Neutral citation [2018] CAT 11

IN THE COMPETITION APPEAL TRIBUNAL

Case Nos: 1275-1276/1/12/17

Victoria House
Bloomsbury Place
London WC1A 2EB

7 June 2018

Before:

PETER FREEMAN CBE QC (Hon)
(Chairman)
PAUL LOMAS
PROFESSOR MICHAEL WATERSON

Sitting as a Tribunal in England and Wales

BETWEEN:

(1) FLYNN PHARMA LIMITED
(2) FLYNN PHARMA (HOLDINGS) LIMITED

Appellants in Case No: 1275/1/12/17
Interveners in Case No: 1276/1/12/17

- v -

COMPETITION AND MARKETS AUTHORITY

Respondent

AND BETWEEN:

(1) PFIZER INC.
(2) PFIZER LIMITED

Appellants in Case No: 1276/1/12/17
Interveners in Case No: 1275/1/12/17

- v -

COMPETITION AND MARKETS AUTHORITY

Respondent

Heard at Victoria House on 30-31 October and 1-2, 7-9, 13-14 and 21-24 November 2017

JUDGMENT

APPEARANCES

Ms Kelyn Bacon QC, Ms Ronit Kreisberger and Mr Tom Pascoe (instructed by Macfarlanes LLP) appeared on behalf of the Flynn Appellants.

Mr Mark Brealey QC, Mr Robert O'Donoghue QC and Mr Tim Johnston (instructed by Clifford Chance LLP) appeared on behalf of the Pfizer Appellants.

Mr Mark Hoskins QC, Mr David Bailey, Mr Hugo Leith and Ms Jennifer MacLeod (instructed by the CMA) appeared on behalf of the Respondent.

Note: Excisions in this Judgment (marked "[…][✂]") relate to commercially confidential information: Schedule 4, paragraph 1 to the Enterprise Act 2002.

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A. SUMMARY

1. This case concerns a CMA decision made in late 2016 fining two companies, Pfizer and Flynn, for charging the NHS unfair prices for the capsule form of an anti-epilepsy drug called phenytoin sodium, previously sold in the UK by Pfizer under the brand name "Epanutin".

2. The CMA found that each company had abused its dominant position, ordered them to lower their prices and imposed fines of nearly £90 million. One of the companies applied to the Tribunal to suspend the decision pending its appeal. The Tribunal refused that application. Both companies appealed the decision to the Tribunal. This document contains our decision on the appeals.

3. Cases of pure unfair pricing are rare in competition law. Authorities find them difficult to bring and are, rightly, wary of casting themselves in the role of price regulators. Generally, price control is better left to sectoral regulators, where they exist, and operated prospectively; *ex post* price regulation through the medium of competition law presents many problems. However, the law prohibits unfair pricing in certain circumstances and in such cases there is no reason in principle why competition law cannot be applied, provided this is done on the correct legal basis and the analysis of evidence is sound.

4. We understand the CMA's concern to deter and punish instances of unfair pricing that infringe the law. However, we have found this particular decision to be wrongly based in certain respects. Whilst we find the CMA was correct that the two companies each held a dominant position, we find the CMA's conclusions on abuse of dominance were in error. The CMA did not correctly apply the legal test for finding that prices were unfair; it did not appropriately consider what was the right economic value for the product at issue; and it did not take sufficient account of the situation of other, comparable, products, in particular of the phenytoin sodium tablet. This means that the CMA's findings on abuse of dominance in this case cannot be upheld.

5. The importance of this case for the public interest makes it desirable to rectify the errors we have found. In a matter as important for government, for the public as patients and as taxpayers, as well as for the pharmaceutical industry itself, the law should be clear

and any decisions made should be soundly based on proper evidence and analysis. It is important that there is a good legal foundation for any future action in this area.

6. As a Tribunal, we have the power to come to a new decision on abuse ourselves, and we were invited to do so by the CMA if necessary. We accept, of course, that one advantage of an appeal "on the merits" is that errors can be corrected by the Tribunal and further cost and delay can be avoided. In many cases, that is entirely proper and we would have followed that course had we felt that it was properly and responsibly available to us.

7. In the present case, however, although our essential finding is that the CMA misapplied the test for unfair pricing, the correct application of that test as we have described it would involve detailed consideration of further information, some of which may need to be obtained and properly tested, and the careful assessment of what normal competitive conditions might have been. A particular example is a better understanding of the evolution of the tablet market and tablet pricing. These are not things that the Tribunal is, in practice, in this case, in a position properly to do.

8. Our provisional view is that we will remit the part of this matter that deals with abuse of dominance to the CMA for further consideration as it sees fit. However, we will invite written submissions from the parties before coming to a final decision on remittal.

9. The rest of this document contains our full assessment and formal decision.

B. INTRODUCTION

10. On 7 December 2016, the Competition and Markets Authority ("CMA")[1] issued a decision entitled "Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK" addressed to Pfizer Limited and Pfizer Inc. (together, "Pfizer"), and Flynn Pharma Limited and Flynn Pharma (Holdings) Limited (together, "Flynn") (the "Decision"). In the Decision, the CMA found *inter alia* that: (i) Pfizer's supply prices to Flynn; and (ii) Flynn's selling prices, for the capsule form of the drug phenytoin sodium, which is used to treat epilepsy, were unfairly high. Pfizer and Flynn were each found to have infringed the Chapter II prohibition under the Competition Act 1998

[1] The abbreviations used in this Judgment are listed in the Appendix, which also sets out the paragraph in the Judgment where each abbreviation is first used.

("CA 98") and Article 102 of the Treaty on the Functioning of the European Union ("TFEU"). The CMA imposed a financial penalty of £84.2m on Pfizer and £5.2m on Flynn and directed Pfizer and Flynn to reduce their prices.

11. Pfizer and Flynn have separately appealed against the Decision, to the extent that it is addressed to each of them, under section 46 of the CA 98. At a case management conference on 8 March 2017, the Chairman ordered that the appeals be heard together and that Pfizer and Flynn each be granted permission to intervene in the other appeal. This is the single Judgment on those appeals, which have a number of overlapping grounds between them, although it will be necessary to consider the distinct grounds of appeal raised by each of Pfizer and Flynn.

C. FACTUAL BACKGROUND

12. The Decision contains a lengthy section on the factual background to the infringements. Pfizer and Flynn each disputed certain of the facts found by the CMA. They also strongly objected to the CMA's overall characterisation of the facts as set out in the Decision and to the omission of certain facts that they asserted were relevant. It will be necessary for us later in this Judgment to consider some of the factual matters in dispute in detail, as well as certain of the criticisms levied at the CMA. In this section of the Judgment, we summarise the basic factual background to this case, which is not in dispute save where otherwise stated.

(1) The Appellants

13. Pfizer Inc. is a research-based global biopharmaceutical company. Pfizer Limited is its indirectly wholly-owned subsidiary in the UK. Pfizer's principal activities are the discovery, development, manufacture and marketing of pharmaceutical products globally, including in the UK.

14. Flynn Pharma Limited is a pharmaceutical company engaged in the sale and marketing of pharmaceutical products. Its business model focusses on the acquisition and rescue of "end-of-life" pharmaceutical products. These are mature drugs for which demand is declining, which may be for a variety of reasons. Flynn Pharma Limited is a wholly-owned subsidiary of its holding company, Flynn Pharma (Holdings) Limited.

(2) Phenytoin sodium and epilepsy

15. Phenytoin sodium is a type of anti-epileptic drug ("AED"). Epilepsy is a neurological condition which leads to the occurrence of recurrent seizures in the brain. Whilst one-off seizures are not uncommon, in some individuals the balance between excitation and inhibition of activity in brain cells is persistently disturbed such that seizures recur spontaneously. This condition is termed epilepsy. The condition can be highly debilitating for sufferers with a material impact on their health and life possibilities.

16. Once a diagnosis of epilepsy has been made, it is usual for AEDs to be prescribed to a patient to try to control the frequency of seizures. Phenytoin, which has anti-seizure properties, is one of the longest-established AEDs, having been first commercialised in 1938. It is often administered as a sodium salt, phenytoin sodium. Although phenytoin was for a long time one of the most frequently used AEDs worldwide, its use in the UK has declined (and is estimated currently to be declining at around 4-6% per annum). Other than in emergency situations, in which it is used in injectable form, phenytoin is generally no longer prescribed as a first-line, or single, treatment for epilepsy. Two particular characteristics of phenytoin may have contributed to its decline in use in the UK. First, phenytoin has what is referred to as a narrow therapeutic index ("NTI"). This essentially means that 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. Secondly, the pharmacokinetics of phenytoin, namely how the drug moves through the body from its absorption to its eventual break-down and excretion, are non-linear. Both of these characteristics make it difficult for practitioners to regulate precisely the appropriate dose.

17. Phenytoin sodium is available in the UK in a variety of forms, including as capsules and tablets. The capsule form of the drug manufactured by Pfizer, but, since September 2012, supplied by Flynn (the "Pfizer-Flynn Capsule(s)"[2]), is available in four strengths: 25mg, 50mg, 100mg and 300mg. Phenytoin sodium capsules manufactured by Pfizer are also sold into the UK by parallel importers, for the most part in the 100mg strength. In addition, capsules in the 100mg strength only have been manufactured and supplied

[2] Where it is necessary to distinguish between Pfizer and Flynn, we refer in the alternative to "Pfizer's Products" or to "Flynn's Products".

by NRIM Limited ("NRIM")[3] since April 2013 (the "NRIM Capsule(s)"). The tablet form is only available in the 100mg strength. Its main manufacturer/supplier in the UK is Teva UK Limited ("Teva") (the "Teva Tablet(s)") although there are other manufacturers/suppliers.

18. Although relatively few patients newly diagnosed with epilepsy are now prescribed phenytoin sodium, as opposed to another AED, there are cases where it remains a therapeutically useful third-line treatment. There is also a community of established users who are stabilised on the treatment and for whom it is effective. At the time of the Decision, the CMA estimated that there were around 48,000 patients taking phenytoin sodium capsules in the UK.

(3) The provision and pricing of pharmaceutical products in the UK

(a) The manufacture and distribution of pharmaceutical products

19. Before selling a pharmaceutical product in the UK, a marketing authorisation ("MA") must be obtained from the Medicines and Healthcare Products Regulatory Agency ("MHRA"). The MHRA will only grant an MA if the pharmaceutical product meets satisfactory safety, quality and efficacy standards in treating the condition for which it is intended. Typically, a full initial application[4] for an MA will involve submitting the results of pre-clinical toxicological and pharmacological tests as well as clinical trials, which together allow an assessment of the safety and efficacy of the product. The MA holder is legally responsible for making sure the product complies with the terms of the MA and other applicable legislation or regulatory requirements. A company which holds an MA may either manufacture the pharmaceutical product itself or contract with a third party to manufacture the product on its behalf.

20. Pharmaceutical products are usually distributed by one of three routes: (i) a traditional wholesale model ("TWM"); (ii) a reduced wholesaler model ("RWM"); or (iii) a direct to pharmacy model ("DTP"). Under a TWM, the product is sold to all pharmaceutical wholesalers who wish to stock it, often at a standard discount to the list price specified in what is known as the Drug Tariff (see paragraphs 33 to 35 below). Wholesalers then

[3] NRIM was acquired by Auden McKenzie Holdings Limited in 2014, which itself has since been acquired by Actavis plc.
[4] An abridged application procedure is applicable in certain circumstances.

supply the product to pharmacies and may also offer discounts to attract business. An RWM has a reduced number of wholesalers but individual discounts may be negotiated with each of them. Under a DTP, the product is sold direct to pharmacies and the supplier directly sets the prices paid by pharmacies. For any given model, one or more wholesalers, sometimes referred to as pre-wholesalers, may be appointed to provide logistics services. Pre-wholesalers and wholesalers may also deliver to hospitals which make purchases directly from suppliers, often following a competitive tender process.

(b) The prescribing and dispensing of phenytoin sodium capsules

21. The key elements of prescribing and dispensing phenytoin sodium capsules within the UK's National Health Service ("NHS")[5] may be summarised as follows.

22. Following a diagnosis of epilepsy, the appropriate AED is identified and prescribed by specialist healthcare professionals. A prescription can either be "open" (which means that it is written generically so that the pharmacist can choose whether to dispense the generic or a branded version of the product) or "closed" (which means that the specific brand or manufacturer of the product is specified, leaving the pharmacist no choice as to which product to dispense). It was common ground in these appeals that the vast majority of phenytoin sodium capsule prescriptions are open.

23. The prescriptions are dispensed by retail pharmacists who purchase stock from specialist pharmaceutical wholesalers and/or directly from the manufacturers, depending on the applicable wholesale model.

24. Decisions as to the prescribing and dispensing of phenytoin sodium and other AEDs are informed by clinical guidance issued by specialist bodies such as the MHRA, the National Institute for Health and Care Excellence ("NICE"), the Commission on Human Medicines ("CHM"), and/or published in the British National Formulary ("BNF")[6]. That clinical guidance on the appropriate use of phenytoin and other AEDs has taken the form of various statements made over time. The Decision places heavy reliance on a "continuity of supply" principle, meaning that the clinical guidance has the effect that patients who are stabilised on a particular manufacturer's phenytoin

[5] A description of the overall structure of the NHS is set out at paragraphs 3.78 to 3.80 of the Decision.
[6] The BNF is a reference book for doctors and pharmacists which is authored jointly by the British Medical Association and the Royal Pharmaceutical Society.

sodium capsule are generally maintained on that manufacturer's capsule and should not be switched to another manufacturer's capsule. Although it is disputed whether this amounts to a principle, we use the term "Continuity of Supply" to refer to this feature of clinical practice.

25. In particular, in October 2004, NICE published guidance (CG20) entitled "The diagnosis and management of the epilepsies in adults and children in primary and secondary care". That guidance explained that:

> "4.8.8 Changing the formulation or brand of AED is 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."

26. In January 2012, NICE published guidance (CG137) entitled "Epilepsies: diagnosis and management" (the "NICE Guidance 2012"), which replaced its earlier CG20 guidance. It stated that:

> "1.9.1.4 Consistent supply to the child, young person or adult with epilepsy of a particular manufacturer's AED preparation is recommended, unless the prescriber, in consultation with the child, young person, adult and their family and/or carers as appropriate, considers that this is not a concern. Different preparations of some AEDs may vary in bioavailability or pharmacokinetic profiles and care needs to be taken to avoid reduced effect or excessive side effects…"

27. In July 2013, an *ad hoc* expert group of the CHM made recommendations on a range of issues relating to brand/generic prescribing and switching between formulations for AEDs. It published a report, entitled "Formulation switching of antiepileptic drugs" (the "CHM Report"), which stated:

> "…A review of a number of published studies on the issue of potential harm arising from generic substitution of AEDs did not show clear evidence of actual harm arising from switching formulations. However the lack of robust evidence of harm does not exclude the possibility that significant harm may sometimes occur, given the inherent limitations in the design of these mostly observational studies, as already reflected in the BNF with regard to phenytoin and carbamazepine, and more generally in the NICE AED guidance.
>
> […]
>
> The Group expressed a view that in general terms there was a need to maintain continuity of supply of a specific product for certain AEDs. The specific product could be either a branded product or a generic. Continuity of supply from the same manufacturer was the key issue, rather than whether the product was branded or a generic."

28. The CHM Report identified three groups of AEDs which were categorised by the degree of concern of the potential risk related to switching between products.

Phenytoin was in Category 1 entitled "definite concerns", in respect of which specific prescribing, supply and dispensing measures were needed to ensure consistent supply of a particular product. It was proposed that the BNF should be asked to include this guidance as to the identified categories:

> "The advice will need careful wording of text to ensure the message that continuity of supply from the same manufacturer is clearly stated to be the key issue rather than whether the product is branded or generic. There was agreement that terms such as "branded generic" should be avoided since this could lead to confusion."

29. On 11 November 2013, the MHRA published guidance entitled "Antiepileptics: changing products" (the "MHRA Guidance"). It adopted the recommendations set out in the CHM Report in relation to the classification of AEDs into three categories as follows:

> "When a generic medicine is shown to be bioequivalent (has the same effect on the body) to the original ('reference') product, as defined by the relevant regulations and guidelines, these products can be considered to be clinically equivalent.
>
> However, concerns about switching between different manufacturers' products of [AEDs] have been raised by patients and prescribers. These include switching between branded original and generic products, and between different generic products of a particular drug.
>
> Different AEDs vary considerably in their characteristics, which influence the risk of whether or not switching between different manufacturers' products of a particular drug may cause adverse effects or loss of seizure control.
>
> Following a review of the available evidence, the [CHM] considered the characteristics of AEDs and advised that they could be classified into three categories, based on therapeutic index…, solubility and absorption, to help prescribers and patients decide whether it is necessary to keep using a supply of a particular manufacturer's product.
>
> **Category 1 – Phenytoin, carbamazepine, phenobarbital, primidone**
>
> For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product.
>
> […]
>
> **Advice for healthcare professionals**
>
> If a patient should be maintained on a specific manufacturer's product, this should be prescribed either by specifying a brand name or by using the generic drug name and name of the manufacturer (marketing authorisation holder).
>
> **Additional advice for pharmacists**
>
> Dispensing pharmacists should ensure the continuity of supply of a particular product when the prescription specifies it. If the prescribed product is unavailable, it may be necessary to dispense a product from a different manufacturer to maintain continuity of treatment of that

AED. Such cases should be discussed and agreed with both the prescriber and patient (or carer).

Usual dispensing practice can be followed when a specific product is not stated.

Information for patients

Patients should take careful note of the name and manufacturer of their antiepileptic medicine and should check with their doctor or pharmacist if they are dispensed an unfamiliar medicine. […]"

30. The CHM wrote to healthcare professionals on 11 November 2013 to draw their attention to the MHRA Guidance, and the BNF and the NICE Guidance 2012 were subsequently updated to take account of it.

(c) The pricing framework for pharmaceutical products

31. The pricing framework for pharmaceutical products is described at paragraphs 3.118-159 of the Decision. Whilst certain aspects of the pricing framework as described in the Decision are a matter of contention in these appeals, it is useful to highlight some agreed general elements.

32. Under the NHS system, the patient or end user of a medicine generally does not pay for that medicine. Rather, it is paid for by the NHS. NHS Clinical Commissioning Groups ("CCGs")[7] are responsible for providing and funding health services in their local areas, and reimburse pharmacies for the cost of medicines dispensed by them.

