5.9); and Flynn's primary case that the CMA should conduct a price comparison between its own prices and £30 Drug Tariff price of Tablets (on the basis that £30 was the DHSC's approximation of the economic value of Tablets).

¹⁴⁷⁶ As part of its fourth ground of appeal of the 2016 Infringement Decision, Pfizer submitted that it could not be in breach of Article 102, essentially because of the vertical nature of its relationship with Flynn and its distance from Flynn's pricing, there being no finding in the 2016 Infringement Decision that Pfizer abused Flynn's market, *Phenytoin* [2018] CAT 11, paragraph 446.

Pfizer and Flynn jointly developed their strategy, and that strategy was based on a clear-sighted view, by both, of making substantial profits which they agreed to split, providing each with a satisfactory and significant share.¹⁴⁷⁷ This joint intention is reflected in a strategy document relating to the arrangements which stated that, even if the Parties had lost 50% of market, they would still make more than £20 million in terms of additional profit.¹⁴⁷⁸

6.445 Conducting a comparison based solely on margins would divorce the assessment of unfairness from the supply prices actually charged by Flynn to its customers, as well as the economic value of the product. For instance, this would allow Flynn to rely on its position in the supply chain (and the inflated supply prices it agreed to pay to Pfizer, in the knowledge it would make very substantial profits of its own) to avoid drawing comparisons between its prices and those that might be charged in effectively competitive markets.

6.446 Adopting this approach would also enable Flynn to escape liability for charging prices which bore no reasonable relation to the economic value of the product. Drawing from the conclusion of the CAT in dismissing Pfizer's Ground 4, 'we consider that would be a surprising outcome which is not consistent with the effective application of Article 102 and the protection of consumers from unfair pricing that it imposes.'¹⁴⁷⁹

Pfizer's representations

6.447 Pfizer made representations that the CMA should consider Teva's ASP in any comparison. Pfizer has submitted that its Capsule ASPs were in line with:

6.447.1 Teva's ASPs during the Relevant Period.¹⁴⁸⁰

6.447.2 The weighted average of all Tablet ASPs during the Relevant Period.¹⁴⁸¹

6.447.3 The lowest level of the Teva ASP during the Relevant Period.¹⁴⁸²

6.448 For the reasons described above, the CMA does not consider a comparison against Teva's prices to be informative for the purposes of assessing fairness given that they reflected Teva's market power. Furthermore, given Teva's price differential over Milpharm and Wockhardt for the majority of the Relevant Period while also maintaining a majority share of supply, any weighted average would likewise be subject to the same concerns as it would be inflated by Teva's market power.

¹⁴⁷⁷ *Phenytoin*, paragraph 457.

¹⁴⁷⁸ PHT00164, Presentation slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27), page 11.

¹⁴⁷⁹ *Phenytoin* [2018] CAT 11, paragraphs 454 and 455.

¹⁴⁸⁰ PRC03488, Pfizer's response to the SO and DPS, paragraph 20.

¹⁴⁸¹ PRC03488, Pfizer's response to the SO and DPS, paragraph 20.

¹⁴⁸² PRC03901, Pfizer's response to the Letter of Facts, paragraph 18(c).

- 6.449 However, even if the CMA did consider Teva's ASP in its comparison, Figure 6.9 shows that Pfizer's prices were above Teva's ASPs during Period 3 following the initial price reductions until January 2014. As such, despite the presence of Teva's market power, this comparison does not undermine the CMA's finding that Pfizer's prices were unfair in themselves. In fact this comparison understates the comparative difference as Pfizer operates at an upstream level of the supply chain, so one would expect lower ASPs compared with Teva's ASPs.
- 6.450 Pfizer has also submitted that it is the price at launch that is relevant and that Pfizer's price in September 2012 (at the point of Milpharm's entry into the market) was set at 50% below the ASP that Wockhardt and Milpharm charged at that point.¹⁴⁸³
- 6.451 The CMA disagrees that this indicates that Pfizer's Prices were fair during the Relevant Period. Milpharm's price at launch is not a meaningful comparator. The CMA has concluded that there was not effective price competition between Teva and Wockhardt in Period 2 prior to Milpharm's entry. Instead, Teva's inflated ASPs were not significantly impacted by Wockhardt's entry and remained high and stable and close to the level they stood at prior to Wockhardt's entry (when Teva was a monopolist).
- 6.452 Accordingly, Milpharm's entry price (which was even higher than Teva's ASP in September 2012) was set in circumstances where prices in the market remained inflated by Teva's previous exercise of market power, such that its ASP on entry is in no way a reliable benchmark for an effectively competitive price.
- 6.453 Relying on Milpharm's entry price also ignores the critical dynamic that occurred following its entry. Notwithstanding the substantial limitations on competition that prevailed within the market, Milpharm rapidly reduced its prices following its entry in an attempt to gain, and retain, what market share it could.
- 6.454 By December 2012 (just three months after its entry) Milpharm's ASP was already 50% lower than it had been at entry (£11.77 [or £35.31 for 84 Tablets]) and it continued to fall in 2013, reaching a low of £5.51 (or £16.53 for 84 Tablets) in June 2014. These price falls show that it would be wholly inappropriate to rely on Milpharm's entry price as a benchmark for an effectively competitive price.
- 6.455 It is also relevant to observe that, despite the relatively substantial decline in its ASP from entry, Tablets remained a very strong performer within Milpharm's portfolio, supporting the conclusion that, as a result of the very high prices that prevailed in the market prior to Milpharm's entry, even a relatively significant decline in its ASP was not reflective of the market being effectively competitive.¹⁴⁸⁴

¹⁴⁸³ PRC03901, Pfizer's response to the Letter of Facts, paragraph 18(a) and (c).

¹⁴⁸⁴ PRE00181, Milpharm internal document, UK Top 20 INN - Planning (sent to [REDACTED]) 260115.pptx, page 8.

6.456 Notwithstanding that Pfizer's ASP during the entire Relevant Period was upstream from Wockhardt and Milpharm's prices, Pfizer's ASP was nevertheless significantly higher than Wockhardt and Milpharm's ASPs during Period 3 following the initial price falls until the beginning of Wockhardt's supply issues in January 2014 (as shown by Figure 6.9 above).

6.457 In particular, given that Pfizer's ASP was upstream from Milpharm's and Wockhardt's prices, this comparison does not undermine the CMA's finding that Pfizer's Prices were unfair in themselves.

III. Other AEDs

a. Introduction

6.458 As explained above, the CMA is required to fairly evaluate any prima facie valid comparisons or argument advanced by the undertaking(s) under investigation that prices were fair when compared to competing products.

6.459 As part of the evidence it submitted during the appeal of the 2016 Infringement Decision to the CAT, Pfizer, through its expert witness [Pfizer Expert Witness 2], put forward evidence relating to other AEDs.¹⁴⁸⁵ [Pfizer Expert Witness 2] highlighted five AEDs in particular¹⁴⁸⁶ (the 'Comparator AEDs') as providing 'a relevant benchmark against which to assess Pfizer's supply price' for Capsules.¹⁴⁸⁷ Pfizer described these Comparator AEDs as '[Pfizer Expert Witness 2]'s five, most reliable, comparator AED products'.¹⁴⁸⁸ These are:

6.459.1 Branded topiramate (known as Topamax);

6.459.2 Branded lamotrigine (known as Lamictal);

6.459.3 Branded levetiracetam (known as Keppra);

6.459.4 Branded oxcarbazepine (known as Trileptal); and

6.459.5 Generic ethosuximide.

6.460 [Pfizer Expert Witness 2]'s view was that these AEDs are relevant benchmarks because they are similar products to Capsules¹⁴⁸⁹ (specifically, these AEDs treat

¹⁴⁸⁵ PRE00720, The First Expert Report of [Pfizer Expert Witness 2], 7 February 2017, considered 19 AEDs whilst PRE00154, the Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017 focused on 5 of these AEDs.

¹⁴⁸⁶ The CMA notes that these are all in their solid formulation making them the most similar to phenytoin sodium capsules.

¹⁴⁸⁷ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 53.

¹⁴⁸⁸ PRE00627, Pfizer's Written Closing Submission, paragraph 125.

¹⁴⁸⁹ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 36.

the same condition, with similar levels of efficacy and a comparable lack of serious side effects).¹⁴⁹⁰

- 6.461 [Pfizer Expert Witness 2] also relied on the fact that none of the Comparator AEDs are subject to the same stringent guidance on Continuity of Supply as applies to phenytoin sodium, ie pharmacies can switch patients between different versions of these products due to pricing or other considerations.¹⁴⁹¹ [Pfizer Expert Witness 2]'s view was that, as a result of not being subject to Continuity of Supply, the markets for these AEDs would be more competitive and that higher prices for other AEDs in other markets that appeared to be competitive would suggest that phenytoin sodium capsule prices could not be unfairly high.¹⁴⁹²
- 6.462 Based on his assessment of these AEDs, [Pfizer Expert Witness 2] drew the following conclusions:
- 6.462.1 several Comparator AEDs have reimbursement prices that exceed the supply prices charged by Pfizer and Flynn and this is sufficient to show that Pfizer's supply price is not abnormally high¹⁴⁹³;
- 6.462.2 the reimbursement prices of the four branded AEDs listed above (Topamax, Lamictal, Keppra and Trileptal) are significantly higher than those of equivalent generic products (topiramate, lamotrigine, levetiracetam and oxcarbazepine), often many years after first generic entry occurs¹⁴⁹⁴; and
- 6.462.3 the significant difference between the prices paid by the DHSC for branded and generic versions of these AEDs therefore suggests that it is not particularly uncommon for the DHSC to pay prices that are far in excess of the cost plus 6% ROS¹⁴⁹⁵ benchmark proposed by the CMA.¹⁴⁹⁶
- 6.463 The CMA has considered [Pfizer Expert Witness 2]'s evidence afresh in order to determine whether any of the Comparator AEDs are a meaningful comparator for the purposes of assessing the fairness of the Parties' prices for Capsules during the Relevant Period. The CMA has also gathered further information, not included in [Pfizer Expert Witness 2]'s original report, from public sources - including data relating to the sales volumes of the generic and branded versions of the Comparator AEDs over the period 2004 to 2021.

¹⁴⁹⁰ PRE00720, First Expert Report of [Pfizer Expert Witness 2], 7 February 2017, paragraph 123; and PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraphs 32 and 33.

¹⁴⁹¹ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 35.

¹⁴⁹² *Phenytoin* [2018] CAT 11, paragraph 396.

¹⁴⁹³ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 36.

¹⁴⁹⁴ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 37.

¹⁴⁹⁵ In its 2016 Infringement Decision, the CMA allocated a ROS of 6% to Pfizer's Products. In carrying out its updated analysis, the CMA has found that it is appropriate to increase the ROS allocated to Pfizer's Products from 6% in the CMA's 2016 Infringement Decision to 10% on remittal.

¹⁴⁹⁶ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 37.

6.464 Flynn has submitted that the CMA has failed to address seven other AEDs which it referred to in a single slide put forward during its oral hearing on 27 January 2016, during the CMA's Previous Investigation.¹⁴⁹⁷ Flynn has not put forward any additional evidence or analysis during the Remittal Investigation relating to these seven AEDs. The CMA has addressed Flynn's representations in Annex E.

b. The CMA's findings

6.465 As described in section 4.C.II, comparators must be sufficiently similar to allow for a 'meaningful' comparison.¹⁴⁹⁸ Further, the competitiveness of the market from which a comparator is taken is a significant factor.¹⁴⁹⁹ Prices which do not reflect sufficiently effective competition are highly unlikely to be meaningful comparators.

6.466 With this in mind, the CMA has conducted a two-fold analysis:

6.466.1 First, it has considered the product characteristics of the Comparator AEDs to determine whether they are sufficiently similar to Capsules so as to provide the basis for a meaningful comparison.

6.466.2 Second, without prejudice to its conclusions in respect of product characteristics, the CMA has additionally considered the relevant context and competitive conditions applicable to the prices of the Comparator AEDs put forward by [Pfizer Expert Witness 2], to establish whether they might represent a meaningful comparator for assessing the fairness of the Parties' prices for Capsules.

i. Differences in product characteristics

6.467 [Pfizer Expert Witness 2] considered the Comparator AEDs to be sufficiently similar to Capsules. [Pfizer Expert Witness 2] noted that these AEDs treat the same condition, with similar levels of efficacy and a comparable lack of serious side effects.¹⁵⁰⁰ [Pfizer Expert Witness 2] relied heavily on the evidence provided by [Pfizer Expert Witness 1] relating to the 'efficacy' of phenytoin sodium capsules.¹⁵⁰¹

6.468 However, the CMA finds that there are several significant clinical differences between Capsules and the Comparator AEDs. In particular: Capsules have a number of undesirable product characteristics not present in the Comparator AEDs; the Comparator AEDs are used to treat different seizure types and patient

¹⁴⁹⁷ See PRC03492, Flynn's Response to the SO, paragraphs 8.46 and 8.47.

¹⁴⁹⁸ See for example *Albion Water II* [2008] CAT 31, paragraphs 252 and 253.

¹⁴⁹⁹ For further support for this point, see also *Scandlines*, paragraphs 172 and 173; *Phenytoin* [2018] CAT 11, paragraph 390; *Phenytoin CoA*, paragraphs 155 and 172; and *Aspen*, paragraph 199.

¹⁵⁰⁰ PRE00720, First Expert Report of [Pfizer Expert Witness 2], 7 February 2017, paragraph 123, and PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraphs 32 and 33.

¹⁵⁰¹ PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, paragraphs 5.7 and 5.8. In response to the SO, Pfizer again submitted that the critical fact is that phenytoin sodium is effective at controlling seizures (PRC03488, Pfizer's response to the SO and DPS, paragraph 24(b)). While the CMA does not disagree with this statement, that alone is not a reason to consider the Comparator AEDs to be sufficiently similar to Capsules to allow for a meaningful comparison, for the reasons set out in this section

groups; the Comparator AEDs were all first line treatments during the Relevant Period, as reflected in clinical guidance; and the Comparator AEDs continue to be prescribed to new patients (reflecting clinical views on their relative benefits) and have been increasing in volumes. These differences are described further below.

ii. Clinical differences

6.469 [Pfizer Expert Witness 2] referred specifically to Capsules and the Comparator AEDs having a comparable efficacy and a comparable lack of serious side effects.¹⁵⁰²

6.470 As described in section 6.B.V, phenytoin sodium has several product characteristics that result in clinical limitations. Whilst efficacy is important in deciding what treatment to prescribe, clinicians would not consider efficacy in isolation from other features of a particular treatment. Reflecting this, phenytoin sodium's characteristics and related clinical limitations have resulted in its marginalisation as an ongoing treatment for epilepsy patients.

6.471 In this respect, phenytoin sodium is very different to the Comparator AEDs put forward by [Pfizer Expert Witness 2]. Whilst [Professor of Neurology] noted that it could be difficult to compare tolerability between different drugs, he identified numerous potential side effects of phenytoin sodium which are not present in the same combination in other AEDs.¹⁵⁰³

6.472 The CMA has taken account of [Pfizer Expert Witness 1]'s evidence regarding the 'efficacy' of Capsules.¹⁵⁰⁴ However, taken together, the characteristics of phenytoin sodium distinguish the drug from the Comparator AEDs put forward by [Pfizer Expert Witness 2].

c. Differences in preferred usage and the relevant prescribing guidelines

6.473 In practice, there are a large number of AEDs available to treat patients with epilepsy. The NICE guidance refers to over 20 AEDs for the treatment of epilepsy and, for any given type of epileptic seizure, there are typically several AEDs that can be used to treat a patient. The NICE guidance¹⁵⁰⁵ refers to 16 different AEDs alone (including phenytoin) for the treatment of people with focal seizures.

6.474 For these purposes, the NICE guidance separates AEDs into three main categories:

¹⁵⁰² PRE00720, First Expert Report of [Pfizer Expert Witness 2], 7 February 2017, paragraph 123; and PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraphs 32 and 33.

¹⁵⁰³ PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraphs 17 and 18.

¹⁵⁰⁴ See PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017.

¹⁵⁰⁵ PHT00092, NICE Clinical Guidance CG137 (2012), The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care (CMA document reference PD13), Appendix E: Pharmacological Treatment (CMA document reference PD13), Table 1 (this Guidance has been updated and replaced by Epilepsies in children, young people and adults, NICE guideline (NG217), last updated on 27 April 2022).

6.474.1 First-line AEDs, which are the first treatments recommended by NICE for the treatment of epilepsy.

6.474.2 Second-line AEDs, which may be used in combination with a first-line AED as an adjunctive treatment, if a patient's seizures are not completely controlled on any of the first-line AEDs.¹⁵⁰⁶

6.474.3 Third-line AEDs,¹⁵⁰⁷ which may be considered if first-line and second-line AEDs are ineffective or not tolerated by a patient.¹⁵⁰⁸

6.475 Typically, lamotrigine or levetiracetam (both of which were selected as comparators by [Pfizer Expert Witness 2]) will be prescribed in the first instance,¹⁵⁰⁹ with 50% of patients becoming seizure free on the first AED prescribed.¹⁵¹⁰ In fact, all of the Comparator AEDs put forward by [Pfizer Expert Witness 2] were used as a first-line treatment for at least one seizure type¹⁵¹¹ during the Relevant Period, namely:¹⁵¹²

6.475.1 Topiramate: first-line treatment for myoclonic seizures;

6.475.2 Lamotrigine: first-line treatment for generalised tonic-clonic, absence, and focal seizures;

6.475.3 Levetiracetam: first-line treatment for myoclonic and focal seizures;

6.475.4 Ethosuximide: first-line treatment for absence seizures; and

¹⁵⁰⁶ PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, page 6, paragraph 4.6.

¹⁵⁰⁷ There are two main reasons why a drug may be categorised as a third-line treatment: first, older drugs such as phenytoin sodium may be moved down to a third-line treatment, for example, due to characteristics that make them harder to administer or because they are more likely to have side effects than newer drugs (see PRC01817, [Professor of Neurology] call note, 10 December 2020, paragraph 19; and second, newer drugs may initially be categorised as a third-line treatment until increased clinical experience has been established, after which they might be used as a first-line treatment (see PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 4.8).

¹⁵⁰⁸ PAD00055, The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care (as last updated on 11 February 2020), NICE Clinical Guidance CG137 (2012) (this Guidance has been updated and replaced by Epilepsies in children, young people and adults, NICE guideline (NG217), last updated on 27 April 2022), for example, paragraph 1.9.3.5.

¹⁵⁰⁹ [Professor of Neurology] explained to the CMA that the first choice of an AED will be based on the seizure type, personal preference/familiarity of the consultant with the drug and what is best for the individual patient, with patient tolerability being a key factor. See PRC01815, [Professor of Neurology] call note, 26 November 2020, paragraph 7.

¹⁵¹⁰ PRC01815, [Professor of Neurology] call note, 26 November 2020, paragraph 9.

¹⁵¹¹ Myoclonic seizures are sudden brief and almost shock-like involuntary single or multiple jerks due to abnormal excessive or synchronous neuronal activity and are associated with polyspikes on an Electroencephalogram. Generalised tonic-clonic seizure is a seizure of sudden onset involving generalised stiffening and subsequent rhythmic jerking of the limbs, which is the result of rapid widespread engagement of bilateral cortical and subcortical networks in the brain. Absence seizure is a seizure characterised by behavioural arrest associated with generalised spike wave activity on an Electroencephalogram.

Focal seizure is a seizure that originates within networks limited to one hemisphere of the brain, discretely localised or more widely distributed.

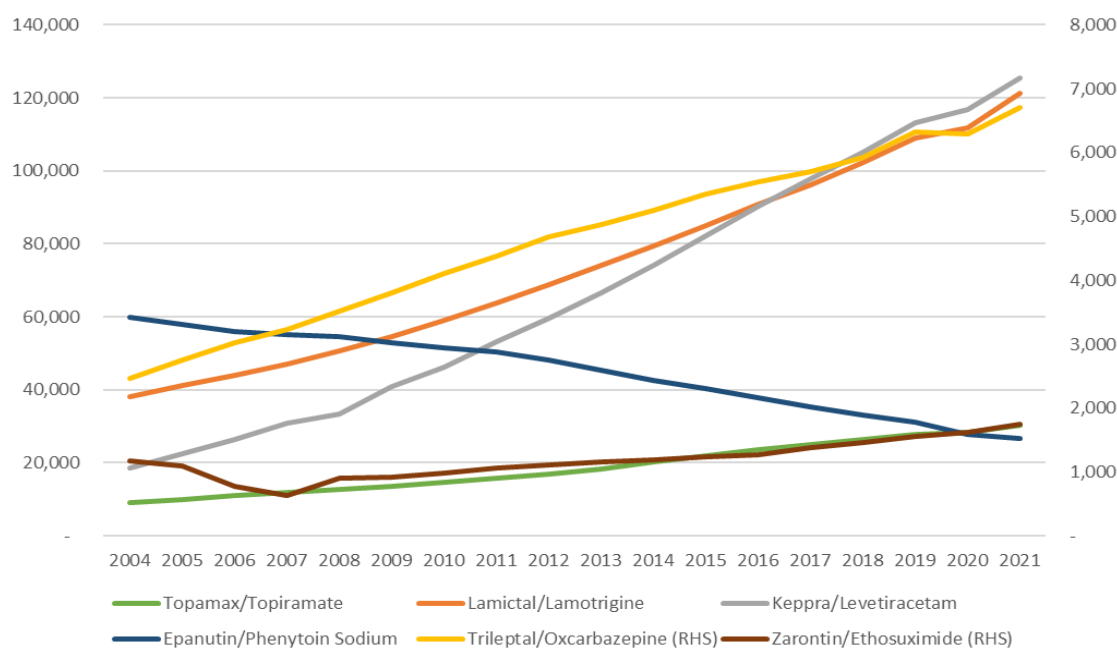
¹⁵¹² PHT00092, NICE Clinical Guidance CG137 (2012), The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care (CMA document reference PD13) (this Guidance has been updated and replaced by Epilepsies in children, young people and adults, NICE guideline (NG217), last updated on 27 April 2022), Appendix E: Pharmacological Treatment (CMA document reference PD13), Table 1.

6.475.5 Oxcarbazepine: first-line treatment for generalised tonic-clonic and focal seizures.¹⁵¹³

6.476 Reflecting their continued prescription to new patients, Figure 6.10 shows that the estimated number of patients in England for all the Comparator AEDs has increased over recent years.

6.481 This is a significant point of differentiation between Capsules and the Comparator AEDs. Due to concerns relating to the drug's clinical characteristics described above, phenytoin sodium was categorised by NICE as a third-line AED during the Relevant Period and was only recommended for the ongoing treatment of focal seizures.¹⁵¹⁴ As a result, Capsules were predominantly prescribed to a relatively small and declining group of legacy patients and were only very rarely prescribed to new patients. The decline in the usage of phenytoin sodium over a number of years reflects this.

Figure 6.10: Estimated patient numbers in England



Notes:

The estimated patient numbers in England have been calculated by the CMA using the quantity data contained within the PCA data for England, PAD00021, PAD00105-PAD00120. See also: [Prescription Cost Analysis \(PCA\) Monthly Administrative Data - Datasets - Open Data Portal BETA \(nhsbsa.net\)](#)

¹⁵¹³ The NICE guidance was last updated and replaced in April 2022 by *Epilepsies in children, young people and adults*, NICE guideline (NG217), updated on 27 April 2022. There have been some changes to the recommendations on the use of the Comparator AEDs. Lamotrigine, levetiracetam and ethosuximide remain first-line treatments for certain seizure types, whilst topiramate is now only recommended as a third-line or 'add-on' treatment, and oxcarbazepine is now only recommended as a second-line or 'add-on' treatment.

¹⁵¹⁴ PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13) (this Guidance has been updated and replaced by *Epilepsies in children, young people and adults*, NICE guideline (NG217), last updated on 27 April 2022), Appendix E: Pharmacological Treatment (CMA document reference PD13). A focal seizure is a seizure that originates within networks limited to one hemisphere, discretely localised or more widely distributed.

A DDD for each drug has been obtained from the WHO. It has been assumed that one DDD will be formed by a single strength of the tablet/capsule. The number of DDDs for each strength of the tablet/capsule has been calculated and divided by 365 to obtain an estimated number of patients for each strength. The number of patients for each strength have been summed in the above figure.

i. Conclusion on product characteristics

- 6.482 The CMA's view is that the differences between Capsules and the Comparator AEDs described above means that, from a product perspective, these AEDs are not sufficiently similar to Capsules to allow for a meaningful comparison.
- 6.483 This conclusion is supported by the CAT's findings in *Phenytoin* and Flynn's own internal documents.
- 6.484 The CAT previously found that the case for drawing meaningful comparisons with other AEDs was 'considerably less compelling than that for tablets' on the basis that these AEDs 'differ widely as products even though they address the same medical condition'.¹⁵¹⁵
- 6.485 Flynn's internal documents also support the view that the differences in clinical characteristics and usage make the Comparator AEDs unsuitable as comparators for Capsules.
- 6.486 In responding to questions from Epilepsy Action about Flynn's price increases and the subsequent price of Capsules compared to other AEDs, [Flynn Director 1] (Flynn's [REDACTED]) cautioned against drawing direct comparisons with the prices of other AEDs due to product differences:

*the only direct comparison is with the Phenytoin Sodium tablets 100mg... A comparison with the prices of other AEDs is more complicated in that it implies or presumes an equivalence of the active drugs and doses used. Equally as you are aware, some AEDs are indicated as first line, adjunctive therapy, tertiary use, or not recommended depending upon the characteristics of the seizure type or patient sub-population.*¹⁵¹⁶

- 6.487 [Flynn Director 1] continued to provide a few selected comparisons but, in relation to the comparisons, notes: 'I must caution you that they do not imply in any way that these are viable or clinically reasonable alternatives or dose comparisons'.¹⁵¹⁷

¹⁵¹⁵ *Phenytoin* [2018] CAT 11, paragraph 398.

¹⁵¹⁶ PHT00388, Email from [Flynn Director 1] (Flynn) to [REDACTED] (Epilepsy Action) dated 23 October 2012, Message from [Flynn Director 1] (Flynn Pharma) (CMA document reference 00145.524).

¹⁵¹⁷ Flynn has submitted that the CMA has misinterpreted [Flynn Director 1]'s comments and, in fact, [Flynn Director 1]'s comments 'obviously did not mean that Flynn did not see the prices of other AEDs as comparable to capsules'. Flynn submits that '[t]he fact that [Flynn Director 1] goes on to provide a list of possible alternatives and their prices shows that Flynn did see the prices of other AEDs as comparable to capsules' (PRC03903, Flynn's response to the Letter of Facts, paragraph 5.19). Whilst the CMA has only used this as supportive evidence, the CMA does not consider that an ordinary reading of the internal document supports Flynn's submission. Three of the comparators listed by [Flynn Director 1] in his email were also in the list of seven comparators put forward by Flynn during its oral hearing on 27 January 2016 in the Previous Investigation.

d. **Context and Competitive Conditions**

i. ***Topamax, Lamictal, Keppra and Trileptal***

Branded and generic drugs and open and closed prescriptions

- 6.488 Four of the five comparisons made by [Pfizer Expert Witness 2] (those relating to Topamax, Lamictal, Keppra and Trileptal) are between the Parties' prices for the supply of generic Capsules and the prices of **branded** versions of the Comparator AEDs following generic entry.
- 6.489 In order to assess the appropriateness of these comparisons it is necessary to set out some context relating to the typical supply of generics and branded products in the United Kingdom.
- 6.490 At the expiry of the patent, generic versions of a branded 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'. Generic versions of branded drugs are, to all intents and purposes, the same product (they are considered bioequivalent). From a therapeutic perspective, there is no discernible difference between the branded and generic versions of a drug.
- 6.491 In the UK, the suppliers of unbranded generic drugs are in principle free to set their prices as they choose. This is based on the assumption that competition between generic manufacturers will bring down prices, once they are free to enter the market and compete.¹⁵¹⁸ Competition from generic drugs typically results in significant price falls.¹⁵¹⁹
- 6.492 In order to incentivise the dispensing of generic drugs in the UK, GPs are encouraged to write 'open' prescriptions using the drug's generic (rather than its brand) name, unless there are specific clinical reasons not to.¹⁵²⁰ An open prescription ensures that, where a therapeutically equivalent generic product is available, pharmacies are able to dispense either that generic or the branded product.¹⁵²¹
- 6.493 Where drugs are prescribed generically, 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 have an incentive to dispense the cheapest drug available so as to maximise the margin they are able to make between the price they pay for the drug and its respective Drug Tariff price. Generic suppliers

¹⁵¹⁸ See <https://www.gov.uk/government/publications/health-service-medical-supplies-costs/health-service-medical-supplies-costs-bill-factsheet>

¹⁵¹⁹ See Pharmaceutical Sector Inquiry Final Report (8 July 2019) paragraph 212 see https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

¹⁵²⁰ PHT00130, OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007 (CMA document reference PD7), paragraph 2.34.

¹⁵²¹ See PHT00130, OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007 (CMA document reference PD7); paragraphs 2.29-2.30.

therefore typically compete on price to incentivise pharmacies to dispense their product and win market share from the competing branded and generic suppliers.

- 6.494 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%,¹⁵²² thereby demonstrating that the majority of UK GP prescriptions are written in open form.
- 6.495 However, notwithstanding the prevalence of open prescriptions, some prescriptions are still written by using the name of the branded (rather than generic) product. These prescriptions are referred to as 'closed' prescriptions. Where a pharmacist receives a closed prescription, they have no option but to dispense the branded product. Branded prescriptions are reimbursed under the PPRS and not the Drug Tariff.¹⁵²³
- 6.496 Following genericisation, the originator typically has three strategies it can employ with regards to its branded product with a view to continuing to make profits:¹⁵²⁴
- 6.496.1 Option one: the originator may choose to compete on price with generic entrants with a view to protecting its sales volumes. In order to do this, the originator is likely to lower its price and compete with the generic manufacturers after they have entered the market.
- 6.496.2 Option two: the originator may choose not to compete on price with generic entrants and instead maintain a higher price for its branded product. In these circumstances, the originator would sacrifice significant volumes and would focus on maintaining higher prices for closed prescriptions.¹⁵²⁵
- 6.496.3 Option three: choose not to compete on price and instead maintain a higher price for its branded product and introduce a generic version of the drug at a lower price. This would allow the originator to receive a higher price for any patients who are on a closed prescription but also allow it to protect some of its sales via the lower-priced generic version.
- 6.497 It is important to note, when considering the appropriateness of any comparators, that Capsules are an **unbranded** generic product and do not fit into any of the categories set out above. This is because the barriers to entry and expansion that exist in respect of the Capsules market have meant that the process of

¹⁵²² Pharmaceutical Services Negotiating Committee, NHS Statistics – Dispensing statistics graphs, available at <https://psnc.org.uk/funding-and-reimbursement/nhs-statistics/>

¹⁵²³ See PHT00130, OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007 (CMA document reference PD7).

¹⁵²⁴ PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 4.6, notes that different originators respond differently to competition.

¹⁵²⁵ Originators can also enter into brand equalisation deals where they provide a discounted, blended price on the condition that the customer purchases all its requirements, generic and branded, from the same supplier.

genericisation has resulted in a substantial increase in the prices of the drug whilst Pfizer and Flynn have also maintained high volumes.

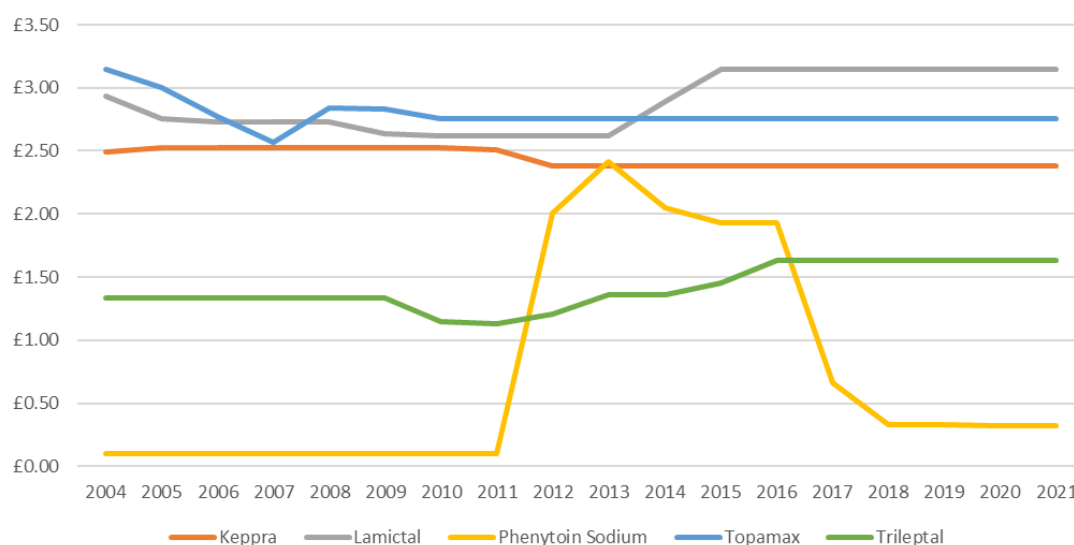
The CMA's Analysis

- 6.498 The CMA has concluded above that the Comparator AEDs are not sufficiently similar to Capsules to be meaningful comparators. The CMA has conducted the analysis in this section for completeness (without prejudice to its conclusion that the Comparator AEDs are, in any event, not sufficiently similar to offer a meaningful comparator).
- 6.499 The analysis set out below demonstrates that the price of each of the four branded Comparator AEDs [Pfizer Expert Witness 2] used in his analysis has been maintained at a high level following generic entry, while the vast majority of the market volumes have switched to cheaper generic versions of the drug. This is consistent with each of the respective originators taking the decision not to compete on price with generic entrants and instead focus on maintaining higher prices for whatever closed prescriptions are written for their drug (the second of the three options a branded owner has when genericisation occurs, as listed above).
- 6.500 In these circumstances, the price of these branded Comparator AEDs cannot serve as a meaningful comparator in assessing the fairness of the Parties' prices for Capsules, as they are likely to be reflective of a strategy by respective suppliers to not compete on prices. As such, the branded Comparator AED prices only apply to a very small proportion of the overall volumes in their respective markets. This strategy would not be consistent with finding that the prices of the branded Comparator AEDs represent the results of price competition as the originators have apparently taken the decision to not compete on price and to sacrifice volumes.
- 6.501 Further, the appropriateness of the branded Comparator AEDs is further undermined by the fact that Capsules are a *generic* drug which has maintained both very high prices and volumes. To the extent any meaningful comparison can be conducted, that comparison would need to be made against the prices of generic entrants that have entered the market and competed against each other for the higher volumes associated with open prescriptions. The prices of such generic entrants are both likely to be reflective of price competition and relate to the part of the market which has higher aggregate volumes.
- 6.502 As set out above, [Pfizer Expert Witness 2] put forward four branded AEDs as potential comparators (all of which face generic competition). These were:
- 6.502.1 Topamax (which has a generic version, topiramate);
- 6.502.2 Lamictal (which has a generic version, lamotrigine);
- 6.502.3 Keppra (which has a generic version, levetiracetam); and

6.502.4 Trileptal (which has a generic version, oxcarbazepine).

6.503 In his report, [Pfizer Expert Witness 2] states that several of the Comparator AEDs have reimbursement prices for the branded products that exceed the supply prices charged by Pfizer and Flynn for their generic Capsules.¹⁵²⁶ Figure 6.11 shows that the cheapest price of a DDD¹⁵²⁷ of phenytoin sodium capsules was lower than three of the branded comparators between 2012 and 2016 and higher than Trileptal.¹⁵²⁸

Figure 6.11: Price of the cheapest DDD for branded AEDs and for phenytoin sodium capsules in England between 2004 and 2021¹⁵²⁹



Notes:

1. The price of the cheapest DDD for branded AEDs in England have been calculated by the CMA using the quantity and NIC data contained within the PCA data for England, PAD00021, PAD00105-PAD00120.
2. A DDD for each drug has been obtained from the WHO. The price of a DDD for each of the different tablet/capsule strengths has been calculated for each year. Figure 6.11 shows the price of a DDD for the strength with the lowest average cost over the period (equal lowest in the case of Phenytoin).