The Drug Tariff

33. The Drug Tariff[8] sets out the reimbursement that pharmacies can claim from the NHS when fulfilling NHS prescriptions. It is produced on a monthly basis by the NHS. The prices listed in the Drug Tariff reflect any voluntary or statutory price controls that may apply. Under the Drug Tariff arrangements, a pharmacy is reimbursed for medicines dispensed at a basic price minus any clawback discount. This price has been variously

[7] In Scotland, the equivalents to CCGs are Regional Boards which devolve responsibility for health service budgets to Community Health Partnerships; in Wales, the equivalents are Local Health Boards; and in Northern Ireland the equivalent is the Health and Care Social Board which works with six Health and Social Care Trusts (para 3.79 of the Decision).

[8] There is a common Drug Tariff in England and Wales. Separate Drug Tariffs are published in Scotland and Northern Ireland.

referred to in these appeals as the "reimbursement price" or the "Drug Tariff Price". For convenience, in this Judgment we use the term "Drug Tariff Price".

34. Products covered by the Drug Tariff are assigned to one of three categories (A, C or M) which determine the Drug Tariff Price for the product. Two of those categories are relevant for present purposes. Category C comprises drugs which are not readily available as a generic. The Drug Tariff Price of a Category C drug is based on a list price for a particular proprietary product, manufacturer or, as the case may be, supplier. Category M comprises drugs which are readily available as generics. The Drug Tariff Price of a Category M drug is based on a calculation that incorporates a volume-weighted average selling price derived from information submitted to the Department of Health ("DH") by eligible suppliers participating in Scheme M (as described at paragraphs 40 to 44 below) and the margin to be retained by pharmacies as agreed between the DH and the Pharmaceutical Services Negotiating Committee ("PSNC").

35. The Pfizer-Flynn Capsule was added to the Drug Tariff in October 2012 under Category C. According to the Decision, the assignment to this category was agreed between the DH and the PSNC.[9] By contrast, the Teva Tablet is in Category M of the Drug Tariff.

The voluntary schemes

36. A number of voluntary regulatory schemes for controlling the prices of health service medicines, including pharmaceutical products sold to the NHS, have been agreed with industry bodies pursuant to section 261 of the National Health Service Act 2006 (as amended) (the "NHS Act 2006").[10] Section 261(1) describes the purposes of these schemes as limiting the prices of NHS medicines or the profits which may accrue to scheme members.

37. The Pharmaceutical Price Regulation Scheme ("PPRS"), of which both Pfizer and Flynn are members, is a non-contractual voluntary scheme, agreed between the DH[11]

[9] See paras 3.127 and 3.160(c) of the Decision.
[10] Whilst the relevant sections of the NHS Act 2006 refer to the role of the Secretary of State for Health, in practice, that role falls to be discharged by the DH and accordingly, for convenience, we refer to the DH in this context.
[11] The pricing of medicines is reserved to the UK Government, with the exception of Northern Ireland. In the PPRS context, the DH acts on behalf of the UK Government and Northern Ireland which includes the health departments of England, Wales, Scotland and Northern Ireland.

and the Association of the British Pharmaceutical Industry ("ABPI"). It controls the overall profit that scheme members make on the sales of their portfolio of branded licensed medicines to the NHS and limits the ability of scheme members to increase the prices of their branded medicines. It does not apply to generic medicines. Each PPRS is usually in effect for a period of five years. Of particular relevance to these proceedings are the 2009 PPRS (which was effective from 1 January 2009 to 31 December 2013) and the 2014 PPRS (which has been effective since 1 January 2014 and will operate until 31 December 2018).

38. The profit control under the PPRS is based on specified target rates of return, which apply on a portfolio basis (i.e. to a scheme member's entire branded medicines portfolio) rather than to individual products. These target rates of return include allowances for research and development, information and marketing expenses, and, in addition, benefit from a margin of tolerance ("MOT"). The target rates are expressed either as return on capital employed ("ROCE") or return on sales ("ROS"). Under both the 2009 PPRS and the 2014 PPRS, the target ROS is 6% and the target ROCE is 21%. Scheme members who achieve a specified sales value threshold are required to submit an annual financial return ("AFR") to the DH. If a scheme member exceeds its target profit by more than the MOT (which was 40% in the 2009 PPRS and is 50% in the 2014 PPRS), it must repay the excess to the DH and/or reduce prices.

39. The price of individual products subject to the PPRS may only be increased either by applying to the DH for approval to increase a price, which rarely occurs in practice, or by price modulation. Under price modulation, a scheme member can increase the price of an individual product by up to 20% provided that the increase is offset by an appropriate reduction in the prices of other products. Any such modulation is subject to the overall profit control and any general price control mechanism contained in the relevant PPRS. For example, the 2014 PPRS introduced a limit on the overall amount that the NHS spends on branded medicines supplied by scheme members. Another element as regards profit is an allowance granted where products are purchased from an affiliate of the PPRS member (the "Transfer Price Profit Allowance").

40. In relation to generic medicines, the applicable voluntary schemes are known as Scheme M and Scheme W.

41. Scheme W is a voluntary scheme similar in nature to Scheme M, but it applies to wholesalers of Category M generic products. It did not feature materially in these appeals and we do not consider it further.

42. Scheme M, which is for manufacturers, is a non-contractual voluntary scheme for setting the Category M Drug Tariff Price, agreed between the DH and the British Generic Manufacturers Association ("BGMA"). Introduced in June 2005 but revised in March 2010, the scheme applies to manufacturers and suppliers of generic medicines for use in the NHS. Neither Pfizer nor Flynn was in Scheme M at any material time although Teva was a member at all material times.

43. Scheme M sets out the sales and volume information to be provided by scheme members for the purpose of the Category M Drug Tariff Price calculation. It also provides that:

> "Wherever possible, the [DH] will allow changes in market prices to be influenced by existing market mechanisms. This means that, where there is effective competition in respect of any given generic medicine, then the [DH] will not interfere in the operation of the market for that medicine. However, should the [DH] identify any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure, then the [DH] may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned."

44. If a company does not join Scheme M, it will still be subject to any relevant statutory scheme in force.[12]

Statutory powers

45. Sections 261 to 266 of the NHS Act 2006 set out certain other powers of the DH to regulate the prices of NHS medicines or the profits accruing to manufacturers or suppliers. The extent of these powers is disputed in these appeals. In overview, the relevant legislation is as follows. Section 261(4) of the NHS Act 2006 establishes the power to remove a manufacturer or supplier from a voluntary scheme:

> "If any acts or omissions of any manufacturer or supplier to whom a voluntary scheme applies (a "scheme member") have shown that, in the scheme member's case, the scheme is ineffective for either of the purposes mentioned in subsection (1), the Secretary of State may by a written notice given to the scheme member determine that the scheme does not apply to him."

[12] See paragraphs 47 to 48 below.

46. Section 262 of the NHS Act 2006 provided at the material time that:

> **"262 Power to control prices**
>
> (1) The Secretary of State may, after consultation with the industry body—
>
> (a) limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine, and
>
> (b) provide for any amount representing sums charged by that person for that medicine in excess of the limit to be paid to the Secretary of State within a specified period.
>
> (2) The powers conferred by this section are not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies."

47. Sections 263 to 264 confer on the DH a power to establish non-voluntary statutory schemes to control *inter alia* the prices of medicines not covered by a voluntary scheme. In particular, section 263(7) provides that "a statutory scheme may not apply to a manufacturer or supplier to whom a voluntary scheme applies".

48. The non-voluntary statutory schemes in force at any material time[13] only applied to branded medicines. There were no such non-voluntary schemes in force for generic medicines after 2007. Prior to the introduction of (the voluntary) Scheme M, there was a statutory maximum price scheme applicable to generic products in the form of the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000[14] (the "MPS"). From 2000 to 2005 the price of phenytoin tablets was capped under the MPS. The MPS was adopted *inter alia* under section 34 of the Health Act 1999, a provision which was identical in wording to section 262 of the NHS Act 2006, and was revoked on 25 May 2007.

49. According to the Decision (para 3.156), under the regulatory framework in place from the date that Flynn started to market Pfizer-Flynn Capsules, they were exempt from statutory price controls (although this is contested by the Appellants). This was said to be because Pfizer-Flynn Capsules had been sold as generics since September 2012 and, as such, ceased to be subject to any price regulation. As a product, they were not

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[13] These were: the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 (S.I. 2007/1320) (in force from 25 May 2007 to present); the Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008 (S.I. 2008/1938) (in force from 1 September 2008 to 31 January 2009); the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008 (S.I. 2008/3258) (in force from 1 February 2008 to present).
[14] S.I. 2000/1763.

covered by the PPRS or any other voluntary scheme and, because Pfizer and Flynn, as companies, were members of a voluntary scheme, the PPRS, all the products they sold were exempt from the DH's statutory price controls under sections 262 and 263 of the NHS Act 2006.

50. Since the date of the Decision and the filing of these appeals, the Health Service Medical Supplies (Costs) Act 2017 (the "2017 Act") has been enacted (on 27 April 2017) which makes certain amendments to the statutory powers of the DH under the NHS Act 2006. In introducing the relevant Bill to Parliament on its second reading on 24 October 2016, the Secretary of State stated that:

> "…Our concern is that companies have been exploiting the differences between the voluntary and statutory schemes, particularly the loophole, which the Bill seeks to close, that if companies have drugs in both schemes, we are unable to regulate at all the prices of the drugs that would ordinarily fall under the statutory scheme…"

51. Section 4 of the 2017 Act substituted section 262(2) of the NHS Act 2006 with effect from 7 August 2017 such that it now provides:

> "If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine."

(4) The arrangements between Pfizer and Flynn

52. Phenytoin sodium capsules were sold in the UK under the brand name Epanutin from 1938 until September 2012 (when the transaction between Pfizer and Flynn, as described below, took effect). From 2000, they were sold by Pfizer, which acquired the product as part of its purchase of the US pharmaceutical company Warner-Lambert. The capsules were manufactured by Pfizer in Germany and Pfizer was the holder of the MA in the UK. Epanutin was a branded drug subject to control under the PPRS to which Pfizer belonged. The evidence given on behalf of Pfizer was that Epanutin was regarded internally in Pfizer as a "tail" or "established" product, namely a product that did not have patent protection and with its revenue in progressive decline. A dedicated business unit within Pfizer actively managed Pfizer's portfolio of such established products with a view to improving their commercial contribution. In general, this could be achieved by means of a range of potential methods but discontinuation and divestment were also options. Within the tail portfolio, Epanutin had relatively high sales revenues but, according to Pfizer, had been either loss-making or only marginally

profitable for a considerable time. It was also widely known in the market, including within Pfizer, that there was a disparity between the Drug Tariff Price of Epanutin capsules and that of generic phenytoin sodium tablets. For example, in October 2008, the Drug Tariff Price of a pack of 28 x 100mg tablets was £30, whereas the Drug Tariff Price of a pack of 84 x 100mg Epanutin capsules (i.e. three times the volume) was £2.83.

53. Beginning in 2009, Pfizer considered proposals from a number of companies in relation to options for Epanutin, most notably Tor Generics Limited ("Tor") and Flynn. Tor is a company which supplies niche pharmaceutical products to wholesalers. It approached Pfizer in mid-2009 with a proposal that Pfizer's Epanutin capsules be discontinued and re-launched as a generic product marketed by Tor. According to Pfizer, this was proposed on the basis that it would have enabled the price to be reset at a commercially viable level. The Tor price proposal took the Drug Tariff Price of tablets as a starting point.

54. Ultimately, Pfizer did not pursue Tor's proposal. By the time Pfizer formally rejected that proposal, in mid-April 2010, however, it was already in discussions with Flynn regarding Epanutin. Pfizer had approached Flynn in January 2010 to discuss the business development of a number of tail products, of which Epanutin was one. Discussions between Pfizer and Flynn continued over the following two years and included a meeting in March 2010 followed by a further meeting on 1 July 2010 at which Flynn presented a proposal in relation to Epanutin to Pfizer. The detail of the proposal is contained in a copy of Flynn's presentation entitled "Epanutin ® proposal July 2010" which summarised the position of Epanutin at that time as follows:

> "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"

55. In essence, Flynn's proposal was that it would become the MA holder for Epanutin, which would then be de-branded in the UK, with Flynn setting the UK price of the capsules as a generic. References were made in the presentation to the Drug Tariff Price of tablets including the recommendation that:

> "…price is pitched at half of the price for phenytoin tabs initially, i.e. £15 for 28 caps x 100mg."

56. Proposed heads of terms between Flynn and Pfizer (the "Draft Heads of Terms") were subsequently drawn up by Flynn at Pfizer's request by the end of July 2010. That draft document proposed, *inter alia*, that Pfizer's total supply price would be 50% of Flynn's net selling price. A further detailed proposal was produced by Flynn in October 2010 and discussions continued, including internally at Pfizer. Flynn's proposal was eventually approved by Pfizer in September 2011 and arrangements were then made to progress the legal documents.

57. The agreements entered into between Pfizer and Flynn were as follows:

(1) An asset sale agreement dated 27 January 2012 (the "Asset Sale Agreement"), pursuant to which, *inter alia*, Pfizer agreed to transfer the relevant MAs for Epanutin, subject to the necessary regulatory approvals, to Flynn for a nominal sum; and Flynn agreed to submit an application to the MHRA for the transfer of the MAs within 10 business days of receipt of the relevant documents and information from Pfizer.

(2) An exclusive supply agreement dated 17 April 2012 (the "Exclusive Supply Agreement") pursuant to which, *inter alia*, Pfizer agreed, for an initial term of […][✂] years, to supply what were then Epanutin capsules, which it would continue to manufacture, to Flynn. The Exclusive Supply Agreement set the supply prices from Pfizer to Flynn and provided for an annual price review. The supply prices for the capsules were set out in Schedule 1 of the Exclusive Supply Agreement as follows:

Strength	Price per unit
25mg	[…][✂] (per pack of 28 capsules)
50mg	[…][✂] (per pack of 28 capsules)
100mg	[…][✂] (per pack of 84 capsules)
300mg	[…][✂] (per pack of 28 capsules)

In contrast to the proposal set out in the Draft Heads of Terms, the Exclusive Supply Agreement set out exact supply prices rather than making Pfizer's supply prices a percentage of Flynn's selling prices. The Exclusive Supply Agreement also contained an indemnity clause.

(3) A quality agreement was entered into in June 2012 which set out the responsibilities of Pfizer (as manufacturer and supplier) and Flynn (as purchaser in relation to quality assurance).

(5) Communications with the MHRA and the DH

(a) Flynn's application to the MHRA for a change of name

58. In accordance with the terms of the Asset Sale Agreement, Flynn submitted a change of ownership application for all four strengths of the Epanutin capsules to the MHRA on 3 February 2012, which was approved by the MHRA on 23 March 2012. The MHRA agreed a six-month transition period with the result that Pfizer's MAs were not cancelled until 23 September 2012.

59. Flynn's subsequent application to the MHRA on 2 May 2012 to change the name of Epanutin to "Phenytoin Sodium Capsules" was met with some concern at the MHRA, primarily in relation to the potential for the name change to cause confusion to patients, prescribers and other healthcare professionals. This led to a series of communications between Flynn and the MHRA regarding the name change. The MHRA also corresponded with the DH regarding the change, having brought the matter to the attention of the DH on 21 June 2012. In the light of the position of the MHRA, Flynn agreed to withdraw its application and submit a new application which would include a communication plan for the name change. Flynn submitted a draft communication

plan to the MHRA on 6 July 2012. Having reviewed the draft, the MHRA wrote to Flynn on 11 July 2012 with its comments, which included the following:

> "In the event of the name change being acceptable to the MHRA, we would wish to see the formal product name as 'Phenytoin Sodium Flynn x mg Hard Capsules' in Section 1 of the SmPC [Summary of Product Characteristics]. However, we would not need or want the name 'Flynn' to appear within the product name on the labelling and packaging intended for marketing."

60. Flynn's communication plan was finally approved by the MHRA on 19 July 2012. Flynn resubmitted its application for a name change on 31 July 2012 with the product name "Phenytoin Sodium Flynn Hard Capsules" (on the basis of the MHRA's indication). By this time, Flynn had received confirmation from the DH that it would not be permitted to launch as a branded product with a price increase (see paragraph 63 below).

61. As part of the communications plan, Flynn wrote to healthcare professionals on 21 September 2012 about the changes it would be implementing (see paragraph 126 below).

(b) Pfizer's and Flynn's discussions with the DH

62. Having been notified by the MHRA of Flynn's name change proposal, the DH contacted Pfizer by email on 21 June 2012 to request details of the divestment to Flynn. Pfizer responded on 22 June 2012, describing the transaction as "still commercially sensitive" and identifying the Epanutin capsule products that were being divested.

63. Flynn contacted the DH on 3 July 2012 to request a meeting, which took place on 18 July 2012 (the "18 July Meeting"). Prior to the meeting, the MHRA and the DH engaged in correspondence which raised the possibility of the price of Epanutin being increased within the PPRS, and the issue was left as a matter for discussion directly between the DH and Flynn. This was one of the options raised by Flynn with the DH at the 18 July Meeting, the other being genericisation. The DH ultimately confirmed to Flynn, on 26 July 2012, that the pricing committee of the PPRS had rejected Flynn's proposal to increase the price of Epanutin within the PPRS. Accordingly, Flynn proceeded with the genericisation option.

64. On 24 September 2012, Flynn launched the Pfizer-Flynn Capsules under the MHRA-approved product name "Phenytoin Sodium Flynn Hard Capsules". As described at paragraph 35 above, the Pfizer-Flynn Capsules were added to the Drug Tariff in October 2012 under Category C (drugs which are not readily available as a generic and for which the Drug Tariff Price is based on a list price for a particular proprietary product, manufacturer or supplier). The Pfizer-Flynn Capsules were agreed by the DH and the PSNC to be the product on which the Drug Tariff Price would be based. Flynn's list prices thus formed the basis for the Drug Tariff Price of the Pfizer-Flynn Capsules.

65. With effect from October 2012, there were substantial increases in the Drug Tariff Prices of all capsule strengths:

Strength	**Drug Tariff Price pre-September 2012**	**Drug Tariff Price October 2012 to April 2014**[15]	**Flynn's average selling prices ("ASPs") post-September 2012**[16]
25mg	£0.66 (per pack of 28 capsules)	£15.74 (per pack of 28 capsules)	[…][✂] (per pack of 28 capsules)
50mg	£0.67 (per pack of 28 capsules)	£15.98 (per pack of 28 capsules)	[…][✂] (per pack of 28 capsules)
100mg	£2.83 (per pack of 84 capsules)	£67.50 (per pack of 84 capsules)	[…][✂] (per pack of 84 capsules)
300mg	£2.83 (per pack of 28 capsules)	£67.50 (per pack of 28 capsules)	[…][✂] (per pack of 28 capsules)

66. On 6 November 2012, the DH and Flynn met to discuss "the prices and supply of phenytoin sodium capsules". The DH also met Pfizer on 10 January 2013.[17]

D. THE DECISION

67. The CMA's investigation formally commenced in May 2013, following a complaint in September 2012 by the DH to the Office of Fair Trading ("OFT"), as it then was. Initially, the focus of the CMA was on a possible infringement of the Chapter I prohibition and Article 101 TFEU by Pfizer and Flynn, with Pfizer's conduct also being

[15] Decision Table 3.3.
[16] Decision Table 3.6. These are the actual prices at which Flynn sold the Pfizer-Flynn Capsules to pharmacies and wholesalers, which are at a discount to the Drug Tariff Price.
[17] These meetings are considered in more detail in Section G(6)(a) below.

examined in relation to Chapter II CA 98 and Article 102 TFEU. The CMA extended the scope of its investigation in February 2014 to include Flynn's pricing conduct under the Chapter II prohibition and Article 102 TFEU. The infringements found in the Decision relate solely to Chapter II and Article 102 TFEU.