6.504 However, when considering whether a drug is a meaningful comparator, it is misleading to look only at the reimbursement prices of branded drugs. As set out above, owners of branded drugs may choose to maintain high prices following genericisation with a view to capturing higher priced sales resulting from closed prescriptions and, in these circumstances, they do not compete on price with generic manufacturers for open prescriptions. Where a supplier of a branded drug has adopted this strategy, the price it sets will not be the result of effective competition.

¹⁵²⁶ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 36.

¹⁵²⁷ PAD00066, WHOCC, *ATC/DDD Index*, a DDD has been calculated using the WHO definition, and using the reimbursement price.

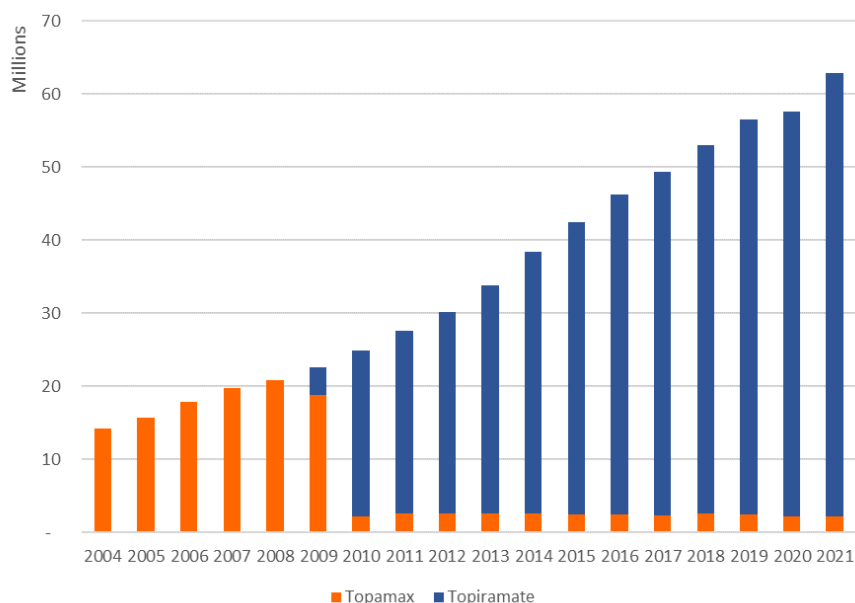
¹⁵²⁸ Phenytoin sodium 100mg, Keppra 1000mg, Lamictal 200mg, Topamax 200mg, Trileptal 600mg.

¹⁵²⁹ Prior to 2012, the price for Phenytoin Sodium is the price for *Epanutin*.

- 6.505 Accordingly, in order to establish whether a drug is a meaningful comparator it is necessary to consider the wider market context in which it is sold. Where the proposed comparator is a branded product, it is necessary to not only consider its price, but also its share of supply. It is also necessary to establish whether there have been generic entrants and, if so, what their prices and volumes are. Given generic drugs are bioequivalent and are typically readily interchangeable with their branded competitors, it is not appropriate to exclude them from any comparative analysis. It is only once this process has been conducted that a conclusion may be drawn as to whether the branded drug might provide a meaningful comparator for assessing the fairness of a price.
- 6.506 In his report [Pfizer Expert Witness 2] stated that each of the four branded Comparator AEDs he put forward is subject to generic competition. He also acknowledged that the reimbursement price of each of these branded AEDs is significantly higher than those of the equivalent generic products.¹⁵³⁰ This suggests that the suppliers of the branded Comparator AEDs have taken the decision not to compete with generic entrants and instead focus on having their branded product dispensed in response to closed prescriptions. This behaviour would not be consistent with the finding that the prices of the branded Comparator AEDs represent the results of price competition, as the originators have apparently taken the decision to not compete on price and to sacrifice volumes.
- 6.507 The CMA has undertaken a volume analysis of each of the four branded Comparator AEDs put forward by [Pfizer Expert Witness 2] and their generic competitors. The volume assessment has been made for the period since genericisation and the purpose of this analysis is to determine the impact that generic entry had on the sales volumes of each of the branded products. This analysis enables an assessment to be made as to whether the prices of the branded Comparator AEDs are set at a level which allows them to successfully compete with the generic entrants for open prescriptions or whether the supplier of the branded drug has, instead, taken the decision to focus on maintaining high prices for the closed prescription part of the market.
- 6.508 Figures 6.12 – 6.15 show the volumes (by the number of capsules/tablets) that were dispensed for each of the branded and generic AEDs put forward by [Pfizer Expert Witness 2] in England between 2004 and 2021.

¹⁵³⁰ PRE00154, Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017, paragraph 38.

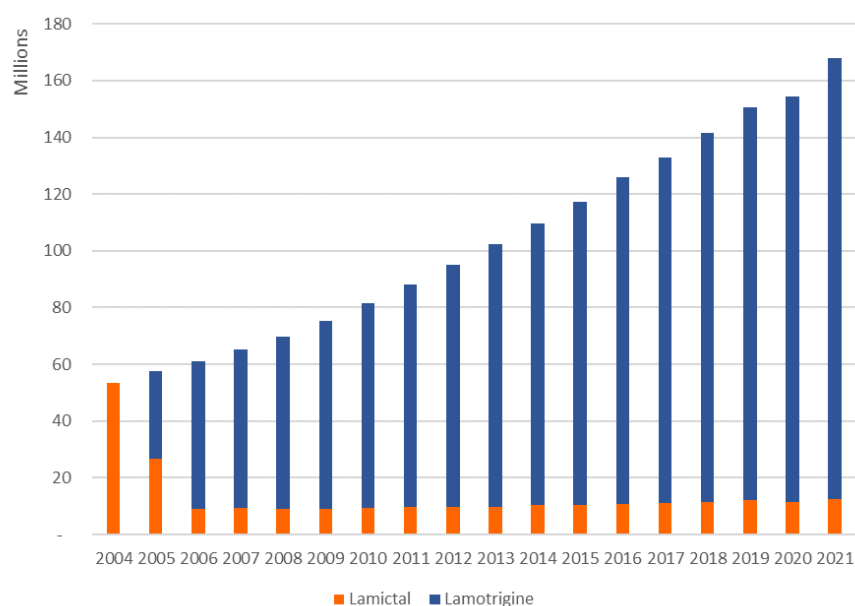
Figure 6.12: Total number of topiramate (generic) and Topamax (brand) tablets dispensed



Notes:

1. The total number of topiramate and Topamax tablets dispensed have been calculated by the CMA using the quantity data contained within the PCA data for England, PAD00021, PAD00105-PAD00120. See also: [Prescription Cost Analysis \(PCA\) Monthly Administrative Data - Datasets - Open Data Portal BETA \(nhsbsa.net\)](https://nhsbsa.net/prescription-cost-analysis-pca-monthly-administrative-data-datasets-open-data-portal-beta)
2. Figure 6.12 contains 25mg, 50mg, 100mg and 200mg strengths. Figures for each individual strength provide the same narrative.
3. Genericisation occurred in 2009.

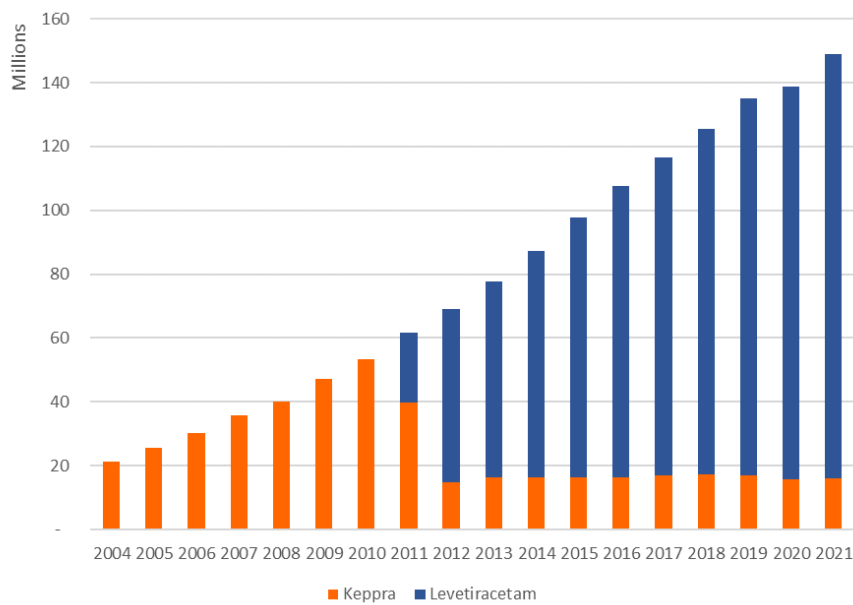
Figure 6.13: Total number of lamotrigine (generic) and Lamictal (brand) tablets dispensed



Notes:

1. The total number of lamotrigine and Lamictal tablets dispensed have been calculated by the CMA using the quantity data contained within the PCA data for England, PAD00021, PAD00105-PAD00120. See also: [Prescription Cost Analysis \(PCA\) Monthly Administrative Data - Datasets - Open Data Portal BETA \(nhsbsa.net\)](https://nhsbsa.net/prescription-cost-analysis-pca-monthly-administrative-data-datasets-open-data-portal-beta)
2. Figure 6.13 contains 25mg, 50mg, 100mg and 200mg strengths. Figures for each individual strength provide the same narrative.
3. Genericisation occurred in 2005.

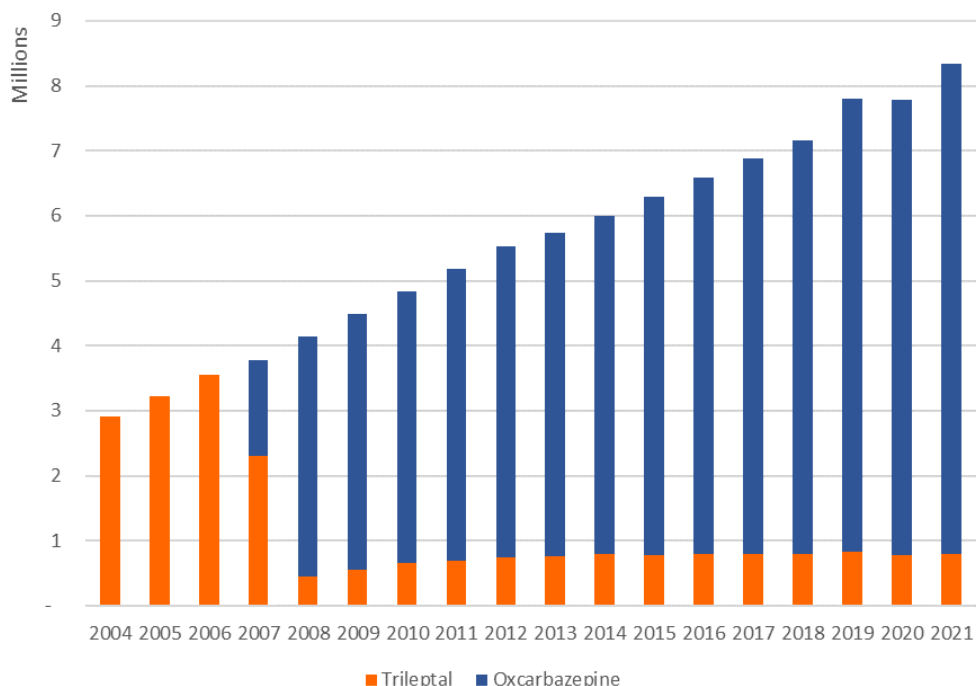
Figure 6.14: Total number of levetiracetam (generic) and Keppra (brand) tablets dispensed



Notes:

1. The total number of levetiracetam and Keppra tablets dispensed have been calculated by the CMA using the quantity data contained within the PCA data for England, PAD00021, PAD00105-PAD00120. See also: [Prescription Cost Analysis \(PCA\) Monthly Administrative Data - Datasets - Open Data Portal BETA \(nhs.uk\)](https://beta.nhs.uk/prescription-cost-analysis-pca-monthly-administrative-data-datasets-open-data-portal-beta)
2. Figure 6.14 contains 250mg, 500mg, 750mg and 1g strengths. Figures for each individual strength provide the same narrative.
3. Genericsation occurred in 2011.

Figure 6.15: Total number of oxcarbazepine (generic) and Trileptal (brand) tablets dispensed



Notes:

1. The total number of oxcarbazepine and Trileptal tablets dispensed have been calculated by the CMA using the quantity data contained within the PCA data for England, PAD00021, PAD00105-PAD00120. See also: [Prescription Cost Analysis \(PCA\) Monthly Administrative Data - Datasets - Open Data Portal BETA \(nhsbsa.net\)](#)
2. Figure 6.15 contains 100mg, 300mg, and 600mg strengths. Figures for each individual strength provide the same narrative.
3. Genericisation occurred in 2007.

6.509 These figures all show that, following lower-priced generic entry (and the decision by the branded supplier not to compete on price), a very large proportion of patient volumes for these four branded Comparator AEDs switched away from the branded version of the drug to the generic version. Four years after genericisation,¹⁵³¹ branded volumes only accounted for between 8% and 19% of total dispensed volumes for each of these branded Comparator AEDs. These proportions have continued to decline over the years and in 2020 branded volumes only accounted for between 4% and 11%.¹⁵³² These share of supply figures, together with the price data, demonstrate that each of the suppliers of these

¹⁵³¹ This period is shorter than the Relevant Period.

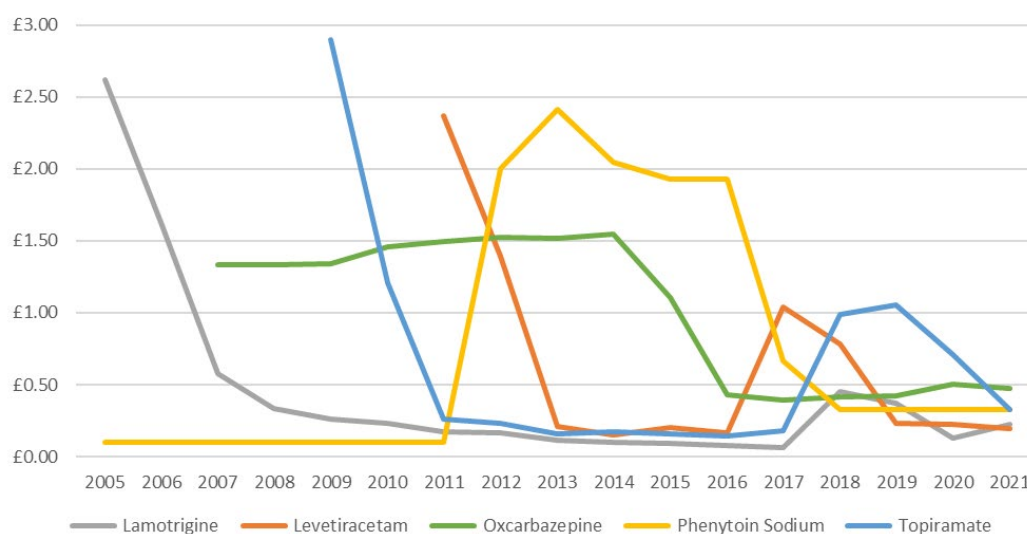
¹⁵³² Pfizer claimed that workable competition is perfectly consistent with a firm achieving only a low market share and that, on its face, suggests more competition, not less: PRC03488, Pfizer's response to the SO and DPS, paragraph 29(a). The CMA disagrees. The four branded AEDs lost the majority of their market share as they were not competing on price with the equivalent, generic versions. As such, the CMA finds that the prices of the four branded AEDs are not reflective of the competitive conditions following generic entry.

branded products have taken the decision to price high and focus on closed prescriptions rather than compete on price with generic entrants.

- 6.510 Therefore, even though each of these markets has apparently been subject to competitive generic entry, the price of the branded product has not been affected by that competition. As such, none of the branded Comparator AEDs [Pfizer Expert Witness 2] has relied upon represent a meaningful comparator for the purposes of assessing whether the Parties' prices were fair. They reflect a decision not to compete on prices and, unlike Capsules, none of these branded Comparator AEDs supply high volumes to the marketplace.
- 6.511 Although the CMA has not conducted an assessment as to whether the prices in the respective generic markets are the result of effective competition, to the extent any meaningful comparison can be conducted, it would need to be made against the prices of generic entrants that have entered the market and have competed against each other for the higher volumes associated with open prescriptions. This comparison does not undermine and, in fact, supports the CMA's analysis that the Parties' prices were unfair.
- 6.512 Following genericisation, three of the four branded Comparator AEDs proposed by [Pfizer Expert Witness 2] (lamotrigine, levetiracetam and topiramate) experienced a sharp and rapid drop in prices for the generic versions.¹⁵³³ The DDD price of each of these drugs then remained significantly below the DDD price of Capsules during the Relevant Period.

¹⁵³³ Genericisation occurred in the following years: Lamictal – 2005, Trileptal – 2007, Topamax – 2009, Keppra – 2011.

Figure 6.16: Price of the cheapest DDD for generic AEDs in England between 2004 and 2021¹⁵³⁴



Notes:

1. The price of the cheapest DDD for generic AEDs in England have been calculated by the CMA using the quantity and NIC data contained within the PCA data for England, PAD00021, PAD00105-PAD00120. See also: [Prescription Cost Analysis \(PCA\) Monthly Administrative Data - Datasets - Open Data Portal BETA \(nhsbsa.net\)](#)
2. A DDD for each drug has been obtained from the WHO. The price of a DDD for each of the different tablet/capsule strengths has been calculated for each year. Figure 6.16 shows the price of a DDD for the strength with the lowest average cost over the period (equal lowest in the case of Phenytoin).

6.513 Figure 6.16 shows the lowest price for a DDD of phenytoin sodium capsules compared to the lowest price for a DDD of the generic versions of the four branded Comparator AEDs.¹⁵³⁵ It shows that the annual generic reimbursement price of Capsules during the Relevant Period is significantly higher than the annual generic reimbursement price of the other AEDs from 2012 to 2021.¹⁵³⁶

6.514 In 2017/2018, the price of a DDD of the three generic versions of the Comparator AEDs with the lowest DDD price increased. This was because all three of these AEDs were granted price concessions by the DHSC following shortages in supply.¹⁵³⁷ However, even at their highest point during this period, the DDD price

¹⁵³⁴ Prior to 2012, the price for Phenytoin Sodium is for *Epanutin*.

¹⁵³⁵ Phenytoin sodium 100mg, Topiramate 100mg, Oxcarbazepine 300mg, Levetiracetam 1000mg, Lamotrigine 200mg.

¹⁵³⁶ Pfizer has criticised the fact that the CMA has not assessed the ASPs charged by the comparator manufacturers and has instead assessed reimbursement prices (PRC03488, Pfizer's response to the SO and DPS, paragraph 29c). However, by comparing the generic reimbursement price for the AEDs with the generic reimbursement price of Capsules, the CMA has compared like with like. In light of the compelling evidence set out in this section indicating that the Comparator AEDs are not sufficiently similar to Capsules to allow for a meaningful comparison, including the additional price and volume data set out, the CMA does not consider it necessary or proportionate to undertake additional analysis based on ASPs for the other AEDs. In addition, the ASPs of the four generic AEDs for a DDD are likely to be even lower than the reimbursement price for a DDD of each of the AEDs and so it is clear that considering their ASPs would not change the CMA's assessment

¹⁵³⁷ PAD00006, PSNC, Price concession archive, Levetiracetam started in July 2017, Lamotrigine started in May 2018 and Topiramate started in December 2017. The PSNC website explains that the DHSC 'could consider setting a price concession for products listed in Part VIIIA and Part VIIIB [of the Drug Tariff] where they are available above the set Drug Tariff reimbursement price. Pharmacy contractors will be automatically reimbursed based on the set price rather than the

for all of these drugs was well below the DDD price for Capsules during the Relevant Period.

- 6.515 Oxcarbazepine experienced a slower and less pronounced fall in the price of a DDD. Nevertheless, the DDD price of oxcarbazepine (and also the branded version, Trileptal) remained notably below the DDD price of Capsules during the Relevant Period.
- 6.516 Pfizer has argued that '[a] product which has lost sales to generics is demonstrably a good comparator for the reason that it clearly faces competition. As it is, the products chosen by [Pfizer Expert Witness 2] faced sustained generic competition and, as a result, significant loss of market share. However, their sales remained significant and their prices (and margins) substantially above the level that the CMA considers unlawful. This demonstrates that similar products in competitive markets can and do sustain prices in excess of the price Pfizer charged for its product.'¹⁵³⁸
- 6.517 The CMA does not accept Pfizer's analysis. It is necessary to look at the market context within which the branded Comparator AEDs have lost sales. As set out above, the prices of these branded Comparator AEDs do not reflect the level of price competition following generic entry and do not reflect the prices being paid in the relevant markets for the vast majority of volumes sold. Instead, they reflect the originators' apparent decision to sacrifice market share in favour of maintaining high prices for closed prescriptions. Accordingly, the prices of these branded Comparator AEDs cannot serve as a meaningful comparator in assessing the fairness of the Parties' prices for Capsules.¹⁵³⁹
- 6.518 Pfizer has also submitted that it does not accept that the price of generic and branded drugs cannot be compared.¹⁵⁴⁰ This misrepresents the CMA's position. The CMA has not said that a branded comparator could never theoretically be appropriate for a generic drug. For example, an originator may choose to compete on price with generic entrants (option 1 of the list of options set out above). However, the CMA has established that each of the Comparator AEDs are not sufficiently similar to Capsules to offer a meaningful comparison. In addition, it has

Drug Tariff listed price.' Price concessions last for one month and then need to be reapplied for. See <https://psnc.org.uk/funding-and-reimbursement/reimbursement/price-concessions/>. Price concessions can be applied for if there are supply shortages that mean the price of the product has increased.

¹⁵³⁸ PRE00627, Pfizer's Written Closing Submission, paragraph 120.

¹⁵³⁹ Pfizer has claimed that the CMA's position is that each of the four products identified by [Pfizer Expert Witness 2] was priced at a level that would be unlawful if those firms were dominant even though those prices were regulated by price and profit controls in the PPRS and had been sustained in the face of competition and volume loss (PRC03488, Pfizer's response to the SO and DPS, paragraph 27). This is not the CMA's position, as the CMA is looking at whether the prices of the four branded AEDs, having lost the majority of their volumes to lower priced generic entrants, are meaningful price benchmarks for the Parties' supply prices; or whether, in this case, the appropriate prices for comparison purposes would be the prices of the generic entrants now accounting for the vast majority of volumes. Moreover, if the suppliers are not dominant then the question of their prices being an abuse does not even arise. It is notable that, unlike Capsules, the four branded Comparator AEDs have lost substantial volumes whilst maintaining their high prices.

¹⁵⁴⁰ PRC03488, Pfizer's response to the SO and DPS, paragraph 28

considered whether the price of the four branded Comparator AEDs could represent a price which would provide a meaningful comparison and concluded that is not the case. This is because, in respect of each of these AEDs, it is apparent the originator has taken a decision to not compete with generic entrants on price and sacrificed substantial volumes (as shown by Figures 6.12 – 6.15). In this context, it does mean that the prices of these branded Comparator AEDs cannot serve as meaningful comparators for assessing the fairness of the Parties' prices for Capsules because they were not the result of price competition.

- 6.519 Pfizer has submitted that 'the CMA appears determined to conclude that there is not one AED comparator product, on any market, that can shine any light on the lawful price of phenytoin sodium capsules' and that the 'unavoidable conclusion is that the CMA has chosen to dismiss all these comparators because each and every one of them offers a clear exculpatory reference point, when considering the price of phenytoin sodium capsules'.¹⁵⁴¹
- 6.520 This is not the case. The CMA has conducted a thorough and objective assessment of [Pfizer Expert Witness 2]'s Comparator AEDs. That assessment led to the first conclusion that the Comparator AEDs were not sufficiently similar to Capsules to be a meaningful comparator. The CMA could have stopped its analysis at that point as that conclusion is determinative. However, the CMA proceeded to conduct an objective analysis of the market context in which the branded Comparator AEDs are sold and concluded that Pfizer's representation that the prices of those branded products represented the result of a competitive process following generic entry was flawed. The analysis which the CMA has set out in respect of this is both clear and objective: the prices achieved by the branded Comparator AEDs are not the result of price competition because, in respect of each of the AEDs in question, the originator has taken the decision not to compete on price with its generic competitors.
- 6.521 In addition, although the CMA has not conducted an assessment as to whether the prices being earned by the generic entrants are the result of sufficiently effective competition, it stands to reason that, if any weight should be given to a comparison between the prices of the four Comparator AEDs and the Parties' prices for Capsules, the consistent comparison would be between the Parties' prices and the prices of the generic versions of the four Comparator AEDs put forward by [Pfizer Expert Witness 2]. These prices appear to be reflective of some level of generic competition and, after all, the purpose of this exercise is to find sufficiently similar comparators, the prices of which are the result of sufficiently effective competition.
- 6.522 Figure 6.16 shows that the lowest price for a DDD of Capsules during the Relevant Period was significantly higher than the lowest price for a DDD of the generic

¹⁵⁴¹ PRC03488, Pfizer's response to the SO and DPS, paragraph 31.

versions of the four AED comparators.^{1542, 1543} This comparison does not indicate that the Parties' prices during the Relevant Period were fair or undermine the CMA's conclusion that the Parties' prices were unfair in themselves. In fact, the comparison provides further support for the CMA's conclusions.

ii. Ethosuximide

6.523 Unlike the four branded Comparator AEDs described above, [Pfizer Expert Witness 2] did use the prices of generic ethosuximide for the purposes of the comparison put forward.

6.524 However, there are significant differences between Capsules and ethosuximide in terms of product characteristics. Ethosuximide is the only AED out of the five selected by [Pfizer Expert Witness 2] which was not recommended, at all, for the treatment of focal seizures (the only type of seizure for which phenytoin was recommended as a third-line treatment) during the Relevant Period. Instead, the NICE guidance shows that ethosuximide was only recommended to treat one specific seizure type, absence seizures. Capsules were listed as a 'do not offer AED' for this seizure type.¹⁵⁴⁴ As such, there is no overlap between ethosuximide and Capsules in terms of their clinical use and the patient base they treat.

6.525 Unlike phenytoin sodium, ethosuximide was recognised as a first-line therapy¹⁵⁴⁵ and, owing to more favourable clinical characteristics, is not subject to the same concerns around switching patients and Continuity of Supply.¹⁵⁴⁶

6.526 In addition to the differences in product characteristics and usage between Capsules and ethosuximide (which have been set out above), the CMA has identified market features which mean that the comparison with ethosuximide does not indicate that the Parties' prices were fair or support the conclusions drawn by Pfizer.

6.527 First, annual patient numbers for ethosuximide are very small and significantly lower than for Capsules during the Relevant Period. In 2016, there were only approximately 1,300 patients treated with ethosuximide in England, compared to around 38,000 patients taking phenytoin sodium capsules. See Figure 6.10 above.

¹⁵⁴² Phenytoin sodium 100mg, Topiramate 100mg, Oxcarbazepine 300mg, Levetiracetam 1000mg, Lamotrigine 200mg.

¹⁵⁴³ In addition, the ASPs of the four generic AEDs for a DDD are likely to be even lower than the reimbursement price for a DDD of each of the AEDs, making a comparison with the Parties' prices even less favourable.

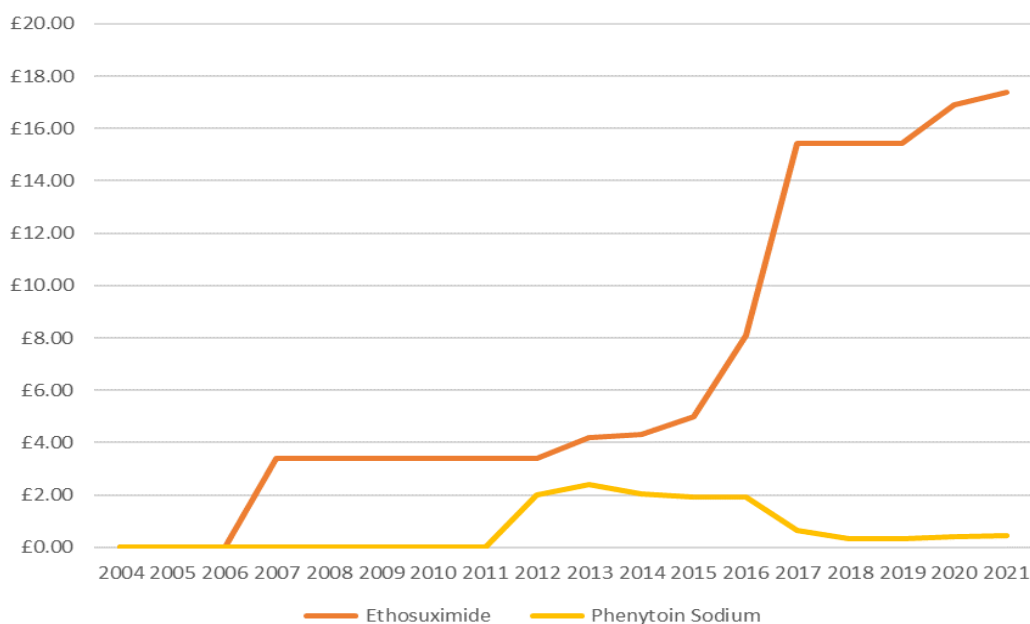
¹⁵⁴⁴ PHT00092, NICE Clinical Guidance CG137 (2012), The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care (CMA document reference PD13) (this Guidance has been updated and replaced by Epilepsies in children, young people and adults, NICE guideline (NG217), last updated on 27 April 2022), Appendix E: Pharmacological Treatment (CMA document reference PD13), Appendix E, Table 1.

¹⁵⁴⁵ PHT00092, NICE Clinical Guidance CG137 (2012), The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care (CMA document reference PD13) (this Guidance has been updated and replaced by Epilepsies in children, young people and adults, NICE guideline (NG217), last updated on 27 April 2022), Appendix E: Pharmacological Treatment (CMA document reference PD13), page 28, paragraph 1.9.5.1.

¹⁵⁴⁶ PAD00027, *Generic and branded anti-epileptic drugs*, Epilepsy Society. Ethosuximide is in category 3 rather than category 1 like Phenytoin.

6.528 Second, the price of ethosuximide has been subject to very significant price increases. Figure 6.17 shows a DDD for Zarontin between 2004 and 2006, and ethosuximide from 2007 to 2018 once it was de-branded in 2007. This shows that the DDD cost for ethosuximide was higher than the DDD cost for phenytoin sodium capsules over the Relevant Period. Figure 6.17 also shows that the cost of ethosuximide increased further between 2014 and 2021. The CMA understands that the production of the Zarontin branded version of the drug was stopped due to difficulties in meeting quality standards and, at the time, there were no alternative licensed capsules available.¹⁵⁴⁷

Figure 6.17: Price of a DDD for ethosuximide between 2004 and 2021



Notes:

1. The price of the cheapest DDD for ethosuximide and phenytoin sodium in England have been calculated by the CMA using the quantity and NIC data contained within the PCA data for England, PAD00021, PAD00105-PAD00120. See also: [Prescription Cost Analysis \(PCA\) Monthly Administrative Data - Datasets - Open Data Portal BETA \(nhsbsa.net\)](#)
2. A DDD for each drug has been obtained from the WHO. The price of a DDD for each of the different tablet/capsule strengths has been calculated for each year. Figure 6.17 shows the price of a DDD for the strength with the lowest average over the period (equal lowest in the case of Phenytoin).
3. Prior to 2008 the price of a DDD for ethosuximide shows the price of the branded version Zarontin.
4. Prior to 2012 the price of a DDD for phenytoin sodium shows the price of the branded version *Epanutin*.

6.529 The CMA does not consider that the price of product with such a small market size and which has been subject to such significant increases following genericisation is likely to be a price reflective of effective competition. The CMA does not, therefore, consider the price of ethosuximide to be a meaningful comparator for assessing the fairness of the Parties' prices for Capsules.¹⁵⁴⁸

¹⁵⁴⁷ PAD00046, Epilepsy Action, *Epilepsy charity warns of 'confusion over discontinuation of medicine'*.

¹⁵⁴⁸ Pfizer claimed (PRC03488, Pfizer's response to the SO and DPS, paragraph 30) that, by dismissing the possibility that generic ethosuximide might provide a comparator, the CMA is engaged in a search for a perfect comparator, and the

e. Conclusion

6.530 In light of the assessment set out above, the CMA finds that Comparator AEDs are not meaningful comparators for the purposes of assessing the fairness of the Parties' prices for Capsules.

6.531 Furthermore, to the extent that a comparison is considered, the appropriate and consistent comparison would be between the generic versions of the four branded comparator AEDs put forward by [Pfizer Expert Witness 2] and Capsules. This comparison does not indicate that the Parties' prices during the Relevant Period were fair or undermine the CMA's conclusion that the Parties' prices were unfair in themselves. In fact, the comparison provides further support for the CMA's conclusions.

CMA has implicitly concluded that the price of ethosuximide is also abusive. This is not the CMA's position, nor are these relevant questions for the purposes of the CMA's assessment. Further, while the CMA agrees with Pfizer that both ethosuximide and phenytoin sodium capsules treat epilepsy and that patients often try a number of different AEDs, these factors alone do not support a conclusion that ethosuximide is a meaningful comparator for Capsules, for the reasons set out in this sub-section.

7. Economic value

- 7.1 This section explains how the CMA's assessment, set out in sections 5 and 6 above, assesses the factors relevant to the economic value of the Parties' products on both the supply and demand side.
- 7.2 In *Phenytoin* the Court of Appeal clarified that 'economic value needs to be factored in and fairly evaluated, *somewhere*, but it is properly a matter which falls to the judgment of the competition authority as to where in the analysis this occurs'.¹⁵⁴⁹ As long as 'it is properly factored into "Plus" or "fairness" or into some other part of the test [...] there is no incremental obligation to take it into account again, as a discrete advantage or justification for a high price'.¹⁵⁵⁰ Rather, when properly applied, the test should be capable of evaluating economic value.¹⁵⁵¹
- 7.3 For instance, the Court of Appeal noted that, 'when evaluating patient benefit it would be possible to measure its economic value in the Plus element of Cost Plus, or even in the fairness element. Equally, if there is evidence of the prices being charged in relevant, comparator, markets which were effectively competitive then those prices could be capable of acting as proxy evidence of the economic value of patient benefit.'¹⁵⁵² As recognised by the CAT, determining the 'economic value' of a product involves a considerable margin of appreciation¹⁵⁵³ with appropriate weight being given to factors on both the supply and demand side.¹⁵⁵⁴
- 7.4 Consistent with this, given that there is no free-standing assessment of economic value outside of the assessments of excessiveness and unfairness,¹⁵⁵⁵ the CMA has evaluated the economic value of the Parties' products as part of the application of the *United Brands* framework adopted and applied above:
- 7.5 As part of its assessment of whether the Parties' Prices were excessive for the purposes of the first limb of the *United Brands* test, the CMA has considered the Parties' costs of supply and what would be an appropriate rate of return for the Parties' products. The CMA has determined that Pfizer's and Flynn's Prices were materially above this level.
- 7.6 As part of its assessment of whether the Parties' prices were unfair in themselves for the purposes of the second limb of the *United Brands* test, the CMA has considered whether there are any relevant demand side factors not reflected in the

¹⁵⁴⁹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172 (emphasis as in original).

¹⁵⁵⁰ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172 (emphasis as in original).

¹⁵⁵¹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.

¹⁵⁵² *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.

¹⁵⁵³ *Albion Water I* [2006] CAT 23, paragraph 310 and *Albion Water II* [2008] CAT 31, paragraphs 216 and 263. See also *Phenytoin* [2018] CAT 11, paragraphs 407 and 425.

¹⁵⁵⁴ *Albion Water II* [2008] CAT 31, paragraph 225. See also *Phenytoin* [2018] CAT 11, paragraph 411.

¹⁵⁵⁵ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 282.

costs of supply which increase the economic value of the Parties' products above Cost Plus and might serve to justify the prices charged as fair and not abusive.¹⁵⁵⁶

- 7.7 The CMA has also assessed potential comparators advanced by the Parties to determine whether the prices of these comparators might indicate what customers would be prepared to pay for Capsules in an effectively competitive market and, if so, whether the Parties' prices might be considered fair when compared to any such comparators identified.
- 7.8 The CMA has, therefore, properly considered demand side factors in its assessment of economic value. Having carefully considered all the relevant evidence in the round, the CMA has concluded that demand side factors in this case, including patient benefit, do not result in economic value beyond or additional to the economic value already reflected in the Parties' Cost Plus figures.
- 7.9 This does not mean that the CMA has failed to account for demand side factors (including patient benefit) or determined that Capsules have zero demand side value. The existence of some level of patient benefit is likely to be a pre-requisite for the commercial viability of any drug. In the absence of such a benefit, a drug is less likely to be prescribed and consequently may be commercially unattractive to manufacture. The CMA recognises that treatment with Capsules does provide a benefit to those being prescribed the drug. However, based on the CMA's evaluation of the evidence, the CMA does not consider that demand side factors in this case justify prices above the Parties' Cost Plus figures.

A. Assessment of economic value as part of unfair in itself

- 7.10 The CMA has taken account of the wider context within which Pfizer and Flynn imposed their prices and whether there were any factors specific to the drug which enhance the value of Capsules from the customer's perspective¹⁵⁵⁷ and might serve to justify the Parties' prices as fair and not abusive.¹⁵⁵⁸ The CMA considered the following factors as part of its assessment in *Unfair in itself*.
- 7.11 First, Capsules are a very old, generic drug which has long been off patent and in the third stage of the drug life cycle. Whilst the age of a drug might not affect whether or not it is an important treatment (although in this instance the status of Capsules and their use as a treatment for epilepsy has significantly diminished over time), it should nevertheless have an impact on price. When drugs are in the third stage of the drug life cycle, competition is expected to bring prices down and keep them low even where the drug in question continues to deliver significant benefits to patients.¹⁵⁵⁹ Accordingly, the fact that an old, generic drug may still be essential for some patients should be of limited relevance, given that in the third

¹⁵⁵⁶ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).

¹⁵⁵⁷ See *Albion Water II* [2008] CAT 31, paragraph 222.

¹⁵⁵⁸ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).

¹⁵⁵⁹ See section 2.B.

stage of the drug life cycle the degree of competition faced by suppliers is the primary driver for prices.

- 7.12 Second, in this case there was no product improvement, innovation, investment or commercial risk-taking, or any other identifiable enhancement to the product or its supply which might justify the significant price increases imposed by the Parties.¹⁵⁶⁰
- 7.13 Third, insofar as it is possible to attach an economic value to patient benefit, a qualitative assessment of the product's characteristics does not support the attribution of additional economic value above Cost Plus. The evidence shows that Capsules had long been superseded by therapeutically superior alternative treatments. This was formally recognised by NICE, which categorised phenytoin sodium as a third line AED as a result of its therapeutic limitations. The evidence gathered by [Professor of Neurology] corroborates this point and highlights a variety of concerns related to the clinical characteristics of Capsules.¹⁵⁶¹ Reflecting this, Capsules were only very rarely prescribed to new patients during the Relevant Period. For legacy patients, the evidence of [Professor of Neurology] suggests that if there were no barriers to switching,¹⁵⁶² or if they were to have been first diagnosed during the Relevant Period, these patients would have been treated with a different AED due to the therapeutic limitations of Capsules.¹⁵⁶³
- 7.14 Fourth, there is no evidence of any willingness on the part of the DHSC or CCGs to pay a significantly higher price for the product than had been paid before September 2012, or any recognition of specific demand side factors generating additional value (in particular any benefit to patients, innovation or product improvement). The volume and strength of concerns raised across different NHS stakeholders (including the DHSC, CCGs and clinicians) regarding the scale of the Parties' price increases is relevant to the assessment of economic value and fairness.¹⁵⁶⁴ As was the case in *Albion Water II*, this distinguishes the present case from other instances in which the European Commission and the Court of Appeal found that non-cost related factors increased the economic value of the product being supplied.¹⁵⁶⁵ Whilst the DHSC recognised the need for Capsules to remain

¹⁵⁶⁰ See section 6.B.

¹⁵⁶¹ See section 6.B.

¹⁵⁶² In respect of barriers to switching between phenytoin sodium products, these arose mainly from the clinical limitations of the drug, in particular its NTI and non-linear pharmacokinetics: see section 2.A.

¹⁵⁶³ See section 6.B.

¹⁵⁶⁴ The Court of Appeal held that 'in broad terms the economic value of a good or service is what a consumer is willing to pay for it' and that economic value 'is an economic concept which describes what it is that users and customers value and will reasonably pay for'. See *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 154 and 171.

¹⁵⁶⁵ In *Scandlines*, the European Commission set out that the 'demand-side is relevant mainly because customers are notably willing to pay more for something specific attached to the product/service that they consider valuable' (see paragraph 227). In that case, the customer acknowledged that the port of Helsingborg represented a value to Scandlines and its customers because of its unique location close to Elsinore (see paragraph 241). As recognised by the Tribunal, in *Attheraces* the pre-race data was 'of considerable value' and 'clearly very valuable' to customers and for which they were 'readily willing to pay a premium' (see the discussion of *Attheraces* in *Albion Water II* [2008] CAT 31, paragraph 226 and in *Phenytoin* [2018] CAT 11, paragraph 410).

available to patients¹⁵⁶⁶ and that this might require ‘some increase in prices’,¹⁵⁶⁷ the Parties’ Cost Plus figures already reflect increases compared to Pfizer’s Pre-September 2012 Prices (very significantly so for Flynn) and provide a return that is appropriate to achieve this.

- 7.15 Fifth, the evidence in this case demonstrates that the Parties’ prices had, in practice, a detrimental impact on the end customer (in this case, the NHS). In contrast to the situation in *Scandlines* and *Attheraces*, CCGs do not derive any downstream revenues from Capsules. Instead, CCGs have had to find the additional funds required to pay the Parties’ prices from within their already constrained budgets. As was also the case in *Albion Water II*, this distinguishes the facts of this case from *Attheraces*, where the Court of Appeal recognised that the customer alleging unfair pricing continued to earn ‘a handsome profit’ from the onward supply of the pre-race data in a competitive downstream market.¹⁵⁶⁸ In this case, the Parties’ price increases forced the NHS to spend an additional £169 million¹⁵⁶⁹ on Capsules during the Relevant Period, without any additional benefits for patients.¹⁵⁷⁰

B. Assessment of economic value as part of unfair when compared

- 7.16 The CMA has also considered whether any of the potential comparators put forward by the Parties might indicate what customers would be prepared to pay for Capsules in an effectively competitive market. As recognised by the Court of Appeal in *Phenytoin*, ‘if there is evidence of prices being charged in relevant,

¹⁵⁶⁶ PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health’s response of 15 August 2013 to the OFT’s s.26 Notice information request of 26 June 2013 (CMA document reference 00367.9).

¹⁵⁶⁷ In the meeting between Flynn and the DHSC in July 2012, Flynn told the DHSC that ‘it would not be economically viable for Flynn to continue selling Epanutin capsules as a brand without an uplift in price’: PHT00047, Note of a meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health’s response of 15 August 2013 to the OFT’s s.26 Notice information request of 26 June 2013 (CMA document reference 00367.9). In the meeting between the DHSC and Flynn in November 2012, Flynn told the DHSC that ‘whilst Flynn was keen to maintain supply and availability, it could not do so at the Epanutin price or within the limits (of price increase) permitted within PPRS’ and that Flynn ‘might have to discontinue the product if it did not make sufficient margin’: PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

¹⁵⁶⁸ See *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 214. See also *Albion Water II* [2008] CAT 31, paragraph 226 and *Phenytoin* [2018] CAT 11, paragraph 451.

¹⁵⁶⁹ The CMA has calculated the NHS’s annual spend on Capsules using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices. The CMA has calculated the NHS spend on Capsules over the Relevant Period at pre-2012 Drug Tariff prices and also at post-2012 Drug Tariff prices (taking into account the reduction of the Drug Tariff price in 2014) to calculate the additional spend as a result of the price increases.

¹⁵⁷⁰ The letter sent to the Parties by the GMMMG on 10 October 2012 set out the views of one of Pfizer’s major CCG customers that the price increase was ‘completely unjustified given the product is unchanged’, that the price increases ‘may make innovative new medicines less affordable for the NHS, due to £41Million being avoidably wasted into continued supply of an existing freely available product’ and that ‘[t]he NHS nationally will be adversely affected by £36Million per year [...] This increase in cost will provide no additional health benefit for patients’. See PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00145.527).

comparator, markets which were effectively competitive then those prices could be capable of acting as proxy evidence of the economic value of patient benefit'.¹⁵⁷¹

I. Phenytoin sodium tablets

- 7.17 The Parties have argued that the £30 Drug Tariff price of Tablets reflected what the DHSC was willing to pay and considered to be the value of Capsules during the Relevant Period.¹⁵⁷²
- 7.18 The evidence relevant to this proposed comparator demonstrates that the £30 Drug Tariff price: (i) was significantly above actual market supply prices charged by suppliers (at the equivalent level of the supply chain to Flynn) for the majority of the Relevant Period; (ii) was not a competitive price (or reflective of any degree of competition); and (iii) was the result of, and continued to reflect, the significant monopoly price increases previously imposed by Teva. Finally, the CMA has gathered a significant body of evidence which clearly demonstrates that the DHSC and CCGs were not 'willing to pay' the Parties' prices and did not consider the far higher Drug Tariff price of Tablets to be an appropriate benchmark (and that Pfizer and Flynn were clearly aware of this view).¹⁵⁷³
- 7.19 The CMA has also considered whether Tablets ASPs (which would be the like-for-like comparison with Flynn's Prices) might indicate that the Parties' prices were fair. The CMA has concluded that competition between Tablets suppliers was subject to significant limitations and that Tablet ASPs were not, at any stage, reflective of effective competition.¹⁵⁷⁴
- 7.20 Without prejudice to this conclusion, the CMA has nevertheless conducted a comparison between the Parties' prices and the lowest ASPs of Milpharm and Wockhardt during a short period of increased competition when there were three Tablets suppliers in the market. Notwithstanding a number of factors which limited the scope of competition, and the short period of time for that competition to bring down prices, this comparison does not support the conclusion that there was a reasonable relationship between the Parties' prices and the economic value of their products:
- 7.17.1 Flynn: Flynn's ASP during the Relevant Period was 229% and 172% higher than Milpharm's and Wockhardt's lowest monthly ASP respectively during the period of three player supply. Furthermore, Flynn's ASP during the Relevant Period was significantly above *all* of the Tablet suppliers' ASPs for the *whole* period of three player supply (including Teva's),

¹⁵⁷¹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.

¹⁵⁷² See section 6.C.

¹⁵⁷³ See section 6.C. See also Annex B and Annex C.

¹⁵⁷⁴ See section 6.C.

following the initial price reductions that took place in the period September to December 2012.¹⁵⁷⁵

7.17.2 Pfizer: Pfizer's ASP during the Relevant Period was 127% and 88% higher than Milpharm's and Wockhardt's lowest monthly ASP during the period of three player supply. Furthermore, Pfizer's ASP during the Relevant Period was significantly above Milpharm's and Wockhardt's ASPs across the period of three player supply, following the initial price reductions that took place in the period September to December 2012. This was despite Pfizer operating upstream from Milpharm and Wockhardt.¹⁵⁷⁶

II. Other AEDs

7.21 The CMA has concluded that the Comparator AEDs advanced by Pfizer as '[Pfizer Expert Witness 2]'s five, most reliable, comparator AED products' are significantly different from Capsules in their product characteristics and usage. Furthermore, [Pfizer Expert Witness 2] adopted the branded version of four AEDs for his comparison. This is not the appropriate comparison in circumstances where there has been generic entry, the branded drug has retained its high prices and not sought to compete with generic entrants and, as a result, has lost the vast majority of its volumes to lower priced generics. The only comparison which might be informative on the fairness of the Parties' prices would be against the generic prices of these AEDs.

7.22 Significantly, a comparison between the Parties' prices and the prices of these four generic AEDs shows that the four generics have, in fact, fallen significantly below both Pfizer's and Flynn's supply prices for Capsules during the Relevant Period.¹⁵⁷⁷ Accordingly, the prices of the four generics do not indicate that the Parties' prices during the Relevant Period were fair or undermine the CMA's conclusion that the Parties' prices were unfair in themselves. The lower prices of these first line AEDs likewise does not indicate that Capsules should command a premium above Cost Plus for therapeutic benefit.¹⁵⁷⁸

C. No reasonable relationship between price and economic value

7.23 As recognised by the CAT in *Albion Water II*, neither *Scandlines* nor *Attheraces* 'excludes the possibility that, in the absence of relevant non-cost-related factors, the very excessiveness of a price could be sufficient to establish that the price

¹⁵⁷⁵ See section 6.C.

¹⁵⁷⁶ See section 6.C.

¹⁵⁷⁷ See section 6.C.

¹⁵⁷⁸ These four AEDs are recommended by NICE as first-line treatments for focal seizures (for which Capsule are prescribed) and they continue to be prescribed to new patients due to their clinical benefits. For instance, generic lamotrigine and levetiracetam (two of the AEDs put forward by Pfizer) are both recommended by NICE as first-line monotherapy for people with focal seizures. Between these two drugs and phenytoin sodium there are at least 11 other AEDs which NICE recommends should be prescribed (in various different combinations), prior to considering treatment with phenytoin.

bears no reasonable relation to the economic value of the product/service being provided'.¹⁵⁷⁹

7.24 In the circumstances of this case, in order for Pfizer's Prices and Flynn's Prices to have a reasonable relationship with the economic value of the products during the Relevant Period, Pfizer's Pre-September 2012 Prices must have understated the economic value of Capsules by a very significant degree. Furthermore, for Pfizer, its Cost Plus figures, which themselves reflect an increase in the Pre-September 2012 Prices, must also vastly understate the economic value of the product. The CMA's assessment does not indicate that this is the case.

7.25 Pursuant to the CMA's assessment described above, the CMA has concluded that demand side factors in this case – taken together – do not result in the economic value of the Parties' products being above the value already reflected in their Cost Plus figures.

7.26 The Parties' prices during the Relevant Period were materially above Cost Plus as shown in Table 7.1 below. Accordingly, the CMA concludes that:

7.23.1 Pfizer's Prices bore no reasonable relationship to the economic value of Pfizer's Products; and

7.23.2 Flynn's Prices bore no reasonable relationship to the economic value of Flynn's Products.¹⁵⁸⁰

Table 7.1: The Parties' excesses above Cost Plus during the Relevant Period

	Capsule strength			
	25mg	50mg	100mg	300mg
Pfizer's excess (%)	24%	91%	667%	653%
Pfizer's excess (£ per pack)	£0.88	£3.20	£32.67	£32.10
Flynn's excess (%)	139%	77%	37%	42%
Flynn's excess (per pack)	£8.26	£6.27	£14.55	£16.30

Source: CMA analysis in section 5.

7.27 Even in the event that the evidence could support some additional economic value above Cost Plus (which for the reasons above, the CMA does not consider is the case), and whilst the CAT recognised that placing a precise monetary value on

¹⁵⁷⁹ *Albion Water II* [2008] CAT 31, paragraph 225.

¹⁵⁸⁰ For the reasons set out in section 5, the CMA has also concluded that the excesses set out in Table 7.1 were sufficiently material to be excessive. In respect of Pfizer's excesses for 25mg capsules, Pfizer's excesses are consistent with the levels found to bear no reasonable relationship to economic value in *Deutsche Post*. Flynn submitted that its prices must be significantly or disproportionately above Cost Plus to bear no reasonable relationship to economic value: PRC03492, Flynn's response to the SO, paragraph 1.26. As set out in section 5, the full extent of Flynn's excesses is not evident when considered in percentage terms alone as these are calculated by reference to Flynn's costs, which are inflated by the supply prices that Flynn pays to Pfizer. In any event, whilst any assessment must be made on a case-by-case basis, the level of Flynn's excesses are consistent with the levels found to bear no reasonable relationship to economic value in *Deutsche Post* and, for 25mg and 50mg capsules, consistent with the level found to bear no reasonable relationship to economic value in *Albion Water II* [2008] CAT 31.

patient benefit is difficult,¹⁵⁸¹ the factors described above suggest that any such additional value would be low. Given the substantial disparity between the Parties' Cost Plus figures and the Parties' prices presented in Table 7.1 above, this would still preclude any possibility of a reasonable relationship between the Parties' prices and the economic value of their Products. As noted by Lord Justice Green in his judgment:

*[t]he CMA has advanced what seem to me to be plausible submissions that given the very high disparity existing between cost, [return on sales] and ultimate price the possibility of any "economic value" attributable to patient benefit exerting any effect on the outcome is remote. The Tribunal did not suggest otherwise.*¹⁵⁸²

7.28 For Flynn, the position is even more stark than for Pfizer.

7.29 The CMA has concluded that Pfizer's Prices bore no reasonable relationship to the economic value of Pfizer's Products. Whilst Flynn requires an adequate return to incentivise continued supply, Flynn's Cost Plus figures are already heavily inflated by the supply prices Flynn agreed to pay to Pfizer as part of the arrangements jointly conceived by the Parties. For example, Flynn's Cost Plus figure of £39.84 for 100mg Capsules (representing the large majority of its sales by volume) is:

7.26.1 around 18 times greater than Pfizer's pre-September 2012 price of £2.21; and

7.26.2 around 8 times greater than Pfizer's Cost Plus figure of £4.90.

7.30 As such, despite the absence of any innovation, product improvement or additional value for customers, Flynn's Cost Plus figures are already many multiples of the prices previously paid by the NHS for Capsules and Pfizer's Cost Plus figures. The product supplied by Flynn is identical to the product it received from Pfizer. Flynn did not develop or improve the product or its distribution. Flynn added very little value to the supply chain and undertook only limited commercial activities. As a result, from a demand side perspective, the economic value of Pfizer's Products and the economic value of Flynn's Products should be broadly identical.

7.31 This is relevant to the CMA's assessment of the relationship between Flynn's Prices and the economic value of Flynn's Products.¹⁵⁸³ Reflecting this, even

¹⁵⁸¹ *Phenytoin* [2018] CAT 11, paragraph 419.

¹⁵⁸² *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 173.

¹⁵⁸³ Quoting from the Decision of the European Commission in Aspen, Flynn has submitted that 'only prices that exceed the cost-plus level significantly may amount to an exploitative abuse and the assessment must be made in view of the specific circumstances of each case'. (emphasis added). See PRC03492, Flynn's Response to the SO, paragraph 5.21. The CMA agrees with this point and has considered the arrangements entered into between the Parties and Flynn's agreement to pay Pfizer.

Flynn's Cost Plus Figures are already higher than the ASPs of Tablet suppliers and the prices of the four other generic AEDs described in section 6.C above.¹⁵⁸⁴

- 7.32 In these circumstances, where the CMA has concluded that Pfizer's supply prices are already significantly above the economic value of Capsules (and where the Parties' products are broadly identical), there is no reason from a demand side perspective why Flynn should be entitled to charge prices significantly higher than its Cost Plus. Notwithstanding this, as recognised by CAT, Flynn set its selling Prices 'well above [Pfizer's supply price] and could have reduced its prices and still made a material profit'.¹⁵⁸⁵ Given that Flynn's Prices significantly exceeded its Cost Plus, the CMA has concluded that they bore no reasonable relation to the economic value of Flynn's Products.

¹⁵⁸⁴ Flynn has also submitted that, in considering the economic value of Flynn's Products, '[t]he CMA also fails to account for other factors and fails for example to compare the results of its cost plus methodology with prices of phenytoin tablets and other AEDs'. See PRC03492, Flynn's Response to the SO, paragraph 9.7. This is not correct. In fact, Flynn's Cost Plus figures are significantly higher than these prices. This does not, therefore, support Flynn's case. Instead, it supports the argument that Flynn's Prices bore no reasonable relationship to the economic value of Flynn's Products.

¹⁵⁸⁵ *Phenytoin* [2018] CAT 11, paragraph 456.

8. Other matters

A. Lack of objective justification

8.1 It is open to a dominant undertaking to provide a justification for behaviour that is liable to be caught by the Chapter II prohibition. A dominant undertaking may do so either by demonstrating that its conduct is objectively necessary or by demonstrating that its conduct produces efficiencies which outweigh any anticompetitive effects on consumers.¹⁵⁸⁶

8.2 It is incumbent upon the dominant undertaking to provide all the evidence necessary to demonstrate that the conduct concerned is objectively justified. As the CAT recognised in *Albion Water II*:

*It is for the party alleging an infringement to prove it and not for the dominant undertaking to demonstrate its absence. It is then for the dominant undertaking to raise any plea of objective justification and to support it with arguments and evidence.*¹⁵⁸⁷

8.3 The CMA concludes that the Parties have failed to provide any objective justification for their pricing conduct in this case.

8.4 The Parties have failed to provide any objective justification for imposing price increases of this scale for a generic drug first marketed in 1938, which had been superseded as a first-line AED by superior treatments, and which was sold by Pfizer at a much lower price for a number of years, without there having been any relevant change in costs, risks or any improvement or innovation.^{1588, 1589} The Parties' prices do not reflect any additional benefits having been created for patients by the Parties.

8.5 In contrast to the lack of investment by the Parties, the cost of Capsules to the NHS increased dramatically during the Relevant Period. NHS expenditure on phenytoin sodium capsules increased from £2.3 million in the year prior to September 2012 to approximately £50 million in 2013, an increase of 2,073%.¹⁵⁹⁰

¹⁵⁸⁶ See judgment in case *Post Danmark v Konkurrencerådet* C-209/10, EU:C:2012:172, paragraphs 40 and 41 and case law cited therein. See also case law cited in the European Commission's *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, paragraph 28.

¹⁵⁸⁷ *Albion Water II* [2008] CAT 31, paragraph 70.

¹⁵⁸⁸ This is reflected in the economic value of Pfizer's Products and Flynn's Products and, in particular, the CMA's finding that demand side factors in this case, including patient benefit, do not result in an economic value above the Parties' Cost Plus figures.

¹⁵⁸⁹ Flynn submitted that it was planning to invest in an alternative source of API but as set out in Annex E, Flynn never made any such investments nor established an alternative API source. In respect of its buffer stock holdings, as set out in Annex E, these holdings did not represent any material risk as Flynn was virtually guaranteed to sell these stocks and any associated costs have been captured in Flynn's Cost Plus.

¹⁵⁹⁰ See section 2.D.II.

- 8.6 As part of the CMA's assessment of excessive, unfair and economic value in this case, the CMA has considered and dismissed a number of alleged objective justifications put forward by the Parties.
- 8.7 In particular, the Parties had submitted that the price increases were necessary to ensure the drug's commercial viability.¹⁵⁹¹ However, as set out in section 6.B.II, in fact, the Parties' prices went well beyond any level that might have been required to ensure the drug was commercially viable or sustainable.
- 8.8 The Parties used the Drug Tariff price of Tablets as a yardstick when setting their prices for Capsules. However, the CMA finds that the Drug Tariff price of Tablets was not a meaningful comparator for Capsules.¹⁵⁹² Moreover, in doing so the Parties ignored a number of relevant contemporaneous facts and events that clearly demonstrated that the Parties' reliance on the Drug Tariff price of Tablets was not appropriate.¹⁵⁹³

B. The Chapter II Exclusion

- 8.9 Section 19 of the Act provides that the Chapter II prohibition does not apply to any of the cases in which it is excluded by or as a result of Schedules 1 or 3 of the Act.
- 8.10 The CMA finds that none of the exclusions from the Chapter II prohibition provided for by section 19 or under Schedules 1 or 3 of the Act apply in respect of any of the Infringements.

C. Effect on Trade within the UK

- 8.11 The Chapter II prohibition applies to conduct by a dominant undertaking which may affect trade within the UK.¹⁵⁹⁴
- 8.12 Each of the Infringements was implemented in the UK and had an effect on prices paid by the NHS for Capsules. Accordingly, the CMA concludes that each of the Infringements may have affected trade in the buying and selling of drugs within the whole or part of the UK.

D. Duration

- 8.13 The duration of the Infringements is a relevant factor for determining the financial penalties that the CMA has decided to impose.

¹⁵⁹¹ See section 6.B.II.

¹⁵⁹² See section 6.C.II.d.

¹⁵⁹³ See section 6.C.II.

¹⁵⁹⁴ Section 18(1) of the Act. For the purposes of the Chapter II prohibition, the UK includes any part of the UK: section 18(3) of the Act. To infringe the Chapter II prohibition, a dominant undertaking's conduct does not actually have to affect trade as long as it is capable of doing so: see, for example, *Irish Sugar plc v Commission*, T-228/97, EU:T:1999:246, paragraph 170. There is also no need for the effect on trade within the UK to have been appreciable: *Aberdeen Journals v Director General of Fair Trading* [2003] CAT 11, paragraphs 459 and 460.

- 8.14 Both Pfizer's Prices and Flynn's Prices increased significantly overnight on 24 September 2012, the date on which Flynn de-branded *Epanutin* and commenced selling the product in the UK under the brand name 'Phenytoin Sodium Flynn Hard Capsules'.
- 8.15 In the 2016 Infringement Decision, the CMA found that the duration of the Infringements was from 24 September 2012 to the date of the 2016 Infringement Decision, ie 7 December 2016.¹⁵⁹⁵
- 8.16 In this Decision, the CMA finds that for the purposes of the imposition of a penalty the Infringements had a duration from 24 September 2012 to 7 December 2016.¹⁵⁹⁶

E. Undertakings and attribution of liability

I. Legal framework

a. Undertakings

- 8.17 The Chapter II prohibition applies to conduct on the part of one or more undertakings. An undertaking is any entity engaged in economic activity, regardless of its legal status or the way in which it is financed.¹⁵⁹⁷
- 8.18 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'.¹⁵⁹⁸
- 8.19 The term 'undertaking' designates an economic unit, even if in law that unit consists of several natural or legal persons.¹⁵⁹⁹

b. Attribution of liability

- 8.20 If an undertaking infringes the competition rules it falls, under the principle of personal responsibility, to that undertaking to answer for that infringement.¹⁶⁰⁰
- 8.21 However, in order to enforce competition law it is necessary to attribute liability to legal entities.¹⁶⁰¹

¹⁵⁹⁵ The 2016 Infringement Decision directed the Parties to revise their selling prices for Capsules from 23 January 2017: *2016 Infringement Decision*, CE/9742-13, 7 December 2016, Annex B. The Parties notified the CMA of their compliance with the Directions on 30 January 2017: PRE00712, Pfizer letter to the CMA dated 30 January 2017 and PRE00715, Flynn letter to the CMA dated 30 January 2017.

¹⁵⁹⁶ In its SO in this case, the CMA provisionally found that the infringements alleged therein commenced on 24 September 2012 and ended on 23 January 2017. For reasons of administrative priority, the CMA has decided not to pursue its investigation of the Parties' prices for the period 8 December 2016 to 23 January 2017. The CMA's finding of a shorter duration in this Decision favours the Parties.

¹⁵⁹⁷ C-41/90 *Höfner v Macrotron GmbH*, EU:C:1991:161, paragraph 21.

¹⁵⁹⁸ C-118/85 *Commission v Italian Republic*, EU:C:1987:283, paragraph 7.

¹⁵⁹⁹ C-97/08 P *Akzo Nobel NV v Commission*, EU:C:2009:536, paragraph 55.

¹⁶⁰⁰ C-97/08 P *Akzo Nobel NV v Commission*, EU:C:2009:536, paragraph 56.

¹⁶⁰¹ C-97/08 P *Akzo Nobel NV v Commission*, EU:C:2009:536, paragraph 57.

- 8.22 When attributing liability, the starting point is that those legal entities that directly ‘participated in th[e] breach’ are liable.¹⁶⁰²
- 8.23 Legal entities may also be held liable on the basis of parental liability, if they ‘exercised decisive influence over one or more persons within the “undertaking” who have participated in the infringement’.¹⁶⁰³
- 8.24 The conduct of a subsidiary may be imputed to its parent company where, although having a separate legal personality, the subsidiary did not decide independently upon its own conduct on the market, but instead carried out in all material respects the instructions of the parent company, having regard in particular to the economic, organisational and legal links between those two entities.¹⁶⁰⁴ This is the case because, in such a situation, the parent company and its subsidiary form a single economic unit and therefore a single undertaking for the purpose of the relevant prohibitions.
- 8.25 It is settled case law that where a parent company holds (directly or indirectly) 100% (or nearly 100%) of the shares or voting rights in a subsidiary, 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.¹⁶⁰⁵
- 8.26 In such circumstances, it is sufficient for the CMA to prove that the subsidiary is wholly-owned by the parent company in order to presume that the parent exercises decisive influence over the conduct of the subsidiary. It is for the party in question to rebut the presumption by adducing sufficient evidence to demonstrate that the subsidiary company acted independently on the market.¹⁶⁰⁶

II. Application

- 8.27 For each of the Infringements, the CMA has first identified the legal entity directly involved in the Infringement during the Relevant Period. It has then determined whether liability for the Infringement should be shared with another legal entity, in which case each legal entity's liability will be joint and several.

¹⁶⁰² *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).

¹⁶⁰³ *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22) and C-97/08 P *Akzo Nobel NV v Commission*, EU:C:2009:536, paragraph 58. See also C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 27 citing C-93/13 P and C-123/13 P *Commission and Others v Versalis and Others*, EU:C:2015:150, paragraph 40; C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraph 44; and *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 15 to 22.

¹⁶⁰⁴ C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 27, citing the judgement in C-93/13 P and C-123/13 P *Commission v Versalis*, EU:C:2015:150, paragraph 40; see also Cases C-628/10 P and C-14/11 P *Alliance One v Commission*, EU:C:2012:479, paragraph 43-44 citing C-97/08 P *Akzo Nobel NV v Commission*, EU:C:2009:536, paragraphs 58–59.

¹⁶⁰⁵ C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 28 and the case law cited; Cases C-628/10 P and C-14/11 P *Alliance One v Commission*, EU:C:2012:479, paragraphs 46–48; and C-97/08 P *Akzo Nobel NV v Commission*, EU:C:2009:536, paragraphs 60–61.