68. The key findings in the Decision for the purposes of these appeals are, in broad outline, as follows:

(1) The infringement period was 24 September 2012 to at least 7 December 2016 i.e. the date of the Decision (the "Relevant Period").

(2) Phenytoin sodium capsules were subject to what is termed in the Decision as the "Continuity of Supply" principle (as already described at paragraph 24 above), meaning 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 capsule.

(3) The relevant markets were:

(i) as regards Pfizer: the manufacture of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK (which includes parallel imports as they are distributed in the UK); alternatively, for the period prior to November 2013, the manufacture of phenytoin sodium capsules that are distributed in the UK; and

(ii) as regards Flynn: the distribution of Pfizer-manufactured phenytoin sodium capsules in the UK; alternatively, for the period prior to November 2013, the distribution of phenytoin sodium capsules in the UK.

(4) Each of Pfizer and Flynn separately held a dominant position in their respective relevant markets throughout the Relevant Period. These findings were based, in particular, on the following factors:

(i) Pfizer and Flynn had separately and consistently held very high market shares.

(ii) Pfizer and Flynn's pricing behaviour and financial performance showed they were each able to exercise significant market power.

(iii) Pfizer and Flynn had faced only very weak competitive constraints from parallel imports and NRIM[18].

(iv) Significant barriers to entry had prevented other potential entrants from acting as an effective competitive constraint on either Pfizer or Flynn.

(v) The NHS, whether through the medium of the CCGs or the DH, did not, as a matter of fact, have sufficient countervailing buyer power to effectively constrain either Pfizer's or Flynn's conduct.

(5) Each of Pfizer and Flynn abused their respective dominant positions by charging excessive and unfair prices throughout the Relevant Period. In reaching this conclusion, the CMA determined the following.

(i) The proper approach to assessing whether Pfizer's and Flynn's prices were excessive was a "Cost Plus" approach. This allowed each of Pfizer and Flynn a specified ROS based on their direct costs and a proportion of their indirect costs. For each of Pfizer and Flynn, a ROS of no more than 6% was reasonable. Pfizer's and Flynn's ROS throughout the Relevant Period was significantly higher than 6% and sufficiently so that the CMA determined the prices charged by each to be excessive.

(ii) The economic value of the capsules was Cost Plus as there were no demand-side or non-cost factors to be taken into account which, in fact, increased their value above that level. Pfizer's and Flynn's prices were unfair in themselves as they bore no reasonable relation to the economic value of the capsules. In light of this finding, it was not necessary for the CMA to reach a conclusion on whether those prices were also unfair when compared to competing products. In any event, when it examined potential competing products, there were no products that would provide a meaningful comparison for this purpose.

[18] See paragraph 17 above.

(6) As Pfizer and Flynn each charged different prices and incurred different costs for each of the four different capsule strengths, the CMA found that each of Pfizer and Flynn had engaged in four separate abuses of dominance, making a total of eight findings of infringement.

(7) The infringements were intentional or negligent. Accordingly, the CMA imposed a penalty of £84,196,998 on Pfizer and £5,164,425 on Flynn. The CMA also directed Pfizer and Flynn to reduce their prices.[19]

E. THE APPEALS

(1) Overview

69. As mentioned above, the appeals were heard together, with each of Pfizer and Flynn intervening in the other's appeal. The relief sought in each appeal is for the Decision to be set aside in full (or, in Pfizer's case, in part) or, alternatively, for the penalties to be set aside or reduced.

70. There are seventeen grounds of appeal in total, five for Pfizer and twelve for Flynn. It is more convenient to group the grounds of appeal as they relate to the main issues in the case rather than to deal with them *seriatim*. These issues are, in logical order:

(1) Market definition and dominance (Pfizer Ground 1, Flynn Grounds 1-3).

(2) Abuse – excessive prices (Pfizer Ground 3, Flynn Grounds 4-7).

(3) Abuse – unfair prices (Pfizer Ground 2, Flynn Grounds 8-9).

(4) Pfizer's position as supplier (Pfizer Ground 4).

(5) Penalties – (Pfizer Ground 5, Flynn Grounds 10-12).

(2) Factual witnesses

71. We heard evidence from one factual witness on behalf of Pfizer and two factual witnesses on behalf of Flynn.

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[19] Flynn subsequently made a request to the Tribunal for interim relief pursuant to Rule 24 of the Tribunal Rules, by which it sought the suspension of the CMA's directions pending the determination of these appeals. The request was refused by the Tribunal on 19 January 2017 ([2017] CAT 1).

72. Pfizer called Mr Steve Poulton, who has worked for Pfizer Limited since 1998. His current job title is Joint Venture Operations Lead for the Pfizer Essential Health business unit. From January 2009 to July 2012, he was Head of Pfizer's Established Products Business Unit in the UK (the business unit that arranged the transaction with Flynn in relation to Epanutin capsules). Mr Poulton signed both the Asset Sale Agreement and the Exclusive Supply Agreement on behalf of Pfizer. We found Mr Poulton to be a straightforward and credible witness, giving answers that were sensible and balanced.

73. Flynn's first factual witness was Mr David Walters. Mr Walters has been a director of Flynn Pharma Limited since 2004 and is also a director of Flynn Pharma (Holdings) Limited. We found Mr Walters to be a generally credible witness but inclined to put Flynn's case and to justify his conduct rather than to take an objective view of the facts. Some of his answers lacked focus and/or were embellished with comments to try to put matters in the context that seemed appropriate to him.

74. Flynn's second factual witness was Mr John Beighton who was the Managing Director of Teva from October 2002 to January 2009. He has, since then, held a number of other roles in the generic pharmaceutical industry, most recently as President of Concordia International Corp's International Segment until January 2017, and is a former Chairman of the BGMA. Although called by Flynn, Pfizer was granted permission to put questions to Mr Beighton prior to his cross-examination by the CMA. Mr Beighton's witness statement was very short and primarily described the circumstances of a meeting between Teva and the DH in 2007 at which the pricing of the Teva Tablet was discussed. Although the subject matter of his evidence was of some importance to Flynn and, indeed, to Pfizer, Mr Beighton gave a rather mixed impression as a witness, with very precise recall in some areas, but rather vague in others. He was somewhat cautious and limited in his responses and produced no supporting documentation. However, we found his account of the 2007 meeting to be broadly credible.

(3) Expert witnesses

75. The Tribunal heard evidence from a total of seven experts: three on behalf of Pfizer, three on behalf of Flynn and one on behalf of the CMA.

76. Pfizer's expert witnesses were as follows.

(1) Professor Matthew Walker is a Consultant Neurologist at the National Hospital for Neurology and Neurosurgery, and Professor of Clinical Neurology at University College London. He gave evidence on epilepsy and how it is treated by AEDs, with specific reference to phenytoin. His evidence also addressed the MHRA Guidance and the medical or clinical comparability of phenytoin sodium tablets and phenytoin sodium capsules. Professor Walker was the only witness called who could speak to the medical and clinical background to the case. We found Professor Walker to be a highly competent and impressive witness. Under cross-examination, his evidence emerged largely unchallenged.

(2) Mr Richard Goosey is a board member and Chief Methodologist for Kantar Health UK ("Kantar"), a global healthcare consulting firm. Pfizer commissioned Kantar to conduct a survey of the behaviour of pharmacists as regards their dispensing practice in the UK with respect to phenytoin sodium. We found Mr Goosey to be a credible and competent witness within his specialised field. However, his oral evidence did not add greatly to the data submitted with his written opinion.

(3) Mr Derek Ridyard is a partner and co-founder of RBB Economics LLP. He produced an economic assessment of the Decision, in particular by reference to the CMA's assessment of the relevant market and Pfizer's dominance within that market; its Cost Plus analysis; its conclusion that Pfizer's prices were abusive, including its approach to economic value and the significance of comparisons with other AEDs; and its theory of downstream harm arising from Pfizer's upstream price. Mr Ridyard's written evidence was clear and persuasive. Under cross-examination, he was on occasions more equivocal than in his written evidence.

77. Flynn's expert witnesses were as follows:

(1) Mr Roger Davies has worked in the pharmaceutical industry for over 35 years in a variety of roles including strategy, finance, marketing, business development and consultancy. His evidence related to the activities of generic companies and their pricing strategies; the commercial risks incurred by Flynn;

and Flynn's profitability compared to other generic companies. He also commented adversely on the CMA's use of the Cost Plus method. Although clearly very experienced in his field, Mr Davies' oral evidence was sometimes rather diffuse. Whilst he was quite rightly willing to concede untenable points, on occasions this served to undermine the force of his evidence.

(2) Mr Raphaël De Coninck is a competition economist at Charles River Associates ("CRA"). The reports produced by CRA for the purposes of the CMA investigation and Flynn's appeal set out a benchmark analysis of the profitability of Pfizer-Flynn Capsules as an alternative to the Cost Plus method and criticised the CMA's and Mr Harman's approach in this regard. Mr De Coninck also addressed certain aspects of market definition, including in the form of updated charts produced in the course of the hearing further to requests from the Tribunal. Mr De Coninck gave some useful expert evidence within the areas on which he was asked to contribute.

(3) Mr Richard Williams is a chartered accountant with over 30 years' experience of working with pharmaceutical clients and the DH in relation to UK branded and generic medicine pricing arrangements, in particular the PPRS, on which topics he was clearly highly knowledgeable. In his evidence, he critiqued the CMA's calculation of the level by which Flynn's prices were said to be excessive on various grounds, and its apparent reliance on the PPRS in this regard. He was the only witness with detailed knowledge of the PPRS. Under cross-examination we found him to be open and credible in his answers.

78. The CMA called Mr Greg Harman who is a partner at FTI Consulting and a chartered accountant. Mr Harman's evidence assessed the CMA's approach in the Decision to the allocation of common costs and a reasonable rate of return. He was an impressive expert witness, giving clear and cogent answers within the areas on which he was asked to opine, which were generally confined to the assessment of costs and rates of return. It is unfortunate that his instructions were not more broadly framed, as he was obliged by their narrow nature to assume as correct, or not to comment on, a number of contentious matters, on which his expertise might have been of material assistance to the Tribunal.

79. In light of the overlap between the issues addressed by Mr Williams and Mr Harman, a joint statement was produced by them on the issue of cost allocation which assisted the Tribunal on the limited area it covered.

(4) Other issues in relation to evidence

(a) The position of the DH

80. The CMA did not put forward any factual evidence in these appeals. This was the subject of some criticism by the Appellants, in particular as regards the absence of any direct evidence from the DH.

81. The DH played a significant part in the facts leading to these proceedings. What the DH did, or did not do, at various points in time in relation to the pricing of tablets and capsules, as well as the extent of its statutory powers, and the view it took of those powers, are matters that featured in the cases advanced by all parties and about which the parties have diverging views. As stated above, the CMA's investigation began following a complaint from the DH in September 2012. The CMA spoke and met with DH officials on various occasions during the course of its investigation. Some notes of these calls and meetings drafted by the CMA (and in some cases commented on by the DH), and related correspondence, were available to the Tribunal, although it appeared that the DH personnel involved in the meetings with the CMA did not always have first-hand knowledge of the matters being addressed. Our attention was drawn to these documents specifically in relation to both the reduction of the Teva Tablet price in 2007 to 2008 and the setting of the Pfizer-Flynn Capsule price in 2012. We were also referred to the communications between Flynn and the MHRA, and between the MHRA and the DH, in connection with the proposed name to be applied to the capsule product (see section C(5) above), and a note of a call containing the DH's views on the operation of the PPRS.

82. The DH was represented at the hearing of an application for interim relief brought by Flynn.[20] However, it chose not to intervene in the main proceedings. Nor did any DH official provide witness evidence as part of the CMA's defence. This is notwithstanding that the identities of the two DH officials who attended the meeting with Teva in 2007

[20] See footnote 19 above.

appeared to us to be readily ascertainable and were confirmed by Mr Beighton in the course of the hearing. The CMA did rely on Section 26 Responses provided by the DH (see paragraph 83 below). However, no direct witness evidence from the DH was provided to the Tribunal, and the CMA was therefore in the position of defending its Decision without the benefit of what could potentially have been important direct evidence from the DH on a series of pertinent issues, that the Appellants would have had the opportunity to challenge in cross-examination. Pfizer, in particular, was heavily critical of the absence of any factual evidence from the DH, and considered that the DH's absence had put Pfizer, and the Tribunal, in a difficult position in these appeals. Whilst we appreciate that the DH carefully considered its position in relation to these appeals, including the obvious interest in limiting the cost of the appeals to the taxpayer, given the undoubted relevance of the DH's role to the matters in issue, we consider that our task would have been easier had there been direct evidence before the Tribunal from the DH.

(b) The weight to be attached to responses to section 26 notices

83. In the Decision, the CMA relied significantly on evidence obtained in the form of responses to notices it issued, mainly to pharmacies but also, amongst others, to the DH, using its powers under section 26 CA 98 ("Section 26 Responses"). Pfizer contended that Section 26 Responses constitute "a very weak evidential ground" on which to base an infringement finding. Similarly, Flynn submitted that the Tribunal should not place any substantial weight on Section 26 Responses in circumstances where no relevant witness had been called to give evidence. Each of Pfizer and Flynn relied primarily on the decision of the Tribunal in *Tesco v OFT* [2012] CAT 31 ("*Tesco*") in which the Tribunal essentially held that it would not place substantial weight upon notes of interviews where the individuals in question were not being called to give evidence before the Tribunal and whose evidence would not, therefore, be tested by cross-examination.[21]

84. For its part, the CMA submitted that Pfizer's and Flynn's contentions were without merit. In its written opening submissions, it cited another Tribunal decision, *London Metal Exchange v OFT* [2006] CAT 19, in which it was held, albeit in the context of an

[21] *Tesco* at [138]-[139].

interim measures case, that a Section 26 Response has a similar significance to a witness statement supported by a statement of truth since, under section 44 CA 98, it is an offence if information is provided to the CMA knowingly or recklessly that is false or misleading in a material particular. A slightly more nuanced position was put forward by Mr Hoskins QC for the CMA in opening as follows:

> "..it's a question of weight. You will not give the same weight to a section 26 notice as you will to a live witness who turns up in the box and gives evidence but when you're considering the weight to give to section 26 notices, what you'll also look to see is the extent to which they are corroborated by the other evidence. So that's our submission on what's the evidential value of section 26 notices. They clearly have some weight, it's a matter for you to decide, and in deciding what weight they have, you'll look at them in their own merits… but you'll also look at whether they're corroborated by the surrounding evidence. That's how you deal with them."

85. We consider Mr Hoskins' submission in this regard to be correct and indeed by the time of closing submissions we do not think there was very much between the parties on this point. Our approach to the Section 26 Responses has been to treat them with a measure of caution, taking them generally to be accurate as to the statements they make but: (a) looking for corroboration from other evidence wherever possible; (b) being alert to the fact that they are only answers to specific questions at a point in time and do not necessarily give a comprehensive coverage; and (c) taking particular care where there is plausible contradictory evidence.

(c) Whether adverse inferences should be drawn

86. Finally, we note that Pfizer and Flynn each submitted that the Tribunal was entitled to draw adverse inferences from the CMA's failure to call witnesses, in particular from pharmacies and the DH. Each cited the judgment of the Supreme Court in *Prest v Petrodel Resources Ltd & Others* [2013] UKSC 34, in which Lord Sumption (at [44]) endorsed the view expressed by the House of Lords in *R v Inland Revenue Commissioners, Ex p TC Coombs & Co* [1991] 2 AC 283 in relation to the drawing of adverse inferences:

> "In our legal system generally, the silence of one party in face of the other party's evidence may convert that evidence into proof in relation to matters which are, or are likely to be, within the knowledge of the silent party and about which that party could be expected to give evidence. Thus, depending on the circumstances, a *prima facie* case may become a strong or even an overwhelming case. But, if the silent party's failure to give evidence (or to give the necessary evidence) can be credibly explained, even if not entirely justified, the effect of his silence in favour of the other party may be either reduced or nullified."

In citing the passage above, Pfizer expressly invited the Tribunal to find that all of Mr Beighton's evidence was true, submitting that the absence of any contradictory evidence from the DH or the CMA is dispositive on this question.

87. We do not think that this is an appropriate case in which to draw such an adverse inference. Notwithstanding the observations we have already made in relation to the DH, the evidence on which the CMA wishes to rely, whether at the administrative stage or on appeal, is a matter for it. It is not for us to speculate as to why the CMA did not call factual witnesses. A failure to call witnesses or otherwise to base its case on what may transpire to be incomplete evidence could expose the CMA to the risk that it will fail to convince the Tribunal that it has proven the alleged infringements. In this case, the CMA has chosen to rely on Section 26 Responses, including those from the DH, and other documentary evidence in support of its case and we will determine the appropriate weight to be afforded to the specific evidence. As to Mr Beighton, we have set out our assessment of his evidence above and afford it due weight taking into account the passage of time and the absence of any supporting contemporaneous documentation.

F. THE LEGAL FRAMEWORK

88. Article 102 TFEU provides, insofar as material, as follows:

> "Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.
>
> Such abuse may, in particular, consist in:
>
> (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; […]"

89. The wording of the Chapter II prohibition set out in section 18 CA 98 is materially the same as that in Article 102 TFEU, save that it applies only to conduct that may affect trade within the UK.[22]

[22] The CMA found that the conduct in question may have affected (and indeed did affect) trade in the buying and selling of drugs within the whole or part of the UK and was capable of affecting trade between EU Member States throughout the Relevant Period (see Section 6 of the Decision). Neither Pfizer nor Flynn have challenged this finding in these appeals.

90. Under section 60 CA 98, questions concerning the Chapter II prohibition in relation to competition within the UK must be dealt with in a manner which is consistent with the treatment of corresponding questions under EU law in relation to competition within the EU. In particular, the Tribunal must determine questions concerning the Chapter II prohibition consistently with the approach of the Court of Justice of the European Union (formerly the European Court of Justice) (the "Court of Justice") to Article 102 TFEU. The Tribunal must also have regard to any relevant decision of the European Commission (the "Commission").