¹⁶⁰⁶ C-628/10 P and C-14/11 P *Alliance One v Commission*, EU:C:2012:479, paragraph 47, citing C-97/08 P *Akzo Nobel NV v Commission*, EU:C:2009:536, paragraph 61.

a. Pfizer

- 8.28 Pfizer Limited was directly involved in Pfizer's Infringements. Accordingly, the CMA attributes liability to Pfizer Limited for Pfizer's Infringements and for the resulting financial penalty.
- 8.29 For the duration of Pfizer's Infringements, Pfizer Limited was an indirectly wholly-owned subsidiary of Pfizer Inc.¹⁶⁰⁷ Accordingly, Pfizer Inc had the power to exercise decisive influence over Pfizer Limited and it can be presumed that it did in fact exercise decisive influence over Pfizer Limited for the duration of Pfizer's Infringements.
- 8.30 Pfizer has not submitted to the CMA that Pfizer Inc has not, in fact, exercised decisive influence over Pfizer Limited for the duration of Pfizer's Infringements.
- 8.31 Accordingly, the CMA finds that Pfizer Inc formed part of the same undertaking for the duration of Pfizer's Infringements, and attributes liability to Pfizer Inc on a joint and several basis with Pfizer Limited for Pfizer's Infringements and for the resulting financial penalty.
- 8.32 The CMA considers that Pfizer was and is engaged in an economic activity and, accordingly, finds that Pfizer is and was an undertaking for the purposes of the Chapter II prohibition throughout the Relevant Period.

b. Flynn

- 8.33 Flynn Pharma Limited was directly involved in Flynn's Infringements. Accordingly, the CMA attributes liability to Flynn Pharma Limited for Flynn's Infringements and for the resulting financial penalty.
- 8.34 For the duration of Flynn's Infringements, Flynn Pharma Limited was a wholly-owned subsidiary of Flynn Pharma (Holdings) Limited. Accordingly, Flynn Pharma (Holdings) Limited had the power to exercise decisive influence over Flynn Pharma Limited and it can be presumed that it did in fact exercise decisive influence over Flynn Pharma Limited for the duration of Flynn's Infringements.
- 8.35 This presumption is further supported by the fact that two directors of Flynn Pharma (Holdings) Limited also sat on the board of Flynn Pharma Limited during the Relevant Period.¹⁶⁰⁸

¹⁶⁰⁷ Pfizer confirmed to the CMA that Pfizer Limited was 100% indirectly owned by Pfizer Inc. for the period, 1 January 2010 to 25 June 2015 and the CMA has no reason to believe that this position has changed subsequently; see PHT00248, Pfizer's response of 8 July 2015 to the CMA's s.26 Notice information request of 25 June 2015 (CMA document reference 01357.1).

¹⁶⁰⁸ [Flynn Director 2] and [Flynn Director 1] were directors of both companies. See the annual accounts for Flynn Pharma (Holdings) Ltd for the years ending 31 March 2013 (page 4), PAD00038; 31 March 2014 (page 4), PAD00073; 31 March 2015 (page 4), PAD00075; 31 March 2016 (page 3), PAD00072; and the annual accounts of Flynn Pharma Ltd for the years ending 31 March 2013 (page 1), PRE00716; 31 March 2014 (page 1), PRE00717; 31 March 2015 (page 1), PRE00718; and 31 March 2016 (page 2), PRE00719.

- 8.36 Flynn has not submitted to the CMA that Flynn Pharma (Holdings) Limited has not in fact exercised decisive influence over Flynn Pharma Limited for the duration of Flynn's Infringements.
- 8.37 Accordingly, the CMA finds that Flynn Pharma (Holdings) Limited formed part of the same undertaking for the duration of Flynn's Infringements, and attributes liability to Flynn Pharma (Holdings) Limited on a joint and several liability basis with Flynn Pharma Limited for Flynn's Infringements and for the resulting financial penalty.
- 8.38 The CMA considers that Flynn was and is engaged in an economic activity and, accordingly, finds that Flynn is and was an undertaking for the purposes of the Chapter II prohibition throughout the Relevant Period.

9. The CMA's Actions

A. The CMA's Decision

- 9.1 On the basis of the evidence and analysis set out in this Decision, the CMA has found that Pfizer and Flynn each infringed the Chapter II prohibition by charging unfairly high selling prices for 25mg, 50mg, 100mg and 300mg strength Capsules during the Relevant Period.

B. Directions

- 9.2 Section 33(1) of the Act provides that if the CMA has made a decision that conduct infringes the Chapter II prohibition, it may give to such person or persons as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.
- 9.3 The CMA has not made a finding that the Infringements are ongoing and, therefore, has not issued directions to the Parties to bring the Infringements to an end.

C. Financial Penalties

- 9.4 Section 36(2) of the Act provides that on making a decision that conduct has infringed the Chapter II prohibition, the CMA may require the undertaking(s) concerned to pay a penalty in respect of the infringement.
- 9.5 Pursuant to section 36(3) of the Act the CMA may impose a penalty under section 36(2) only if it is satisfied that the infringement has been committed intentionally or negligently. For the reasons set out below, the CMA finds that the Infringements were committed intentionally or, at the very least, negligently.
- 9.6 The CMA has a margin of appreciation when determining the appropriate amount of a penalty under the Act.¹⁶⁰⁹ Further, the CMA is not bound by its decisions in previous cases under the Act in relation to whether to impose financial penalties or the calculation of any such penalties; rather, it makes assessments on a case-by-case basis,¹⁶¹⁰ having regard to all relevant circumstances and the objectives of its policy on financial penalties. This is in line with its statutory requirements and with

¹⁶⁰⁹ 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 Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (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.

¹⁶¹⁰ 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 *Guidance as to the appropriate amount of a Penalty* (CMA73), published April 2018 (the '**CMA penalties guidance**'), paragraph 2.6.

the twin objectives of the CMA's policy on financial penalties, as reflected in the CMA penalties guidance.¹⁶¹¹ 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 any prohibition(s) under the Act.¹⁶¹²

- 9.7 The CMA has concluded that it is appropriate in the circumstances of this case to exercise its discretion under section 36(2) of the Act to impose financial penalties on Pfizer and Flynn, given the serious nature of the Infringements and to deter similar conduct in the future.

I. The CMA's power to impose a penalty

- 9.8 This section addresses, first, whether Pfizer and/or Flynn meet the criteria for the exemption from financial penalties set out in section 40 of the Act and, second, whether the CMA is satisfied that the Infringements were committed intentionally or negligently, as required by section 36(3) of the Act.

a. Conduct of minor significance

- 9.9 Section 40 of the Act precludes the imposition of a penalty for an infringement of the Chapter II prohibition where the infringing conduct is 'conduct of minor significance'.¹⁶¹³
- 9.10 Regulation 4 of the Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000 defines 'conduct of minor significance' as 'conduct by an undertaking the applicable turnover of which for the business year ending in the calendar year preceding one during which the infringement occurred does not exceed £50 million'.
- 9.11 The Relevant Period commenced on 24 September 2012 and ended on 7 December 2016. Accordingly, the calendar years preceding years during which the Infringements occurred span 2011 to 2015.

¹⁶¹¹ CMA penalties guidance, paragraph 1.3. 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 Draft Penalty Statement(s) or, if there are ongoing settlement discussions, draft penalty calculation(s) have not yet been issued. Since in this case the Draft Penalty Statements were issued prior to that date, the applicable penalties guidance is the version of CMA73 that was published on 18 April 2018.

¹⁶¹² The Act, section 36(7A); CMA penalties guidance, paragraph 1.3.

¹⁶¹³ Section 40(3) provides that 'A person is immune from the effect of section 36(2), so far as that provision relates to decisions about infringement of the Chapter II prohibition, if his conduct is of minor significance ...'. Section 36(2) provides that '[o]n making a decision that conduct has infringed the Chapter II prohibition, the CMA may require the undertaking concerned to pay the CMA a penalty in respect of the infringement'. The CMA may withdraw this immunity where it has investigated conduct of minor significance and, as a result of its investigation, it considers that the conduct is likely to infringe the Chapter II prohibition: see section 40(3)–(8).

i. Pfizer

9.12 Pfizer's turnover exceeded £50 million in every business year ending in a calendar year preceding a year during which the Infringements occurred; accordingly, section 40 does not apply.¹⁶¹⁴

ii. Flynn

9.13 Flynn's turnover in the period 2011 to 2015 was as follows:

Financial year (ending 31 March)	Turnover
2011	£14.2m
2012	£19.2m
2013	£46.5m
2014	£54.1m
2015	£49.9m

9.14 As is evident from the table, Flynn's turnover exceeded £50 million in 2014; for all other financial years preceding years of the Infringements, Flynn's turnover was below £50 million.

9.15 In applying section 40 and regulation 4, the CMA has taken as its starting point the words used by Parliament.¹⁶¹⁵ The CMA has concluded that the text of these provisions does not specify, or at least does not specify clearly, the point in time at which the turnover test should be applied. It is not clear from the wording of these provisions whether (for example) a person will benefit from immunity provided its turnover fell below £50m in *any* one business year preceding a year of the infringement, or whether its turnover must be below £50m in *every* business year preceding a year of the infringement in order to meet the statutory test.

9.16 Given this ambiguity, the CMA has sought to ascertain the intention of section 40 and regulation 4 by considering the text of these provisions in the light of their context and their purpose.¹⁶¹⁶

9.17 As regards the statutory context, sections 39 and 40 provide for specific and limited immunities whereby persons are exempted from the general position (as set out in section 36) that the CMA may require undertakings that have infringed the Chapter I or Chapter II prohibitions to pay a penalty in respect of such infringements. This is reflected in the titles of these sections: 'limited immunity in relation to the Chapter I prohibition' and 'limited immunity in relation to the Chapter II prohibition'. Further,

¹⁶¹⁴ Pfizer's turnover exceeded the £50m turnover threshold in every business year ending in a calendar year preceding a calendar year during which the Infringements occurred.

¹⁶¹⁵ See for example *R v A (No 2)* [2001] UKHL 25, [2001] 3 All ER 1 at [44], as cited in Bennion on Statutory Interpretation (8th ed) at section 11.1.

¹⁶¹⁶ *Hurstwood Properties v Rossendale BC* [2021] UKSC 16 at paragraph 10, *R (Black) v Secretary of State for Justice* [2017] UKSC 81, [2018] AC 215 at paragraph 36(3)–(4).

section 36(7A) specifies that when fixing a penalty the CMA must have regard to the seriousness of the infringement concerned, and the desirability of deterring both the undertaking on which the penalty is imposed and others from infringing the Chapter I and Chapter II prohibitions. Given this context, the CMA considers that any immunity from penalties should be narrowly or strictly construed, so as not to unnecessarily impinge upon these objectives.

- 9.18 In order to understand the purpose of section 40 and regulation 4, the CMA has examined statements made at the time that the Competition Bill was considered by Parliament. First, the CMA has considered a consultation paper and draft bill published by the Department of Trade and Industry in August 1997, which proposes a limited immunity in substantively identical terms to that now set out in section 40.¹⁶¹⁷ The consultation paper elaborates on the justification for this immunity as follows:

Small and Medium Sized Enterprises (SMEs)

*In order to ensure that SMEs are not unduly burdened by the operation of the prohibition, there will be a threshold based on the turnover and/or market share of the firms concerned. As with the similar provision for anti-competitive agreements, it is intended that this will only provide immunity against fines, not against [Director General of Fair Trading] action to halt infringements of the prohibition or against third party actions. The DGFT will also be able to withdraw this immunity after giving notice that he intends to do so.*¹⁶¹⁸

- 9.19 Second, the CMA has considered statements made during parliamentary debates on the Competition Bill. Speaking in the House of Lords in February 1998, for example, Lord Simon of Highbury (then Minister for Trade and Competitiveness in Europe) stated:

.... the Government believe there ought to be some recognition of the compliance costs for small and medium-sized enterprises. We have therefore provided in Clauses 38 and 39 that parties to small agreements and persons whose conduct is of minor significance should be immune from penalties for breaches of the Chapter I and Chapter II prohibitions respectively.

...

¹⁶¹⁷ PAD00125, Department of Trade and Industry, *A prohibition approach to anti-competitive agreements and abuse of dominant position: draft bill*, August 1997, clause 37 (emphasis added). Consultation papers form part of the enacting history and are admissible, at least for the purposes of ascertaining the contextual setting of the legislation or the mischief at which it is aimed: see Bennion on Statutory Interpretation (8th ed) at section 24.9, and the decisions cited therein (*Belhaj v DPP* [2018] UKSC 33 at [22] per Lord Sumption and *Melville Dundas Ltd v George Wimpey UK Ltd* [2007] UKHL 18 at [65] per Lord Neuberger).

¹⁶¹⁸ PAD00125, Department of Trade and Industry, *A prohibition approach to anti-competitive agreements and abuse of dominant position: draft bill*, August 1997, paragraph 6.9 (emphasis added).

*The provisions are not in any sense a licence to SMEs to infringe the prohibitions and, in particular, to abuse a dominant position.*¹⁶¹⁹

- 9.20 The foregoing materials suggest that section 40 and regulation 4 are intended to provide a *limited* exemption from penalties in order to lessen the regulatory burden on small and medium-sized enterprises. It follows, therefore, that where a person surpasses the £50 million turnover threshold, it should not require protection from the ordinary consequences of breaching the Act.
- 9.21 Accordingly, the CMA has concluded that the immunity provided for by section 40 and regulation 4 is limited to those situations where an undertaking's turnover falls below the £50 million threshold in every business year preceding a calendar year in which the infringement occurred. On this interpretation, the definition of 'conduct of minor significance' set out in regulation 4 should be read as 'conduct by an undertaking the applicable turnover of which for the business year ending in the calendar year preceding [every] one during which the infringement occurred does not exceed £50 million'.
- 9.22 As Flynn's turnover surpassed £50 million in one business year preceding a calendar year in which the Infringements occurred (namely, the financial year ending 31 March 2014), the CMA has concluded that the immunity from penalties does not apply.
- 9.23 The CMA has also considered two alternative interpretations. On the first of the alternative interpretations, regulation 4 would encompass 'conduct by an undertaking the applicable turnover of which for the business year ending in the calendar year preceding [any] one during which the infringement occurred does not exceed £50 million'. Because Flynn's turnover fell below £50 million in some of the financial years preceding years in which the Infringements occurred, according to this interpretation section 40 would apply and Flynn would not be liable to pay any penalty in respect of the Infringements.
- 9.24 However, the CMA has concluded that this interpretation gives rise to an absurd result and/or a result that is inconsistent with the general purpose of the legislation:¹⁶²⁰
- 9.24.1 First, this interpretation means that no fine could be imposed for a long-running abuse if the relevant person's turnover fell below £50 million in any one financial year preceding a year of the infringement, even where

¹⁶¹⁹ PAD00054, Competition Bill Report Stage (HL, 19 February 1998), column 363 (emphasis added). In considering these materials, the CMA has had regard to the rule in *Pepper (Inspector of Taxes) v Hart* [1992] UKHL 3, [1993] AC 593 regarding references to Hansard. The CMA's view is that such reference is permissible, given (a) the legislation is ambiguous, (b) the material consists of statements by the Minister responsible for the Bill (Lord Simon), and (c) the statements indicate a clear intention to confine the scope of the section 40 immunity.

¹⁶²⁰ In this context, 'absurdity' refers to "virtually any result which is unworkable or impracticable, inconvenient, anomalous or illogical, futile or pointless, artificial, or productive of a disproportionate counter-mischief": Bennion on Statutory Interpretation (8th ed) at section 13.1. See, for example, *R v McCool* [2018] UKSC 23 at [23]–[25].

the person made very considerable profits from the infringement and irrespective of the seriousness of the infringement. The outcome would be even starker where the person's turnover materially exceeded £50 million for each preceding financial year but one of (say) a 10-year infringement. That would make the application of section 40 at best something of a 'turnover lottery' and at worst would allow infringing undertakings to continue and expand abusive behaviour free from fear of fines where they have previously fallen below the threshold. In the CMA's view, Parliament cannot have intended such an absurd outcome.

9.24.2 Second, and more generally, this interpretation results in an expansive immunity that is difficult to reconcile with Parliament's intention to create a 'limited immunity' from penalties for small and medium-sized enterprises, and with the instruction in s 36(7A) to deter future infringements.

9.25 The second alternative interpretation is a 'year-by-year' approach, whereby regulation 4 is read as 'conduct [*in a particular year*] by an undertaking the applicable turnover of which for the business year ending in the calendar year preceding [*each*] one during which the infringement occurred does not exceed £50 million'.

9.26 This 'year-by-year' interpretation avoids the absurd outcome set out at paragraph 9.24 above. However, under this alternative interpretation the CMA would only be able to impose a penalty in respect of those years of the Infringements where the threshold was exceeded in the financial year ending in the preceding calendar year. The CMA considers that this effect is inconsistent with the intention to carve out a 'limited exemption' from penalties, and it is unlikely that Parliament intended to partition an infringement in this way.

9.27 In any event, the distinction between the CMA's interpretation and this alternative 'year-by-year' approach is of no practical consequence here. Based on the approach adopted by the CMA below to calculating Flynn's fine, Flynn's final penalty would be the same regardless of which interpretation is adopted. That is because, under either approach, Flynn's penalty at step 4 would surpass the 10% statutory cap and would therefore be reduced to the same figure at step 5.

9.28 In summary, the CMA has concluded that the first alternative interpretation produces absurd outcomes. The CMA considers that the effect of the second alternative interpretation is inconsistent with the intention of section 40 and, in any event, would produce the same outcome for Flynn's fine in this case as the interpretation adopted by the CMA.

9.29 Flynn submitted that the CMA's approach constitutes a 'highly restrictive reading of the rules' in circumstances where (i) Flynn's turnover was below the £50 million threshold when Flynn launched its Products at the allegedly infringing price; and (ii)

Flynn's turnover remained below the £50 million threshold for the duration of Flynn's Infringements, with the exception of the financial year ending 31 March 2014.¹⁶²¹

- 9.30 Flynn argued that, as its turnover in the year ending 31 March 2011 (ie the financial year preceding the first year in which Flynn's Infringements occurred) was £14.2 million, the section 40 immunity should be applied to Flynn's conduct for the entire period of Flynn's Infringements. In Flynn's view, the fact that this interpretation could permit a company to continue an infringement for many years after its turnover substantially exceeded £50 million is irrelevant, as that is 'patently not the position here'.¹⁶²²
- 9.31 As set out above, given section 40 and regulation 4 are ambiguous on the question of the point in time at which the turnover test should be applied, the CMA has sought to interpret the meaning of these provisions in light of their 'context and purpose'. This includes consideration of the likely consequences of each interpretation. The interpretation favoured by Flynn, whereby the CMA would consider turnover in the financial year preceding the first year of Flynn's Infringements alone, has been carefully considered by the CMA and rejected on the basis that it would lead to an absurd outcome in many cases. Indeed, in this case, it would allow Flynn to benefit from immunity from a penalty in circumstances where in the first full financial year of Flynn's Infringements (the financial year ending 31 March 2014¹⁶²³) its turnover exceeded £50 million, representing a significant increase in turnover from the financial year preceding Flynn's Infringements (£19.2 million in the financial year ending 31 March 2012) and Flynn continued to charge excessive prices in the next three financial years.

b. Intention and negligence

i. Legal framework

- 9.32 The CMA may impose a penalty on an undertaking which has infringed the Chapter II prohibition only if the CMA is satisfied that the infringement has been committed intentionally or negligently.¹⁶²⁴ The CMA is not, however, obliged to specify whether it considers that the infringement has been committed intentionally or merely negligently.¹⁶²⁵
- 9.33 The CAT has defined the terms 'intentionally' and 'negligently' as follows:

¹⁶²¹ PRC03495, Flynn's response to the DPS, paragraph 2.2.

¹⁶²² PRC03495, Flynn's response to the DPS, paragraphs 2.7 to 2.8.

¹⁶²³ Flynn's Infringements started in September 2012. Flynn's financial year runs from 1 April to 31 March, therefore the first *full* financial year of Flynn's Infringements is the financial year ending 31 March 2014.

¹⁶²⁴ The Act, section 36(3).

¹⁶²⁵ *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, paragraphs 453–455; see also *Argos Ltd v OFT* [2005] CAT 13, paragraph 221.

... an infringement is committed intentionally for the purpose of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition.

*An infringement is committed negligently for the purposes of s 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition.*¹⁶²⁶

9.34 Intention or negligence relates to the facts, not the law. The CMA is not required to show that the undertaking knew that its conduct infringed the Act – what matters is not whether the undertaking was aware of ‘any specific legal characterisation’ of its conduct, but instead ‘whether it was aware of its anti-competitive nature’.¹⁶²⁷ In cases of exploitative abuse, by analogy, this means that the undertaking must have been aware of the exploitative nature of the conduct.

9.35 This is consistent with the approach taken by the EU Court of Justice, which has confirmed that:

*the question whether the infringements were committed intentionally or negligently ... is satisfied where the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty.*¹⁶²⁸

9.36 It follows that ignorance of mistake or law is no bar to a finding of intentional (or a *fortiori*, negligent) infringement, even when such ignorance or mistake is based on independent legal advice.¹⁶²⁹

9.37 These principles were applied by the Court of Appeal in *Ping v CMA*.¹⁶³⁰ The CAT also recently confirmed in *Paroxetine* that the principles set out at paragraphs 9.33 to 9.36 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 at the time not that the Agreements infringed competition law but that they were anti-competitive in nature’.¹⁶³¹

¹⁶²⁶ *Argos Ltd v OFT* [2005] CAT 13, paragraph 221.

¹⁶²⁷ *Royal Mail Plc v Office of Communications* [2019] CAT 27, paragraph 782. See also *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, paragraph 456.

¹⁶²⁸ Case C-280/08P *Deutsche Telekom v Commission* ECLI:EU:C:2010:603, paragraph 124. See also Case T-472/13 *Lundbeck v Commission* ECLI:EU:T:2016:449, paragraph 762. See also *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, paragraph 455.

¹⁶²⁹ Case C-671/11 *Bundeswettbewerbshilfe v Schenker & Co AG* ECLI:EU:C:2013:404, [2013] 5 CMLR 25, paragraphs 38 and 41.

¹⁶³⁰ *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, paragraph 117.

¹⁶³¹ *Generics (UK) Ltd v CMA* [2021] CAT 9 (*‘Paroxetine’*), paragraphs 117 and 121. Flynn submitted that the correct legal test for establishing intention or negligence is whether the conduct was ‘probably’ or ‘clearly’ unlawful, based on the criteria set out by the CAT in *Sainsbury’s v Mastercard* [2016] CAT 11 (PRC03495, Flynn’s response to the DPS, paragraphs 3.2 to 3.3). The CMA rejects this argument. As confirmed by the CAT in *Paroxetine*, the relevant test for intent and negligence remains as set out at paragraphs 9.33 to 9.36 above. The judgment in *Sainsbury’s* considers questions of intention and/or negligence in relation to the specific ‘ex turpi causa’ defence, which is not relevant to the present case.

- 9.38 The case law is clear that an undertaking will be aware of the anti-competitive nature of its conduct where it is aware of the ‘essential facts’ underpinning the legal finding of abuse.¹⁶³² In cases of unfair pricing, therefore, the CMA will consider whether the undertaking knew or should have known the essential facts justifying the CMA’s findings that (i) the undertaking was in a dominant position, and (ii) the undertaking’s price was unfair.
- 9.39 The CMA will assess the relevant evidence objectively and may draw reasonable inferences.¹⁶³³ In some cases, an undertaking’s intention will be confirmed by internal documents. In other cases (and in the absence of evidence to the contrary), the fact that certain consequences are plainly foreseeable will be an element from which the requisite intention may be inferred. Where a dominant undertaking pursues a certain policy which in fact has, or would foreseeably have, an anti-competitive effect, it may be legitimate to infer that it is acting intentionally for the purposes of section 36(3).¹⁶³⁴ Similarly, the fact that an actual or potential contractual partner, or a member of staff, has expressed doubts as to the legality of the conduct can support a finding that the undertaking could not be unaware of the anti-competitive nature of the conduct.¹⁶³⁵

ii. Application to Pfizer

- 9.40 The CMA concludes that Pfizer knew or should have known the essential facts justifying the CMA’s findings that (i) Pfizer was in a dominant position, and (ii) Pfizer’s Prices were unfair.¹⁶³⁶

¹⁶³² Case 322/81 *NV Nederlandsche Banden-Industrie Michelin v Commission* ECLI:EU:C:1983:313, [1983] ECR 3461, 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 system’; Joined Cases T-259/02 to T-264/02 and T-271/02 *Raiffeisen Zentralbank Österreich v Commission* ECLI:EU:T:2006:396, [2006] ECR II-5169, paragraph 206: ‘...whether or not the applicants were aware of the interpretation of the cross-border criterion adopted by the Commission or the case-law is not decisive; what is important is whether they knew of the circumstances specifically giving rise to the capability of the cartel to affect trade between Member States or, at least, whether they could not have been unaware of them’, Case T-286/09 *Intel Corp. v Commission* ECLI:EU:T:2014:547, paragraph 1601: ‘An undertaking is aware of the anti-competitive nature of its conduct where it is aware of the essential facts justifying both the finding of a dominant position on the relevant market and the finding by the Commission of an abuse of that position’ (this point was not at issue in the subsequent decisions of the Court of Justice (C-413/14P) or the General Court (Case T-286/09 RENV)), and Opinion of AG Mazak in Case C-280/08P *Deutsche Telekom v Commission* ECLI:EU:C:2020:212, paragraph 39: ‘First of all, according to the case-law, an undertaking is aware of the anti-competitive nature of its conduct when it is “aware of the factual elements justifying both the finding of the existence of a dominant position on the market and the assessment of [the finding by the Commission of] an abuse of that position” ...Therefore, suffice it to point out that since the awareness of infringing competition rules is not decisive, there may be intentional fault even where the undertaking does not know the interpretation of those rules by the Commission’.

¹⁶³³ See generally *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, paragraphs 110–111.

¹⁶³⁴ *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, paragraph 456.

¹⁶³⁵ Case C-591/16P *Lundbeck v Commission* ECLI:EU:C:2021:243, paragraph 164 and Case C-614/16P *Merck v Commission* ECLI:EU:C:2021:246, paragraph 132.

¹⁶³⁶ The CMA here uses the term ‘unfair’ in the sense explained by Green LJ in *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(i), namely that ‘[t]he basic test for abuse, which is set out in the Chapter II prohibition and in Article 102, is whether the price is “unfair”’.

Dominance

- 9.41 The CMA concludes that Pfizer knew or should have known the following facts, which underpin the finding, upheld on appeal by the CAT,¹⁶³⁷ that Pfizer held a dominant position in the market for the manufacture of Capsules that are distributed in the UK:
- 9.41.1 Pfizer was the sole manufacturer of Capsules distributed in the UK, and accordingly had a market share of 100% during the Relevant Period.¹⁶³⁸
- 9.41.2 Pfizer was able to impose substantial increases in prices on 24 September 2012, notwithstanding the fact that Capsules were a generic drug that was long off-patent and used as a third-line treatment for epilepsy. Moreover, Pfizer was able profitably to sustain those increases over the duration of the Relevant Period.¹⁶³⁹ Pfizer's supply prices to Flynn were between 783% and 1,603% greater than those it charged pharmacies and wholesalers until September 2012.¹⁶⁴⁰
- 9.41.3 Significant and permanent barriers to entry prevented other potential entrants from acting as an effective competitive constraint on Pfizer. To a significant degree, demand for Pfizer's products was inelastic due to Continuity of Supply.¹⁶⁴¹ Pfizer was clearly aware of Continuity of Supply issues relating to phenytoin before the transaction with Flynn, and well before the MHRA Guidance was issued in November 2013.¹⁶⁴² In addition, prior to entering into the Agreements, Pfizer's internal regulatory team had advised that it would take a competitor a minimum of two years to obtain a licence in order to enter the market with an alternative generic phenytoin sodium capsule product.¹⁶⁴³
- 9.41.4 Pfizer's conduct was not meaningfully constrained by NRI's entry, despite the fact that NRI's phenytoin sodium capsules were substantially cheaper than Pfizer's Products.¹⁶⁴⁴ Pfizer was aware of this. For example,

¹⁶³⁷ *Phenytoin* [2018] CAT 11, paragraphs 198 and 251–253.

¹⁶³⁸ *Phenytoin* [2018] CAT 11, paragraphs 107, 237, and 253. Pfizer submitted that the CMA's case rests on the 'highly unusual' proposition that Pfizer's Products were in a market of one product, which excluded even NRI's identical phenytoin sodium capsule competitor product. The CMA does not accept this representation. The fact that the relevant market was narrow in its scope does not mean Pfizer was incapable of understanding its dominant position. When viewed together, the examples set out in this sub-section demonstrate that Pfizer must have been aware, could not have been unaware, or at least ought to have known the essential facts justifying the CMA's conclusion that as the sole manufacturer of Capsules distributed in the UK, it was a dominant undertaking in the relevant market throughout the Relevant Period.

¹⁶³⁹ *Phenytoin* [2018] CAT 11, paragraphs 107, 242–243, and 251.

¹⁶⁴⁰ See Table 2.4.

¹⁶⁴¹ *Phenytoin* [2018] CAT 11, paragraphs 250–251.

¹⁶⁴² *Phenytoin* [2018] CAT 11, paragraphs 124–125.

¹⁶⁴³ PRE00156, First Witness Statement of [Pfizer Director 1], 7 February 2017, paragraphs 44 and 72, and PHT00200, Document of 1 August 2011 entitled '*Briefing for [Pfizer President 1] about the Epanutin divestment*': Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.154).

¹⁶⁴⁴ *Phenytoin* [2018] CAT 11, paragraphs 160, 189, 247 and 251.

upon learning that NRIM had been granted an MA, Pfizer expected that Flynn would be able to retain two-thirds of the market.¹⁶⁴⁵

9.41.5 Similarly, the supply of phenytoin sodium capsules available to parallel importers was limited and was not sufficiently reliable to generate effective competitive pressure on Pfizer.¹⁶⁴⁶ A presentation given by Flynn to Pfizer in July 2010 recorded the Parties' expectation that 'even if 50% of sales of 100mg were lost to [parallel imports] the upside would still be >£20m'.¹⁶⁴⁷ In addition, the Parties' decision to transfer the MAs to Flynn enabled Flynn to register a trademark, thereby creating a further barrier to competition for parallel importers.¹⁶⁴⁸

9.41.6 Despite communicating their clear dissatisfaction with the price increases, neither the DHSC nor CCGs were in fact able to exercise buyer power in a way that effectively constrained Pfizer's conduct.¹⁶⁴⁹ The contemporaneous documents highlight that Pfizer did not expect the DHSC to be able to intervene effectively: for example, [Pfizer Director 1]'s presentation to the UK Management Forum noted that no 'regulatory restrictions' had been identified;¹⁶⁵⁰ and when asked by the DHSC about its prices, Pfizer refused to engage and took the position that the pricing of Capsules was 'nothing to do with Pfizer'.¹⁶⁵¹

Abuse

9.42 The CMA concludes that Pfizer knew, or should have known, the essential facts establishing that its prices during the Relevant Period were unfair:

¹⁶⁴⁵ Shortly after Pfizer became aware of NRIM's MA, [Pfizer Director 1] sent an internal email in which he stated that: '[t]his was one of the key risks we identified, but we didn't expect it to happen until some time after we had divested the brand. ... It is difficult at this stage, until we know more, to evaluate the impact on our numbers, as it depends on what NRIM choses to do and how Flynn reacts. At worst, they could each secure 50% of the market volume; although I would expect Flynn to be able to retain more like 2/3': PHT00221, Email of 23 October 2011 from [Pfizer Director 1] Pfizer to [Pfizer President 2] J A Finance and [Pfizer Employee] Pfizer re Epanutin Update detailing the agreement with Flynn and the appearance of NRIM and its Marketing Authority: Pfizer's response of 18 June to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.191).

¹⁶⁴⁶ *Phenytoin* [2018] CAT 11, paragraphs 248–249.

¹⁶⁴⁷ PHT00164, Presentation slides entitled '*A Specialty Care Pharma Company*': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27).

¹⁶⁴⁸ See section 6.B.IV.a.

¹⁶⁴⁹ *Phenytoin* [2018] CAT 11, paragraphs 235 and 252.

¹⁶⁵⁰ PHT00232, Powerpoint Presentation slides entitled '*Established Products Epanutin proposal for UKMF Dec 2010 - Follow Up Meeting April 2011*': Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.117). [Pfizer Director 1] before the CAT said that this statement referred to regulatory restrictions regarding de-branding rather than pricing: PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 27, lines 5 to 23. However, possible intervention by the DHSC does not feature in this list of 'key challenges' identified. Moreover, despite the DHSC raising questions with Pfizer regarding its pricing, it did not revise its prices or provide the costs data the DHSC had sought showing that Pfizer was not constrained by the DHSC.

¹⁶⁵¹ PHT00233, Email chain re Epanutin Divestment and enquiring what the list price will be, as sent by Flynn (CMA document reference 00141.423), and PHT00060, Email of 27 February 2013 between Department of Health Staff [[DHSC Employee 5], [DHSC Employee 1], [DHSC Employee 3] and [DHSC Employee 8] (DHSC)] forwarding on redacted email from Pfizer - re Outstanding actions from the Meeting with DHSC on 10 January 2013: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.22).

- 9.42.1 As noted above, Pfizer imposed substantial overnight price increases for a generic drug, the prices of which had previously been stable for a significant number of years.
- 9.42.2 Pfizer's Prices materially exceeded any reasonable measure of its costs (including a reasonable rate of return).¹⁶⁵² Pfizer did not consider the costs, profitability, or the level of increase that was necessary to ensure a level of profitability that would make the supply of Capsules commercially sustainable.¹⁶⁵³ The scale of Pfizer's price increases meant that, on Pfizer's own measures of profitability, nearly five years of losses were recovered within two months from September 2012 (more than four years before the end of the Relevant Period).¹⁶⁵⁴
- 9.42.3 Pfizer knew that it was only in the UK that it entered into arrangements of the type agreed with Flynn and significantly increased its prices well above those that it charged for identical Capsules in other European jurisdictions.¹⁶⁵⁵
- 9.42.4 Pfizer's Prices reflected its substantial market power. Pfizer was aware of its market power¹⁶⁵⁶ and exploited this to impose significant price increases overnight on the NHS which it maintained for over four years. In doing so, Pfizer wilfully ignored DHSC and customer concerns, and did not engage constructively to resolve those concerns.¹⁶⁵⁷ The DHSC approached Pfizer, both directly and indirectly through Flynn, with questions about the price increases and the justifications for these.¹⁶⁵⁸ A letter sent by a group of 12 CCGs, the GMMM, in October 2012 which was copied to Pfizer, made clear their concerns regarding the scale of the price increases, which they characterised as 'unnecessary and unwarranted' and an 'abuse of a monopoly supply position', and providing 'no additional health benefit for patients'.¹⁶⁵⁹ Internal documents show that Pfizer closely monitored complaints received from CCGs and negative media reports.¹⁶⁶⁰ Pfizer was aware of a GP's letter which noted that

¹⁶⁵² See section 5.

¹⁶⁵³ See section 6.B.II.a.

¹⁶⁵⁴ See section 6.B.II.a.

¹⁶⁵⁵ See section 6.B.III.

¹⁶⁵⁶ See section 6.B.IV.b and paragraph 9.41 above. See also PHT00353 Email of 15 October 2012 from [Pfizer Employee] Pfizer to [[Pfizer Employee] and others] Pfizer (CMA document reference 00141.469): 'If I remember correctly: [...] A price increase is only possible (from a commercial perspective) if there is no other manufacturer selling the same molecule (otherwise they would be undercut on price) and/or physicians are slow to switch from the brand As this is an Epilepsy product, physicians are slow to switch patients to generic alternatives and so Flynn have been able to increase price.'

¹⁶⁵⁷ See section 6.B.IV.c and Annex B and Annex C.

¹⁶⁵⁸ See Annex C and section 6.B.IV.c.

¹⁶⁵⁹ PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.527).

¹⁶⁶⁰ PHT00360, Pfizer document titled *Epanutin Capsules UK Marketing Authorisation Divestment to Flynn Pharma: External Communications Activity To Date*, dated 7 February 2013 (CMA document reference 00141.562); PHT00361, Email chain of 12 March 2013 between [Pfizer Employee] (Pfizer) and [Pfizer Employee 3] (Pfizer) and another, FW: Epanutin Caps – [X]/CCG – Outputs [sic] from meeting 11.03.13 (CMA document reference 00141.583).

‘there is no generic market for phenytoin’ due to the inability to switch patients to other phenytoin sodium products and the ‘exploitation of this loophole has cost the NHS a serious amount of money when budgets are being reduced, has caused anxiety in people with epilepsy, and has no clinical justification whatsoever’.¹⁶⁶¹ An internal Pfizer email regarding one complaint noted that a medicines management customer was ‘very concerned [...] [a]buse of monopoly was an expression used!’¹⁶⁶² Despite being aware of these concerns, Pfizer did not reduce its prices in response nor did it provide costs information which the DHSC had sought from Pfizer.¹⁶⁶³

9.42.5 Pfizer knew or should have known that its prices were not justified by any feature of the product and its supply. In particular:

- (a) Pfizer knew that Capsules were a very old drug that was long off-patent and in the third stage of the drug life cycle (where competition is expected to drive the prices of generic drugs down and result in ongoing low prices even where they continue to deliver benefits for patients).¹⁶⁶⁴
- (b) Pfizer knew that there had been no investment, innovation, or improvement to the product or its production or distribution, or changes in Pfizer’s costs or risk which might justify its prices.¹⁶⁶⁵
- (c) Pfizer knew or should have known that patient benefit did not justify its high prices. Pfizer knew that Capsules had long been superseded as a first-line treatment by other AEDs and were generally only rarely prescribed to new patients as a treatment of ‘last resort’.¹⁶⁶⁶ As a result, Pfizer knew that demand for Capsules was sustained predominantly by barriers to switching patients to other treatments,¹⁶⁶⁷ not because of the therapeutic benefits of Capsules relative to other AEDs. Neither Pfizer nor Flynn added any additional benefits for

¹⁶⁶¹ PHT00210, Letters published in the British Medical Journal on 22 January 2013, (CMA document reference 00020.2) and Annex B.

¹⁶⁶² PHT00355, Email of 18 October 2012 from [Pfizer Employee] Pfizer to [[Pfizer Employee 2] and others] Pfizer (CMA document reference 00141.483). See also PHT00356, Email of 12 November 2012 from [Pfizer Employee] Pfizer to [Pfizer Employee 2] Pfizer (CMA document reference 00141.518): ‘[m]y Medicines Management customers in Manchester are having difficulty absorbing the price hike for Epanutin which for them represents hundreds of thousands of pounds in extra costs’.

¹⁶⁶³ See section 6.B.IV.c and Annex C.

¹⁶⁶⁴ PHT00185, Email chain of 17 September 2009 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re the Epanutin Proposal put forward by Tor: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice of 8 May 2013, page 1 (CMA document reference 00141.28).

¹⁶⁶⁵ ‘We want to source the product exactly as now [...]. The incremental revenue will be approximately £20M / year and as nothing else changes significantly, this goes straight through to the bottom line’: PHT00350, Email of 1 December 2011 from [Pfizer Employee 2] Pfizer to [Pfizer Employee] Pfizer (CMA document reference 00141.209) and see PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 13, lines 8 to 21.

¹⁶⁶⁶ See section 6.B.V.c and PHT00185, Email chain of 17 September 2009 between [Tor Employee] Tor Generics and [Pfizer Employee 2] Pfizer re the Epanutin Proposal put forward by Tor: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00141.28).

¹⁶⁶⁷ See paragraph 9.41.3.

patients beyond those that had been available through the *Epanutin* product for many decades.¹⁶⁶⁸

9.42.6 The commercial purpose of the arrangements between Pfizer and Flynn was to remove Capsules from the constraints of the PPRS in order to significantly increase prices to the NHS, thereby generating substantial profits for Pfizer and Flynn.¹⁶⁶⁹ Pfizer's internal documents recognised the 'attractive commercial opportunity to increase revenues significantly due to an anomaly in the Drug Tariff'.¹⁶⁷⁰ Pfizer relied exclusively on the Tablets Drug Tariff price when determining what prices to charge in circumstances where, as [Pfizer Director 1] accepted in his evidence before the CAT, there was no other justification.¹⁶⁷¹ However, as set out below,¹⁶⁷² Pfizer was wrong to rely on the Tablets Drug Tariff as a sole justification for its prices, ignoring a number of events that should have made it pause and reconsider its position. In addition, Pfizer anticipated that the price increases would be unpopular due to the impact on the NHS. In an internal email, [Pfizer Director 1] referred to the potential for 'being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in [a] time of funding crisis'.¹⁶⁷³ For this reason, Flynn told Pfizer that it would publicly defend the price increase in order to shield Pfizer from the anticipated 'pharmacopolitical damage'.¹⁶⁷⁴ which was a key reason for Flynn's involvement in the arrangements.¹⁶⁷⁵ Following a conversation with Flynn, Pfizer reported back internally the view that 'it's ALL about reputation' and the question raised by Flynn of whether 'Pfizer execs want the Daily Mail camped on their doorstep[?]'¹⁶⁷⁶

9.42.7 Pfizer had anticipated the negative impact of its price increases on CCGs and the NHS.¹⁶⁷⁷ In the context of the earlier negotiations with Tor

¹⁶⁶⁸ See section 6.B.V.b.

¹⁶⁶⁹ See section 6.B.VI.a, and *Phenytoin* [2018] CAT 11, paragraph 457.

¹⁶⁷⁰ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31).

¹⁶⁷¹ 'So we didn't look at the profitability. We had – we were looking at price, and the reason why this project was able to even be established was because we had an established benchmark price in the market for the same medicine. If that price benchmark hadn't been there, we couldn't have done this. We would have had no justification': PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 79, line 24, to page 80, line 5.

¹⁶⁷² See paragraph 9.63 onwards.

¹⁶⁷³ PHT00187, Internal Pfizer e-mail chain of 2 February 2010 [from [Pfizer Employee] to [Pfizer Director 1]] re Epanutin: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.57).

¹⁶⁷⁴ PHT00164, Presentation slides entitled '*A Specialty Care Pharma Company*': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27) and PHT00193, Document entitled '*Epanutin Proposal, October 2010*': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹⁶⁷⁵ See section 6.B.VI.b.

¹⁶⁷⁶ PHT00198, Internal Pfizer e-mail [from: [Pfizer Employee 3] to: [Pfizer Director 1] and Pfizer Employee 2] of 17 June 2011 re Flynn and the possible advantages of going with Flynn re divestment: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.137).

¹⁶⁷⁷ See section 6.B.VII.

regarding similar proposals for Capsules,¹⁶⁷⁸ individuals within Pfizer raised concerns regarding the ethics of significant price increases.¹⁶⁷⁹ [Pfizer Employee 1] of Pfizer noted that, although ‘the top line money looks great’, the proposal ‘would increase the price of phenytoin capsules to the NHS drastically and to be frank, doesn’t feel right’.¹⁶⁸⁰ Moreover, customer complaints sent to Pfizer made clear the significant negative impact of the price increases on the NHS.¹⁶⁸¹

iii. **Application to Flynn**

- 9.43 The CMA concludes that Flynn knew or should have known the essential facts justifying the CMA’s findings that (i) Flynn was in a dominant position and (ii) Flynn’s Prices were unfair.¹⁶⁸²

Dominance

- 9.44 The CMA concludes that Flynn knew or should have known the following facts, which underpin the finding, upheld on appeal by the CAT,¹⁶⁸³ that Flynn held a dominant position in the market for the distribution of Capsules in the UK:

9.44.1 Flynn had a very significant market share (between 64% and 90% by number of Capsules) during the Relevant Period.¹⁶⁸⁴

9.44.2 Flynn was able to impose substantial price increases on 24 September 2012, notwithstanding the fact that Capsules were a generic drug that was long off-patent and used as a third-line treatment for epilepsy. Moreover, Flynn was able profitably to sustain those increases over the duration of the Relevant Period.¹⁶⁸⁵ Flynn’s ASPs were between 2,366% and 2,682%

¹⁶⁷⁸ Tor proposed an equivalent Drug Tariff price for 84 x 100mg capsules of £76.50, similar to the Drug Tariff price of Capsules from October 2012 to April 2014 of £67.50. See PHT00184, Document entitled ‘*Epanutin/Phenytoin generic switch*’: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00141.636).

¹⁶⁷⁹ Tor proposed an equivalent Drug Tariff price for 84 x 100mg capsules of £76.50, similar to the Drug Tariff price of Capsules from October 2012 to April 2014 of £67.50. See PHT00184, Document entitled ‘*Epanutin/Phenytoin generic switch*’: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00141.636).

¹⁶⁸⁰ PHT00183, Internal Pfizer email chain of 23 July 2009 [from [Pfizer Employee 1] to [Pfizer Employee 2] and [Pfizer Employee]] re Tor Generics Proposed Project: Pfizer’s response of 18 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00141.21).

¹⁶⁸¹ See Annex B.

¹⁶⁸² The CMA here uses the term ‘unfair’ in the sense explained by Green LJ in *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(i), namely that ‘[t]he basic test for abuse, which is set out in the Chapter II prohibition and in Article 102, is whether the price is “unfair”’.

¹⁶⁸³ *Phenytoin* [2018] CAT 11, paragraphs 198 and 251–253.

¹⁶⁸⁴ *Phenytoin* [2018] CAT 11, paragraphs 107, 237 and 253; and 2016 Infringement Decision, CE/9742-13, paragraph 4.216. Flynn submitted that there is no precedent for a finding of a separate market for a particular molecule in capsule format manufactured by a particular supplier and excluding tablets containing the very same molecule (PRC03495, Flynn’s response to the DPS, paragraph 3.6.1). Even assuming this is correct, the CMA does not view this as relevant or determinative. The fact that the relevant market was narrow in its scope does not mean that Flynn was incapable of understanding its dominant position. When viewed together, the examples set out in this sub-section demonstrate that Flynn must have been aware, could not have been unaware, or at least ought to have known the essential facts justifying the CMA’s conclusion that as the major distributor of Capsules in the UK, it was a dominant undertaking in the relevant market throughout the Relevant Period.

¹⁶⁸⁵ *Phenytoin* [2018] CAT 11, paragraphs 107, 242–243, and 251.

higher than Pfizer's supply prices prior to entering into the arrangements with Flynn,¹⁶⁸⁶ and the difference between Pfizer's and Flynn's ASPs per pack¹⁶⁸⁷ was between 662% and 1,800% higher than Pfizer's ASP per pack prior to the arrangements.¹⁶⁸⁸

- 9.44.3 Significant and permanent barriers to entry prevented other potential entrants from acting as an effective competitive constraint on Flynn. To a significant degree, demand for Flynn's Products was inelastic due to Continuity of Supply.¹⁶⁸⁹ Flynn was clearly aware of Continuity of Supply issues relating to phenytoin (covering both Capsules and Tablets) before the transaction with Pfizer, and well before the MHRA Guidance was issued in November 2013.¹⁶⁹⁰ Flynn knew that Continuity of Supply meant that its customer base was 'to a significant degree guaranteed'.¹⁶⁹¹ Moreover, Flynn actively relied upon Continuity of Supply in order to protect its own sales; for example, in late 2013 and early 2014 Flynn wrote to Boots and Lloyds referring them to the guidance and warning them of the risks of switching patients away from Flynn's product in order to deter them from switching and to protect its own sales.¹⁶⁹²
- 9.44.4 Flynn's conduct was not meaningfully constrained by NRIM's entry, despite the fact that NRIM's phenytoin sodium capsules were substantially cheaper than Flynn's Products.¹⁶⁹³ In his evidence before the CAT, [Flynn Director 2] explained that Flynn was not 'particularly concerned about NRIM'¹⁶⁹⁴ as it anticipated that NRIM's strategy was 'not ... to start a "race

¹⁶⁸⁶ See Table 2.6.

¹⁶⁸⁷ That is, the difference between the prices charged by Flynn and the prices charged by Pfizer to Flynn.

¹⁶⁸⁸ See section 6.B.II.b.

¹⁶⁸⁹ *Phenytoin* [2018] CAT 11, paragraphs 250–251.

¹⁶⁹⁰ *Phenytoin* [2018] CAT 11, paragraph 124 and 126–128. See also, for example, PHT00363, Email from [Flynn Director 2] (Flynn) to [Flynn Non-executive Director 1] dated 16 March 2010, Subject: 'Correction – capsules not tablets' (CMA document reference 00145.12), an email sent by [Flynn Director 2] in March 2010, in which [Flynn Director 2] states that 'this is an area where tablets and capsules are recognised as NOT being readily interchangeable, so doctors and patients would be reluctant to switch'. Flynn submitted that the MHRA Guidance was published in November 2013, 14 months after Flynn launched its Products, and Flynn could not have been expected to anticipate this development (PRC03495, Flynn's response to the DPS, paragraph 3.6.2); however, this argument overlooks the fact that (i) NICE guidance recommending against changing the formulation or brand of AED had been in place since at least 2004 (see section 2.A); and (ii) the notes of a telephone call between Flynn and the MHRA in June 2012 confirm that the MHRA referred Flynn to the NICE guidance and informed Flynn that the MHRA was 'planning to issue further guidance to prescribers to this effect': see PHT00104 (CMA document reference 00380.23), page 2.

¹⁶⁹¹ See *Phenytoin* [2018] CAT 11, paragraph 346.

¹⁶⁹² PHT00108, correspondence dated 8 October 2013 to 10 March 2014 with Boots/Alliance regarding Phenytoin switching: Annex 16a of Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.20), pages 16–18 and PHT00170, correspondence dated 8 October 2013 to 10 March 2014 with Celesio regarding Phenytoin switching: Annex 15 of Flynn's response of 7 April 2014 to the CMA's s.26 Notice information request of 5 March 2014 (CMA document reference 00505.19), pages 27 to 29. See also *Phenytoin* [2018] CAT 11, paragraph 128: 'the basic point remains that Flynn was relying on continuity of supply to try to protect its own sales'.

¹⁶⁹³ *Phenytoin* [2018] CAT 11, paragraphs 160, 189, 247 and 251.

¹⁶⁹⁴ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 127, line 25, to page 128, line 1.

to the bottom” on price but rather to build up a 30-50% share of the market’.¹⁶⁹⁵

9.44.5 Similarly, the supply of phenytoin sodium capsules available to parallel importers was limited and ‘spasmodic’,¹⁶⁹⁶ and therefore insufficiently reliable to generate effective competitive pressure on Flynn.¹⁶⁹⁷ A presentation given by Flynn to Pfizer in July 2010 recorded the Parties’ expectation that ‘even if 50% of sales of 100mg were lost to [parallel imports] the upside would still be >£20m’.¹⁶⁹⁸ In addition, the Parties’ decision to transfer the MAs to Flynn (which Flynn’s internal documents identified as one of ‘the strategic options in preventing parallel imports to the UK’)¹⁶⁹⁹ enabled Flynn to register a trademark, thereby creating a further barrier to competition for parallel importers.¹⁷⁰⁰

9.44.6 Despite communicating their clear dissatisfaction with the price increases directly to Flynn, neither the DHSC nor CCGs were in fact able to exercise buyer power in a way that effectively constrained Flynn’s conduct.¹⁷⁰¹ In addition, Flynn emphasised the possibility that it may have to discontinue Capsules as a means of exerting ‘negotiation leverage’ over the DHSC.¹⁷⁰²

Abuse

9.45 The CMA concludes that Flynn knew, or should have known, the essential facts establishing that its prices during the Relevant Period were unfair:

9.45.1 As noted above, Flynn imposed substantial overnight price increases for a generic drug, the prices of which had previously been stable for a significant number of years.

¹⁶⁹⁵ PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 52. Flynn submitted that it was aware of the grant of approval for NRIM’s Capsules in September 2011, and that it expected NRIM to gain sales from Flynn (PRC03495, Flynn’s response to the DPS, paragraph 3.6.3). This is not disputed by the CMA; however, it is evident from [Flynn Director 2]’ evidence that Flynn did not expect NRIM to pose a sufficient competitive threat.

¹⁶⁹⁶ PAD00031, [Flynn Director 2] Cross Examination, day 4, page 109, lines 4-7.

¹⁶⁹⁷ *Phenytoin* [2018] CAT 11, paragraphs 248–249.

¹⁶⁹⁸ PHT00164, Presentation slides entitled ‘A Specialty Care Pharma Company’: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27).

¹⁶⁹⁹ PHT00162, Presentation slides entitled ‘A Specialty Care Pharma Company’: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00145.91) (emphasis added).

¹⁷⁰⁰ See section 6.B.IV.a.

¹⁷⁰¹ *Phenytoin* [2018] CAT 11, paragraph 235 and 252. Flynn submitted (without identifying supporting evidence) that it proceeded on the basis that it was constrained in its ability to determine the price of phenytoin sodium tablets by the significant regulatory and commercial powers that could be yielded by the NHS (PRC03495, Flynn’s response to the DPS, paragraph 3.6.4). As set out in Annex C and section 2.D, Flynn was in contact with the DHSC throughout late 2012 and was fully aware of the DHSC’s concerns regarding Flynn’s Prices. Despite this, Flynn refused to provide costs information requested by the DHSC, and did not take steps to reduce its prices. This is not consistent with a genuine belief that Flynn expected the DHSC to impose any meaningful limits on Flynn’s conduct.

¹⁷⁰² *Phenytoin* [2018] CAT 11, paragraph 233, and PAD00031, [Flynn Director 2] Cross Examination, day 4, pages 174, lines 1-16.

- 9.45.2 Flynn's Prices materially exceeded any reasonable measure of its costs (including a reasonable rate of return).¹⁷⁰³
- 9.45.3 Flynn's Prices reflected its substantial market power. Flynn was aware of its market power and furthermore, Flynn sought to raise further the barriers to competition.¹⁷⁰⁴ Flynn exploited its market power to impose significant overnight price increases on the NHS which it maintained for over four years. In doing so, Flynn wilfully ignored DHSC and customer concerns, and did not engage constructively to resolve those concerns.¹⁷⁰⁵ Shortly after the implementation of the price increases, the DHSC raised concerns with Flynn in relation to the lack of explanation or justification.¹⁷⁰⁶ Similarly, multiple CCGs complained directly to Flynn at the time of the price increases.¹⁷⁰⁷ These complaints explicitly and strongly contested the significant price increases, highlighted the absence of any therapeutic (or other) justification and raised concerns about harm to CCG budgets and the impact on patient care. For example, a letter sent by a group of 12 CCGs, the GMMMG, in October 2012 which was copied to Flynn, made clear their concern regarding the scale of the price increases, which they characterised as 'unnecessary and unwarranted' and an 'abuse of a monopoly supply position', and providing 'no additional health benefit for patients'.¹⁷⁰⁸ Similarly, Flynn was aware of a GP's letter which noted that 'there is no generic market for phenytoin' due to the inability to switch patients taking Capsules to other phenytoin sodium products and the 'exploitation of this loophole has cost the NHS a serious amount of money when budgets are being reduced, has caused anxiety in people with epilepsy, and has no clinical justification whatsoever'.¹⁷⁰⁹ Despite being 'fully aware' of these 'legitimate concerns', Flynn did not reduce its prices in response to the DHSC or CCGs' requests for Flynn to do so,¹⁷¹⁰ nor did

¹⁷⁰³ See section 5. Flynn submitted that the profitability of Flynn's Products were entirely consistent with that of Flynn's other products (whether measured by reference to gross margin, product contribution or return on sales), and was consistent with industry norms in the generic sector more generally. Flynn also submitted that the allocation of common costs has a significant impact on the level of the alleged excesses in this case, and Flynn had no method of knowing the methodology that the CMA would adopt (PRC03495, Flynn's response to the DPS, paragraphs 3.73-3.74). As set out in section 5, the CMA considers there to be a number of conceptual flaws with the approach to determining a reasonable rate of return put forward by Flynn. Primarily, these are that an analysis of profit margins is not informative of how returns compare to investment and risk, and that Flynn's ROS comparisons do not control for the specific and unusual economics of Flynn's supply of Capsules. This includes that Flynn's profit margins are suppressed by the high input cost that it paid to Pfizer during the Relevant Period.

In relation to common costs, the CMA's analysis shows that its findings are unaffected by the choice of common cost allocation methodology.

¹⁷⁰⁴ See section 6.B.IV.b.

¹⁷⁰⁵ See section 6.B.IV.c. and Annex B and Annex C.

¹⁷⁰⁶ See Annex C and section 2.D.

¹⁷⁰⁷ See Annex B.

¹⁷⁰⁸ PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.527).

¹⁷⁰⁹ PHT00210, Letters published in the British Medical Journal on 22 January 2013, (CMA document reference 00020.2) and see Annex B.

¹⁷¹⁰ PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DHSC)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18).

it provide its cost of goods information to the DHSC despite several requests that it do so.¹⁷¹¹

9.45.4 Flynn knew or should have known that its prices were not justified by any feature of the product and its supply. In particular:

- (a) Flynn knew that Capsules were a very old drug¹⁷¹² that was long off-patent and in the third stage of the drug life cycle (where competition is expected to drive the prices of generic drugs down and result in ongoing low prices even where they continue to deliver benefits for patients);
- (b) Flynn knew that there had been no investment, innovation, or improvement to the product or its production or distribution which might justify its prices. Flynn stated that the product remained 'qualitatively and quantitatively identical in all but product name' to *Epanutin*.¹⁷¹³ Flynn undertook limited commercial activity in relation to Capsules and assumed 'very little business risk';¹⁷¹⁴ and
- (c) Flynn knew or should have known that patient benefit did not justify its high prices. Flynn knew that Capsules had long been superseded as a first-line treatment by other AEDs.¹⁷¹⁵ Flynn also acknowledged that the patient benefit provided by the drug had been declining in relative terms following 'the emergence of newer more effective' treatment options.¹⁷¹⁶ Capsules were generally only rarely prescribed to new patients as a treatment of 'last resort'.¹⁷¹⁷ As a result, Flynn knew that demand for Capsules was sustained predominantly by barriers to switching patients to other treatments,¹⁷¹⁸ not because of the therapeutic benefits of Capsules relative to other AEDs. Neither Flynn nor Pfizer added any additional benefits for patients beyond those that had been available through *Epanutin* for many decades.¹⁷¹⁹

9.45.5 The commercial purpose of the arrangements between Flynn and Pfizer was to remove Capsules from the constraints of the PPRS in order to increase prices to the NHS significantly, thereby generating substantial

¹⁷¹¹ See section 2.D and Annex C.

¹⁷¹² See PHT00401, Flynn internal document titled 'Phenytoin (2)' (CMA document reference 00145.827).

¹⁷¹³ PHT00212, Flynn Draft Communication Plan of August 2012 for the Introduction of Phenytoin Sodium Flynn Hard Capsules: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.581), page 2.

¹⁷¹⁴ See sections 5 and 6.B.V.b, and *Phenytoin* [2018] CAT 11, paragraph 346.

¹⁷¹⁵ See PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DHSC)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18), page 4.

¹⁷¹⁶ See PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DHSC)] re Flynn Pharma: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice information request of 26 June 2013 (CMA document reference 00367.18), page 4.

¹⁷¹⁷ See section 6.B.V.c.

¹⁷¹⁸ See paragraph 9.45.3.

¹⁷¹⁹ See section 6.B.V.

profits for Flynn and Pfizer.¹⁷²⁰ One of Flynn's [X] recognised, in an explanation to another shareholder, that 'there is tremendous scope to increase the price of the Capsules, which can only be done by [de-branding] the product'.¹⁷²¹ Flynn anticipated that the price increases would be unpopular due to the impact on the NHS and recognised that a key reason for its involvement in the supply of Capsules was to offer reputational protection for Pfizer.¹⁷²² For this reason, Flynn told Pfizer that it would publicly defend the price increase in order to shield Pfizer from the anticipated 'pharmacopolitical damage'.¹⁷²³ Regarding the possibility of Pfizer pursuing the price rise without Flynn, Flynn told Pfizer that 'it's ALL about reputation' and asked whether 'Pfizer execs want the Daily Mail camped on their doorstep[?]'.¹⁷²⁴ In another document, Flynn's other [X], considering the question of whether Pfizer might discontinue the arrangements, set out his view that: 'such a future scenario is implausible. Were it to be so, Pfizer would need [...] [to] return to the earlier NHS pricing and in effect, publicly acknowledge through its actions, that the original sale was an opaque arrangement to conveniently enhance their returns in the interim period'.¹⁷²⁵ Further, a 'Q&A' document prepared for use by employees staffing Flynn's telephone helpline recognised that Flynn could be asked by patients 'is this anti-competitive?' and 'is this just some kind of cosy relationship with Pfizer to implement a massive price increase?'.¹⁷²⁶

- 9.45.6 Flynn had anticipated the negative impact of its prices on CCGs and the NHS.¹⁷²⁷ The contemporaneous evidence shows that senior members of staff within Flynn had concerns regarding the level of the price increases and these concerns were expressly raised with Flynn's management shortly after Flynn's high prices were imposed. An email sent by [Flynn Employee 1], Flynn's [X], in October 2012 to [Flynn Director 2] (copying [Flynn Director 1]) states 'I still have reservations about the price level agreed with DH. I am not prepared to get into discussion and debate with customers about this'.¹⁷²⁸ Moreover, both the DHSC and customer

¹⁷²⁰ See section 6.B.VI.a, and *Phenytoin* [2018] CAT 11, paragraph 457.

¹⁷²¹ PHT00363, Email from [Flynn Director 2] (Flynn) to [Flynn Non-executive Director 1] dated 16 March 2010, Subject: 'Correction – capsules not tablets' (CMA document reference 00145.12).

¹⁷²² See section 6.B.VI.b.

¹⁷²³ PHT00164, Presentation slides entitled '*A Specialty Care Pharma Company*': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.27) and PHT00193, Document entitled '*Epanutin Proposal, October 2010*': Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.65).

¹⁷²⁴ PHT00198, Internal Pfizer e-mail [from: [Pfizer Employee 3] to: [Pfizer Director 1] and Pfizer Employee 2] of 17 June 2011 re Flynn and the possible advantages of going with Flynn re divestment: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.137).

¹⁷²⁵ See PHT00401, Flynn internal document titled '*Phenytoin (2)*' (CMA document reference 00145.827).

¹⁷²⁶ PHT00375, Flynn document titled '*Question & Answer Briefing Framework for Helpline Respondents*' (CMA document reference 00145.390).

¹⁷²⁷ See section 6.B.VII.

¹⁷²⁸ PHT00379, Email chain of 12 October 2012 between [Flynn Employee 1] (Flynn) and [Flynn Director 2] (Flynn), FW: Phenytoin Sodium Flynn hard capsules (CMA document reference 00145.477).

complaints sent to Flynn made clear the significant negative impact of the price increases on the NHS.¹⁷²⁹ For example, in an email sent by [X] CCG in October 2012 to Flynn, a deputy chief nurse noted that the price increase for an average sized CCG equates to hundreds of thousands of pounds of cost pressure.¹⁷³⁰

- 9.46 Flynn submitted that its conduct cannot be found to be intentional or negligent given ‘neither the DHSC ... nor the CMA was prepared to be forthcoming on the question of what was a lawful price’.¹⁷³¹ In this regard, Flynn pointed to its meetings with the DHSC in 2012, during which ‘the DHSC did not at any stage give Flynn any indication as to what it regarded as an acceptable price’; and to its meetings with the CMA in 2014 and 2021, during which the CMA ‘did not specify what it considered to be a non-excessive price’.¹⁷³²
- 9.47 The CMA does not accept these representations. First, the ‘special responsibility’ of dominant firms requires them to avoid exploitative abuses.¹⁷³³ As a dominant supplier, Flynn was under a duty to avoid charging unfairly high prices. It is clear from the evidence described above that Flynn knew or should have known that its prices were unfair, irrespective of whether the DHSC or the CMA specified a lawful price. For example, complaints from CCGs and other NHS stakeholders clearly contested Flynn’s Prices as unjustified.¹⁷³⁴ Notwithstanding this, Flynn continued to charge unfairly high prices. Second, in respect of the DHSC, it is not the responsibility of a customer to identify a price level that can be justified. In any event, it is clear that the DHSC challenged the high prices Flynn imposed as being, in its view, unjustified and asked Flynn for cost data to explain why its prices could be justified. As set out above, Flynn refused to provide this cost data. Third, in respect of the CMA, it is not for competition authorities to impose a particular course of action for undertakings from among all the various potential courses of action which would not breach competition law.¹⁷³⁵ Notwithstanding this, other than one reduction in April 2014,¹⁷³⁶ Flynn took no steps to materially amend its prices until required to do so by the Directions issued by the CMA in December 2016.

iv. Uncertainty

- 9.48 The Parties submitted that the law relating to unfair pricing was sufficiently uncertain that they could not reasonably have been expected to understand that their conduct was unlawful. In support of this argument, the Parties pointed to the

¹⁷²⁹ See Annex B and Annex C.

¹⁷³⁰ PHT00381, Email chain of 15 October 2012 between [X] and [Flynn Director 2] (Flynn), forwarding an email from [X] (Medicines Management Pharmacist) to Flynn, RE: Price change for phenytoin capsules (CMA document reference 00145.481).

¹⁷³¹ PRC03495, Flynn’s response to the DPS, paragraph 3.11.

¹⁷³² PRC03495, Flynn’s response to the DPS, paragraph 3.11.3.

¹⁷³³ *Justin Gutmann v First MTR South Western Trains Limited* [2021] CAT 31, paragraph 65.

¹⁷³⁴ See Annex B.

¹⁷³⁵ Case T-167/08 *Microsoft v Commission* ECLI:EU:T:2012:323, paragraph 95.

¹⁷³⁶ See section 2.D.II.

judgments of the CAT and the Court of Appeal, and to what they describe as changes in the CMA's case.¹⁷³⁷

- 9.49 The premise of the Parties' argument is mistaken, as it is not necessary for an undertaking to be aware of the law or the precise legal characterisation of its conduct in order for it to commit an intentional or negligent infringement. The relevant question is not whether Flynn and Pfizer knew or should have known that their prices were against the law, but instead whether they were, or should have been, aware that their conduct was anti-competitive or exploitative in nature.¹⁷³⁸ As set out above, the CMA has concluded that each of Flynn and Pfizer knew (or should have known) the essential facts relating to the anti-competitive or exploitative nature of their conduct. These essential facts described at paragraphs 9.41 to 9.46 above have remained the same throughout the original investigation, the appeals, and the Remittal Investigation.
- 9.50 Furthermore, unfair pricing is not a 'novel' legal concept or type of abuse. It has been recognised and included as a form of abuse of a dominant position since the creation in 1957 of the European Economic Community, the predecessor to the European Union, and has been part of domestic competition law since the enactment of the Act on 1 March 2000. It is explicitly listed as an abuse in the Chapter II prohibition (and in Article 102 TFEU). The legal test for excessive and unfair pricing was first set out by the Court of Justice in its seminal *United Brands* judgment in 1978,¹⁷³⁹ and still applies today.¹⁷⁴⁰
- 9.51 Protecting customers against exploitation is one of the underlying core purposes of competition law, and unfair pricing is an obvious example of such exploitation. Unfair pricing has been the subject of several UK and EU cases and decisions, and

¹⁷³⁷ The CMA does not agree with the Parties' characterisation of changes to the CMA's case. Pfizer stated that (i) 'having previously identified the tablet ASPs as a potential answer to the fact that Pfizer benchmarked against the [Drug Tariff] price tablets at trial, the Revised SO now abandons that argument altogether', and (ii) 'the CMA's case on the relevance of the tablet ASPs also rests on an *ex post* analysis of complex price and non-price information concerning the interactions between Teva and its competitors, which formed no part of the CMA's original case' (PRC03488, Pfizer's response to the SO and DPS, paragraphs 41(b)-(c)). Flynn stated that the CMA has reversed its position on 'material issues' including in particular whether or not the 'in itself' and 'competing products' tests were 'true alternatives' in the sense that if the CMA relied on one to find abuse then it had no obligation to evaluate other *prima facie* evidence that prices were fair (PRC03495, Flynn's response to the DPS, paragraphs 3.13-3.16).

¹⁷³⁸ See by analogy, *Generics (UK) Ltd v CMA* [2021] CAT 9 ('*Paroxetine*'), paragraphs 117 and 121. Flynn submitted that the correct legal test for establishing intention or negligence is whether the conduct was 'probably' or 'clearly' unlawful, based on the criteria set out by the CAT in *Sainsbury's v Mastercard* [2016] CAT 11 (PRC03495, Flynn's response to the DPS, paragraphs 3.2 to 3.3). The CMA rejects this argument. As confirmed by the CAT in *Paroxetine*, the relevant test for intent and negligence remains as set out at paragraphs 9.33 to 9.36 above. The judgment in *Sainsbury's* considers questions of intention and/or negligence in relation to the specific 'ex turpi causa' defence, which is not relevant to the present case.