91. Paragraph 3(1) of Schedule 8 CA 98 requires the Tribunal to determine these appeals on the merits by reference to the grounds of appeal set out in the notices of appeal filed by each of Pfizer and Flynn. Pursuant to paragraph 3(2) of Schedule 8 the Tribunal may:

> "…confirm or set aside the decision which is the subject of the appeal, or any part of it, and may—
>
> (a) remit the matter to the CMA,
>
> (b) impose or revoke, or vary the amount of, a penalty,
>
> (c) …
>
> (d) give such directions, or take such other steps, as the CMA could itself have given or taken, or
>
> (e) make any other decision which the CMA could itself have made."

92. The legal burden of establishing an infringement of Article 102 and Chapter II CA 98 is on the CMA and the standard of proof is the civil standard of the balance of probabilities. We must also take account of the presumption of innocence under Article 6(2) of the European Convention for the Protection of Human Rights and Fundamental Freedoms to which Pfizer and Flynn are entitled in a case such as this involving alleged infringements of the CA 98 that may result in the imposition of financial penalties. That presumption is also a general principle of EU law under Article 48(1) of the Charter of Fundamental Rights of the European Union.

G. MARKET DEFINITION AND DOMINANCE

(1) Overview of the CMA's findings

93. We first summarise the CMA's findings on market definition and dominance which are set out in full in Section 4 of the Decision. Given the length of the Decision, our summary of the CMA's findings, here and elsewhere in this Judgment, necessarily omits much of the detail of the CMA's analysis. Instead, we seek to highlight, in particular, those parts of the Decision which are contested in these appeals to assist in understanding this Judgment.

94. Section 4 of the Decision begins with a description of the high prices profitably sustained by Pfizer and Flynn for a "prolonged period" of over 4 years as evidence that neither Pfizer nor Flynn were subject to effective pricing constraint and were able to act independently of competitors, customers and consumers to an appreciable extent (Decision Section 4.A.I).[23]

95. As set out at paragraph 68(3) above, the CMA found the relevant markets to be (Decision para 4.9): as regards Pfizer, the manufacture of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK (which includes parallel imports as they are distributed in the UK); and as regards Flynn, the distribution of Pfizer-manufactured phenytoin sodium capsules in the UK. The CMA recognised that these were very narrow product markets, but considered them appropriate in the specific circumstances of the case and the products involved.

96. The Decision emphasised the importance of the CMA's observations of Pfizer's and Flynn's pricing behaviour and, as a consequence, the CMA's assessment that it did not need to conduct any formal SSNIP test (also known as the "hypothetical monopolist" test). [24] The CMA also found that the competitive constraints faced by Pfizer and Flynn were broadly similar, even though they operated at different levels of the supply chain.

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[23] This part of the Decision relies *inter alia* on what we define in paragraph 255 below as the Price Comparison over Time.

[24] Decision para 4.32. This test considers whether, in response to a small but significant non-transitory increase in price, typically of 5-10%, by a hypothetical monopolist supplying the product in question, sufficient consumers would switch to an alternative product so as to render that price increase unprofitable. If so, the alternative product is part of the same relevant market. In this context, the CMA was mindful to avoid the so-called "cellophane fallacy", where the undertaking in question appears already to have exercised its market power by raising its prices above competitive levels.

97. The CMA considered other candidate products as potential substitutes for Pfizer-Flynn Capsules, namely (i) NRIM Capsules; and (ii) tablets and other AEDs. It focussed on patients who were stabilised on phenytoin sodium capsules as it was common ground that new patients formed a low proportion of the total market size.[25]

98. In setting the context for the market definition exercise, the CMA emphasised the characteristics of phenytoin, particularly its NTI, the relevant NICE and MHRA Guidance, and the effect that, in the CMA's view, these factors had on the behaviour of pharmacists when meeting prescriptions. The factors identified were said to have led to a high degree of dependency of patients on the manufacturer's phenytoin sodium capsule on which they were stabilised and hence to what we have already referred at paragraph 24 above as Continuity of Supply.

99. In considering possible substitution between Pfizer-Flynn Capsules and NRIM Capsules, the CMA examined evidence on comparative price and volume movements over the Relevant Period, and on dispensing practice, including the Section 26 Responses, primarily those from pharmacies.

100. On prices, the CMA found that Flynn and Pfizer were able to maintain high prices throughout the Relevant Period, starting in September 2012. This was despite pharmacies having a significant commercial incentive to dispense the cheaper NRIM Capsules against an open prescription. That commercial incentive arose because the Drug Tariff Price was the same for the 100mg Pfizer-Flynn Capsule and the NRIM Capsule, meaning that pharmacies were reimbursed at the same level regardless of which 100mg capsule they dispensed. In April 2013, NRIM launched its product at a price lower than Flynn's. Flynn did not reduce its prices until April 2014, having negotiated a price reduction from Pfizer between December 2013 and February 2014. In May 2014, Flynn moved to an RWM, cutting the number of its wholesalers, and the discount off the Drug Tariff Price it offered them, which increased Flynn's ASPs, and should have made NRIM Capsules even more attractive commercially. From June 2014

[25] In relation to new patients (i.e. those who were not yet stabilised on any manufacturer's product), the CMA acknowledged that there may be some form of competitive interaction between different types of phenytoin sodium capsules, phenytoin sodium tablets and, indeed, other AEDs (subject, we assume, to clinical assessments). However, given that the number of new patients being prescribed phenytoin is low, the CMA considered that an analysis of such interactions would be unlikely to change the conclusions reached on the appropriate market definition. See Decision para 4.40 and footnotes 593-595.

onwards, after NRIM had itself reduced its prices, the CMA found little or no evidence of price competition between Flynn and NRIM, and prices remained stable, with NRIM's price noticeably lower than Flynn's.

101. On volumes, NRIM's commencement of supply in April 2013 initially attracted a considerable switching of volume from Flynn, leading to NRIM gaining an estimated share of just over a fifth of all 100mg phenytoin sodium capsules distributed in the UK by November 2013. The MHRA Guidance in November 2013 seemed to have caused volumes to stabilise, at least progressively, and the CMA found that NRIM did not subsequently increase its share to any great extent whatever the difference in pricing when compared to Pfizer-Flynn Capsules.

102. The price and volume evidence was considered by the CMA to be consistent with the Section 26 Responses obtained by the CMA from pharmacies. The CMA sent notices to ten major pharmacy groups, covering some 50% of UK pharmaceutical supply, and which included all of NRIM's major customers. Of these ten groups, eight stated that over the Relevant Period they sought to ensure Continuity of Supply. The Decision includes a selection of quotes from the Section 26 Responses.

103. Two of the largest pharmacy groups, Boots UK Limited ("Boots") and Lloyds Pharmacy Limited ("Lloyds"), had, however, prior to November 2013, switched to dispensing NRIM Capsules based on commercial considerations (the cost of NRIM Capsules being lower than Pfizer-Flynn Capsules). They accounted for the vast majority of NRIM's sales. Nonetheless, Boots and Lloyds specifically confirmed to the CMA in Section 26 Responses that they had changed their dispensing behaviour when the MHRA Guidance was issued in November 2013, and from around that point onwards reverted to observing Continuity of Supply (i.e. respected the then stabilised position of patients on a particular product). The CMA found this to be corroborated by purchase data obtained from Boots and Lloyds.

104. The CMA concluded that the evidence showed that NRIM Capsules did not provide a sufficient competitive constraint on either Pfizer or Flynn to warrant NRIM's inclusion in the relevant markets.

105. As to tablets and other AEDs, the CMA found that there was no noticeable evidence, whether qualitative or quantitative, of any competitive interaction between tablets and

Pfizer-Flynn Capsules. Given that tablets, which were an alternative formulation of the same phenytoin sodium molecule, did not impose a sufficient competitive constraint on phenytoin sodium capsules to warrant their inclusion in the relevant markets, it could be inferred that other AEDs would also not be within the relevant markets.[26]

106. The CMA thus concluded that the relevant markets should be no wider than Pfizer-Flynn Capsules. However, it acknowledged that market definition is only a step towards determining whether an undertaking is dominant, not an end in itself. Given that the evidence showed that at least Boots and Lloyds had substituted NRIM Capsules for Pfizer-Flynn Capsules between April 2013 (when NRIM started supplying capsules) and November 2013 (when the MHRA Guidance was published), the CMA also assessed whether Pfizer and Flynn held dominant positions in wider alternative relevant markets which included NRIM. These alternative markets only applied for the period September 2012 to November 2013 (i.e. the part of the Relevant Period prior to the MHRA Guidance) and consisted of all phenytoin sodium capsules manufactured for and/or distributed in the UK (thereby also including NRIM subsequent to its commencement of supply).

107. As to dominance, in light of the CMA's finding that the competitive constraints faced by Pfizer and Flynn were broadly similar, such that the downstream constraints faced by Flynn determined to a significant extent the upstream constraints faced by Pfizer, the CMA assessed dominance generally rather than at each level of supply. The CMA found that Pfizer and Flynn each separately held a dominant position in their respective relevant markets throughout the Relevant Period. It based this conclusion on (i) their high market shares; (ii) their pricing behaviour and profitability of their pricing conduct; (iii) the weak competitive constraints from NRIM and parallel imports; (iv) high barriers to entry which prevented other potential entrants from acting as an effective competitive constraint on either Pfizer or Flynn; and (v) the absence of sufficient countervailing buyer power held by the NHS or its constituent parts. The CMA decided that its finding of dominance applied even on its wider alternative definitions of the relevant market.

[26] We discuss specific aspects of the evidence relating to tablets and other AEDs in Section H(5)(c) below.

(2) The grounds of appeal

108. In relation to market definition, as part of Ground 1 of its appeal, Pfizer contended that the CMA erred when it concluded that NRIM Capsules did not compete directly with Pfizer-Flynn Capsules.[27] By Ground 1 of its appeal, Flynn contended that the CMA had wrongly excluded NRIM Capsules from its market definitions (completely or, on the CMA's alternative market definitions, from November 2013 onwards). The Appellants did not contend for a wider market definition, for example that tablets and/or other AEDs should be included in the relevant markets. Thus, the issue in dispute was a narrow one, namely whether, contrary to the CMA's findings, NRIM Capsules exercised a sufficient competitive constraint on Pfizer-Flynn Capsules such that they should have been found to be in the relevant markets for the whole Relevant Period.

109. Pfizer and Flynn each challenged the CMA's findings of dominance (Pfizer Ground 1 and Flynn Grounds 2-3), with the main focus being on the countervailing buyer power issue. Flynn, in particular, submitted that the CMA had not made any finding of dominance on a market that included NRIM for the whole Relevant Period.

(3) General principles

110. We deal first with the general principles governing the concepts of market definition and dominance.

111. As to market definition, a dominant position cannot be held in the abstract and has to be ascertained with reference to the relevant product and geographic[28] markets. The role of market definition is explained in the Commission's Notice on the definition of the relevant market[29] as follows:

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[27] Whilst Pfizer's Ground 1 was expressed in the Notice of Appeal in terms of a challenge to the CMA's finding that Pfizer was in a dominant position, there is an obvious degree of overlap with Ground 1 of Flynn's appeal, insofar as Pfizer raises issues of competition between NRIM Capsules and Pfizer-Flynn Capsules. In Pfizer's written closing submissions, Ground 1 was re-named "Market definition/dominance". It is convenient in any case to deal with the overlapping arguments together.

[28] We note for completeness that similar considerations as those that apply to defining the relevant product market apply also to defining the relevant geographic market for the purposes of ascertaining whether an undertaking holds a dominant position. However, the relevant geographic market (see Decision paras 4.184-4.187) is not in issue in this case. Thus, references to the relevant market(s) in this Judgment are in the context of defining the relevant product market(s), unless otherwise stated.

[29] Commission Notice on the definition of relevant market for the purposes of Community competition law (OJ 1997 C 372/5), at paragraph 2.

> "Market definition is a tool to identify and define the boundaries of competition between firms. It serves to establish the framework within which competition policy is applied […]. The main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face."

112. The CMA has adopted equivalent guidance, originally published by its predecessor body, the OFT (the "CMA Guidance").[30]

113. The Decision states (at para 4.3), echoing the CMA Guidance, that:

> "Market definition is a key step in identifying the competitive constraints acting on a supplier of a given product and in identifying whether an undertaking is dominant."

114. *Bellamy & Child* summarises the relevant EU law as follows:

> "The EU Courts have consistently defined the relevant product market as comprising all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use."[31]

115. A clear statement of how market definition should be applied was given by the Tribunal in *Aberdeen Journals Ltd v Director General of Fair Trading*.[32] Having reviewed the relevant jurisprudence, the Tribunal concluded:

> "96. The foregoing cases indicate that the relevant product market is to be defined by reference to the facts in any given case, taking into account the whole economic context, which may include notably (i) the objective characteristics of the products; (ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use; (iii) the competitive conditions; (iv) the structure of the supply and demand and (v) the attitudes of consumers and users.
>
> 97. However, this check list is neither fixed, nor exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned sufficiently compete with each other to be sensibly regarded as being in the same market? Are there other products which should be regarded as competing in the same market? The key idea is that of a competitive constraint: do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm? […]
>
> 101. These issues may overlap to a considerable extent with the assessment of the closely related question of whether an undertaking is dominant in a particular market […]. In general, the definition of the relevant market should not be an abstract exercise detached from the question of dominance…".

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[30] OFT 403, Market definition, originally published by the OFT in 2004 and adopted by the CMA Board.
[31] Rose and Bailey, *Bellamy & Child: European Union Law of Competition* (7th ed, 2013), at para 4.009.
[32] [2002] CAT 4.

116. The test for whether two products are in the same relevant market is often stated to be whether there is a "sufficient degree" of interchangeability between them (see, e.g., C-85/76 *Hoffmann-La Roche v Commission* EU:C:1979:36 ("*Hoffmann-La Roche"*), at para 28).

117. As to dominance, the Decision refers (at para 4.2) to the familiar definition of a dominant position set out by the Court of Justice in C-27/76 *United Brands v Commission* EU:C:1978:22 ("*United Brands*") (at para 65):

> "…a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers."

118. The Court of Justice has emphasised that "such a position does not preclude some competition" and has held that:

> "…even the existence of lively competition on a particular market does not rule out the possibility that is a dominant position on this market since the predominant feature of such a position is the ability of the undertaking concerned to act without having to take account of this competition in its market strategy and without for that reason suffering any detrimental effects from such behaviour." [33]

119. Whilst, in this case, the general legal principles pertaining to market definition and dominance are not in dispute, we enter one note of caution. This relates to the need to avoid the so-called "zero:one" or "binary" fallacy, by which the competition analysis is conducted solely within the context of the defined market. It is fallacious to regard as relevant to the competition analysis only those products defined as falling within the relevant market and to disregard entirely any competitive pressure from those products defined as falling outside it. In our view, competition analysis is always a matter of degree and in each case the degree of competitive pressure, whether from inside or outside the relevant market as defined, must be carefully assessed.

(4) Market definition: discussion

120. In assessing whether the CMA was correct to exclude NRIM Capsules from its market definitions as described above, we consider, first, pharmacy dispensing practice,

[33] *Hoffmann-La Roche* at paras 39 and 70.

including the CMA's reliance on Continuity of Supply; and second, Flynn's and NRIM's prices and volumes.

(a) Pharmacy dispensing practice

(i) Continuity of Supply

121. We have described at paragraphs 24 to 30 above the clinical guidance giving rise to what the CMA has termed Continuity of Supply, noting in particular the MHRA Guidance introduced in November 2013. Whilst there is no specific dispute about the content of the clinical guidance itself, Continuity of Supply is an important part of the CMA's case on market definition, and it is therefore useful to consider the extent to which the clinical guidance was relevant in practice in the present case.

122. Professor Walker's evidence, which was not challenged under cross-examination, was that the MHRA Guidance arose not because of any new clinical evidence, but in response to concerns from patients and patient groups that generic and branded AEDs were not equivalent. In Professor Walker's view, this concern was, as a matter of clinical analysis, over-stated. His conclusion was as follows:

> "[C]onsistency of supply of phenytoin in some patients had long been part of BNF guidance for phenytoin, but more prescriptive guidance came from the MHRA in 2013. The MHRA [G]uidance was not based on new evidence, nor was it based upon evidence of efficacy but on pharmacokinetic considerations that had been known for 30 years. Such guidance came about because of pressure from patients and patient groups. Notwithstanding the MHRA [G]uidance, the clinical risks of switching phenytoin formulations are small and, in my opinion, much smaller than coming off phenytoin or switching from phenytoin to another AED."

123. The Decision states (at para 4.131) that it was common ground between the parties that the MHRA Guidance merely re-iterated the pre-existing and well-known clinical guidance regarding Continuity of Supply.

124. The factual evidence showed that Pfizer and Flynn were each clearly aware of Continuity of Supply issues related to phenytoin before the transaction between them and well before the MHRA Guidance in November 2013. For example, in an internal Pfizer email dated 18 September 2009, Pfizer's Medical Director stated that:

> "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. […]"

125. Mr Poulton's evidence was that it was a key concern for Pfizer from a patient risk perspective to ensure that patients would be supplied with exactly the same product following the agreement with Flynn:

> **Q. (Mr Hoskins)** As you explain, there was no change in the manufacturing arrangements. You continued to manufacture the phenytoin sodium capsules in Germany, as you had done before the deal with Flynn?
>
> **A. (Mr Poulton)** Yes, the active ingredient was manufactured in the US, and preparation of the capsule and the final finishing and manufacturing and packaging was done in Germany, yes.
>
> **Q. (Mr Hoskins)** But no change as a result of the --
>
> **A. (Mr Poulton)** No change, no. That was really important to us that there was no change.
>
> **Q. (Mr Hoskins)** Why was it important?
>
> **A. (Mr Poulton)** Because we wanted patients to have the confidence that it was the same medicine. Something we wanted all along was to maintain continuity of supply for patients to make sure this medicine continued to be available for them so there would be no risk of them, if they were switched to alternatives.

126. Flynn addressed the issue of Continuity of Supply in its communication plan agreed with the MHRA. The text of a letter which was sent to prescribers (a similar communication was also sent to pharmacists) stated:

> "Phenytoin is a drug with [an NTI] and, as such, there may be concerns amongst prescribers and patients regarding any change to the product.
>
> Please be assured 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'."

127. Mr Walters' evidence was that "at the time when the product's name was being changed, it was felt really important to make sure there were no other changes at that moment in time". The evidence also 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 at a time when those pharmacies had begun to dispense NRIM Capsules. For example, the text of a "letter of complaint" from Mr Walters to Boots dated 25 February 2014, and which was supplemented by other written correspondence, phone calls and/or meetings stated *inter alia* that:

> "We wish to make a series of complaints concerning the dispensing of phenytoin sodium capsules 100mg in the Boots retail pharmacy chain:
>
> 1. That Boots purchasing and/or dispensing policy(ies) in relation to Phenytoin Sodium Hard Capsules 100mg since July 2013 (if not earlier) to date, have been contrary to patient interest and safety in failing to give full and proper regard to relevant best practice guidance including but not limited to [*cites the relevant clinical guidance*][…]
>
> […]
>
> …we have been advised of Boots' view (based on your expert internal and external advice), to the effect that if a patient has been switched to the NRIM formulation, they will continue to be supplied this product. We do not agree that this should be the case. In contrast we submit that it flies in the face of pre-existing authoritative guidance and an extensive published literature. We regard this as compounding and repeating the error. At the very least, we believe that the situation should be discussed with the patient/prescriber."

128. There appears to be an element of contradiction here. On the one hand, Flynn was complaining that the switching of patients by Boots to the NRIM Capsule was contrary to the relevant clinical guidance; on the other hand it was objecting to Boots relying on that guidance to keep dispensing the NRIM Capsule to patients once the switch had been made. In cross-examination, Mr Walters explained that there was a technical dispute between Flynn and Boots as to the point at which a patient should be regarded as stabilised on a product such that there should be no switching back. In any event, the basic point remains that Flynn was relying on Continuity of Supply to try to protect its own sales.

129. Notwithstanding the clinical guidance, and as mentioned at paragraph 22 above, it is common ground that the vast majority of prescriptions for phenytoin sodium capsules were generic or open i.e. not specifying any brand or manufacturer. This is acknowledged in the Decision (paras 3.86-3.88). For example, for the first eight months of 2012 (before Flynn began distributing phenytoin sodium capsules in the UK), 62% of prescriptions for phenytoin sodium capsules in England were open. Over the period April 2014 to March 2015 (after the publication of the MHRA Guidance), 91% of prescriptions for phenytoin sodium capsules were open. Thus, the doctors, to whom part of the MHRA Guidance was addressed, appeared largely to be either ignoring it or

leaving it to pharmacists to implement rather than applying it themselves. However, the extent to which, as a matter of fact, pharmacists applied the MHRA Guidance in the great majority of cases where the prescription was open is a critical part of the CMA's findings on market definition since it is that behaviour, at the point of delivery of the product to the patient, which would give effect to Continuity of Supply.

130. The CMA found, as a matter of fact, in the Decision, that Continuity of Supply was a significant barrier to entry. Whilst it accepted at the hearing that pharmacies' dispensing practice was not uniform, it still considered that Continuity of Supply had a significant effect on behaviour and access to the market for supply to patients stabilised on a particular product and that such effect was sufficient for NRIM not to be considered as being in the same market as Pfizer-Flynn Capsules.

131. We accept, as Professor Walker stated, that the clinical guidance on Continuity of Supply was just that - guidance. It did not comprise any binding rule. Doctors and other healthcare professionals no doubt paid close attention to it, but were also entitled to (indeed should) exercise their own clinical judgment. Moreover, the MHRA Guidance, itself, 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.

132. However, the Decision correctly pointed to the actual effect of the guidance on the dispensing practice of pharmacists. Pfizer said the CMA's case was that pharmacists interpreted the guidance more strictly than its wording required them to do, but this is beside the point. What matters, for this competition analysis, is what pharmacists actually did.

133. To the extent that the CMA has sought to elevate Continuity of Supply to some form of binding or absolute rule, that, in our view, would overstate its effect. Nonetheless, the actual impact of Continuity of Supply is obviously relevant in the context of market definition, and the evidence of Mr Poulton and Mr Walters shows that in practice Pfizer and Flynn themselves had regard to it. Indeed, Flynn sought to enforce it by its efforts to persuade Boots and Lloyds not to supply NRIM Capsules.

134. In principle, we can see that Continuity of Supply, and particularly the MHRA Guidance, is capable of having had an effect on the dispensing practice of pharmacists. However, the extent of this effect can only be assessed by reference to the actual behaviour of pharmacists. We do not understand the CMA to be maintaining a different position. We accept that the CMA put less emphasis on Continuity of Supply during the hearing than it did in the Decision but do not regard this change as significant. The key issue is how the clinical guidance was interpreted and applied by pharmacists and their actual dispensing practice.

(ii) Actual dispensing practice

135. In the Decision, the CMA went on to consider evidence of pharmacies' actual dispensing practice. The CMA focussed its analysis on the dispensing behaviour of the major pharmacy chains and wholesalers, which accounted for approximately 50% of pharmacies in the UK. It concluded:

> "4.109 The evidence, which is set out below, demonstrates that over the Relevant Period, the majority of the pharmacy groups (eight out of ten) sought to ensure Continuity of Supply as recommended by the [NICE Guidance 2012] and did not switch stabilised patients from [Pfizer-Flynn Capsules] to NRIM's Product despite the very clear financial incentives to do so.
>
> 4.110 The evidence also demonstrates that the remaining two pharmacy groups (Lloyds and Boots) were initially prepared to switch stabilised patients to NRIM's Product and accounted for the vast majority of NRIM's sales. However, both ceased switching stabilised patients shortly after the publication of the MHRA Guidance after which they also took steps to ensure Continuity of Supply."

136. The Decision relied primarily on Section 26 Responses from pharmacies to support the view that most pharmacies "complied" with Continuity of Supply over the Relevant Period, and that Boots and Lloyds did so following publication of the MHRA Guidance in November 2013, having switched patients to NRIM Capsules prior to that for commercial reasons. We have already considered at Section E(4)(b) above the weight that should be given to the Section 26 Responses, and have made clear that we treat them with a measure of caution. With that caveat in mind, we turn to consider their substance insofar as they relate to pharmacies' dispensing practice.

137. Flynn described the evidence from the pharmacies' Section 26 Responses as ambiguous and unreliable. The point was put with even more force by Pfizer who attacked the substance of the Section 26 Responses in considerable detail. In particular, Pfizer

criticised the CMA for "cherry picking", that is quoting those passages favourable to the CMA's case and ignoring others, and for failing to corroborate or follow-up on the responses in cases where there were obvious discrepancies.

138. We see some force in Pfizer's criticism of the way in which the CMA has presented the Section 26 Responses in the Decision. In particular, we think that the description of those responses at paragraphs 4.114-4.122 of the Decision gives an impression of an almost uniform pattern of pharmacies (with the exception of Boots and Lloyds until November 2013) ensuring Continuity of Supply with no regard for commercial incentives. The position is clearly more nuanced than that. To give just one example identified by Pfizer, the CMA quoted in the Decision various statements by Morrisons including that its pharmacists would only dispense NRIM Capsules in limited circumstances "…if a patient was already on this particular brand, or if the patient was initiating therapy for the first time…" (Decision para 4.116). The Decision did not mention, for example, Morrisons' other statements that "From our work as Pharmacists - options are to fulfil using any manufacturer available. However, this is a product where patients/doctors like to remain on the same brand as bioavailability differences can occur…If written generically, we can supply either"; and "If prescription is written generically, Alliance Healthcare (our wholesaler) sends in the cheapest option available to us. This would usually be the case, unless prescription/patient specifically requires this to be overridden and a specific brand ordered". Indeed the CMA presented a more nuanced position during the hearing, acknowledging in its written closing submissions that the evidence in the Section 26 Responses does not all point in precisely the same direction.

139. Pfizer and Flynn each put forward additional evidence that was said to cast doubt on the robustness of the Section 26 Responses and the CMA's overall conclusion. Mr Goosey, on behalf of Pfizer, submitted a survey report by Kantar which suggested that a large percentage of pharmacists surveyed would dispense the brand they had in stock in response to an open prescription, rather than trying to find out on which manufacturer's product the patient was stabilised. Thus, the survey presented a picture of mixed behaviour by pharmacists. We do not accept, as the CMA suggested, that the survey was inherently defective in terms of sample size or bias towards hospitals. It is what it claims to be, a survey, and as such it suggests that the pattern of dispensing

behaviour for phenytoin capsules was less than uniform. However, we agree with the CMA that the survey does not address the key issue in relation to pharmacy dispensing practice, namely the extent to which pharmacists might dispense NRIM Capsules to patients who are already stabilised on Pfizer-Flynn Capsules and vice versa.

140. The survey asked nine questions, four of which related to phenytoin sodium capsules, four to phenytoin sodium tablets and one to phenytoin sodium generally. The key response relied on by Pfizer was to question 5, which indicated that in response to a prescription for "phenytoin sodium capsules" with no manufacturer's brand specified, 67% of respondents would supply the brand they had in stock. The CMA pointed out that the survey also recorded that only 11% of respondents actually stocked NRIM Capsules. We note further that of the remaining 32% "other" responses to question 5, 89% said they would 'check/supply the patient's usual brand'. The survey also confirmed that pharmacists would generally not supply tablets against a prescription for capsules or vice versa.

141. The survey is informative so far as it goes, but we do not think, particularly in view of the relative stock levels of NRIM Capsules held by the sample of pharmacists surveyed, that it can bear the weight placed on it by Pfizer. Moreover, and in common with the Section 26 Responses, the survey cannot in itself provide evidence of actual dispensing practice. Accordingly, we found the survey evidence to be of limited assistance.

142. Flynn had put forward evidence at the administrative stage, which was investigated and ultimately rejected by the CMA, that in April 2016 Boots had, in response to a "mystery shopping" inquiry placed on behalf of Flynn, fulfilled a private prescription for phenytoin sodium capsules through its online dispensing arm without any check as to whether the patient was stabilised on a particular product. In addition, Flynn had also carried out some other "mystery shopping" exercises at bricks-and-mortar pharmacies, primarily Boots and Lloyds branches. Flynn continued to rely on this evidence at the appeal stage. As Mr Walters said, "..(O)ur mystery shopping exercise clearly shows that when presented with a prescription for the Flynn products, patients were quite often being diverted onto the NRIM product". We note that Boots told the CMA that the online instance was an isolated one and in any case online dispensing accounted for a tiny proportion of the total prescriptions dispensed by it for phenytoin sodium capsules in the period May 2015 to April 2016. As to Flynn's "bricks-and-mortar" exercises,

Flynn provided details to the CMA of more than 20 individual visits to pharmacies in December 2013 and January 2014. The CMA said that in the majority of cases the pharmacies involved acted in accordance with the MHRA Guidance. The report of these visits we have seen accords with that statement made by the CMA, and we therefore accept the CMA's view on this point.

143. Overall, the Section 26 Responses from pharmacies should in our view be regarded as statements of the policy of the pharmacy group in question, at a point in time, and not evidence of actual dispensing practice. It is clear that they cannot be so for various reasons, including, for example, that the dispensing pharmacist may not know the formulation normally given to the patient in question and may have to enquire, which may not be done, or which may not produce a clear answer; or there may be stock or supply issues. However, the Section 26 Responses do show that the pharmacies generally accepted as a matter of policy that Continuity of Supply would be desirable. This is against a background of the great majority of phenytoin sodium capsule prescriptions being open, and a strong commercial incentive to dispense the cheapest product. Statements of policy in the pharmacies' Section 26 Responses cannot in themselves provide conclusive evidence of actual dispensing behaviour by individual pharmacists, but are one element of a range of evidence obtained by the CMA in relation to dispensing practice which needs to be considered in the round.

144. The Section 26 Responses from pharmacies were not the only evidence on which the CMA relied. It also obtained Section 26 Responses from, and met with, NRIM itself. On the whole, this evidence supports the information in the pharmacies' Section 26 Responses and shows that NRIM considered that Continuity of Supply did have a significant effect in practice.

(1) NRIM explained in a response dated 18 March 2014 that three pharmacies/wholesalers decided in mid-2013 (prior to the MHRA Guidance) not to purchase NRIM Capsules for reasons related to the NICE Guidance 2012. NRIM went on to state:

> "When we decided to develop a marketing strength in Phenytoin Sodium capsules and tablets, we assumed that we would be likely to remain the only generic phenytoin sodium product manufacturer in the UK. We had expected that this was an opportunity for us to establish NRIM as the only generic competitor to Pfizer and

> to carve out a market share of around 35-40% in total sales of Phenytoin Sodium capsules in the UK.
>
> However, we had to significantly adjust our sales forecast when in the fourth quarter of 2013, the MHRA issued guidelines entitled "*Antiepileptic drugs: new advice on switching between different manufacturer's products for a particular drug*". In this guidance…the MHRA advised the medical profession that patients who were stabilised on a specific Phenytoin Sodium capsule product manufactured by a specific manufacturer should not be switched to a product manufactured by another manufacturer unless this was done on advice and under the supervision of a doctor or pharmacist.
>
> As a result of these MHRA guidelines our expectation that significant numbers of patients who were stabilised on Pfizer / Flynn Phenytoin Sodium 100mg capsules would switch to our generic Phenytoin Sodium 100mg capsules had to be revised down and we soon realised that it would not be possible to build the forecasted market share for our generic Phenytoin Sodium 100mg capsules in the UK."

(2) NRIM went on to confirm in a later Section 26 Response dated 21 July 2014 that the MHRA Guidance was having an ongoing effect:

> "In our view, the MHRA guidance therefore has had and still has a direct impact on (i) NRIM's sales to existing customers and (ii) NRIM's ability to win new sales. In particular, existing customers are unlikely to switch away from our product in accordance with the MHRA guidance whilst at the same time the MHRA guidance makes it difficult to win over new customers for our products in the UK".

145. The CMA also obtained data from the pharmaceutical wholesaler, Alliance Healthcare Distribution Limited ("Alliance")[34] setting out its sales of phenytoin sodium capsules to its top 20 customers from January 2012 to August 2014, and its sales of NRIM Capsules to its top 10 customers from June 2013 to February 2016 (the "Top 10 Spreadsheet"); monthly purchase data from Boots and Lloyds setting out their purchases of NRIM Capsules from December 2013 to January 2016; aggregated data from the pharmaceutical wholesaler AAH Pharmaceuticals Limited ("AAH")[35] setting out its sales of phenytoin sodium capsules to customers other than Lloyds from January 2012 to at least March 2015; and sales data from NRIM up to July 2016. This was in addition to purchase data obtained from individual pharmacy groups through the Section 26 Responses (Co-Op (up to May 2014); Morrisons (up to August 2014); Sainsbury's (up to April 2014); and Superdrug (up to May 2014)).

[34] Alliance is affiliated with Boots.
[35] AAH is affiliated with Lloyds.

146. Pfizer and Flynn submitted that the Alliance data indicated that three major pharmacy chains other than Boots and Lloyds (Morrisons, Superdrug and Walter Davidson) materially switched their purchases from Flynn to NRIM, even after November 2013. According to Flynn, this trend continued over the Relevant Period with other Alliance customers. Flynn further submitted that this data should have put the CMA on notice of substantial switching and that the CMA should have obtained additional data from the other major pharmacies or wholesalers in order to obtain a complete picture. However, the CMA said that after Boots and Lloyds, the other pharmacies accounted for a relatively small proportion of sales of phenytoin sodium capsules.

147. It appears to us that actual amounts switched by Morrisons, Superdrug and Walter Davidson in 2013 and 2014 were not substantial and do not amount to evidence of material switching. Equally, the suggestion by Flynn that there was a trend of substantial switching is not borne out by the wider evidence. The data tend to show that, apart from Boots, which we know dispensed NRIM Capsules for a substantial period, and which accounted for the great majority of Alliance's sales of NRIM Capsules from June 2013 to February 2016, other pharmacies do not appear to have purchased significant quantities of NRIM Capsules from Alliance in 2013 and 2014. It is the case that following Flynn's move to an RWM in May 2014, Flynn ceased to supply Alliance, which means that the Alliance data cannot inform as to possible switching after that point. Nor can it be assumed that all the sales of NRIM Capsules represent pharmacies switching from Flynn to NRIM, or that pharmacies did not obtain NRIM Capsules from other wholesalers. But even in 2015 and 2016, when Alliance did not have Pfizer-Flynn Capsules to supply, its overall sales of NRIM Capsules to its top 10 customers did not increase, and indeed appear to have decreased over the period May 2014 to February 2016.[36]

148. As to Flynn's suggestion that the CMA should have obtained additional data from other pharmacies or wholesalers, we agree that of course obtaining further data would have enabled the CMA to corroborate with a greater degree of certainty the evidence it obtained from the Section 26 Responses. That said, we accept Mr Hoskins' submission that the CMA had obtained a great deal of evidence, incuding the data we have

[36] According to the Top 10 Spreadsheet, total sales of NRIM Capsules to Alliance's top 10 customers were 7,481 packs in May 2014 and 4,657 packs in February 2016.

described at paragraph 145 above, and that the key question is whether the evidence obtained by the CMA was sufficient and reliable to prove its case.

149. In any event, although individual pharmacy switching data is important, we agree with the submission made by the CMA that it is the overall constraint from NRIM that is relevant to determining whether NRIM Capsules are within the relevant market. We note that Mr Ridyard accepted in cross-examination that it is preferable to assess the overall effect of any switching by reference to aggregate data (which we consider at (b) below):

> "Clearly, as I said earlier, if you want to look at the total – market-wide impact of any switching that may or may not have happened, I think – well, the market share numbers are probably the best place to go, given that each one of these individual pharmacy chains is pretty small in absolute terms, once you get beyond the biggest two."

150. Overall, we think, looking at the evidence in the round, that the CMA was correct that Continuity of Supply had a significant impact, in practice, on pharmacists' dispensing practice, tending to favour the existing supplier of products on which patients were already stabilised. The position is, however, not as unequivocal as the Decision concludes as there was clearly still a degree (even if limited) of switching from Flynn to NRIM after publication of the MHRA Guidance.

151. It should be noted that, to the extent that Continuity of Supply did affect dispensing practice then this would be expected to affect all manufacturers/suppliers. In other words, patients stabilised on the product of a particular manufacturer, including NRIM for phenytoin sodium capsules, and Teva and other tablet manufacturers for phenytoin sodium tablets, would be similarly dependent. This is not expressly stated in the Decision, but at the hearing, Mr Hoskins correctly acknowledged that suppliers such as NRIM would also have a "captive body of patients". Thus the effect of pharmacists' dispensing behaviour, in the light of the clinical guidance, was, perversely, to make it difficult for a new entrant to gain a foothold but, once it had established sales, to make this position easier to entrench. NRIM's success in gaining the custom of Boots and Lloyds, at least for a period, meant that it was then more difficult for Flynn to take sales back from NRIM, at least in relation to supplies intended for patients stabilised on NRIM Capsules.