¹⁷³⁹ Case C-27/79 *United Brands v Commission* EU:C:1978:22.

¹⁷⁴⁰ As recently confirmed by the Court of Appeal in *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 56.

the test for assessing unfair prices was sufficiently clear from the case law before the start of the Relevant Period.^{1741, 1742}

- 9.52 The fact that neither the CMA nor the courts had previously determined that prices having the same features as those at issue are abusive does not mean that Flynn and Pfizer's conduct was not intentional or, at the very least, negligent: it is not necessary to point to a precedent that is a carbon copy of the present case.¹⁷⁴³
- 9.53 Likewise, the fact that the 2016 Infringement Decision raised questions of law that were subsequently considered by the CAT and the Court of Appeal does not alter the CMA's conclusion that the Parties knew or should have known the essential facts justifying the CMA's finding of abuse. Clarifications made by the courts to the legal framework of assessment, (or even the prior absence of an established framework) do not make the finding of an infringement unforeseeable.¹⁷⁴⁴ More specifically, the gradual clarification of a legal concept by the courts¹⁷⁴⁵ does not mean that an undertaking adopting certain conduct¹⁷⁴⁶ which is clearly within the remit of a prohibition based on earlier case law,¹⁷⁴⁷ could not reasonably have foreseen that this prohibition was applicable to its conduct in principle.¹⁷⁴⁸ Indeed, the case law is clear that an infringement may be intentional or negligent in circumstances where there is no legal precedent, provided the undertaking knew or should have known that its conduct was of an anti-competitive nature.¹⁷⁴⁹ Intention or negligence relates to the facts, not to the law, and the fact that a particular case raises questions of law does not mean that the infringement was not intentional or negligent.
- 9.54 In the light of the above, in this case, the clarification of certain aspects of the *United Brands* test in the CAT and the Court of Appeal's judgments did not create any uncertainty during the Relevant Period with regard to the fact that exploiting a dominant position in order to impose unfair selling prices constitutes an infringement of competition law.
- 9.55 In any event, the CAT and Court of Appeal judgments were only issued after the end of the Relevant Period and could not, therefore, possibly have led to any uncertainty about the legal test to be applied in excessive pricing cases during the

¹⁷⁴¹ To name just a few: Case C-27/79 *United Brands v Commission* EU:C:1978:22, *Albion Water Ltd v Water Services Regulation Authority* [2008] CAT 31, *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, *Attheraces Ltd v British Horseracing Board Ltd* [2007] EWCA Civ 38.

¹⁷⁴² To name just a few: Case C-27/79 *United Brands v Commission* EU:C:1978:22, *Albion Water Ltd v Water Services Regulation Authority* [2008] CAT 31, *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, *Attheraces Ltd v British Horseracing Board Ltd* [2007] EWCA Civ 38.

¹⁷⁴³ See, for example, Case C-457/10P *AstraZeneca AB v Commission* EU:C:2012:770, paragraph 164.

¹⁷⁴⁴ See Case C-295/12 P *Telefónica SA v Commission* paragraphs 147 and 148 ECLI:EU:C:2014:2062 and Case T-612/17 *Google LLC v European Commission* ECLI:EU:T:2021:763 at paragraph 618.

¹⁷⁴⁵ Here: the application in practice of certain elements of the *United Brands* test.

¹⁷⁴⁶ Here: a dominant undertaking taking advantage of its market power to impose unfairly high prices without any corresponding increase in costs or other objective justification.

¹⁷⁴⁷ Here: the prohibition on imposing excessive and unfair prices.

¹⁷⁴⁸ See, to the same effect, *AC-Treuhand v Commission*, T-99/04, EU:T:2008:256, paragraphs 143 to 150.

¹⁷⁴⁹ *Generics (UK) Ltd v CMA* [2021] CAT 9 at paragraphs 123 and 125.

Relevant Period. Furthermore, Flynn's pricing conduct with regard to Capsules constituted an abuse within the meaning of the Chapter II prohibition under the *United Brands* test as applied during the Relevant Period (see 2016 Infringement Decision) as well as following the Court of Appeal's clarification of the law (for the reasons set out above).

- 9.56 More importantly still, the Court of Appeal's clarifications led to a more favourable interpretation of the law for the Parties than could have been assumed during the Relevant Period based on the wording of the legal test set out in *United Brands*. In these circumstances, there can be no scope to conclude that Pfizer and Flynn's Infringements could not have been committed intentionally or negligently.
- 9.57 In reaching this conclusion, the CMA has also considered the Parties' representations on Green LJ's judgment in 2019 regarding the CMA's application to amend its Grounds of Appeal.¹⁷⁵⁰ Green LJ simply noted that 'in deciding whether Pfizer acted negligently it remains open to Pfizer to refer to the CMA's position, and to uncertainty in the law as evidenced by changes in that position, as relevant and significant mitigation'. He did not suggest that either of these factors precluded a finding of intention or negligence on Pfizer or Flynn's part, and/or the imposition of a (substantial) penalty¹⁷⁵¹ and for the reasons set out above, the CMA concludes that they do not.
- 9.58 In considering the Parties' submissions regarding uncertainty, the CMA has also had regard to the significant volume of communications from clinicians and CCGs, as well as the clear and explicit dissatisfaction expressed by the DHSC at the time of the price increases.¹⁷⁵² In Flynn's words, it 'took a lot of criticism from payers and healthcare professionals regarding the price increase'.¹⁷⁵³
- 9.59 Whilst intention and negligence are not about an undertaking's awareness of the law but, rather, the facts, in this case there is nevertheless clear evidence that the Parties appreciated the possibility that their prices could constitute an infringement. The letter sent by the GMMM (and copied to both Parties) shortly after the beginning of Pfizer and Flynn's Infringements specifically raised the possibility that the price increases constituted an abuse of a dominant position.¹⁷⁵⁴ An internal

¹⁷⁵⁰ PRC03488, Pfizer's response to the SO and DPS, paragraph 42; PRC03495, Flynn's response to the DPS, paragraph 3.15.

¹⁷⁵¹ In granting the CMA's application, Lord Justice Green stated that: "*If the appeal is allowed ... then it seems to me that in deciding whether Pfizer acted negligently it remains open to Pfizer to refer to the CMA's position, and to uncertainty in the law as evidenced by changes in that position, as relevant and significant mitigation. ... [I]f and insofar as the CMA was then to adopt another decision [on remittal] to address and remedy defects identified in the Judgment, Pfizer could at that stage still pray in aid changes in the earlier position of the CMA as relevant.*" *CMA v Flynn Pharma Ltd* [2019] EWCA Civ 1631, paragraph 42.

¹⁷⁵² See Annex B and Annex C.

¹⁷⁵³ PHT00401, Flynn, *Phenytoin* (2) (CMA document reference 00145.827).

¹⁷⁵⁴ PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.527).

Pfizer email regarding a complaint noted that a medicines management customer was ‘very concerned [...] [a]buse of monopoly was an expression used!’¹⁷⁵⁵

9.60 In addition, Flynn’s contemporaneous documents demonstrate that it appreciated the possibility of its prices potentially constituting an infringement of competition law. For example, a non-executive director of Flynn recommended that Flynn seek legal advice regarding whether the Prices constituted an abuse of a dominant position,¹⁷⁵⁶ and a ‘Q&A’ document prepared for use by employees staffing Flynn’s telephone helpline included the questions ‘is this anti-competitive?’ and ‘is this just some kind of cosy relationship with Pfizer to implement a massive price increase?’.¹⁷⁵⁷ As noted above, the fact that questions were raised regarding the legality of the conduct (both by customers and, in Flynn’s case, by a director of the business¹⁷⁵⁸) supports a finding that the Parties could not have been unaware of the anti-competitive/exploitative nature of its conduct.¹⁷⁵⁹

9.61 For the reasons described above, the CMA has concluded that during the Relevant Period Pfizer knew (or should have known) all the essential facts which led the CMA to conclude that its conduct was anti-competitive in nature. Any change in the CMA’s case in litigation many years later does not change this, nor does it render the anti-competitive/exploitative nature of the Parties’ Prices during the Relevant Period unforeseeable.

v. *Tablets*

9.62 The Parties have submitted that, because they benchmarked their prices against the Drug Tariff price of Tablets, their conduct cannot have been intentional or negligent.¹⁷⁶⁰

9.63 The CMA does not accept the Parties’ submissions.

9.64 There were a number of objective factors which should have made the Parties aware that the Drug Tariff price was not an appropriate benchmark.

¹⁷⁵⁵ PHT00355, Email of 18 October 2012 from [Pfizer Employee] Pfizer to [[Pfizer Employee 2] and others] Pfizer (CMA document reference 00141.483). See also PHT00356, Email of 12 November 2012 from [Pfizer Employee] Pfizer to [Pfizer Employee 2] Pfizer (CMA document reference 00141.518): ‘[m]y Medicines Management customers in Manchester are having difficulty absorbing the price hike for Epanutin which for them represents hundreds of thousands of pounds in extra costs’.

¹⁷⁵⁶ PHT00126, Email chain of 24 October 2012 between [Flynn Non-executive Director 2] [REDACTED], [Flynn Director 1] Flynn and [REDACTED] [REDACTED] discussing the letter re the Abuse of Monopoly – Epanutin Marketing and Distribution Changes and Flynn: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00145.535).

¹⁷⁵⁷ PHT00375, Flynn document titled ‘Question & Answer Briefing Framework for Helpline Respondents’ (CMA document reference 00145.390).

¹⁷⁵⁸ PHT00126, Email chain of 24 October 2012 between [Flynn Non-executive Director 2] [REDACTED], [Flynn Director 1] Flynn and [REDACTED] [REDACTED] discussing the letter re the Abuse of Monopoly – Epanutin Marketing and Distribution Changes and Flynn: Flynn’s response of 21 June 2013 to the OFT’s s.27 Notice information request of 8 May 2013 (CMA document reference 00145.535).

¹⁷⁵⁹ Case C-591/16P *Lundbeck v Commission* ECLI:EU:C:2021:243, paragraph 164 and Case C-614/16P *Merck v Commission* ECLI:EU:C:2021:246, paragraph 132.

¹⁷⁶⁰ PRC03488, Pfizer’s response to the SO and DPS, paragraphs 11 and 44. PRC03495, Flynn’s response to the DPS, paragraph 3.7.1.

- 9.65 First, the Parties knew that Tablets were subject to the same clinical guidance advising against switching as Capsules.¹⁷⁶¹ Given the impact of the guidance on competition for the supply of Capsules, they would have been aware of the potential for the guidance to have a distortive effect on competition between Tablets suppliers.
- 9.66 Second, the Parties were also aware that the price of Capsules had been significantly increased by Teva ahead of its meeting with the DHSC. Furthermore, it was publicly available information that, at £30, the Drug Tariff price remained significantly above the prices paid by the NHS previously.
- 9.67 The combination of these two factors should have raised immediate concerns regarding the use of Tablets as a benchmark for a fair price. Pfizer's internal documents show that, in practice, it did recognise the result as being unusual. Pfizer's internal documents describe the level of the £30 Drug Tariff price as an 'anomaly'.¹⁷⁶² [Pfizer Director 1] likewise described the difference between the Drug Tariff prices for Capsules and Tablets at this time as being 'quite different from what you would normally expect'.¹⁷⁶³
- 9.68 Third, the Parties knew that a comparison between the Parties' supply prices for Capsules and the Drug Tariff price for Tablets was not a 'like for like' comparison. The Drug Tariff price was downstream from the Parties' supply prices and Tablets were priced under a different regulatory framework to Capsules (ie Tablets were included in scheme M). As a result, the Drug Tariff price was likely to be significantly above actual supply prices for Scheme M drugs.¹⁷⁶⁴
- 9.69 Fourth, the Parties knew that the volume of Tablets dispensed was substantially lower than that of Capsules, and therefore that the drugs differed significantly in terms of their overall cost to the NHS.¹⁷⁶⁵
- 9.70 Furthermore, the Parties' reliance on the £30 Drug Tariff price of Tablets is based on their view that this reflected the DHSC's assessment of the value of the drug and was what the DHSC had determined it was happy with and was willing to

¹⁷⁶¹ PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31), ("Industry has, rightly, made a big deal of epilepsy drugs being one of the key medicines where you shouldn't mess with the presentation that a patient is stabilised on – with a great deal of expert medical and pharmacy support.")

¹⁷⁶² PHT00076, Internal Pfizer email chain of 22 September 2009 [from [Pfizer Director 1] to [Pfizer Employee 2]] re Epanutin 'Adoption' Deal: Pfizer's response of 18 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00141.31).

¹⁷⁶³ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 40, lines 20-23.

¹⁷⁶⁴ As explained by the PSNC in its published guidance, the DHSC often sets category M reimbursement prices at levels substantially above the upstream supply prices. See PAD00020, PSNC, *Retained margin (Category M)*. The [Former Teva Director] also described the reimbursement prices for category M drugs as being 'significantly higher' than suppliers' selling prices, with at one stage category M drug tariff prices being 'two or three times higher than the prices that were being provided by generics companies', PAD00030, [Former Teva Director] Cross Examination, day 5, page 15, lines 9-13. A report by Oxera found that the retained margin uplift to Category M Drug Tariff prices is on average in the region of 100%: PAD00004, Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 2.27.

¹⁷⁶⁵ See section 6.C.II and Annex C.

pay.¹⁷⁶⁶ The Parties adopted this view without having participated in or having any direct knowledge of the meeting between Teva and the DHSC five years earlier on which they rely to support their view. Before the CAT, [Pfizer Director 1] explained that ‘this was the conclusion I drew from what we [sic] actions we saw in the marketplace’.¹⁷⁶⁷ [Pfizer Director 1] confirmed that Pfizer did not speak to anyone from Teva or the DHSC about what happened at the meeting and that Pfizer relied purely on an inference relating to the outcome of the meeting.¹⁷⁶⁸ However, there is a significant body of contemporaneous evidence showing that the DHSC and CCGs were not willing to pay the Parties’ increased prices and raised strong concerns with the Parties both before and shortly after they imposed their price increases. The Parties’ assumptions and inferences regarding the DHSC’s apparent willingness to pay their prices wilfully ignored the objections and concerns raised by the DHSC itself, as well as CCGs (which bore the cost of the higher prices), all of which directly contradicted the Parties’ sole justification for the price increases imposed.

- 9.71 The multiple events which should have made the Parties aware that the DHSC and CCGs were not happy with and willing to pay their prices are comprehensively set out in Annex B and Annex C to this Decision.
- 9.72 Whilst Flynn, as the final supplier to wholesalers and pharmacies, was in direct contact with and attended two separate meetings with the DHSC, there were also a significant number of events which made, or should have made, Pfizer aware of the concerns.¹⁷⁶⁹ These include: the previous discussions between Pfizer’s finance team and the DHSC described by [Pfizer Director 1]; the letter sent to Pfizer by the GMMMG on 10 October 2012 (as well as other complaints from CCGs directly to Pfizer); and the discussion between the DHSC and Pfizer on 10 January 2013. Furthermore, it is also reasonable to assume that at a meeting on 12 November 2012¹⁷⁷⁰ (six days after Flynn’s meeting with the DHSC), Flynn communicated the DHSC’s concerns to Pfizer following its discussions with the DHSC.¹⁷⁷¹
- 9.73 Notwithstanding the Parties’ submissions regarding the DHSC’s willingness to pay their prices, [Flynn Director 2] (one of Flynn’s [X]) confirmed that DHSC had made it clear they were ‘very unhappy’ with the increased prices. [Flynn Director 2] also confirmed that, following the meeting with the DHSC in November 2012, he understood that the DHSC was not happy with the use of the Tablets Drug Tariff price as a benchmark.¹⁷⁷² The CAT also concluded that Flynn was aware of the DHSC’s opposition to the price increases: ‘[w]hen it was suggested by the MHRA

¹⁷⁶⁶ See section 6.C.II.

¹⁷⁶⁷ PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 47, lines 11-12.

¹⁷⁶⁸ See PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 37 lines 24 and 25 and page 38, lines 1-3.

¹⁷⁶⁹ See further Annex B and Annex C.

¹⁷⁷⁰ PHT00055, Email between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH) forwarding on email from Flynn following on from the meeting on 6th November 2012 (DH15) (CMA document reference 00367.17).

¹⁷⁷¹ Pfizer did not submit otherwise in its response to the CMA’s DPS (in which the CMA made this same point at paragraph 1.33.2).

¹⁷⁷² PAD00031, [Flynn Director 2] Cross Examination, day 4, page 158, lines 16 to 20 and page 167, lines 8 to 14.

that Flynn should approach the DH to discuss pricing, it was made clear to Flynn by the DH that it was not happy either with the Tablet price or with Flynn's increased capsule prices'.¹⁷⁷³

- 9.74 However, despite this evidence showing that the DHSC, and other key stakeholders, did not accept the scale of the price increases, and the fact a more reasonable course of action was available to the Parties (by reducing their prices and engaging constructively with DHSC¹⁷⁷⁴), the Parties continued to impose their high prices and did not engage constructively or sufficiently with the DHSC to resolve what Flynn noted were 'legitimate concerns' regarding the prices it was imposing.
- 9.75 Nor did the Parties re-engage in discussions with the DHSC after the OFT opened its investigation in May 2013, or at any stage of the subsequent the OFT and CMA investigation. The failure of the Parties to re-engage with the DHSC further undermines the force of their claim that the Tablets Drug Tariff Price was an appropriate benchmark for them to use and had been relied upon in "good faith". If they believed this, given the obvious discrepancy between their understanding of the DHSC's views on Tablets and the position the DHSC took in practice, they would have been expected to have contacted the DHSC to gain its views, and potentially its support, on this point.
- 9.76 Instead, despite the significant body of evidence that showed DHSC objected to the use of the Tablets Drug Tariff price as a price benchmark, the Parties continued to impose their very high prices, believing it was reasonable, instead, to rely upon an inference drawn from what happened to the Tablets Drug Tariff price following the meeting between Teva and DHSC in October 2007.
- 9.77 In light of these factors, the CMA does not accept the Parties' submissions that their conduct was neither intentional nor negligent on the basis that they increased their prices by reference to the Drug Tariff price of Tablets.

vi. Conclusion on intention and negligence

- 9.78 In light of the above, the CMA concludes that Flynn and Pfizer each committed their respective Infringements intentionally or, at least, negligently.
- 9.79 As a result, the CMA has discretion as to whether to impose a penalty on Flynn and Pfizer in respect of their respective Infringements and, if so, what the appropriate amount of a penalty under the Act would be.

¹⁷⁷³ *Phenytoin* [2018] CAT 11, paragraph 232.

¹⁷⁷⁴ This possibility had been raised by the GMMM in its letter to the Parties on 10 October 2012. The letter from the GMMM set out that '[t]he only credible alternative is that the companies must make a case for a **modest** price increase, but this must stand up to economical and clinical justification'. See further Annex C.

9.80 The CMA considers that it is appropriate in the circumstances of this case to exercise its discretion under section 36(1) of the Act to impose substantial penalties on both Flynn and Pfizer in respect of their respective Infringements, given the seriousness of these Infringements and in order to deter similar conduct in the future.

D. Calculation of financial penalties

I. Summary of the CMA's penalty calculation

- 9.81 To address the fact that all four of Pfizer's Infringements took place in the same relevant product and geographic market, in line with its margin of appreciation, the CMA has chosen to issue one single fine in relation to all four of Pfizer's Infringements. It has used Pfizer's relevant turnover for all of its UK sales of Capsules when calculating the appropriate amount of the penalty for Pfizer, effectively treating all four of Pfizer's Infringements as one single infringement for penalty purposes. This approach is favourable to Pfizer as separate penalties for each individual infringement may well have resulted in a higher overall penalty.
- 9.82 Similarly, to address the fact that all four of Flynn's Infringements also took place in the same relevant product and geographic market, in line with its margin of appreciation, the CMA has chosen to issue one single fine in relation to all four of Flynn's Infringements. It has used Flynn's relevant turnover for all of its UK sales of Capsules when calculating the appropriate amount of the penalty for Flynn, effectively treating all four of Flynn's Infringements as one single infringement for penalty purposes. This approach is favourable to Flynn, as separate penalties for each individual infringement may well have resulted in a higher overall penalty. In particular, the application of the statutory cap in step 5 of the penalty calculation separately to each of Flynn's individual Infringements, could have well led to a total final penalty exceeding 10% of Flynn's worldwide turnover in its last business year.¹⁷⁷⁵
- 9.83 The following tables set out a summary of the CMA's penalty calculations for Flynn and Pfizer. The remainder of this section then explains the penalty calculations.

¹⁷⁷⁵ The statutory cap (section 36(8) of the Act) applies separately to each separate infringement found by the CMA. See, eg Barrett Estate Services Ltd and Others v. Office of Fair Trading [2011] CAT 9 at 36: 'We agree with the OFT that the evidence in this case did not support a finding of a single continuous infringement, and accordingly that it was entitled to impose a separate penalty in respect of each individual infringement. It is clear from section 36 of the 1998 Act that the ceiling of 10% only applies to fines imposed for infringement of the Chapter I and II prohibitions (and, where applicable, Articles 101 and 102 TFEU) and that it applies to each separate infringement of those prohibitions.'

Table 9.1: Summary of the CMA's penalty calculations in respect of Pfizer

Step'	Description	Calculation
	Relevant turnover	£12,006,702
1	Starting point	30%
	Penalty after step 1	£3,602,011
2	Adjustment for duration	4.25
	Penalty after step 2	£15,308,545
3	Adjustment for aggravating and mitigating factors	10% uplift
	Penalty after step 3	£16,839,400
4	Adjustment for specific deterrence and proportionality	Adjustment required
	Penalty after step 4	£63,300,000
5	Adjustment to ensure statutory cap is not exceeded	No adjustment required
	Penalty after step 5	£63,300,000
6	Adjustment for leniency and/or settlement	No adjustment required
	Final penalty	£63,300,000

Table 9.2: Summary of the CMA's penalty calculations in respect of Flynn

Step	Description	Calculation
	Relevant turnover	£20,611,428
1	Starting point	30%
	Penalty after step 1	£6,183,428
2	Adjustment for duration	4.25
	Penalty after step 2	£26,279,571
3	Adjustment for aggravating and mitigating factors	10% uplift
	Penalty after step 3	£28,907,528
4	Adjustment for specific deterrence and proportionality	No adjustment to below the statutory cap required
5	Adjustment to ensure statutory cap is not exceeded	Adjustment required
	Penalty after step 5	£6,704,422
6	Adjustment for leniency and/or settlement	No adjustment required
	Final penalty	£6,704,422

II. Step 1 – starting point

9.84 The starting point for determining the level of financial penalty which will be imposed on an undertaking is calculated having regard to (i) the relevant turnover of the undertaking; and (ii) the seriousness of the infringement and the need for general deterrence.¹⁷⁷⁶

a. Relevant turnover

9.85 The relevant turnover is the turnover of the undertaking in the relevant product and geographic market affected by the infringement in the undertaking's last business year. In this context, an undertaking's last business year is the financial year preceding the date when the infringement ended.¹⁷⁷⁷

9.86 The Relevant Period for the purposes of this Decision is the period 24 September 2012 to 7 December 2016.

¹⁷⁷⁶ CMA penalties guidance, paragraph 2.3.

¹⁷⁷⁷ CMA penalties guidance, paragraph 2.11. Relevant turnover is calculated after the deduction of sales rebates, value added tax and other taxes directly related to turnover.

- 9.87 Accordingly, in calculating Pfizer and Flynn’s respective penalties, the CMA has used the relevant turnover of Pfizer in the financial year ending 31 December 2015 and the relevant turnover of Flynn in the financial year ended 31 March 2016.
- 9.88 The relevant markets affected by Pfizer and Flynn’s Infringements are the markets for the manufacture of Capsules for distribution in the UK, and the distribution of Capsules in the UK.¹⁷⁷⁸
- 9.89 Accordingly, based on the financial data provided to the CMA in this case, the CMA has used a figure of £12,006,702 as Pfizer’s relevant turnover and a figure of £20,611,428 as Flynn’s relevant turnover.
- b. Seriousness of Pfizer and Flynn’s Infringements and the need for general deterrence**
- 9.90 The CMA will apply a rate of up to 30% to an undertaking’s relevant turnover in order to reflect the seriousness of the particular infringement (and ultimately the extent and likelihood of actual or potential harm to competition and consumers). In applying the starting point, the CMA will also reflect the need to deter the infringing undertaking and other undertakings generally from engaging in that type of conduct in the future.¹⁷⁷⁹
- 9.91 In making this case-specific assessment, the CMA will take into account how likely it is that the type of infringement at issue will, by its nature, cause harm to competition and consumers. As set out in its penalties guidance, the CMA will generally use a starting point between 21% and 30% for the most serious types of infringement, including hardcore cartel activity and the most serious abuses of a dominant position.¹⁷⁸⁰ In relation to infringements of the Chapter II prohibition, this will typically include conduct which is inherently likely to have a particularly serious exploitative or exclusionary effect, such as excessive and predatory pricing.¹⁷⁸¹
- 9.92 The CMA will also consider whether it is appropriate to adjust the starting point upwards or downwards to take account of the specific circumstances of the case that might be relevant to the extent and likelihood of harm to competition and ultimately to consumers.¹⁷⁸²
- 9.93 Finally, the CMA will consider whether the starting point for a particular infringement is sufficient for the purpose of general deterrence. In particular, the

¹⁷⁷⁸ *Phenytoin* [2018] CAT 11, paragraphs 68(3) and 198.

¹⁷⁷⁹ CMA penalties guidance, paragraph 2.4.

¹⁷⁸⁰ CMA penalties guidance, paragraph 2.6.

¹⁷⁸¹ CMA penalties guidance, paragraph 2.6.

¹⁷⁸² CMA penalties guidance, paragraph 2.8: these circumstances may include, for example, the nature of the product, the structure of the market (including the market shares of the undertaking(s) involved in the infringement), the actual or potential effect on competitors and third parties, and the actual or potential harm caused to consumers.

CMA will consider the need to deter other undertakings, whether in the same market or more broadly, from engaging in the same or similar conduct.¹⁷⁸³

i. The likelihood of unfair pricing, by its nature, to have a particularly serious exploitative effect

- 9.94 Pfizer and Flynn's Infringements involve unfairly high pricing, which the CMA considers amounts to one of the most serious forms of abuse of a dominant position,¹⁷⁸⁴ especially in a case like this, where it caused direct and considerable harm to the NHS and to patients. The CAT has confirmed that unfairly high pricing may constitute a serious abuse.¹⁷⁸⁵
- 9.95 Protecting consumers from exploitation is one of the core aims of competition law.¹⁷⁸⁶ Unfair pricing, by its very nature, goes to the heart of one of the key harms that competition law is designed to avoid – namely, consumers (especially end customers) being exploited by unfair prices.
- 9.96 While other types of abuses of dominance (ie exclusionary conduct such as predatory pricing) and cartels seek to restrict competition with a view to the infringing parties being able to charge artificially/excessively high prices, companies involved in unfair pricing directly exploit the absence of (effective) competition to impose such prices.
- 9.97 The prices resulting from unfair pricing can be, and the CMA considers in this case were, considerably higher than those which might usually be achieved through many forms of exclusionary conduct or the cartelisation of a market. Further, the harmful effects of unfair pricing are often more sustainable and persist for longer than other forms of serious anti-competitive practice such as cartelisation, and do not require undertakings to incur the risks and costs normally associated with such other forms of anti-competitive practice (for example, the risk that one of the cartelists may apply for leniency, and the costs of monitoring compliance with the cartel).
- 9.98 Consequently, the CMA considers that the harm to consumers which results from unfair pricing is amongst the most serious types of harm caused by any form of anti-competitive practice, and unfair pricing constitutes one of the most serious abuses of a dominant position.
- 9.99 The CMA therefore considers that a starting point of 30% should be applied to both Pfizer and Flynn in this case.

¹⁷⁸³ CMA penalties guidance, paragraph 2.9.

¹⁷⁸⁴ CMA penalties guidance, paragraph 2.6.

¹⁷⁸⁵ *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, paragraph 531.

¹⁷⁸⁶ See, eg *Attheraces Ltd v British Horseracing Board Ltd* [2007] EWCA Civ 38, paragraph 119: 'Fourthly, it has to be borne in mind that, as stated in Bronner, the law on abuse of dominant position is about distortion of competition and safeguarding the interests of consumers in the relevant market' (emphasis added).

ii. Harm to competition and consumers in the specific relevant circumstances

9.100 The CMA considers that the specific circumstances of Pfizer and Flynn's Infringements were such that the harm to the NHS and patients was significant.

Nature of the product (including nature and extent of demand)

9.101 Capsules are used to treat epilepsy, a serious neurological condition.

9.102 They are an old generic drug, long off-patent, and used as a third-line treatment for epilepsy, having been superseded by other AEDs as a first-line treatment. The Parties made no improvements to the product nor created any additional benefits for patients.

9.103 Notwithstanding this, approximately 57,500 patients in the UK were treated with Capsules in 2012, and for patients who are stabilised on the product ensuring a stable course of treatment is essential to maintaining their quality of life.¹⁷⁸⁷

9.104 There is longstanding clinical guidance advising against switching patients between different manufacturers' phenytoin products, including between different manufacturers' phenytoin sodium capsules, due to phenytoin sodium's NTI and non-linear pharmacokinetics.¹⁷⁸⁸ In addition, there are clinical and patient concerns around switching patients stabilised on phenytoin sodium to alternative AEDs or ceasing treatment altogether.¹⁷⁸⁹

9.105 The ability of CCGs to avoid the significant cost increase was therefore severely restricted by the nature of the product and their inability to switch to alternative products. At the same time, the harm caused to patients was also exacerbated by the fact that those stabilised on the product could not switch away and the unfairly high prices therefore affected the other treatments/medication that CCGs could provide.

The structure of the market including market shares and barriers to entry

9.106 Throughout the Relevant Period Pfizer held a monopoly in the market for the manufacture of Capsules that are distributed in the UK¹⁷⁹⁰ and Flynn held a very significant share (between 64% and 90% by number of Capsules) of the market for the distribution of Capsules in the UK.¹⁷⁹¹ As a result, the market coverage of Pfizer and Flynn's Infringements was extensive and they were likely to cause harm to a large number of CCGs and, ultimately, patients.

¹⁷⁸⁷ See section 2.A.VI.

¹⁷⁸⁸ See section 2.A.V.

¹⁷⁸⁹ See section 2.A.VI.

¹⁷⁹⁰ See section 3.

¹⁷⁹¹ 2016 Infringement Decision, CE/9742-13, paragraph 4.216.

- 9.107 Entry conditions in the markets for the manufacture and distribution of phenytoin sodium capsules were not conducive to new entrants, or to expansion by existing competitors. The CAT previously noted that the existence of ‘high barriers to entry’ were supportive of its finding of dominance.¹⁷⁹² Consistent with this, there was no competitive entry during the Relevant Period which was able to constrain sufficiently either Pfizer’s Prices or Flynn’s Prices. The Parties were, therefore, able to sustain unfairly high prices for over four years.
- 9.108 The guidance on Continuity of Supply had a significant impact, in practice, on pharmacists’ dispensing practice and meant that Flynn’s customer base in the UK was to a significant degree guaranteed.¹⁷⁹³ Continuity of Supply therefore operated as a significant barrier to entry¹⁷⁹⁴ and allowed the Parties to behave to an appreciable extent independently of customers (CCGs), consumers (patients) and, in Flynn’s case, competitors.¹⁷⁹⁵
- 9.109 Furthermore, the Parties envisaged that the design of the commercial arrangements (ie to transfer the MAs to Flynn enabling Flynn to register a trademark) themselves would provide additional protection for their prices from parallel imports by raising barriers to competition.¹⁷⁹⁶

The actual effect of Pfizer and Flynn’s Infringements on end customers and patients

- 9.110 Unfair pricing causes direct harm to customers and consumers through the charging of artificially high prices. As set out above, Pfizer and Flynn’s Infringements imposed direct and substantial harm on the end customer – the NHS – and in particular on the direct purchasers such as CCGs as well as consumers (here patients).¹⁷⁹⁷
- 9.111 Despite the significant scale of the NHS budget, legitimate demands for healthcare will always exceed its level and resources have to be prioritised.¹⁷⁹⁸ Pfizer and Flynn’s Infringements resulted in the NHS paying significantly more for all strengths of Capsules when compared to the prices that the NHS was paying prior to September 2012, without any objective justification for the unfairly high prices charged. Prior to September 2012, the NHS’s annual spend on Capsules was approximately £2 million; in contrast, following the price increases the NHS’s annual spend on Capsules was £50 million in 2013, £42 million in 2014, £37 million in 2015, and £35 million in 2016.¹⁷⁹⁹

¹⁷⁹² *Phenytoin* [2018] CAT 11, paragraph 250.

¹⁷⁹³ *Phenytoin* [2018] CAT 11, paragraphs 150 and 346.

¹⁷⁹⁴ *Phenytoin* [2018] CAT 11, paragraph 151.

¹⁷⁹⁵ *Phenytoin* [2018] CAT 11, paragraph 251.

¹⁷⁹⁶ See section 6.B.IV.a and *Phenytoin* [2018] CAT 11, paragraph 151.

¹⁷⁹⁷ See section 6.B.VII.

¹⁷⁹⁸ See section 6.B.VII.

¹⁷⁹⁹ See section 6.B.VII. and Table 6.6.