(b) Volumes and prices

152. It was common ground between the parties in this case that it is necessary to consider the evolution of a product market over the entire period in question (C-457/10 P *AstraZeneca v Commission* EU:C:2012:770). However, Pfizer and Flynn saw this as a way of extending the effect of NRIM's entry over the whole Relevant Period whilst the CMA saw it as a reason to disregard it.

153. Ms Bacon QC for Flynn submitted that it was helpful to examine what happened during the Relevant Period as a whole by reference to four sub-periods. These were: the period between the launch of the Pfizer-Flynn Capsule and NRIM's commencing sales (September 2012 - April 2013 – "Period 1"); the period after NRIM had commenced sales but before the MHRA Guidance was issued (April 2013 - November 2013 – "Period 2"); the period immediately after the issue of the MHRA Guidance (November 2013 - May 2014 – "Period 3"); and the period from May 2014 to the date of the Decision in December 2016 ("Period 4"). We refer to these sub-periods where appropriate below for the purpose of examining particular issues and events within the Relevant Period before considering the evolution of the market over the entire period, but do not regard them as anything other than useful shorthand.

154. The data relied on by the CMA comprised information derived from Flynn's and NRIM's sales data and industry data on dispensing volumes. The evidence on market shares, sales volumes and prices was set out in various forms in the Decision, the pleadings and in documents submitted in the course of the hearing. One example is the chart relied on by the CMA in its written closing submissions, which illustrates both ASPs and volumes for Flynn and NRIM's 100mg product over the Relevant Period. The vertical lines delineate the four sub-periods described above. The chart does not show parallel imports or any other capsule strengths and so does not give a complete picture.

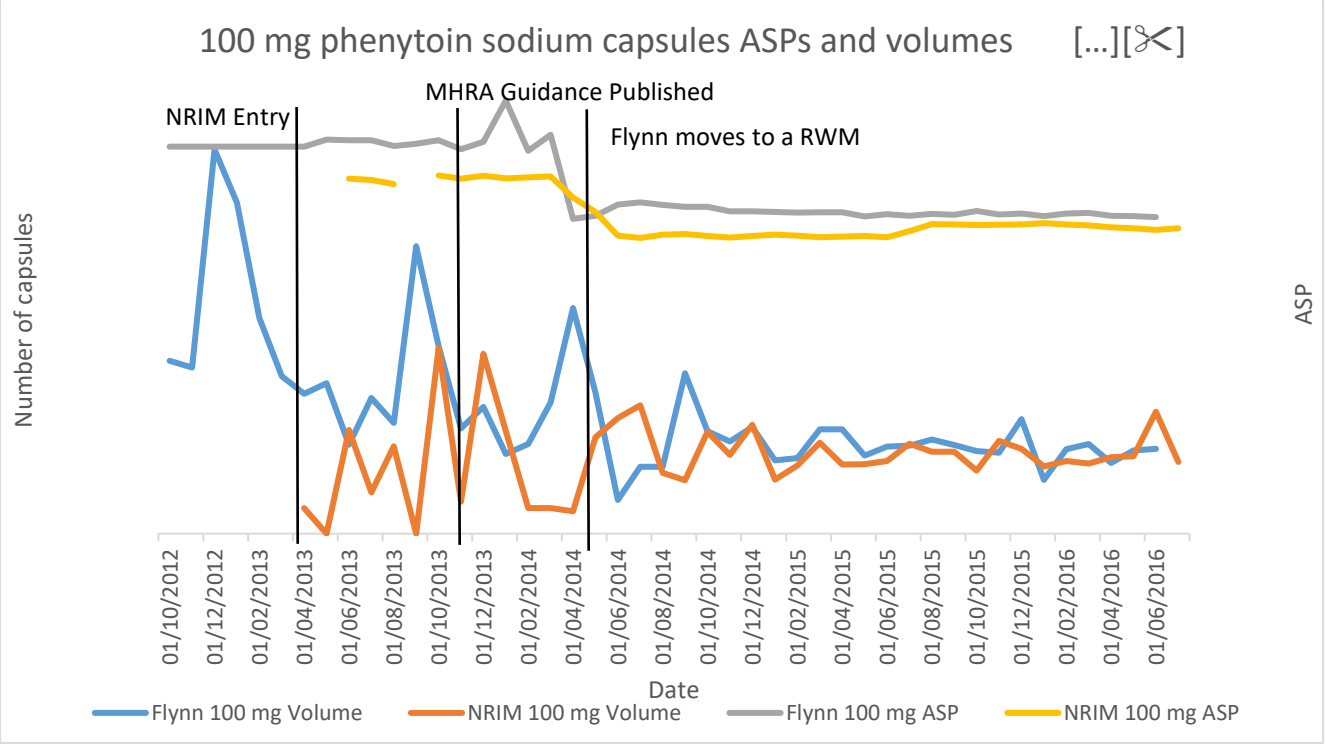

Figure 1: 100mg phenytoin sodium capsules ASPs and volumes

155. Another example was the quarterly market share data set out in table form in Flynn's Notice of Appeal (which gave an implied share for parallel imports), and on which Flynn relied in support of its case that there was clear evidence of switching between Pfizer-Flynn Capsules and NRIM Capsules and that NRIM's share of sales increased over the Relevant Period. According to Flynn, the tables showed that NRIM Capsules gained share steadily throughout the period that NRIM had been selling capsules, including since 2013. However, as NRIM only supplied the most common 100mg capsule strength, Flynn submitted that it was most relevant to look at the figures for that strength which, according to Flynn, also showed a decisive switch to NRIM and away from Flynn; and again indicated continued sales growth since 2013.

156. Our observations and findings in relation to volumes and prices are as follows.

Period 1: September 2012 to April 2013 (pre-NRIM commencing sales)

157. In Period 1, Flynn is the sole capsule supplier. Its volumes rise, and then fall, after launch in September 2012, and its ASP remains steady. NRIM, self-evidently, has no sales during this period. The CMA said this was indisputably a period in which the relevant market consisted solely of the Pfizer-Flynn Capsule. Pfizer and Flynn said

they already knew NRIM had obtained an MA. They therefore expected NRIM's launch and were already subject to the anticipated competitive pressure that would result.

158. The contemporaneous documents show that prior to the launch of the Pfizer-Flynn Capsule in September 2012, Pfizer and Flynn were aware that NRIM had in August 2011 obtained a UK MA for the 100mg capsule strength. Pfizer became aware of NRIM's MA on 14 October 2011. Mr Poulton sent an internal email on 23 October 2011 in which he stated that:

> "…This 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 chooses 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…"

159. Similarly, Flynn referred to the NRIM MA in correspondence it sent to the MHRA in June 2012. Mr Walters' evidence was that Flynn always believed that there would be other suppliers of generic phenytoin sodium capsules as well as parallel imports. Pfizer's and Flynn's case was therefore that they were anticipating generic competition from the start.

Period 2: April 2013 – November 2013 (post-NRIM commencing sales and pre-MHRA Guidance)

160. NRIM launched its 100mg capsule in April 2013. It was significantly cheaper to dispense than Pfizer-Flynn Capsules, and NRIM immediately gained sales from Flynn, primarily because Boots and Lloyds switched to NRIM for commercial reasons. The data shows that when NRIM started to supply capsules, there were considerable volume fluctuations but little price effect. Flynn accepted that the volume figures for Q4 2013 were unreliable and we do not therefore have regard to them. The figures do, however, suggest that by the end of Q3 2013 NRIM had succeeded in achieving an overall share of 12%, and 17% of the 100mg capsule volumes.

161. There was some evidence of targeted discounting in this period. Flynn said it granted a discount to a pharmacy customer in August 2013, for the period September 2013-April 2014, after the customer claimed it could obtain 100mg capsule supplies more cheaply from other sources. The CMA said it was not clear whether the customer referred to NRIM or to parallel imports, but in any case the discount offered by Flynn

in response to this request was not significant, or replicated elsewhere, and did not lead to any generalised price reduction. We do not disregard the discount granted but we are not aware of widespread discounting, which we would have expected to see reflected in Flynn's ASP data if their view that they were in direct competition with NRIM who was in the same relevant market were correct, but which is not evident.

Period 3: November 2013 to May 2014 (post-MHRA Guidance)

162. In Period 3, Flynn's ASP increases[37], then reduces, from April 2014, after which NRIM's ASP also reduces, in June 2014. Flynn's volumes appear to rise in line with its price reduction, whilst NRIM's volumes fall sharply before rising again as its own price is reduced. By the end of Q2 2014, NRIM's overall share of volumes was 21%, and it had 28% of the 100mg capsule volumes. However, care must be taken not to read too much into month by month fluctuations in volume, owing to changes in order patterns between pharmacies and wholesalers.

163. The reasons for Flynn's and NRIM's respective price reductions were a matter of dispute between the parties.

164. In April 2014, around a year after NRIM's entry, Flynn reduced its ASPs for its 100mg and 300mg capsules. Thus, for example, its ASPs for 100mg capsules were reduced from approximately £[…][✂]per pack of 84 in September 2012-March 2014, [[…][✂] *by about one fifth*]. Pfizer and Flynn contended that the reduction was made in response to competitive pressure from NRIM, whereas the CMA said the price reduction was envisaged under the Exclusive Supply Agreement which provided for an annual price review. Mr Walters' evidence was that a higher supply price was envisaged for the first year of the agreement**,** and hence a reduction was foreseen commercially. This suggests that, at the least, NRIM's presence was not the direct cause of the price reduction which was part of the original commercial planning.

165. However, in this regard, it is important to re-iterate that NRIM only supplied the 100mg capsule strength. This strength accounted for the bulk of phenytoin dispensed (73-4% in the period 2011-2015) although it may be assumed that competitive pressures on the

[37] Flynn said this brief increase was a recording error following a credit agreed with a particular customer and stemmed from its pre-wholesaler under-recording monthly volumes for that customer. The CMA did not dispute this.

100mg strength would have a corresponding effect on others. Flynn pointed out that the 300mg dosage strength could be substituted by three 100mg capsules. It was not in dispute that Flynn's price reduction was made only in relation to the 100mg and 300mg strengths; it was not made in relation to the 25mg and 50mg strengths with which, on no view, did NRIM directly compete.

166. The evidence in relation to the price reduction itself was mixed. Clause 14.2 of the Exclusive Supply Agreement provided for an annual price review […][✂] […][✂] […][✂]. […][✂][…][✂] […][✂][…][✂][…][✂]. Flynn appears first to have raised the matter with Pfizer in August 2013, but a price review meeting did not take place until December 2013. An agreement with Pfizer on a supply price reduction was eventually reached in February 2014, backdated to 1 January 2014.

167. In an email sent to Pfizer on 21 January 2014, Mr Walters stated:

> "Further to our meeting on 16th December, our proposed pricing review is as follows:
>
> We are experiencing significant competition for the 100mg in the market place from a) the NRIM generic and b) PIs, mainly from Spain. We request, therefore, a 20% reduction in the current cost of goods, to be retrospectively applied to our current safety stockholding."

168. Pfizer stated in its letter of 3 February 2014 confirming a supply price reduction that:

> "Reductions in the supply price for the 100mg and 300mg doses reflect the need to respond to competitive pricing pressures in the market place, which you described in detail at our meeting.
>
> In light of these circumstances, Pfizer sincerely hopes and anticipates that Flynn will use the price reductions confirmed in this letter to compete more effectively by reducing its retail price by an amount that is at least equivalent to the price reductions provided for in this letter".

169. However, in cross-examination Mr Walters indicated that competition from NRIM was not the primary reason for the price reduction:

> **Q. (Mr Hoskins)** The decision to seek a price review in December 2013 was not triggered by fear of competition from NRIM, was it?
>
> **A. (Mr Walters)** The decision to seek the price change was related to the agreement for the additional year, and not specifically to NRIM. It doesn't mean that we didn't discuss the markets and the [intelligence] we had regarding NRIM's shares. But as I mentioned earlier, we weren't particularly concerned about NRIM. We expected to lose some market share to them, and our intelligence told us that they – their usual habit was to take it to a certain level, and then basically desist. And their target

> was one of the two largest retail chains in the country. And they were successful.

170. Mr Walters went on to indicate that in the period prior to reaching agreement with Pfizer on a supply price reduction, it became obvious to Flynn that they were beginning to lose more sales to NRIM.

171. It was suggested to Mr Walters in cross-examination that the contemporaneous record stating that the price reduction for the 100mg capsule strength was a response to competition from NRIM was drafted because it would be advantageous to be able to refer to competition to NRIM in light of the, by then ongoing, CMA investigation. In response, Mr Walters stated:

> "…But what you're saying is we basically were manipulating it to answer to the CMA. We didn't have a clue where the CMA were going at that stage."

172. We accept Mr Walters' evidence that Flynn did not specifically manipulate the written justification for the reduction in its supply price from Pfizer in the light of the CMA investigation. However, we also note his acknowledgment that the price reduction was not initially motivated by competition from NRIM. Ms Bacon accepted in closing submissions that it was not in dispute that the initial talks with Pfizer were sought on the basis of the Exclusive Supply Agreement but submitted that the only explanation for Flynn passing on the price reduction it obtained from Pfizer to Flynn's own customers was that there was price competition with NRIM. Flynn did, after a short delay, which Flynn said was explained by its holding stocks of product supplied at the old price, pass on the price reduction with effect from 1 April 2014, having notified the DH of the price change in March 2014.

173. The CMA relied, in this regard, on a section of a witness statement of Dr David Fakes of Flynn which was submitted in the course of the interim relief application[38] and in which he stated, in a different context, that "[i]n the normal course of business, were Pfizer to reduce its input price, Flynn would look to pass on all, or as much as possible, of that reduction to our customers, by reducing its selling prices by an appropriate amount. Flynn is not comfortable with the proposal that it should charge its customers a price based on a higher input price than it is actually paying (and simply retain that

[38] See footnote 19 above.

increased differential)". We note this evidence, but do not place any great weight on it given that Dr Fakes was not a witness in these proceedings and was not cross-examined on this evidence, and nor was Mr Walters asked about it.

174. We find it quite credible that Flynn initially sought a price reduction based on the terms of its Exclusive Supply Agreement with Pfizer and then as its view of the effect of NRIM's activities hardened, used the benefit of that reduction to improve its price in comparison to that of NRIM. We do not think these two factors are mutually exclusive.

175. NRIM reduced its ASPs for 100mg capsules to below Flynn's in June 2014. The CMA said this was not a response to Flynn's earlier price reduction, but was because the Drug Tariff Price, which was, itself, derived from Flynn's price, had fallen with effect from May 2014 to below NRIM's selling price. Flynn submitted that all NRIM had to do was to ensure that its prices were below the Drug Tariff Price, such that pharmacies were not reimbursed for NRIM Capsules at less than they paid for them. NRIM could have maintained its ASPs at the same level as Flynn's or even higher, but it chose to reduce them to below Flynn's, and the only explanation for that, according to Flynn, was so that NRIM would remain price competitive. In light of the evidence on NRIM's commercial strategy (see paragraphs 185 to 188 below), we think it more likely that the CMA's explanation for what triggered NRIM's price reduction is correct. In any event, whatever the reason for NRIM's price reduction, we note that no further price reductions were made either by NRIM or by Flynn in the Relevant Period.

176. Finally, we note that in May 2014, Flynn moved its trading arrangements to an RWM basis (dropping Alliance and retaining AAH and Phoenix) and reduced the standard discount off the Drug Tariff Price that it offered to wholesalers. The CMA maintained that this reduced the commercial attractiveness of Pfizer-Flynn Capsules relative to NRIM Capsules, as it reduced the difference between the Drug Tariff Price and Flynn's ASPs for every capsule strength, and that this was not the action of an undertaking being threatened by sufficient competitive constraints for the purpose of market definition. Mr Walters accepted in cross-examination that Flynn's wholesale prices for all its products increased as a result of the move to an RWM, but his evidence was that this process had begun in 2013; that the RWM was common practice within the industry; and that the selected wholesalers benefitted from the RWM as they would supply higher volumes across Flynn's entire portfolio thereby benefitting from higher

overall returns even though their percentage margin was lower. We accept Mr Walters' evidence in this regard and in light of it do not regard the move to an RWM as being informative one way or the other as to the extent of the competitive constraints on Flynn.

Period 4: June 2014 to December 2016

177. In Period 4, volume fluctuations steadily reduced, and the ASPs of both suppliers remained stable and not far apart in absolute terms. The volumes of 100mg capsules supplied by Flynn and NRIM remained approximately equal and stable in Period 4, suggesting that demand was not declining at any noticeable rate in that sub-period, although an overall decline of around 4-6% per annum is referred to in the Decision. Similarly, NRIM's overall share of volumes remained relatively stable.

Overall period

178. Overall, Pfizer and Flynn argued strongly that the level of fluctuation both in volumes and price between Pfizer-Flynn Capsules and NRIM Capsules showed a competitive interaction, initially very strong and then stabilising in line with normal market behaviour. The CMA said the interaction was not sufficient to put Pfizer-Flynn Capsules and NRIM Capsules in the same relevant market.

179. Mr Ridyard considered the data to be consistent with a competitive market, at least in the period before November 2013. In his expert opinion, if the behaviour at issue were benchmarked against industry norms, both the volume loss and price effects were consistent with competition. He referred to independent studies which showed, he said, that substantial falls in volumes for recently off-patent drugs were around 40% and that the price response by the originator product was normally much lower than that for other generics. In his view, the pattern of Flynn's launch, after having taken over the product from Pfizer, and NRIM's entry conformed to this broad pattern of market behaviour. We note Mr Ridyard's view, but do not agree that the particular circumstances of this case, namely the debranding of Epanutin and its subsequent launch by Flynn at a much higher price, can be easily likened to the position of a drug coming off patent and being exposed to generic competition. In our view his analogy with the position of recently off-patent drugs is not applicable to the case in hand.

180. This comment applies equally to Mr Davies' industry evidence, to the extent that he also described the situation of a product coming off patent. In any event, even in a situation not involving patent expiry, Mr Davies considered that intense price competition would not be observed until there were four players in the market (i.e. the originator and three generic entrants).

181. Mr De Coninck gave limited evidence on market definition to the effect that the pattern of price behaviour as between Flynn and NRIM, in relation to the 100mg and 300mg capsule strengths, showed that NRIM did constrain Flynn's prices in that category. On the basis of the observed price data alone, he characterised Flynn's price reduction in April 2014 as a response to NRIM's lower sale prices, but accepted that he had not considered any factual material in this regard. In light of the available factual evidence, we therefore found this aspect of his opinion to be of limited assistance. Mr De Coninck also considered that differences in price levels were not informative as to whether two products were part of the same relevant market; rather it was changes to price levels that were relevant. Further, even if it were relevant to look in isolation at the size of the price difference, the difference between Flynn's 100mg ASP and NRIM's ASP following NRIM's price reduction in June 2014 was less than 10% and reduced over the period to around, or even below, 5%. In Mr De Coninck's view, this difference was not material for the purpose of informing any conclusion as to the pricing constraint exerted by NRIM.