- 9.112 The practical consequence of these increased costs was that CCGs had to relocate funding from other services and treatments. The consumer harm arising from Pfizer and Flynn's Infringements is not only the pecuniary effect of high prices on the resources of the NHS (although that is serious enough) but also the consequent effect on the health and well-being of patients affected by the reallocation of resources, and therefore on public health overall.¹⁸⁰⁰
- 9.113 The evidence provided by CCG representatives underscores the impact of Pfizer and Flynn's Infringements:
- 9.113.1 [X] of the GMMM¹⁸⁰¹ explained that 'this will have impacted on the range of services the [Greater Manchester] CCGs could provide to patients and money which was earmarked for different treatments would have been diverted to cover the additional costs for Phenytoin Capsules. Other patients will have had their treatments delayed, stopped or changed as a result.'¹⁸⁰¹
- 9.113.2 [X] of Somerset CCG noted that '[t]he approximate £1.2 million spent on phenytoin capsules over the period from September 2012 to [January 2017] has meant that Somerset CCG has been unable to spend that money on commissioning other elements of patient care and at a time of growing demand on the NHS, the additional costs has contributed to the Somerset CCG now having a forecast deficit on its budget, which places additional pressures on the CCG and healthcare staff within Somerset.'¹⁸⁰²
- 9.113.3 Immediately after the price increases, the Grafton Group of six CCGs wrote to the Chief Pharmaceutical Officer stating that this 'increase in cost will provide no additional health benefit for patients, but will undoubtedly compromise other services that we will not be able to afford to commission as a result'.¹⁸⁰³
- 9.114 The Parties were also made aware of the detrimental impact of their significant prices increases on the NHS and patients at the time of their price increases. In November 2012, the DHSC had warned Flynn that the price increases imposed 'made the total cost very difficult for them, more visible and hitting hard NHS pockets'.¹⁸⁰⁴ Furthermore, complaints raised by clinicians and CCGs immediately

¹⁸⁰⁰ *Flynn v CMA*, Judgment on Interim Relief, [2017] CAT 1, paragraph 105.

¹⁸⁰¹ PRE00004, First Witness Statement of [X], 10 January 2017, paragraph 11.

¹⁸⁰² PRE00003, First Witness Statement of [X], 10 January 2017, paragraph 16.

¹⁸⁰³ PHT00118, Letter of 25 October 2012 from Nene CCG to [X] regarding Epanutin; Changes of Marketing Distribution; Impact on UK Patients: Enclosed with Nene CCG's e-mail of 10 July 2013 to the OFT about the Epanutin price increase (CMA document reference 00210.2).

¹⁸⁰⁴ PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

after the price increases raised strong concerns regarding the harm to the NHS and patients.¹⁸⁰⁵

iii. General deterrence

9.115 The CMA has also taken into account whether the starting point is sufficient to deter other undertakings, whether in the same market or more broadly, from engaging in the same or similar conduct.¹⁸⁰⁶

9.116 Unfairly high pricing by definition generates significant excess profits for undertakings which engage in such conduct. Since the potential gains from such conduct are so great, the CMA considers that a high starting point is appropriate in order to ensure that other dominant firms are deterred from imposing unfair prices in particular if, like here, they are unavoidable trading partners for captive customers.

9.117 Penalties need to be sufficiently high to signal the importance and moral obloquy attached to the infringement, and to reinforce to undertakings generally that engagement in such conduct will, if detected, carry serious consequences for the undertakings that engage in them. The deterrence of excessive costs being imposed on the NHS through anti-competitive and/or exploitative practices is a significant part of how the CMA seeks to achieve its publicly stated objective of protecting vulnerable consumers.¹⁸⁰⁷

9.118 Pfizer and Flynn's Infringements are unlikely to be an isolated example of such conduct within the pharmaceutical sector in the UK and more broadly in other industries: similar cases have been, or are being, investigated in the UK, by the European Union, and in EU member states.¹⁸⁰⁸ As set out in section 2.B.II, the profit opportunities associated with niche generics such as phenytoin sodium are widely recognised within the pharmaceutical industry.

9.119 The CMA has also had regard to the changes to the DHSC's powers following the amendments to the NHS Act introduced by the Costs Act. As discussed in section 2.C.II.i above, and below at paragraph 9.189.3, these powers are as yet untested, and will not be exercised before the DHSC has had the opportunity to undertake a period of consultation. If the CMA were to reduce the starting point on the basis of

¹⁸⁰⁵ See Annex B.

¹⁸⁰⁶ CMA penalties guidance, paragraph 2.9.

¹⁸⁰⁷ See eg CMA Annual Plan 2020/21, §3.10 and CMA Annual Plan 2019/20, §2.28; the need to protect vulnerable consumers has also been emphasised by the Secretary of State for Business, Energy and Industrial Strategy, *Modernising Consumer Markets – Consumer Green Paper*, April 2018, Annex A, p.68.)

¹⁸⁰⁸ See, for example, Italian Competition Authority (AGCM): 'A480 – Price increase of Aspen's drugs', Measure No. 26185, the decision against the multinational pharmaceutical company Aspen of 29 September 2016 (appeal by Aspen dismissed by the Consiglio di Stato on 13 March 2020); and Danish Competition and Consumer Authority (KFST): 'CD Pharma has abused its dominant position by increasing their price by 2,000 percent', Case no. 14/08469, CD Pharma's pricing of Syntocinon. See also the CMA's decisions in Case 50277: Hydrocortisone tablets, 15 July 2021, and Case 50395: Liothyronine tablets, 29 July 2021. See also Case AT.40394: Aspen, Commission decision, 10 February 2021.

the mere possibility of future regulatory intervention, then the impact of the penalty in terms of general deterrence would be significantly weakened.

9.120 In any event, even if the DHSC was in a position to exercise these powers immediately, this would not change the CMA's conclusion that a starting point of 30% is appropriate. That is because general deterrence does not solely seek to deter undertakings within a particular sector or industry; rather, the CMA's objective is to deter other dominant undertakings from engaging in the same or similar conduct, regardless of the relevant product or service.¹⁸⁰⁹ The DHSC's expanded powers are limited to the pharmaceutical sector, and therefore have no deterrent effect on undertakings outside that industry.

iv. Parties' representations

9.121 Both parties submitted that the 30% starting point is too high in light of (i) the nature of the Infringements; (ii) the specific facts of the case; and (iii) the need for general deterrence.¹⁸¹⁰

9.122 In relation to the nature of the Infringements, Flynn submitted that a starting point of 30% should be reserved for 'clear cut' infringements of competition law; if the highest starting point was routinely selected, the CMA would be left with no remaining room to mark out the seriousness of the 'very worst cases' such as hard-core horizontal cartels.¹⁸¹¹ Flynn also claimed that a 30% starting point is inconsistent with the CMA's past decisional practice.¹⁸¹²

9.123 Similarly, Pfizer submitted that the CMA's conclusion that the starting point should be higher for excessive pricing than for other hardcore infringements cannot be justified: cartels involved dishonesty and secrecy, whereas Pfizer's prices were fully transparent.¹⁸¹³

9.124 As regards the specific facts of the case, the Parties submitted that the CMA cannot treat Pfizer and Flynn's Infringements as being more serious because they relate to a pharmaceutical product used to treat a serious neurological disorder, or because the ultimate purchaser was the NHS. Flynn further submitted that its conduct in fact secured the long-term supply of Capsules to patients in the UK when the future of the product was otherwise uncertain.¹⁸¹⁴

¹⁸⁰⁹ See, for example, *Ping Europe Limited v CMA* [2018] CAT 13, paragraph 241: '[t]he CMA was also correct to consider deterrence on Ping, other golf club manufacturers and other manufacturers and wholesalers in retail sectors more generally. Whilst objective justification and individual exemption are fact-specific exercises, the fine should deter other manufacturers from engaging in similar conduct...'.
¹⁸¹⁰ PRC03488, Pfizer's response to the SO and DPS, paragraph 45(b)(i); and PRC03495, Flynn's response to the DPS, paragraph 4.2.
¹⁸¹¹ PRC03495, Flynn's response to the DPS, paragraph 4.2.
¹⁸¹² PRC03495, Flynn's response to the DPS, paragraph 4.4.
¹⁸¹³ PRC03488, Pfizer's response to the SO and DPS, paragraph 45(b)(i).
¹⁸¹⁴ PRC03495, Flynn's response to the DPS, paragraph 4.7.1 and 4.9.2.

- 9.125 Regarding the need for general deterrence, Pfizer submitted that, in light of the CMA's investigations since 2012, participants in the pharmaceutical market were now 'fully aware of the risks of excessive pricing'; consequently, there is no need to impose a large fine in order to underline this risk.¹⁸¹⁵ In addition, both Parties submitted that the existence of the DHSC's new powers was an important factor mitigating against the need for general deterrence.¹⁸¹⁶
- 9.126 The CMA does not accept these representations.
- 9.127 First the CMA agrees that 'hard core' horizontal cartel activities are among the most serious type of infringement; it disagrees, however, that this means that unfair pricing must be given a lower starting point. The CMA penalties guidance is clear that the CMA will generally use a starting point between 21–30% for conduct that is inherently likely to have a serious exploitative effect, such as excessive pricing. There is no need for 'head room' for the CMA to mark out the 'very worst cases', since unfair pricing is one of those. Further, the CMA does not accept Pfizer's argument that its conduct should be distinguished from other hardcore infringements on the basis that its prices 'were fully transparent'. The impact of exploitative pricing on consumers is not lessened by a dominant undertaking's openness in charging unfair prices. On the contrary, as noted above, prices resulting from unfair pricing can be, and the CMA considers in this case were, considerably higher than those which might usually be achieved through many forms of exclusionary conduct or the cartelisation of a market, and, as set out in paragraph 9.97 above, its harmful effects are generally more sustainable and longer-lasting than those of other forms of serious anti-competitive practice.
- 9.128 Second, Flynn's arguments regarding past decisional practice overlook the fact that the CMA is not bound by its previous penalty decisions, and only needs to ensure that there is broad consistency in its approach to the CMA penalties guidance, which it has done in this case; each case is dependent on its facts.¹⁸¹⁷ In any event, the CMA's recent decisions in Case 50395 *Liothyronine* and Case 50277 *Hydrocortisone* both adopted the maximum 30% starting point in respect of unfair pricing infringements.¹⁸¹⁸
- 9.129 Third, the CMA does not rely solely on the nature of the product and the impact on the NHS (and patients) to justify the 30% starting point; while these were important considerations as set out in paragraphs 9.101 to 9.105 and 9.110 to 9.114 above, they were just some of the factors taken into account by the CMA in its overall assessment of the seriousness of Pfizer and Flynn's Infringements. Moreover, in

¹⁸¹⁵ PRC03488, Pfizer's response to the SO and DPS, paragraph 45(b)(v).

¹⁸¹⁶ PRC03488, Pfizer's response to the SO and DPS, paragraph 45(b)(vi); and PRC03495, Flynn's response to the DPS, paragraph 4.8.3.

¹⁸¹⁷ *Eden Brown Ltd v OFT* [2011] CAT 8 at 78; *Roland (UK) Ltd v CMA* [2021] CAT 8, paragraph 87.

¹⁸¹⁸ Case 50395 *Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK*, 29 July 2021, paragraph 7.57 and Case 50277 *Hydrocortisone tablets: Excessive and unfair pricing and anti-competitive agreements*, 15 July 2021. Both cases are currently on appeal to the Competition Appeal Tribunal, including on the question of the appropriate starting point percentage.

relation to Flynn's submission that its conduct secured the long-term supply of Capsules that would otherwise have been discontinued, the CMA has found that the Parties' Prices significantly exceeded any level that may have been required to ensure the drug's commercial viability.¹⁸¹⁹

9.130 Fourth, in relation to the need for general deterrence, the CMA considers that applying a lower starting point would risk undermining the clear message for other dominant undertakings that they should not engage in similar conduct. The CMA does not accept that an increase in the number of investigations relating to unfair pricing in the pharmaceutical sector means that a lower starting point and a less effective deterrent would now be appropriate. As explained above, general deterrence does not solely seek to deter undertakings within a particular sector or industry; rather, the CMA's objective is to deter other dominant undertakings from engaging in the same or similar conduct, regardless of the relevant product or service. In addition, the CMA has explained above why the existence of the DHSC's new powers does not mitigate against the need for general deterrence.

c. Calculation at the end of step 1

9.131 For the above reasons, the CMA considers that Pfizer and Flynn's Infringements are among the most serious infringements of competition law. The CMA therefore considers that a starting point of 30% is appropriate and within the CMA's margin of appreciation in relation to the Infringements.

9.132 The CMA therefore calculates, using the relevant turnover set out above at paragraph 9.89, that at the end of step 1 Pfizer's penalty is £3,602,011 and Flynn's penalty is £6,183,428.

III. Step 2 – adjustment for duration

9.133 The CMA may adjust the penalty reached at the end of step 1 to take into account the duration of the infringement. Where the total duration of an infringement is more than one year, the CMA will round up part years to the nearest quarter year.¹⁸²⁰

9.134 In this Decision, the CMA has adopted the Relevant Period from the 2016 Infringement Decision. The duration is, therefore, 24 September 2012 to 7 December 2016, which is a period of four years and two months.¹⁸²¹ Accordingly, applying the relevant principles of the CMA penalties guidance, the CMA has increased the relevant penalty at the end of step 1 by a factor of 4.25.

¹⁸¹⁹ See section 6.B.II.

¹⁸²⁰ CMA penalties guidance, paragraph 2.16.

¹⁸²¹ The Relevant Period proposed in the SO began on 24 September 2012 and ended on 23 January 2017 (being the date from which the Parties were directed to revise their selling prices): see SO, paragraphs 6.8–6.11.

a. Calculation at the end of step 2

9.135 Accordingly, Pfizer's proposed penalty at the end of step 2 is £15,308,545, and Flynn's proposed penalty at the end of step 2 is £26,279,571.

IV. Step 3 – adjustment for aggravating and mitigating factors

9.136 The CMA may increase a penalty at step 3 where there are aggravating factors, or decrease it where there are mitigating factors. A non-exhaustive list of aggravating and mitigating factors is set out in the CMA penalties guidance.¹⁸²²

a. Pfizer

9.137 The CMA considers that the involvement of Pfizer's senior management both within the UK and internationally should be taken into account as an aggravating factor at step 3. In particular:

9.137.1 [Pfizer Director 1], [REDACTED], was involved in devising, proposing and carrying out Pfizer's decision to increase the prices charged for its Capsules.¹⁸²³

9.137.2 [Pfizer President 2], [REDACTED], formally approved Pfizer's plan to increase the prices of its Capsules.¹⁸²⁴

9.137.3 [Pfizer President 1], [REDACTED], was briefed on the deal with Flynn, including the proposed price increases.¹⁸²⁵

9.138 Pfizer submitted that, in this case, director involvement should be a mitigating, rather than an aggravating factor, because its senior management had had reasonable grounds on which to consider that Pfizer's Capsule prices were fair. Specifically, Pfizer stated that it had benchmarked its prices in good faith against the Drug Tariff price of Tablets which it understood to be a bespoke, lawful price agreed by the DHSC. Pfizer also points to the fact that the CAT considered [Pfizer Director 1] to be a straightforward and credible witness.¹⁸²⁶

9.139 The CMA does not agree that the involvement of Pfizer's senior management constitutes a mitigating factor. On the contrary, it has concluded that it constitutes an aggravating factor. In particular, it considers that the evidence relating to the Drug Tariff price of Tablets does not undermine the conclusion that Pfizer and its senior management knew (or should have known) the essential facts underpinning the findings that Pfizer's Prices were unfair.

¹⁸²² CMA penalties guidance, paragraphs 2.18 and 2.19.

¹⁸²³ See section 2.D.I.

¹⁸²⁴ See section 2.D.I and PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 28, line 21 to page 29, line 3, and page 62, lines 13-15.

¹⁸²⁵ See section 2.D.I and PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 28, line 6, to page 29, line 15.

¹⁸²⁶ PRC03488, Pfizer's response to the SO and DPS, paragraphs 45(d)(i) and 45(d)(ii).

- 9.140 As set out in Annex B and Annex C, both before and after the implementation of the price increases, there were multiple events and occasions that should have made the Parties (including Pfizer's senior management) pause and reconsider whether their reliance on Tablets as a benchmark for the prices of Capsules was appropriate. In light of these events, it was not reasonable or appropriate for the Parties to impose and continue to charge unfairly high prices on the basis that the DHSC was, in fact, willing to pay these prices and did not have 'any serious objection' to them. It should have been very clear to the Parties (including Pfizer's senior management) that their inferences and assumptions were not supported by the views of the DHSC, or those of the wider NHS, and that their reliance on the £30 Drug Tariff price for Tablets took place in a vacuum, without any meaningful regard to the actual events and conversations around them. The multiple events which should have made the Pfizer aware that the DHSC and CCGs were not happy with and willing to pay their prices.
- 9.141 Therefore, whether or not [Pfizer Director 1] was a credible witness and did in fact consider the Drug Tariff price of Tablets to be a valid benchmark which Pfizer continued to rely on to justify its unfairly high prices with regard to Capsules, this does not change the fact that he (and other senior management involved, to the extent that they held the same belief) should have known better. As confirmed by the CAT, company directors have an additional responsibility, beyond that of other employees, not to infringe the law.¹⁸²⁷
- 9.142 Therefore, even if Pfizer's senior management in this case had acted merely negligently (which is disputed), the CMA concludes that in the absence of any legitimate aim of the infringing conduct, an uplift for director-level involvement would still be justified.¹⁸²⁸
- 9.143 Due to their active role in devising, proposing and implementing Pfizer's Infringements, the CMA also considers that the involvement of Pfizer's senior management in this case was particularly reprehensible and should therefore be treated as a factor which 'aggravates' Pfizer's Infringements.¹⁸²⁹
- 9.144 In the light of the above, the CMA concludes that the involvement of Pfizer's senior management in Pfizer's Infringements should be taken into account as an aggravating factor at step 3, and not as a mitigating factor. As for the appropriate level of the uplift, the CMA concludes that an uplift of 10% is justified. 10% is below

¹⁸²⁷ Confirmed by the CAT in *Ping*, paragraph 244.

¹⁸²⁸ In *Ping* the CAT specifically left open the possibility that even in cases of 'mere' negligence, an uplift for director involvement might be appropriate (*Ping* [2018] CAT 13, paragraph 248). In that case, it found that an uplift was not justified based on the specific facts, in particular because *Ping*'s directors sought to pursue a legitimate aim with their restrictive policy.

¹⁸²⁹ The CAT stated in *Ping* that in cases concerning public (as opposed to secret) infringing conduct, director-level knowledge alone should not be treated as an aggravating factor as an uplift would otherwise become meaningless. Instead, an uplift should be reserved for more reprehensible behaviour (*Ping* [2018] CAT 13, paragraph 247).

the uplifts imposed in some other cases (up to 20%),¹⁸³⁰ yet reflects the active role which Pfizer's senior management played in Pfizer's Infringements, despite the serious harm it caused to patients and the NHS.

b. Flynn

i. Aggravating factors

9.145 The CMA concludes that the involvement of Flynn's directors and senior management, particularly [Flynn Director 2] and [Flynn Director 1], in the planning and implementation of Flynn's Infringements should be taken into account as an aggravating factor at step 3.¹⁸³¹

9.146 Flynn's directors were central to the planning, negotiation and implementation of the agreement with Pfizer and Flynn's pricing decisions. They were aware of the essential facts described above underpinning the CMA's findings of dominance and abuse. For example, Flynn's directors were directly involved in correspondence with the DHSC, CCGs, clinicians and its own senior commercial staff in which concerns were raised regarding the level of Flynn's prices.¹⁸³² As set out above, Flynn's Infringements had a significant adverse impact on the NHS (with its finite resources) and on patients.

9.147 Flynn submitted to the CMA that an uplift is not appropriate, as:

9.147.1 there was no basis for [Flynn Director 2] and/or [Flynn Director 1] to conclude that their conduct was anti-competitive or raised substantial competition law concerns; and

9.147.2 an uplift would be unfair and discriminatory, as senior management will always be involved in pricing decisions in a company of Flynn's size.¹⁸³³

9.148 These arguments are not accepted. Flynn's directors and senior management took advantage of Flynn's dominant position in the market for the distribution of Capsules in the UK, and the absence of any effective competitive constraints, in order to impose prices that materially exceeded any reasonable measure of its

¹⁸³⁰ See, for example, (1) CMA infringement decision regarding the supply of groundworks products to the construction industry (case 50415), paragraph 6.52, available at https://assets.publishing.service.gov.uk/media/604633538fa8f577c7dc58f8/Case_50415_-_CMA_Decision.pdf; (2) CMA infringement decision regarding the supply of precast concrete drainage products (case 50299), paragraph 6.44, available at https://assets.publishing.service.gov.uk/media/5dfb98e7ed915d54a62419a6/Nonconfidential_decision_201219_----.pdf; the CAT did not address the uplift in its decision on FP McCann's appeal dated 22 December 2020 in *FP McCann v CMA* [2020] CAT 28; (3) both CMA infringement decisions relating to Nortriptyline tablets (case 50507.2), (a) market sharing, paragraph 7.61, available at https://assets.publishing.service.gov.uk/media/5f115b4dd3bf7f5baab7a5e4/Market_Sharing_Decision.pdf; (b) information exchange, paragraph 7.61, available at https://assets.publishing.service.gov.uk/media/5ef469bcd3bf7f7142efc039/Information_Exchange_Decision.pdf; Lexon appealed the decision but not the 15% uplift relating to director involvement, *Lexon (UK) Limited v CMA* [2021] CAT 5.

¹⁸³¹ See section 2.D.I.

¹⁸³² See Annex B and Annex C.

¹⁸³³ PRC03495, Flynn's response to the DPS, paragraphs 4.11 and 4.13.

costs. It is not necessary for individual directors and managers to know that the undertaking's prices were unfair as a matter of law in order for their involvement to aggravate the infringement.

- 9.149 As set out in paragraph 9.141 above, company directors have an additional responsibility, beyond that of other employees, not to infringe the law.¹⁸³⁴
- 9.150 Therefore, even if Flynn's conduct in this case had been merely negligent (which is disputed), the CMA considers that in the absence of any legitimate aim of the infringing conduct, an uplift for director-level involvement would still be justified.¹⁸³⁵
- 9.151 The CMA also concludes that due to the active role played by Flynn's directors (see above), the director-level involvement in Flynn's Infringements in this case was particularly reprehensible and should therefore be treated as a factor which 'aggravates' Flynn's Infringements.
- 9.152 The suggestion that smaller companies should be exempted from uplifts for director and senior management involvement was considered and rejected by the CAT in *Ping*. The CAT noted that 'society has a greater expectation that senior management will lead by example and abide by the law ... This holds true even if the undertaking is relatively small'.¹⁸³⁶ That expectation applies to [Flynn Director 2] and [Flynn Director 1], both of whom played an instrumental role in Flynn's Infringements.
- 9.153 In the light of the above, the CMA concludes that an uplift to reflect the involvement of Flynn's directors and/or senior management in Flynn's Infringements is appropriate. As for the appropriate level of the uplift, the CMA concludes that an uplift of 10% is justified. 10% is below the uplifts imposed in some other cases (up to 20%),¹⁸³⁷ yet reflects the active role which directors and senior management played in Flynn's Infringements, despite the serious harm it caused to patients and the NHS.

¹⁸³⁴ Confirmed by the CAT in *Ping*, paragraph 244.

¹⁸³⁵ In *Ping* the CAT specifically left open the possibility that even in cases of 'mere' negligence, an uplift for director involvement might be appropriate (*Ping* [2018] CAT 13, paragraph 248). In that case, it found that an uplift was not justified based on the specific facts, in particular because *Ping*'s directors sought to pursue a legitimate aim with their restrictive policy.

¹⁸³⁶ *Ping Europe Ltd v CMA* [2018] CAT 13, paragraph 246.

¹⁸³⁷ See, for example, (1) CMA infringement decision regarding the supply of groundworks products to the construction industry (case 50415), paragraph 6.52, available at https://assets.publishing.service.gov.uk/media/604633538fa8f577c7dc58f8/Case_50415_-_CMA_Decision.pdf; (2) CMA infringement decision regarding the supply of precast concrete drainage products (case 50299), paragraph 6.44, available at https://assets.publishing.service.gov.uk/media/5dfb98e7ed915d54a62419a6/Nonconfidential_decision_201219_-----.pdf; the CAT did not address the uplift in its decision on FP McCann's appeal dated 22 December 2020 in *FP McCann v CMA* [2020] CAT 28; (3) both CMA infringement decisions relating to Nortriptyline tablets (case 50507.2), (a) market sharing, paragraph 7.61, available at https://assets.publishing.service.gov.uk/media/5f115b4dd3bf7f5baab7a5e4/Market_Sharing_Decision.pdf; (b) information exchange, paragraph 7.61, available at https://assets.publishing.service.gov.uk/media/5ef469bcd3bf7f7142efc039/Information_Exchange_Decision.pdf; Lexon appealed the decision but not the 15% uplift relating to director involvement, *Lexon (UK) Limited v CMA* [2021] CAT 5.

ii. Mitigating factors

- 9.154 Flynn submitted that any fine should be substantially reduced on the basis of genuine uncertainty; it submitted that there was genuine uncertainty on the part of both Flynn and the CMA.¹⁸³⁸
- 9.155 Genuine uncertainty as to the law is a potential mitigating factor when an informed assessment of the application of the law to particular facts leaves an undertaking and its advisers with good reason to consider that the conduct in question might be lawful. There is no such good reason here. For the reasons set out above, the CMA considers that it should have been evident at the time of Flynn's Infringements that Flynn's Prices were exploitative and unlawful. There is no basis for the notion that Flynn had every reason to consider that its conduct complied with competition law. Flynn's own internal documents show that it was alive to the possibility that its Prices could be 'anti-competitive', and had been told by one of its directors to seek legal advice on this question.¹⁸³⁹
- 9.156 It was clear throughout the Relevant Period that excessive and unfair pricing on the part of a dominant undertaking constitutes an infringement of the Chapter II Prohibition and/or (at the time) Article 102 TFEU. Excessive pricing is not a 'novel' legal concept or type of abuse. Section 18(2)(a) of the Act expressly prohibits the abuse of a dominant position by imposing unfair selling prices and, as noted above, as early as 1978 the EU Court of Justice set out the law on unfair pricing in *United Brands*: that judgment remains good and applicable law.
- 9.157 As set out in paragraphs 9.51 to 9.60 above, protecting consumers against exploitation through the imposition of unfair selling prices is one of the core purposes of competition law, and neither the clarification of certain aspects of the *United Brands* test in the CAT and the Court of Appeal's judgments, nor changes in the CMA's position during the appeals, created any uncertainty during the Relevant Period with regard to the fact that exploiting a dominant position in order to impose unfair selling prices constitutes an infringement of competition law.
- 9.158 In these circumstances, there can be no scope to grant a discount for uncertainty regarding the law.
- 9.159 In addition, Flynn submitted that when assessing mitigation, the CMA should have regard to the following factors:

¹⁸³⁸ PRC03495, Flynn's response to the DPS, paragraphs 4.14 and 4.15.

¹⁸³⁹ See PHT00375, Flynn document titled 'Question & Answer Briefing Framework for Helpline Respondents' (CMA document reference 00145.390) and PHT00126, Email chain of 24 October 2012 between [Flynn Non-executive Director 2] [X], [Flynn Director 1] Flynn and [X] [X] discussing the letter re the Abuse of Monopoly – Epanutin Marketing and Distribution Changes and Flynn: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.535).

9.159.1 the fact that in July 2014 Flynn asked the CMA what would be a reasonable margin, and did not receive a response; and

9.159.2 the fact that Flynn fully cooperated with the CMA and its investigation.¹⁸⁴⁰

9.160 As a dominant undertaking, Flynn had a special responsibility to ensure that its conduct in relation to Capsules did not amount to an abuse. Flynn was not entitled to shift the burden to the CMA to identify for Flynn, during its investigation, a lawful price.¹⁸⁴¹ It is also clear, from its interactions with the CMA, the DHSC and CCGs, that during the Relevant Period Flynn was aware of concerns regarding its prices, including in relation to the legality of such prices. Notwithstanding this, Flynn continued to impose unfairly high prices until it was required to reduce them by the Directions issued by the CMA in December 2016. This does not, therefore, constitute a mitigating factor.

9.161 Further, cooperation with a CMA investigation will not constitute a mitigating factor where a party has merely respected CMA time limits¹⁸⁴² and acted in a manner consistent with the normal conduct of a reasonable party. Flynn has not provided any examples of cooperation that it considers to be 'over and above' what was reasonably expected of it.

9.162 Therefore, the CMA has concluded that there are no relevant mitigating factors to be taken into account at step 3 for Flynn or Pfizer.

c. Calculation at the end of step 3

9.163 As set out above, the CMA concludes that an uplift of 10% of Pfizer's penalty is appropriate at step 3, taking into account the involvement of Pfizer's senior management, and the lack of mitigating factors. At the end of step 3, Pfizer's penalty is therefore £16,839,400.

9.164 As set out above, the CMA concludes that an uplift of 10% of Flynn's penalty is appropriate at step 3, taking into account the involvement of Flynn's directors and senior managers and the lack of mitigating factors. At the end of step 3, Flynn's penalty is therefore £28,907,528.

V. Step 4 – adjustment for specific deterrence and proportionality

9.165 The penalty may be adjusted at this step to achieve the objective of specific deterrence (that is, to ensure that the penalty imposed on the infringing undertaking

¹⁸⁴⁰ PRC03495, Flynn's response to the DPS, paragraph 4.16.

¹⁸⁴¹ See to this effect, Case T-167/08 *Microsoft v Commission*, paragraph 95, where the General Court rejected Microsoft's argument that the Commission should itself first have established, by means of a decision amenable to judicial review, the appropriate remuneration rate before it could impose a periodic penalty payment on Microsoft. The General Court held that, '*although the Commission undoubtedly has the power to find that an infringement exists and to order the parties concerned to bring it to an end, it is not for the Commission to impose upon the parties its own choice from among all the various potential courses of action which are in conformity with the Treaty or with a decision imposing behavioural remedies, [...] (see, to that effect, Case T-24/90 Automec v Commission [1992] ECR II-2223, paragraph 52).*'

¹⁸⁴² CMA penalties guidance, paragraph 2.19.

will deter it from engaging in anti-competitive practices in the future), or to ensure that a penalty is proportionate.¹⁸⁴³ In assessing whether an increase or reduction is appropriate at step 4, the CMA will consider appropriate indicators of the undertaking's size and financial position at the time the penalty is being imposed, as well as any other relevant circumstances of the case.¹⁸⁴⁴

9.166 The CMA may increase a penalty figure reached after step 3 to ensure that the penalty to be imposed on the undertaking will deter it from breaching competition law in the future, given its size and financial position and any other relevant circumstances of the case.¹⁸⁴⁵ Specific deterrence increases at step 4 will generally be limited to situations in which an undertaking has a significant proportion of its turnover outside the relevant market, or where the CMA has evidence that the infringing undertaking has made or is likely to make an economic or financial benefit from the infringement that is above the level of the penalty reached at the end of step 3.¹⁸⁴⁶ Where a penalty is a very small percentage of an undertaking's total turnover, the impact of the penalty on that undertaking may be very limited. It is only when the penalty imposed is sufficiently high to make a real impact on the undertaking that the CMA can be confident that the infringing undertaking will take seriously their obligation to comply with competition law in the future.¹⁸⁴⁷

9.167 In addition, there might be exceptional cases where more significant adjustments may be necessary in circumstances where an undertaking's relevant turnover is very low or zero, or does not accurately reflect the scale of an undertaking's involvement in the infringement or likely harm to competition. This might be the case where, for example, where an undertaking's turnover in the last business year before the infringement ended was unusually low.¹⁸⁴⁸

9.168 In considering the appropriate level of any adjustment for specific deterrence, the CMA will ensure that the uplift does not result in a disproportionate or excessive penalty. In carrying out this assessment of whether a penalty is proportionate, the CMA will have regard to the undertaking's size and financial position, the nature of the infringement, the role of the undertaking in the infringement, and the impact of the infringing activity on competition.¹⁸⁴⁹ Ultimately, the assessment of the figure at step 4 is an assessment 'in the round'.¹⁸⁵⁰ This approach was endorsed in *FP McCann Ltd v CMA*, where the CAT held that '[t]he questions arising at Step 4 involve matters of evaluation or judgment. By their very nature, they do not lend

¹⁸⁴³ CMA penalties guidance, paragraphs 2.20 to 2.24.

¹⁸⁴⁴ CMA penalties guidance, paragraph 2.20. The CMA will generally consider three-year averages for profits and turnover, and may consider indicators of size and financial position from the time of the infringement.

¹⁸⁴⁵ CMA penalties guidance, paragraph 2.20.

¹⁸⁴⁶ CMA penalties guidance, paragraph 2.21.

¹⁸⁴⁷ See for example *Lexon (UK) Ltd v CMA* [2021] CAT 5, paragraph 276.

¹⁸⁴⁸ CMA penalties guidance, paragraph 2.22.

¹⁸⁴⁹ CMA penalties guidance, paragraph 2.23–2.24.

¹⁸⁵⁰ CMA penalties guidance, paragraph 2.24.

themselves to elaborate explanations'.¹⁸⁵¹ There is no single right outcome – rather, 'what matters is what figure feels appropriate taking account of all relevant considerations'.¹⁸⁵²

a. Pfizer

9.169 In accordance with paragraphs 2.20-2.24 of the CMA penalties guidance, in its step 4 assessment, the CMA has assessed whether there were any factors which indicated that an uplift of Pfizer's penalty at the end of step 3 (£16,839,400) for specific deterrence and/or any downwards adjustments for proportionality were appropriate and required.

i. Specific deterrence

9.170 The CMA considers that there are a number of different factors which indicate, individually and in the round, that it would be appropriate for Pfizer's penalty at the end of step 3 (£16,839,400) to be increased by a material amount for specific deterrence. In particular, it concludes that both Pfizer's size and financial position and the level of the illegal profits accrued as a direct consequence of Pfizer's Infringements would each on their own justify the proposed uplift.¹⁸⁵³

Turnover outside the relevant market

9.171 Pfizer earns over 99.9% of its worldwide turnover outside of the relevant market. In the last financial year of the Infringements (financial year ending 31 December 2015), Pfizer's turnover in the relevant market was £12,006,702, while its total worldwide turnover was \$48.9 billion, and it earned \$39.2 billion in gross profit.¹⁸⁵⁴

Size and financial position

9.172 The CMA considers that, in light of Pfizer's overall size and financial position, a material uplift is required to ensure that Pfizer is deterred from engaging in anti-competitive and/or exploitative conduct in the future. Unadjusted, Pfizer's penalty for the Infringements would be £16,839,400. This unadjusted penalty would represent only:¹⁸⁵⁵

¹⁸⁵¹ *FP McCann Ltd v CMA* [2020] CAT 28, paragraph 312.

¹⁸⁵² *Ibid*, paragraph 314.

¹⁸⁵³ These factors reflect the key situations that are cited in paragraphs 2.21-2.22 of the CMA penalties guidance as indicators of when it would be appropriate to impose an uplift.

¹⁸⁵⁴ These 2015 results reflect Pfizer's business prior to the Viatrix transaction; ie. they are not restated.

¹⁸⁵⁵ Pfizer's off-patent and generics business was spun-off in 2020 and merged with Mylan to form Viatrix. Accordingly, Pfizer's 2021 and 2020 SEC filings provide restated prior-period information reflecting Pfizer's current organisational structure. The calculations in this Decision are based on Pfizer's restated financial information except where otherwise noted. For completeness, the CMA has also considered the equivalent calculations on the basis of Pfizer's business as it was prior to the Viatrix transaction, and concluded that the impact is minimal. All financial indicators are based on information from Pfizer's publicly available annual reports and accounts, available at <https://investors.pfizer.com/Investors/Financials/SEC-Filings/default.aspx>. The CMA has used data for the financial years ending 31 December 2021; 31 December 2020 and 31 December 2019. All figures have been translated from USD to GBP using the Bank of England's annual average and year end spot exchange rates over the period.

- 9.172.1 0.04% of Pfizer's average annual worldwide turnover over its last three financial years (£41.4 billion), and 0.03% of Pfizer's worldwide turnover for the financial year ending 31 December 2021 (£59.1 billion);
- 9.172.2 0.17% of Pfizer's average annual profit after tax over its last three financial years (£10.1 billion), and 0.10% of Pfizer's profit after tax for the financial year ending 31 December 2021 (£16.3 billion);
- 9.172.3 0.26% of Pfizer's average annual dividends over its last three financial years (£6.5 billion);
- 9.172.4 0.03% of Pfizer's net assets for the financial year ending 31 December 2021 (£57.5 billion); and
- 9.172.5 0.02% of the sum of Pfizer's net assets for the financial year ending 31 December 2021, and Pfizer's total annual dividends over its last three financial years (£77.0 billion).

- 9.173 This means that while Pfizer's Infringements had a significant negative impact on customers and consumers within the UK, the penalty as at the end of step 3 would have very little impact on Pfizer's overall financial position and thus would be insufficient to deter Pfizer from engaging in anti-competitive conduct in future.
- 9.174 Pfizer submitted that the CMA ought to assess whether Pfizer's worldwide turnover is relevantly connected to the Infringements. Pfizer points as an example to the United States of America, where the majority of its turnover is generated, but where the Infringements would not breach antitrust law.¹⁸⁵⁶
- 9.175 This argument is misconceived. Part of the CMA's approach to adjustments at step 4 is directed at ensuring that the policy objective of deterring the infringing undertaking from breaching competition law in the UK in the future is achieved. It is the undertaking – here, Pfizer Limited together with Pfizer Inc¹⁸⁵⁷ – and not just the local subsidiary, that must be deterred. In seeking to deter future infringements of competition law in the UK, it is highly relevant that the unadjusted penalty would represent only 0.04% of Pfizer's average annual worldwide turnover in its last three financial years. The impact of such a penalty on Pfizer is likely to be very limited. However, as described above, in considering the appropriate level of any adjustment for specific deterrence, the CMA will ensure that the uplift does not result in a disproportionate or excessive penalty. In carrying out this assessment of whether a penalty is proportionate, the CMA will have regard to the undertaking's

¹⁸⁵⁶ Pfizer cites in this respect *Kier Group plc v OFT* [2011] CAT 3, paragraphs 169–170 (PRC03488, Pfizer's response to the SO and DPS, paragraph 45(e)(ii)). This is a misreading of the CAT's judgment: the CAT found that the OFT had erred not in taking account of worldwide turnover, but because the 'Minimum Deterrence Threshold' was too mechanistic and did not take account of '*other financial measures and indicators of the deterrent impact [the OFT's] penalties would have*'. As is clear from the analysis above, the CMA has taken account of a number of financial measures when assessing Pfizer's size and financial position.

¹⁸⁵⁷ See section 8.E.

size and financial position, the nature of the infringement, the role of the undertaking in the infringement, and the impact of the infringing activity on competition.¹⁸⁵⁸

Relevant turnover does not reflect the impact of Pfizer's Infringements

- 9.176 Pfizer's relevant turnover (which forms the starting point for the calculation of Pfizer's penalty at step 1) is lower than Pfizer's turnover at other points during the Relevant Period: for example, Pfizer's relevant turnover (£12,006,702) is significantly less than its equivalent turnover during its first full financial year within the Relevant Period, ending 31 December 2013, which amounted to £25,151,618. This indicates that the penalty at the end of step 3 does not fully reflect the serious impact of Pfizer's Infringements, and that an uplift at step 4 is therefore appropriate and required.

Financial benefit

- 9.177 Pfizer's penalty as at the end of step 3 (£16,839,400) is also likely to be significantly below the illegal excess profits that the CMA estimates Pfizer accrued during the Relevant Period as a direct result of its Infringements.
- 9.178 In order to have a sufficient deterrent effect, a penalty needs to not only meet, but exceed by a material amount, the financial benefit accrued as a direct consequence of an infringement.
- 9.179 It is an important part of effective deterrence that an undertaking should not be in a position to earn a profit from infringing competition law even after paying a penalty in respect of that infringement.¹⁸⁵⁹ Nor is it sufficient for any penalty to only neutralise an infringing undertaking's direct financial gains resulting from an infringement. If the penalty imposed on an undertaking for a competition law infringement only neutralises the gains made (ie puts the undertaking in the same position as it would have been absent the infringement) there is little economic incentive for the undertaking not to infringe competition law again: at most, it would risk losing its gains if it was caught and sanctioned.
- 9.180 The need for any penalty imposed in relation to an infringement to exceed the direct financial gains from the infringement by a material amount is particularly relevant for infringements involving the imposition of unfair selling prices where the gains are accrued as a direct result of the infringing conduct (ie charging unfair prices). The CMA considers that simply asking a company to repay the minimum level of its unlawful direct gains (or a small percentage more) would not be sufficient to deter the company from taking the risk of engaging in the same or similar breaches of competition law again in future, in the pharmaceutical sector or

¹⁸⁵⁸ CMA penalties guidance, paragraph 2.23–2.24.

¹⁸⁵⁹ As acknowledged by the CAT in *Napp* [2002] CAT 1, paragraph 510, a penalty that understates the real commercial gain of the infringer risk being ineffective.

in any sector of the economy. This is particularly the case given the possibility that future unlawful conduct may not be detected or subject to enforcement.

- 9.181 The General Court has confirmed the validity of this approach, holding that in the interests of effective deterrence, a fine may be increased so that the final amount exceeds the level of the financial benefit obtained. The level of financial benefit generated by an infringing party does not constitute a 'ceiling' above which a penalty cannot be imposed.¹⁸⁶⁰ Indeed, this is clear from the fact that it is perfectly legitimate for a penalty to be imposed where an infringement has generated no financial benefit at all for the infringing party.
- 9.182 A different approach would also be irreconcilable with the CMA's role in imposing a penalty, which is to punish and deter infringing undertakings.¹⁸⁶¹
- 9.183 In this case, the CMA estimates that during the Relevant Period Pfizer accrued approximately:
- 9.183.1 £58.8 million of total profits in the relevant market;¹⁸⁶² and
- 9.183.2 £57.5 million of profits above Cost Plus in the relevant market.¹⁸⁶³
- 9.184 The penalty at the end of step 3 would therefore represent only 29% of total profits, and 29% of Pfizer's total profits above Cost Plus in the relevant market during the Relevant Period.
- 9.185 The CMA recognises that not all of Pfizer's total profits or profits above Cost Plus were illegal. As set out in section 4, a price is not 'excessive' whenever it exceeds Cost Plus; rather, there must be a material difference between the price charged and Cost Plus. Accordingly, Pfizer was entitled legitimately to earn a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing Cost Plus.
- 9.186 However, Pfizer's Prices exceeded Cost Plus by 24% for 25mg capsules, 91% for 50mg capsules, 667% for 100mg capsules, and 653% for 300mg capsules.¹⁸⁶⁴ Given the size of these additional profits (and in particular for 100mg and 300mg

¹⁸⁶⁰ *Evonik Degussa v Commission*, T-391/09, EU:T:2014:22, paragraphs 239-242: in the interests of deterrence, a fine may be imposed irrespective of whether the parties have obtained any financial benefit from an infringement. The level of any financial benefit obtained may, however, justify increasing the fine so that the final amount exceeds the level of benefit obtained.

¹⁸⁶¹ *Kier Group v OFT* [2011] CAT 3, paragraph 166. (See also the judgment at first instance in *Devenish Nutrition Ltd v Sanofi-Aventis SA* [2009] Ch 390, judgment of Lewison J, paragraphs 46-48: 'in antitrust cases the imposition of fines and an award of exemplary damages serve the same aim: namely to punish and deter anti-competitive behaviour'; and the underlying Commission decision, paragraph 774: 'Payments of damages in civil law actions which have the objective of compensating for the harm caused by cartels to individual companies or consumers cannot be compared with public law sanctions for illegal behaviour' (quoted at paragraph 49 of Lewison J's judgment)).

¹⁸⁶² Total profits are calculated by subtracting direct and common costs attributable to Capsules from Capsules sales revenues. Common costs allocated to phenytoin are assumed to amount to £2.32 per pack, in line with the calculation in Annex I. This figure was calculated using data from September 2012 to January 2017.

¹⁸⁶³ Excesses are calculated by subtracting a reasonable rate of return from total profits. The CMA's assessment of a reasonable rate of return for Pfizer's Products is set out in section 5.B.

¹⁸⁶⁴ See section 5.

capsules, which generated by far the greatest revenues and profits), it is more likely than not that most of Pfizer's profits above Cost Plus would not have been accrued if it had charged a fair price. It is not necessary for the CMA to have calculated the precise level of financial gains that Pfizer has accrued from its Infringements in order to take into account the fact that those gains will, on any reasonable basis, be significant.¹⁸⁶⁵

- 9.187 The CMA therefore considers that, unless a material uplift is applied at step 4, Pfizer's penalty would risk being significantly below the level of direct financial benefit which Pfizer earned from its Infringements.

Changes to the DHSC's price control powers

- 9.188 Pfizer submitted that the DHSC's revised powers are central to any determination of deterrence, and argued that, given the existence of these powers, it is 'wholly unclear who, or what, is being deterred'.¹⁸⁶⁶

- 9.189 The CMA has concluded that the expansion of the DHSC's price control powers under the Health Service Medical Supplies (Costs) Act 2017 does not diminish the requirement for a material uplift at step 4, or the required level of the uplift, for the following reasons:

9.189.1 Specific deterrence is concerned with ensuring that the penalty imposed is sufficient to deter the undertaking concerned from breaching competition law in the future, given its 'specific size and financial position and any other relevant circumstances of the case'.¹⁸⁶⁷ Whether or not the changes to the DHSC's powers may, in theory, constrain Pfizer's ability to engage in unfair pricing in respect of generic medicines within the scope of those powers, they have no relevance to any other potential future breaches of competition law by Pfizer (breaches of the Chapter I or Chapter II prohibition). The assessment of deterrence under step 4 is not limited to seeking to deter Pfizer from committing exactly the same infringement.

9.189.2 In any event, the DHSC's powers are aimed at prospective intervention to reduce and limit the cost of drugs to the NHS, not at punishing and deterring illegal activity. Relying solely on the DHSC's powers would allow undertakings scope to increase prices to excessive and unfair levels and

¹⁸⁶⁵ See for example the approach adopted in *Case CE/8931/08: Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Ltd and Reckitt Benckiser Group plc*, OFT Decision No. CA98/02/2011, 12 April 2011, paragraphs 8.42 to 8.44.

¹⁸⁶⁶ Pfizer cites *Phenytoin* [2018] CAT 11, paragraph 461, where the CAT stated that 'if we had needed to come to a decision on the level of penalties to be applied to Pfizer in this case, we would have given the appropriate uplift for deterrence close scrutiny, particularly having regard to the new price control powers of the DHSC that have recently been passed into law'. (PRC03488, Pfizer's response to the SO and DPS, paragraph 454(e)(i).) These comments were *obiter dicta* and made in the context of general concluding comments. The CMA considers that, given the importance of achieving adequate deterrence (as reflected in s 36(7A)(b) of the Act and in the Penalties Guidelines), it would not be appropriate to reduce Pfizer's penalty on account of the DHSC's revised powers.

¹⁸⁶⁷ CMA penalties guidance, paragraph 2.21.

to retain the resulting excessive profits reaped before the DHSC acted to impose a price limit.

9.189.3 Furthermore, as set out at section 2.C.II.j above, the DHSC's powers remain untested and it is yet unclear if, when and how the DHSC will seek to use such powers in the future. Given this, the new powers do not in practice serve as a sufficiently strong deterrent such that a lesser penalty is justified.

9.190 In light of all the above factors considered in the round, the CMA finds that a penalty of £16,839,400 would not be sufficient to effectively deter Pfizer from breaching competition law in the future. The CMA therefore considers that the proposed penalty as at the end of step 3 should be increased by a material amount to £63,300,000.

9.191 A penalty at this level is slightly lower than the penalty proposed for Pfizer in the DPS (£65,000,000). At that point, a penalty of £65,000,000 amounted to approximately 0.20% of Pfizer's average annual worldwide turnover in its last three financial years, a level which, considered in the round, was considered appropriate to achieve a meaningful deterrent effect and at the same time proportionate and not excessive in the light of the seriousness of Pfizer's Infringements and all other relevant circumstances of the case.

9.192 The slight reduction in the level of the overall penalty proposed for Pfizer in this Decision is due to the slight reduction in the duration of the Relevant Period between the issue of the SO (on which the DPS was based) and this Decision.¹⁸⁶⁸ The change resulted in some changes to steps 1 and 2 of Pfizer's penalty calculation, and led to a slightly reduced penalty at the end of step 3 in this Decision: in the DPS, the penalty at the end of step 3 was approximately £18.5 million; as a result of the slightly reduced duration and its impact on steps 1 and 2, the penalty at the end of step 3 in this Decision is approximately £1.7 million lower.¹⁸⁶⁹

9.193 In principle, and notwithstanding the reduction in duration, the CMA considers that a fine at the level proposed in the DPS (£65,000,000) and potentially higher may still have been appropriate to ensure that Pfizer is effectively deterred from breaching competition law in the future. This reflects the fact that Pfizer's worldwide turnover in its latest accounts, released since the DPS was issued, has increased materially from the previous financial year, as has the average worldwide turnover in the last three financial years. However, given the reduced duration of the

¹⁸⁶⁸ See above. While the SO provisionally adopted a Relevant Period of 24 September 2012 to 23 January 2017, the Relevant Period adopted in this Decision is the same as in the 2016 Infringement Decision (24 September 2012 to 7 December 2016).

¹⁸⁶⁹ Specifically, in the context of step 1, the CMA used the relevant turnover of Pfizer in the financial year ending 31 December 2015 (rather than the subsequent year). It also reduced the duration multiplier for the purposes of step 2 from 4.5 (as applied in the DPS) to 4.25 in this Decision.

Relevant Period since the issuing of the DPS and its impact on the level of penalty at the end of step 3 (as noted above, a reduction of approximately £1.7 million), the CMA has decided in the specific circumstances of this case, to reflect this reduction in Pfizer's penalty calculation and, as such, the CMA has increased the level of penalty at the end of step 4 to £63,300,000.

9.194 A penalty of £63,300,000 would represent:

9.194.1 108% of Pfizer's total profits in the relevant market during the Relevant Period; and

9.194.2 110% of Pfizer's profits above Cost Plus in the relevant market during the Relevant Period.

9.195 It exceeds Pfizer's likely gains from Pfizer's Infringements and is in line with the principle that any penalty imposed should exceed the financial benefit accrued as a direct consequence of an infringement by a material amount in order to be a meaningful deterrent.¹⁸⁷⁰

9.196 In conclusion, taking account of all of the factors set out in paragraphs 9.171 to 9.195 above, the CMA finds that it is appropriate to uplift Pfizer's penalty at step 4 to £63,300,000 for the purposes of specific deterrence.

ii. Proportionality

9.197 In considering the appropriate level of uplift for specific deterrence, and the appropriateness of the overall penalty proposed, the CMA needs to ensure that the overall penalty imposed is not disproportionate or excessive.¹⁸⁷¹ The CMA has concluded that the proposed uplift does not result in a penalty that is disproportionate or excessive, having regard to Pfizer's size and financial position as well as the nature and impact of Pfizer's Infringements.

9.198 A penalty of £63,300,000 equates to:¹⁸⁷²

9.198.1 0.15% of Pfizer's average annual worldwide turnover over its last three financial years (£41.4 billion), and 0.11% of Pfizer's worldwide turnover for the financial year ending 31 December 2021 (£59.1 billion);

9.198.2 0.63% of Pfizer's average annual profit after tax over its last three financial years (£10.1 billion) and 0.39% of Pfizer's profit after tax for the financial year ending 31 December 2021 (£16.3 billion);

¹⁸⁷⁰ In reaching this conclusion, the CMA was mindful of the fact that, while some of these profits could have been legitimately accrued by Pfizer, most of them would not have been accrued if Pfizer had charged a fair price.

¹⁸⁷¹ CMA penalties guidance, paragraph 2.24.

¹⁸⁷² All figures have been translated from USD to GBP using the Bank of England's annual average and year end spot exchange rates over the period.

9.198.3 0.97% of Pfizer's average annual dividends over its last three financial years (£6.5 billion);

9.198.4 0.11% of Pfizer's net assets for the financial year ending 31 December 2021 (£57.5 billion); and

9.198.5 0.08% of the sum of Pfizer's net assets for the financial year ending 31 December 2021, and Pfizer's total annual dividends over its last three financial years (£77.0 billion).¹⁸⁷³

9.199 A penalty at this level is therefore not disproportionate or excessive by reference to any of Pfizer's relevant financial indicators, in particular having regard to the very serious nature of Pfizer's Infringements and their considerable impact on the NHS and patients.

9.200 Pfizer submitted that when assessing proportionality, the CMA should (also) take into account the burden of cost and time imposed on Pfizer in responding to two investigations and a full round of litigation.¹⁸⁷⁴ The CMA rejects this contention. The costs of the appeals are properly a matter for the CAT and the appellate Courts. Moreover, absent any 'inordinate or inexcusable delays'¹⁸⁷⁵ (of which there are none in this case), the ordinary burdens of the investigation are not a proper basis on which to reduce the penalty at step 4.

iii. Calculation at the end of step 4 – Pfizer

9.201 Taking a step back and assessing Pfizer's proposed penalty of £63,300,000 in the round, the CMA concludes that a penalty at this level is appropriate in the light of all the relevant factors and circumstances, including Pfizer's size and financial position, the serious nature of Pfizer's Infringements, the significant level of harm caused and the level of excess profits generated by Pfizer as a direct result of Pfizer's Infringements. In particular, the CMA considers that a lower penalty would be insufficient to deter Pfizer from infringing competition law in the future.

9.202 Therefore, at the end of step 4, the CMA considers that a penalty of £63,300,000 is appropriate.

b. Flynn

9.203 In accordance with paragraphs 2.20-2.24 of the CMA penalties guidance, in its step 4 assessment, the CMA has assessed whether there were any factors which

¹⁸⁷³ The CMA assesses its proposed penalty against the sum of net assets and prior year dividends as a means of guarding against circumvention risk. For example, where a penalty might represent a high proportion of net assets but net assets have been reduced by the distribution of dividends.

¹⁸⁷⁴ PRC03488, Pfizer's response to the SO and DPS, paragraph 45(e)(iii).

¹⁸⁷⁵ In *FP McCann v CMA*, the CAT found that, although it could not exclude the possibility that in certain cases it might be appropriate to reduce a penalty at step 4 on the grounds of delay, doing so would not be appropriate unless the passage of time amounted to an 'inordinate or inexcusable delay': *FP McCann Ltd v CMA* [2020] CAT 28 at paragraphs 269-270.

indicated that an uplift of Flynn's penalty at the end of step 3 (£28,907,528) for specific deterrence and/or any downwards adjustments for proportionality were appropriate and required.

i. Specific deterrence

- 9.204 The CMA considers that there are two separate factors which demonstrate, individually and in the round, that it would be appropriate for Flynn's penalty at the end of step 3 (£28,907,528) to be increased for specific deterrence.¹⁸⁷⁶

Relevant turnover does not reflect the impact of Flynn's Infringements

- 9.205 Flynn's relevant turnover (which forms the starting point for the calculation of Flynn's penalty at step 1) is significantly lower than Flynn's turnover at other points during the Relevant Period: for example, Flynn's relevant turnover (£20,611,428) is significantly below its equivalent turnover during its first full financial year within the Relevant Period, ending 31 March 2014, which amounted to £30,077,666. Consequently, Flynn's relevant turnover, and therefore the unadjusted penalty at the end of step 3, do not adequately reflect the harmful effect of Flynn's Infringements on the NHS and ultimately patients, suggesting the need for an uplift.

Financial benefit

- 9.206 Flynn's penalty as at the end of step 3 (£28,907,528) is also likely to be below the illegal excess profits that the CMA estimates Flynn accrued during the Relevant Period as a direct result of Flynn's Infringements.
- 9.207 As set out at paragraphs 9.178 to 9.182 above, the CMA takes the view that (in unfair pricing cases in particular) the amount of any penalty imposed needs to exceed any unlawful financial gain accrued as a direct consequence of the infringement by a material amount in order to constitute an effective deterrent.
- 9.208 In this case, the CMA estimates that during the Relevant Period Flynn accrued approximately:
- 9.208.1 £37.2 million of total profits in the relevant market;¹⁸⁷⁷ and
- 9.208.2 £35.7 million of profits above Cost Plus in the relevant market.¹⁸⁷⁸
- 9.209 The penalty at the end of step 3 would represent 78% of total profits, and 81% of Flynn's profits above Cost Plus in the relevant market during the Relevant Period.

¹⁸⁷⁶ These factors reflect the situations that are cited in paragraphs 2.21–2.22 of the CMA penalties guidance as indicators of when it would be appropriate to impose an uplift.

¹⁸⁷⁷ Total profits are calculated by subtracting direct and common costs attributable to Capsules from Capsules sales revenues.

¹⁸⁷⁸ Profits above Cost Plus are calculated by subtracting a reasonable rate of return from total profits. The CMA's assessment of a reasonable rate of return for Flynn's Products is set out in section 5.

9.210 For the reasons set out at paragraph 9.185 above, the CMA recognises that not all of Flynn's total profits or profits above Cost Plus in the relevant market were 'excessive' and therefore illegal. Given the size of the profits earned by Flynn, however, it is more likely than not that most of Flynn's profits would not have been accrued if it had charged a fair price. As recognised by the CAT, Flynn 'could have reduced its prices and still made a material profit'.¹⁸⁷⁹ This, too, suggests the need for an uplift at step 4 to ensure that Flynn's penalty exceeds the financial benefit accrued by it as a direct consequence of Flynn's Infringements by a material amount.

9.211 For the reasons set out in paragraphs 9.205 to 9.210 above, therefore, the CMA concludes that it would in principle be appropriate to apply an uplift to Flynn's unadjusted penalty at the end of step 3.

ii. Proportionality

9.212 However, in considering the appropriate level of uplift for specific deterrence, and the appropriateness in the round of the overall penalty proposed, the CMA needs to ensure that the overall penalty imposed is not disproportionate or excessive.¹⁸⁸⁰

9.213 Flynn's unadjusted penalty at the end of step 3 (£28,907,528) is high by reference to Flynn's worldwide turnover, indicating the need for a downwards adjustment: it amounts to 48% of Flynn's average annual worldwide turnover over its last three financial years (£60.2 million); and 43% of Flynn's worldwide turnover in the financial year ended 31 March 2021 (£67,044,220).¹⁸⁸¹

9.214 Since the CMA has chosen to treat Flynn's Infringements as a single infringement for penalty purposes, the highest level of a fine that may be imposed on Flynn is £6,704,422 (ie 10% of its most recent worldwide turnover).¹⁸⁸² Therefore, as a practical matter, the CMA has not assessed for the purposes of step 4 the proportionality of any fine for Flynn above the statutory cap and has instead considered whether a fine at that maximum level would be disproportionate or

¹⁸⁷⁹ *Phenytoin*, [2018] CAT 11, paragraph 456. [Flynn Director 2] accepted in his evidence before the CAT that Flynn would have sold Capsules if it had been able to achieve a 5% return on sales and that at a 2% return on sales, Capsules would have been more attractive than about half of Flynn's portfolio during 2013, 2014 and 2015: PAD00031A, [Flynn Director 2] Cross Examination, day 4, page 201, line 11 to page 204, line 3.

¹⁸⁸⁰ CMA penalties guidance, paragraph 2.24.

¹⁸⁸¹ All financial indicators are based on information from Flynn's publicly available annual report and accounts, available at <https://find-and-update.company-information.service.gov.uk/company/05875486/filing-history>. The CMA has used data for the financial year ending 31 March 2021; the financial year ending 31 March 2020; the period from 30 September 2018 to 31 March 2019 and the financial year ending 30 September 2018. In 2019, Flynn changed its accounting period from the year to 30 September to the year to 31 March. As a result, Flynn's 2019 accounts are presented for the six months to 31 March 2019 only. In estimating Flynn's average turnover, gross profit and PAT in the last three financial years, the CMA has assumed that Flynn generated revenues and profits at a constant rate and annualised its 2019 figures accordingly. In addition, Flynn's accounts for the six months to 31 March 2019 show that it had not paid out any dividends in this period. Flynn's 2019 accounts cover a truncated period only and may not cover the period when dividends are ordinarily distributed. In these circumstances, the CMA considers that it is more informative to consider dividends paid out in the previous three full year periods. The CMA's calculations as relate to dividends therefore use dividend distributions in the financial years ending in 2021, 2020 and 2018.

¹⁸⁸² In accordance with section 36(8) of the Act.

excessive in the circumstances of this case.¹⁸⁸³ The CMA concludes that a reduction below £6,704,422¹⁸⁸⁴ is neither appropriate nor necessary having regard to Flynn's financial indicators and the nature and impact of Flynn's Infringements.¹⁸⁸⁵

9.215 A penalty at the statutory maximum (£6,704,422) would represent approximately:

9.215.1 11% of Flynn's average annual worldwide turnover over its last three financial years (£60.2 million); and 10% of Flynn's worldwide turnover in the financial year ended 31 March 2021 (£67,044,220);

9.215.2 95% of Flynn's average annual profit after tax over its last three financial years (£7.1 million) and 79% of Flynn's profit after tax for the financial year ending 31 March 2021 (£8.5 million);

9.215.3 124% of Flynn's average annual dividends over its last three financial years (£5.4 million);

9.215.4 17% of Flynn's net assets for the financial year ending 31 March 2021 (£38.7 million); and

9.215.5 12% of the sum of Flynn's net assets for the financial year ending 31 March 2021, and Flynn's total annual dividends over its last three financial years (£54.9 million).

9.216 While a penalty of £6,704,422 is relatively high by reference to Flynn's worldwide turnover in its last financial year, as well as its average annual worldwide turnover and average annual profit after tax in the last three financial years, the CMA does not consider that it is disproportionate or excessive, including with regard to the very serious nature of Flynn's Infringements and the considerable impact they had on the NHS and patients. Further, it amounts to only 18% of Flynn's total profits in the relevant market and only 19% of Flynn's total profits above Cost Plus in the relevant market during the Relevant Period and is therefore likely to be well below the financial benefit (excess profits) generated by Flynn as a direct result of its Infringements. An even lower penalty would risk seriously undermining the need for penalties to achieve effective deterrence.

¹⁸⁸³ As recently confirmed by the CAT in Case [2020] CAT 28 - *FP McCann v CMA*, paragraph 354, as a matter of principle, it is open to the CMA to conclude in Step 4 of its penalty assessment that the appropriate penalty, when expressed as a percentage of the turnover of the last year before the decision, should be greater than 10% of an undertaking's worldwide turnover, that is above the level of the statutory cap which applies in Step 5.

¹⁸⁸⁴ Requiring a reduction of more than 75% leading to a penalty that would be less than 18% of Flynn's total profits in the relevant market and less than 19% of Flynn's total profits above Cost Plus in the relevant market during the Relevant Period.

¹⁸⁸⁵ See CMA penalties guidance, paragraph 2.23.

9.217 In addition, a penalty of £6,704,422 appears neither disproportionate nor excessive by reference to Flynn’s net assets or the dividends it has paid.¹⁸⁸⁶

9.218 Finally, the CMA has concluded that it would be inappropriate to reduce Flynn’s penalty at step 4 (further) on account of the length of the investigation and appeals, as argued by Flynn.¹⁸⁸⁷ As set out at paragraph 9.200 above, the costs of the appeals are properly a matter for the CAT and the appellate Courts. Moreover, absent any ‘inordinate or inexcusable delays’¹⁸⁸⁸ (of which there are none in this case), the ordinary burdens of the investigation are not a proper basis on which to reduce the penalty at step 4.

iii. Calculation at the end of step 4 – Flynn

9.219 Given the reduction of Flynn’s penalty to the statutory maximum at step 5, the CMA has not determined the specific level of penalty that would have been proportionate above that level. Based on the above, the CMA has concluded that a penalty for Flynn at the statutory maximum of £6,704,422 would be neither disproportionate nor excessive.

VI. Step 5 – adjustment to prevent maximum penalty from being exceeded

9.220 Pursuant to section 36(8) of the Act, no penalty imposed by the CMA for an infringement of the Chapter I or the Chapter II prohibition may exceed 10% of the worldwide turnover of the undertaking in its last business year.¹⁸⁸⁹ The relevant business year for these purposes will be the one preceding the date on which the decision of the CMA is taken or, if figures are not available for that year, the one immediately preceding it. The penalty will be adjusted if necessary to ensure that it does not exceed this maximum.¹⁸⁹⁰

9.221 Based on the worldwide turnover set out in Pfizer’s latest accounts for the financial year ended 31 December 2021, no adjustment is required at this step as Pfizer’s penalty at the end of step 4 represents 0.11% of Pfizer’s applicable turnover.¹⁸⁹¹

9.222 The latest accounts available to the CMA for Flynn are for the financial year ended 31 March 2021. In that year, Flynn’s worldwide turnover was £67,044,220. Since

¹⁸⁸⁶ The CMA does not consider dividends to be a particularly useful financial metric in the context of its proportionality assessment.

¹⁸⁸⁷ Flynn submitted that the length of the investigation and appeals, and the resulting burdens of cost and management time, should be taken into account when reviewing the proportionality of any fine. PRC03495, Flynn’s response to the DPS, paragraph 4.18.

¹⁸⁸⁸ In *FP McCann v CMA*, the CAT found that, although it could not exclude the possibility that in certain cases it might be appropriate to reduce a penalty at step 4 on the grounds of delay, doing so would not be appropriate unless the passage of time amounted to an ‘inordinate or inexcusable delay’ - *FP McCann Ltd v CMA* [2020] CAT 28 at paragraphs 269-270.

¹⁸⁸⁹ Calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000, SI 2000/309, as amended by The Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004, SI 2004/1259; see CMA penalties guidance, paragraphs 1.11 and 2.25. See also footnote 1775 on the application of the statutory cap in case of multiple infringements.

¹⁸⁹⁰ CMA penalties guidance, paragraph 2.25.

¹⁸⁹¹ Pfizer’s worldwide turnover in the financial year ended 31 December 2021 was £59.1 billion.

the CMA has chosen to treat Flynn's Infringements as a single infringement for penalty purposes, the maximum penalty which could be imposed on Flynn in respect of Flynn's Infringements is 10% of this total, which is £6,704,422. As a result, the penalty for Flynn has been reduced to that figure.¹⁸⁹²

a. Calculation at the end of step 5

9.223 At the end of step 5, Pfizer's penalty is therefore £63,300,000 and Flynn's penalty is £6,704,422.

VII. Step 6 – application of reductions for leniency, settlement, and voluntary redress schemes

9.224 Step 6 provides an adjustment for leniency, settlement, and/or voluntary redress in appropriate cases. No such adjustment is appropriate for either Pfizer or Flynn in this case.

9.225 Accordingly, at the end of step 6:

9.225.1 Pfizer's penalty in respect of Pfizer's Infringements is £63,300,000.

9.225.2 Flynn's penalty in respect of Flynn's Infringements is £6,704,422.

E. Payment of financial penalties

9.226 For the reasons set out above, in accordance with section 36(2) of the Act, the CMA requires:

9.226.1 Pfizer to pay a penalty of £63,300,000; and

9.226.2 Flynn to pay a penalty of £6,704,422.

9.227 Each of the above penalties will become due to the CMA in its entirety and must be paid to the CMA by close of banking business on 22 September 2022. If that date has passed and (a) the period during which an appeal against the imposition, or amount, of that penalty may be made has expired without an appeal having been made, or (b) such an appeal has been made and determined, the CMA may

¹⁸⁹² Flynn's turnover in the financial year ending 31 March 2021 (£67,044,220) is higher than its turnover in the financial year preceding the 2016 Infringement Decision (FY15 = £51,644,247). As the CMA has chosen to impose fines at the statutory maximum level in both the 2016 Infringement Decision and in this Decision, this increase means that Flynn's penalty on remittal (£6,704,422) is higher than the penalty imposed on Flynn in the 2016 Infringement Decision (£5,164,425).

Flynn submitted that it has a '*legitimate expectation that the CMA should not ... impose a higher penalty than in the Original Decision when the CMA's only ability to do so arises from Flynn having succeeded in its appeal*' (PRC03495, Flynn's response to the DPS, paragraph 1.8). This is not accepted. The CMA penalties guidance is clear that the CMA should seek to determine the appropriate fine by reference to the financial position of the undertaking *at the time the penalty is imposed* (see paragraph 2.20). The correctness of this position has been confirmed by the Competition Appeal Tribunal in *FP McCann Ltd v CMA* [2020] CAT 28 at paragraph 307.

commence proceedings to recover from the undertaking in question, as a civil debt due to the CMA, any amount payable which remains outstanding.¹⁸⁹³

21 July 2022

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Julie Bon, Deputy Chief Economic Adviser, 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

¹⁸⁹³ Section 37(1) of the Act.