182. We accept that the disparity between Flynn's and NRIM's prices does not necessarily rule out the possibility of NRIM exerting competitive pressure, as Mr De Coninck asserted. However, in this case, there is an additional consideration relevant to whether or not the price difference was material, at least from the buyer's perspective, namely the Drug Tariff Price, which we discuss below. In relation to the 5-10% differential, the CMA cited the Tribunal's statement in *Burgess v OFT*[39] that in terms of a conventional SSNIP test, a 10% differential with no evidence of switching away from the higher-priced product would normally be a strong indication of the exercise of market power without significant competitive constraint. We agree with that statement in principle, although there is no absolute rule in this regard, but note that in the present case the CMA did not consider it appropriate to conduct a SSNIP test.

[39] [2005] CAT 25.

183. Over the Relevant Period, price interaction was relatively limited. 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. Whilst we appreciate that pressure on prices does not have to be reflected in constant price changes, as Mr De Coninck opined, it is also notable that this was Flynn's only formal price reduction as notified to the NHS in the whole Relevant Period, and that Flynn sought no further price reductions from Pfizer under the Exclusive Supply Agreement, which provided for annual price reviews. According to the Decision (para 4.80) Pfizer stated in the course of the CMA's investigation that it had opposed further reductions to the supply prices in case this would "give credence to the misplaced allegations in the CMA investigation". The CMA did not accept this explanation as there was no evidence in support and because, in the CMA's view, it showed that Pfizer and Flynn were able to choose to ignore market developments in terms of claimed ongoing price competition. We tend to agree with the CMA on this, although we accept that there was no direct evidence from Pfizer or Flynn before us on this point.

184. In relation to the observed market behaviour, we do not find the volume interactions are in themselves sufficient to establish that NRIM Capsules were competing with Pfizer-Flynn Capsules. What could be more significant would be changes in volumes in response to price variations. As we have seen, apart from NRIM's launch at a price below that of Flynn, there was only one further instance of a price reduction against which to assess changes in volume.

185. There are two further important reasons for finding that NRIM did not compete sufficiently strongly with Flynn for NRIM Capsules to be regarded as being in the same relevant market as Pfizer-Flynn Capsules. First, there is the evidence related to NRIM's commercial strategy. Flynn's view of this strategy indicated that the level of competition from NRIM was likely to be less than vigorous. In his witness statement, Mr Walters said:

> "…the effect of competition on prices in generic markets depends on the nature and commercial priorities of the competitor. In this case Flynn knows (as is common knowledge in the industry) that NRIM's commercial strategy is not generally to start a "race to the bottom" on price but rather to build up a 30-50% share of the market. This is exactly what happened in the case of phenytoin capsules."

186. When asked in cross-examination what he meant by this, Mr Walters' response was as follows:

> "Well, this really comes back to competitor intelligence, and it's – if you observed the behaviour of a company like NRIM, they know that once they've achieved a certain level of market penetration, if they then continue in a price war, which is effectively what you're suggesting that they should do, then basically ultimately the drug tariff would be affected and their income would also be affected. So generally, as a policy, it's not something that they do. As – it's very different when NRIM itself was acquired because it went to a company who operated in a different way. This simply comes back to knowing your competitors. It's simple market intelligence."

187. Mr Walters went on to say, as set out at paragraph 169 above, that Flynn was not "particularly concerned about NRIM". Thus, even if competition from NRIM was anticipated at the time the Pfizer-Flynn Capsule was launched and ultimately came to pass, it was clear that the degree of competition would be limited.

188. This description of NRIM's commercial strategy is consistent with one of NRIM's own Section 26 Responses (also cited at paragraph 144(1) above) in which it states, in relation to the position prior to the MHRA Guidance, that:

> "When we decided to develop a marketing strength in Phenytoin Sodium capsules and tablets, we assumed that we would be likely to remain the only generic Phenytoin Sodium product manufacturer in the UK. We had expected that this was an opportunity for us to establish NRIM as the only generic competitor to Pfizer and to carve out a market share of around 35-40% in total sales of Phenytoin Sodium capsules in the UK."

189. The second reason is that the financial incentive for pharmacies and wholesalers to stock an alternative product is given by the difference between the Drug Tariff Price (which is, in general, what pharmacies receive) and the cost of each of the alternative drugs to them i.e. the margin between the Flynn or NRIM ASP and the Drug Tariff Price, and not by the difference between the sales prices of the drugs themselves. Pharmacies and wholesalers share this margin between them. This gives a clear financial incentive to substitute the cheaper for the more expensive, and would lead one to expect very high levels of switching if, indeed, the clinical guidance did not inhibit it. Between June 2014 and May 2015 the available margin was £[…][✂] on Pfizer-Flynn Capsules and £[…][✂] on NRIM Capsules (based on pack size of 84 capsules). The equivalent figures between June 2015 and June 2016 were £[…][✂] for Pfizer-Flynn Capsules and £[…][✂] for NRIM Capsules. Given the disparity between the margin available on Pfizer-Flynn Capsules and NRIM Capsules, we would expect there to have been a strong price incentive on pharmacies to purchase NRIM Capsules rather

than Pfizer-Flynn Capsules, yet we see very little change in the overall volumes purchased from NRIM in the period after May 2014 and no further price changes.

190. It is also clear to us that normal price competition between Flynn and NRIM (i.e. at a level sufficient to place them in the same relevant market) was constrained by other factors, principally the effect of the applicable clinical guidance on pharmacies' dispensing practice. We accept that this practice was not uniform, but it was nonetheless significant, and substantial stabilisation seems to have set in after the MHRA Guidance was issued in November 2013. We note that volumes continued to fluctuate in the period up to May 2014 and we have discussed the price reductions that occurred around then but do not see either of these as evidence of strong competition between NRIM and Flynn after the issuing of the MHRA Guidance in November 2013.

191. We note that for some situations, for example tenders by hospitals for phenytoin supplies, the concern for patients already stabilised on a particular supplier's product does not arise. We were told, however, that these only comprise some 5% of the total market so in our view are not sufficiently significant to alter our conclusion.[40]

(5) Market definition: conclusion

192. Market definition is a necessary step in assessing whether an undertaking holds a dominant position, which cannot exist in the abstract. Nevertheless, care must be taken to see market definition as a means of conducting an appropriate analysis rather than an end in itself. The key question in dispute is whether NRIM Capsules exercised a sufficient competitive constraint on Pfizer-Flynn Capsules to be regarded as being in the same relevant market.

193. There was a considerable amount of evidence and argument on market definition which we have considered in some detail above but the issue is actually a very narrow one, whether NRIM Capsules are to be included in the relevant market definition or not. No party is arguing for the inclusion of phenytoin in tablet form, far less for any other AED. The CMA accepts that parallel imports of Pfizer-manufactured phenytoin sodium capsules also fall within its relevant market definitions.

[40] See footnote 25 above.

194. We have considered whether there are grounds for dividing the Relevant Period for the purposes of market definition. It is obvious that the situation was different in some respects at different sub-periods, for example the situation before NRIM's launch was not the same as in the period after it; we have also noted the effect on pharmacies' behaviour of the MHRA Guidance in November 2013 and the price reductions by Flynn and by NRIM in May and June 2014 respectively. We have also observed the volume fluctuations at different times, as set out for the 100mg capsule strength in Figure 1.

195. We do not think it is sensible, however, to have a different definition of the relevant market for such short different parts of the Relevant Period. The main characteristics of the market are broadly similar over the whole period, and the degree of competitive pressure exerted by NRIM, whilst it may have varied, does not in our view appear to have been sufficiently strong to constrain Flynn's behaviour to a sufficient extent at any time. Some degree of substitutability or competition is not sufficient in itself to regard the products as forming part of the same relevant market. Bearing in mind the purpose of market definition, and the need to consider the possible competitive effect of NRIM throughout the dominance assessment, it does not make sense to find that its product falls in or out of the relevant market from one month to the next. It is better to decide one way or the other for the whole Relevant Period.

196. Overall, we find, looking at all the evidence in the round, that there was clearly some competitive interaction between Flynn and NRIM, but that this interaction was limited in its scope and effect. Continuity of Supply, 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. NRIM did not supply the whole capsule range (although we do not exaggerate the effect of this). It also appears that NRIM's commercial strategy was not to threaten Flynn's position beyond a certain point, and Mr Walters said that this kind of strategy by NRIM was common knowledge in the industry. The mutually reactive behaviour by the two companies was in practice modest. NRIM achieved a significant volume share in the 100mg strength, and then appears to have accepted a degree of pricing parity and stability, not seeking to advance to a position further than it had reached and also possibly finding it difficult to do so had it tried. In our view, on balance, the NRIM Capsule is better regarded as outside the relevant market for the purposes of this case.

197. We therefore conclude that the CMA was correct in its delineation of the relevant market to exclude the NRIM Capsule. As such, it is not necessary for us to consider the arguments on the CMA's alternative market definition. Had we found it necessary to do so, we would have been concerned that the CMA's alternative market definition may suffer from difficulty over the start and end dates, and from the awkwardness of changing the definition by month to which we have referred.

198. We therefore uphold the CMA's findings on market definition. We stress, however, that this does not remove NRIM Capsules from the analysis altogether or avoid the need to consider the degree of competitive pressure imposed by NRIM over the Relevant Period in the consideration of dominance that follows.

(6) Dominance: discussion

199. In relation to dominance, we have summarised at paragraphs 107 to 109 above the CMA's findings and the relevant grounds of appeal. Pfizer and Flynn's key contention in this context was that the CMA was incorrect to find that the DH did not have countervailing buyer power sufficient to constrain Pfizer's or Flynn's conduct so as to prevent them from holding dominant positions on their respective relevant markets.

(a) Countervailing buyer power

200. The reasons given by the CMA (Decision para 4.323) for finding that there was no countervailing buyer power were that: (i) the structure of the NHS meant that it was difficult for the NHS to exert buyer power over Pfizer and Flynn; (ii) CCGs were not able to exercise any choice of product; and (iii) the DH did not have material countervailing buyer power through the power to regulate prices of phenytoin sodium capsules. Pfizer's and Flynn's challenge centred on the latter point, with the arguments put forward with some emphasis by Pfizer, and to a lesser extent by Flynn.

201. It was not in dispute that an undertaking with significant market power may not be dominant if its customer has a sufficient degree of countervailing buyer power effectively to constrain the undertaking's conduct. Relevant authorities in this context include the Tribunal's judgments in *Genzyme Limited v OFT* [2004] CAT 4 and *National Grid plc v Gas and Electricity Markets Authority* [2009] CAT 14 ("*National Grid*").

202. For example, in *National Grid*, the Tribunal stated (at para 60), citing an earlier judgment:

> "In *Hutchison 3G UK Limited v Office of Communications* [2005] CAT 39, the Tribunal described the proper approach to the assessment of countervailing buyer power ("CBP"):
>
> > "[T]he right question is not the binary one of whether CBP exists or not. In other words, it is not enough to ask whether there is CBP, and if so to hold that there cannot be [dominance]. CBP is the power of counterparties to offset the powers of the party whose allegedly superior powers are under consideration, and the important question is what degree of CBP is there, and (bearing in mind all the circumstances) does it operate to a sufficient extent so as to mean that there is no [dominance]? CBP is not an absolute concept in terms of its strength. It is a concept which embodies a possible range of strengths. In any case where it is relevant, the relevant question is likely to be not whether there is CBP or not, but whether there is any CBP, and if so how much and what effect does it have." (paragraph [110(c)]).
>
> The question to be addressed in this context is thus not just the presence or absence of CBP on the part of [British Gas – the buyer], but the degree of such CBP and the extent to which it operated as a constraint on [National Grid's – the supplier's] ability to exert market power."[41]

203. It is clear from this jurisprudence that to be an effective constraint on behaviour the buyer in question must not only have the theoretical capability of exercising countervailing pressure on suppliers but there has to be a real possibility that this pressure will be exercised in practice and to a sufficient extent.

204. Countervailing buyer power as it is normally understood in competition law terms relates to the bargaining position of the buyer, and could arise, for example, if a commercially significant buyer was able to make a credible threat to switch to a competing supplier. In this case, although in one form or another the DH, whether through the NHS or the CCGs, was by far the largest purchaser of pharmaceutical products in the UK, and indeed was effectively the only end customer for Pfizer-Flynn Capsules, the CMA's view was that it was so organised that in practice it did not habitually deploy the influence that might result from this position in a way that exerted price constraint over suppliers. Further, Continuity of Supply affected the extent to which CCGs could choose to purchase alternative products. Thus, the CMA found that the structure of the NHS meant that it was difficult for the NHS to exert buyer power over Pfizer and Flynn and that CCGs had no choice but to purchase Pfizer-Flynn

[41] The relevant paragraph of *Hutchison* referred to "SMP" rather than dominance i.e. significant market power which is the equivalent term for dominance in the telecommunications context of that case.

Capsules. Pfizer and Flynn did not put forward any specific arguments to the contrary. That being the case, it is hard to see how it could realistically be said that the DH could, in practice, exert any material buyer power, as normally understood in competition law terms, such as to influence the pricing behaviour of Flynn and Pfizer.

205. Indeed, Pfizer confirmed in its pleadings that it was not suggesting that buyer power lay in the hands of end users or prescribers, but rather that the buyer power in question derived from the unique position, statutory powers and non-statutory leverage of the DH. This aspect of countervailing buyer power is better described as a form of regulatory power. Pfizer and Flynn submitted that the DH had a range of informal and formal powers available to it, including to: (i) engage in discussions with Pfizer and/or Flynn requesting information about the product and inviting them to reduce their prices by consent; (ii) invite Flynn to join Scheme M, following which the DH could intervene to ensure that the NHS paid a reasonable price for the product concerned in accordance with the terms of Scheme M; (iii) exercise its compulsory powers via a new statutory scheme to govern generic products under section 263 of the NHS Act 2006, or direct price regulation under section 262; and/or (iv) if necessary, and if the CMA was correct that the DH did not have the powers in (iii), exercise the section 261(4) power to expel Pfizer and Flynn from the PPRS. They argued that, in any event, they set their prices in the expectation that these powers were applicable to them and relied on the DH's interactions with Teva in 2007 in relation to the Teva Tablet price.

206. We described the provisions of Scheme M and the relevant provisions of the NHS Act 2006 in outline at paragraphs 42 to 51 above. Pfizer invited us to find that the DH had, at the material time, the necessary power to regulate the price of Pfizer-Flynn Capsules and declined to do so. The CMA submitted that the Appellants' contentions regarding the DH's powers were unfounded, but that in any event it was not necessary for us to determine the exact nature of the DH's powers because the DH did not in fact exercise any legal powers to regulate the price of Pfizer-Flynn Capsules, even though it had expressed material concerns over that pricing. Insofar as the DH had any power, or Pfizer or Flynn believed that there was any risk that the DH might exercise its powers (which was not admitted by the CMA), this did not give rise to a sufficient degree of countervailing buyer power effectively to constrain their conduct.

207. We agree with the CMA in this respect and do not consider that it is necessary for us to decide the precise extent of the DH's powers as a question of statutory interpretation or otherwise. 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 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.

208. Both Pfizer and Flynn relied on the DH's actions in relation to the Teva Tablet in 2007 and Flynn relied on evidence of its own meetings with the DH in 2012. In this regard, it is necessary to examine the relevant factual background in more detail.

Teva's 2007 meeting with the DH

209. From 2000 to 2005 the price of phenytoin tablets was capped under the MPS (see paragraph 48 above). In March 2005, the maximum price for a pack of 28 x 100mg Teva Tablets was £1.70. Following the introduction of Scheme M and Category M in 2005, the Drug Tariff Price of a pack of 28 x 100mg Teva Tablets rose to £113.62 in October 2007, an approximately 67-fold increase. In or around that time, the DH had a meeting with Teva. As set out at paragraph 74 above, Mr Beighton gave evidence as to the circumstances of that meeting. The material parts of his very short witness statement were as follows.

> "4. Whilst I was at Teva, Teva sold phenytoin tablets 100mg (the "Tablets") in the UK. The Tablets fell within Category M of the then Drug Tariff, which provides details of the reimbursement price that is paid to pharmacies for dispensing a particular product. Teva filed quarterly returns with the DH for the Tablets under Scheme M.
>
> 5. During 2006 to October 2007, the Drug Tariff price of the Tablets increased. The price increase prompted the DH to intervene. I do not recall the precise dates but to the best of my recollection [in] or around October 2007, Teva was contacted by an official from the DH who requested a meeting with Teva. The meeting was called because the DH wanted to discuss the pricing of the Tablets.
>
> 6. I attended that meeting and recall that we were told that the DH wanted the price of the Tablets to be reduced. The DH also told us that if Teva did not cooperate they had the power to bring the price down itself but would prefer to do it with our cooperation. It was my understanding that the DH had a range of different powers

to regulate prices of medicinal products supplied in the UK, including generic products such as the Tablets, which it could use to bring down the price – and that is what I understood the DH to be referring to when it said it could use its powers to bring down the price of Tablets.

7. We identified a reduced price for the Tablets. I do not recall the precise price that we tabled to the DH officials but I do recall that they wanted us to implement a phased reduction for the prices for the Tablets ultimately to a lower level.

8. The price reductions were subsequently implemented. It was my understanding from my dealings with the DH at the time that the DH was satisfied and if it was not happy with the revised prices it could intervene again. The DH did not contact me again in relation to the pricing of the Tablets."

210. Mr Beighton provided some further details of the meeting with the DH at the hearing, primarily in response to the questions put to him by Mr Brealey QC for Pfizer. In particular, he said that the DH officials did not accept Teva's initial price proposal which Mr Beighton thought, based on the information in the Decision shown to him during cross-examination, must have been £40. He said the DH officials proposed a further reduction over time to £30 to be introduced in phases. Mr Beighton was unable to recall the precise origin of the £40 figure but thought it was probably about half of the actual price Teva was achieving for the tablet at that time. Following the meeting with the DH, Teva gradually reduced the price of its tablets and the £30 figure became the Drug Tariff Price that was eventually applicable from October 2008 (see Decision para 3.484).

211. We note that Mr Beighton's witness statement described the prior price increase in rather passive terms, simply stating that "During 2006 to October 2007, the Drug Tariff price of the Tablets increased". However, at the hearing, he acknowledged the instrumental role played by Teva in causing the price to rise. Mr Beighton said, in response to a question from the Tribunal, that Teva was able to "nudge" its price upwards by reference to the Drug Tariff Price. The following quarter the DH would use the new "nudged-up" Teva price to determine the next Drug Tariff Price. Teva would then see that pharmacists were getting reimbursed more and would then take the opportunity to push the price up again. Mr Beighton said that Teva was able to do this because it was "the only company making this *(the tablet)* product".

212. This specific account of the DH's intervention to secure a reduction in the Teva Tablet price is not confirmed by any contemporaneous note or record, and we have no direct evidence from the DH itself. However, neither the fact of the meeting nor the

subsequent price reduction by Teva was in dispute, and these are referred to in the Decision (paras 3.478-3.479, and 3.484), based *inter alia* on Teva's own Section 26 Response to the OFT dated 4 June 2013. A Section 26 Response from the DH dated 14 August 2013, in response to a series of questions from the OFT in relation to the increase in the price of tablets, referred to the meeting as follows:

> "ii. While not formally using the provision in Scheme M, DH officials met with the company, which agreed to lower the price.
>
> iii. The agreement to lower the price was a verbal one and Teva did not make any representations to the Department."

213. The CMA did not seriously contest Mr Beighton's account of the meeting, although it disagreed that it meant that the DH was "happy" with the price of tablets. Mr Beighton's recollection is not comprehensive, but he appears to be clear on the main elements of the meeting, which he described as "difficult". As set out at paragraph 87 above, we afford Mr Beighton's evidence due weight, taking into account the passage of time and the absence of contemporaneous documentation.

Flynn's 2012 meetings with the DH

214. We referred at paragraphs 63 and 66 above to Flynn's meetings with the DH in 2012. At the 18 July Meeting, Flynn raised two options with the DH: either to retain the product as a brand and apply for a one-off price increase under the PPRS, or to genericise the product, in which case the capsules would be priced at a discount of approximately 10-20% to the Drug Tariff Price of tablets. The proposal to increase the price of Epanutin within the PPRS was ultimately rejected by the PPRS's pricing committee.

215. The DH passed its complaint to the CMA in September 2012 (see paragraph 67 above).

216. The Decision records (para 3.396) that Flynn and the DH had a conversation on 23 October 2012 which the DH described in an email as "an exploratory conversation about costs".

217. On 1 November 2012, one of Flynn's board members, Mr Roiter, sent an email to Mr Walters and Mr Fakes in which he stated that:

> "…Flynn is not a member of Scheme M […] If we had been members then we could have increased the price but the starting point would have been the Pfizer brand product price and generally not higher, is that correct? The ultimate power of the Secretary of State to regulate prices seems quite useless here as they cannot force us to sell the product. This must be all about negotiation. The NHS needs the product. We want to sell the product but do not have to and we need to make a reasonable profit. Somewhere between these positions will be the final price to be agreed. That price must take into account the price of competitors e.g. the generic tablets of Teva."

218. Mr Walters responded in an email on the same day: "I am not sure about whether or not the brand price would have come into it had we been members, but other than that, I agree with you". When asked in cross-examination whether the email correspondence was an accurate summary of where Flynn stood with the DH, Mr Walters responded:

> "Well, basically, yes. I mean he's just saying that, you know, nobody can make us sell the products. So we can if we wish, we can discontinue the product. But that's the ultimate power, of the Secretary of State, could be to make us reduce the price to a level that we simply cannot see as being viable…"

219. Flynn had a further meeting with the DH on 6 November 2012 (at Flynn's request) (the "6 November Meeting"). Two notes of the 6 November Meeting were produced, one by the DH and one by Flynn. The DH's note records:

> "[…] 5. [Flynn] defended the current price. It was 25% below the tablet presentations. It said that the tablets accounted for £48 million of NHS sales – not insignificant. In response, DH said that it had never confirmed that it was content with the price of the tablets but it would be inappropriate to comment further on this because a third party was involved in the supply of this presentation.
>
> 6. Concentrating on Flynn, DH said it was unsighted on how the company arrived at the current prices and was keen to find out so that it could decide whether they were justified. However, Flynn said that there were many additional costs involved (e.g. it was planning to create a dual source supply chain to secure future supplies of the medicine). More importantly, it had a commercially confidential agreement in place with Pfizer that prevented the sharing of cost of goods information.
>
> 7. DH understood [Flynn's] position, but emphasised that without more information, it was unable to consider whether the price increases were justified. In these circumstances, it was likely that it would consider what other options it had available. It noted, for example, that previously there had been a maximum price scheme for generic medicines and action such as this could not be ruled out in this case. Due to the narrow therapeutic index of the medicine in question, the Department did not consider that this was a competitive market. Further, it did not consider comparisons with the [tablet] 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. […]"

220. Flynn's own note records:

> "[DH official] stated that Scheme M relies on competition, which as there is no direct competition for capsules currently on the market, does not apply to this product. Phenytoin Sodium Capsules therefore fall outside PPRS and Scheme M. In [DH official's] view, the product falls between the two schemes…they do not know our cost breakdown and DH currently have no justification of value for money that they need from us. ([DH official]) Unless they can understand it, the DH has to go away and see what powers are available to it to do something about it.
>
> We advised that we could not disclose our cost of goods that we pay Pfizer under our supply agreement as this would breach our confidentiality agreement with them.
>
> [DH official] confirmed they recognised the need for some increase in prices, but needed to be able to justify the large increase as value for money. DW advised we might have to discontinue the product if we didn't make sufficient margin. [DH official] 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 [Scheme M] was introduced.
>
> DW stated that the main element of our costs was the cost of the finished product we are supplied.
>
> We felt that the discussion with DH PPRS on price at launch was sanctioned by default as it went unchallenged. [DH official] stated that this could not be the case as PPRS had no remit on pricing of generic products and that Scheme M was not a pricing approval. We should not (in [DH official's]) view; assume that the DH and NHS are happy with the price of the tablets…"

221. Flynn sent a follow-up letter on 16 November 2012 offering further information and welcoming further discussions with the DH. The DH acknowledged receipt in an email which said "We will get back to you in due course".

222. Mr Walters' evidence in cross-examination in relation to the November meeting and the follow-up letter was as follows:

> "So basically we were actually under the impression that this was the beginning of a negotiation process, and as we said at the end of the letter we sent to them outlining the various areas, we would welcome further discussion on these matters."

223. According to Flynn's own meeting note, Mr Walters told the DH that Flynn might have to discontinue the product if it did not make sufficient margin. Mr Walters accepted in his written evidence that Flynn had made it clear to the DH, and also at an earlier stage to the MHRA, that unless a price rise was implemented, it would not be commercially viable to supply the product. To the extent this was characterised by the CMA in the Decision as a threat by Flynn to discontinue the product, this was strongly contested by Flynn, and Mr Walters described it as simply "outlining the facts". On being pressed on the matter in cross-examination by Mr Hoskins to the effect that DH and MHRA

officials perceived this as a threat (although we note that no such threat was expressly recorded in the DH meeting note), Mr Walters responded as follows:

> "If we gave that impression, then I do apologise, but actually, I don't think it's the impression that they should have taken from it because, as I've said in the witness statement, it's certainly fair to say that we made it clear to the DH and the MHRA that unless we could implement a pricing increase, it was not commercially viable to supply the product. We've also indicated through those statements that we were open to negotiation. We'd already offered to keep it in the PPRS. Already offered."

224. Both the DH and the Flynn meeting notes record that Flynn was unable to disclose its cost of goods information due to its confidentiality arrangements with Pfizer.

Pfizer's internal views of the DH's powers/meeting with the DH

225. In his written and oral evidence, Mr Poulton explained that it was Pfizer's understanding, when considering options for Epanutin, that if the price of phenytoin sodium capsules was increased to a level to which the DH objected, the DH would be able to intervene. He expected any debranded capsule product to be placed within Category M because the Teva Tablet was also in that category and to be subject to the possibility of price revision by the DH as a consequence. Whilst he was not sure at what stage he became aware of the movements in the price of the Teva Tablet, it was no later than in the course of Pfizer's discussions with Tor. In an internal email sent on 3 August 2010, Mr Poulton stated that "The [DH] reduced the Category M price of phenytoin tablets in 2008 to £30. The previous price was ~£110. This indicates the value of this medicine to the NHS." Mr Poulton stated that his understanding at the time was that the Teva price reduction "reflected a DH-sanctioned price re-set". His interpretation of what happened in the market was that, without the DH intervening, "there was no other 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", and this conclusion was confirmed by Tor and Flynn, who held the same opinion. As time passed, and the DH made no further intervention, Mr Poulton took the view that the DH had accepted the Teva price as fair. He stated that:

> "…our inference, our conclusion, was that the [DH] had found the trebling of the price unacceptable, had intervened with Teva to bring the price down to where it was before, the equivalent of a £90 for our 84 doses. They could have intervened to bring it down further. They didn't. Therefore, our inference was that the [DH] was happy with the price that they were at previously, the price that they remained at, and that represented a fair value of this medicine, otherwise they would have intervened to bring it down further".

226. Pfizer referred us to a number of other contemporaneous documents indicating its belief, even as late as May 2013, that the DH could require a price reduction on the Pfizer-Flynn Capsules. For example, a May 2013 internal sales note recorded:

> "Key to note is the ongoing discussions between Flynn and the [DH] on the pricing of this generic with a possible significant price cut a significant possibility. Pfizer would be likely to have to mirror this price cut to maintain the deal and market volume. This price cut was included in budget from AP2 but is now anticipated in H2. There will be an upside of c. £0.4m […] per month of delay to the possible reduction in manufacturing price (from AP7) under current normal supply volumes as well as a further upside from AP9 of up to c. £0.3m per month if we don't see the anticipated generic entry".

227. As mentioned at paragraph 66 above, the DH met Pfizer (though not, we understand, Mr Poulton, who had moved on to a new position by then) on 10 January 2013. Discussion of Epanutin does not appear to have been the primary purpose of the meeting, but the section of the redacted meeting note under the item "AOB" (any other business) records as follows:

> "Epanutin
>
> 12. In light of the recent divestment and significant price increase of Epanutin, the Department sought comments from the company in respect of the increased expenditure to the NHS.
>
> 13. The company stated that the product was sold to Flynn Pharma as it was no longer economically viable to keep it on. No further information was given at the time of the meeting, however the company undertook to look into the Department's concerns and revert in due course.
>
> 14. When asked by the Department whether they considered modulating the product, the company confirmed that in considering the savings requirements of the scheme, they decided to focus on the more innovative products rather than the tail end products.
>
> 15. In response to the Department's query that Epanutin was still manufactured by them, they confirmed that it was manufactured in Ireland *[sic]* and therefore could offer no more information at the moment but would investigate the issues raised".[42]

228. In a follow-up email sent to the DH on 26 February 2013, Pfizer stated "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 its pricing strategy".

[42] According to the Decision (fn 481), the reference to Ireland was incorrect. Pfizer manufactures phenytoin sodium capsules in its plant in Freiburg, Germany.

229. It may well be that both Pfizer and Flynn were under the belief that the DH had intervened to reduce the price of phenytoin tablets, by some process, and clearly considered that the DH might seek to negotiate the price of phenytoin capsules if it so wished, although it is less clear whether they thought, at the time, that the DH had legal powers directly to control the price. That does not in itself indicate that the DH constrained their conduct.

230. It is important not to confuse the issue of whether the DH intervened to reduce the tablet price with the (albeit related) question of whether Flynn and Pfizer were justified in setting the launch price for Pfizer-Flynn Capsules by reference to the tablet price. We have broadly accepted Mr Beighton's evidence as to what happened between the DH and Teva. The CMA said that the fact of a price reduction obtained in this way tells us nothing as to the DH's acceptance or otherwise of the price; merely that the reduction happened. Pfizer and Flynn invited us to conclude that the DH regarded the tablet price as fair. We have no direct comment from the DH on this point. Nevertheless, we are most reluctant to draw the inference Pfizer and Flynn wish. We 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.[43]

231. It is not clear that the events relating to the Teva Tablet price reduction resolve the issues relating to the DH's attitude to the capsule price increase. Pfizer-Flynn Capsules were placed in Category C rather than Category M and the concern referred to by Mr Poulton about the DH's powers in relation to Category M products (or under Scheme M, he was not sure which) would not directly arise. Mr Walters said that if the DH had invited Flynn to join Scheme M, they would very likely have agreed. However, this invitation never came. Mr Walters confirmed in cross-examination that Flynn did not offer to join Scheme M at any stage, nor could the DH have forced Flynn to join it as it was a voluntary scheme.

232. When it was suggested by the MHRA 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 (albeit, as regards the tablet price, at the

[43] Although the DH complained much later (in 2012) to the OFT about Teva's prices also.

6 November Meeting rather than the earlier 18 July Meeting). Flynn maintains that it thought, in late 2012 and early 2013, that it was engaging in a dialogue, if not a negotiation, with the DH about its prices, and was surprised when the DH did not continue this after January 2013. However, in fact, the DH had already in September 2012 complained to the OFT about Flynn's prices. We were not shown any evidence that Flynn sought to pursue the dialogue with the DH any further after January 2013.

233. As to the discontinuance point, whether or not the DH and MHRA officials in question perceived a threat by Flynn to discontinue, a matter on which we have no direct evidence, we note that from Mr Walters' own account it is clear that Flynn applied a certain amount of "negotiation leverage", which was not, in our view, consistent with the DH exercising countervailing buyer power. We also note that in their interactions with the DH in late 2012 and early 2013, effectively Flynn referred the DH to Pfizer in relation to Flynn's cost of goods, whilst Pfizer declined to comment to the DH on Flynn's pricing, saying it was a matter for Flynn.

234. We find it very difficult to conclude from these events that by early 2013 Pfizer or Flynn's conduct was in practice constrained either by intervention from the DH, or anticipation of that intervention. As Mr Poulton acknowledged, even by 2012 it was more than five years since the events related to the tablet price. This made him less, rather than more, concerned at the possibility of DH intervention against the capsule price. Flynn itself, having taken the position that it was unable to disclose its cost of goods to the DH as requested, as this information was confidential to Pfizer, and having failed to pursue the matter, did nothing further about its prices until towards the end of 2013 when it sought a reduction from Pfizer as foreseen by the provisions of the Exclusive Supply Agreement. As to Pfizer, we note the May 2013 internal sales report referring to ongoing pricing discussions between the DH and Flynn, but see this as a subjective assessment that does not add anything to the evidence on this point.

235. 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.

(b) Other factors relied on by the CMA

236. In the Decision, the CMA relied on a number of other factors in support of its findings of dominance.

237. As an indicator of dominance, the CMA placed some reliance on high market shares. Obviously, the CMA's assessment of shares derives from its findings on market definition and the relevant period for scrutiny. As a matter of law it is well-established that high market shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position.[44]

238. In relation to high prices and profitability, there is here some danger of circularity of logic, as Pfizer has pointed out, because whether prices and profits are excessive in terms of competition law is one of the key issues in the case. The CMA says that it is nonetheless possible to rely on the fact of the level of prices and profits to establish dominance, without ascribing, at that stage, any significance to them as evidence of abuse, and referred us to EU jurisprudence to that effect.

239. In *United Brands*, the Court of Justice said (at paragraphs 67-68), in assessing whether the undertaking in question (UBC) held a dominant position:

> "In order to find out whether UBC is an undertaking in a dominant position on the relevant market it is necessary first of all to examine its structure and then the situation on the said market as far as competition is concerned.
>
> In doing so it may be advisable to take account if need be of facts put forward as acts amounting to abuses without necessarily having to acknowledge that they are abuses."

240. In T-321/05 *AstraZeneca v Commission* EU:T:2010:266, the General Court, in considering the effect both of higher prices charged by AstraZeneca and its high market share (relevant to possible dominance), said (at paragraph 261):

> "Furthermore…the fact that AZ was able to maintain a much higher market share than those of its competitors while charging prices higher than those charged for other [products] is a relevant factor showing that AZ's behaviour was not, to an appreciable extent, subject to competitive constraints from its competitors, its customers, and, ultimately, consumers."

[44] See, e.g. *Hoffmann-La Roche* at para 41; C-62/86 *AKZO Chemie BV v Commission* EU:C:1991:286 at para 60.

241. We agree with the CMA 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.

242. As to prices, Flynn set the launch price for Pfizer-Flynn Capsules at a level that represented a very large increase over the previous price charged by Pfizer for Epanutin. We accept that Pfizer maintains that the previous price was depressed to a level of at best bare profitability by the operation of the PPRS. We are not here judging the merits of that claim, merely noting that the price increase was very large.

243. As we have already described in Section G(4)(b) above, Flynn's initial price was maintained, subject to minor fluctuations, throughout the Relevant Period with the exception of the one price reduction in April 2014 for the 100mg and 300mg capsule strengths. Similarly, Pfizer's supply price to Flynn remained unchanged apart from one reduction in February 2014.

244. Without in any way pre-judging whether Pfizer's and Flynn's prices were excessive and unfair so as to infringe competition law, it is possible to state, as the CMA's finding indicates, that Pfizer's and Flynn's behaviour in relation to prices was not, to an appreciable extent, subject to competitive constraint from its competitors or customers.

245. As to the level of profits, we attach less importance to this as an indicator of dominance than we do to price behaviour. We merely note that the Pfizer-Flynn Capsule was a very profitable product for Flynn, accounting for more than half its net profit from 2013 to 2015. As to the profitability to Pfizer of phenytoin capsules supplied to Flynn, while the CMA has offered no evidence as to how it compares to that for other Pfizer products, it is clear from the Decision that the absolute level was high.[45]

246. The next issue is the more general level of competitive constraint provided by NRIM and parallel imports. We have already considered above, in some detail, the factual and other issues in this regard.

247. As to pressure from NRIM, the CMA pointed to the stabilisation of prices and volumes after the initial period of relative volatility following NRIM's launch and before the

[45] See, e.g., Decision para 4.6.

MHRA Guidance. We have already found, contrary to the views of Mr Ridyard and Mr De Coninck, that there was not sufficiently effective competition between them for NRIM to be in the same relevant market and there was clear evidence that NRIM offered only limited competition as a result of its commercial strategy. All this suggests that Flynn (and Pfizer) faced only limited constraint as a result of NRIM's selling of its capsules.

248. As to pressure from parallel imports, we note that the CMA did not regard this as significant, mainly because of uncertainties of supply. This was not disputed. We also note that Mr Poulton referred to Pfizer's efforts to limit supply in other EU countries to the needs of the local market and that Mr Walters referred at the hearing, in response to a question from the Tribunal, to Flynn's concern to protect its trade mark rights from use by parallel importers.

249. We therefore accept the CMA's view of the limited competitive constraints on Flynn and Pfizer in this context.

250. Finally, in relation to barriers to entry and potential competition, the CMA did not list Continuity of Supply as a distinct factor in its assessment of dominance but referred to it when analysing what it saw as the limited competitive pressure on Flynn and the much reduced effect of potential competition. The CMA took the view that new entry was unlikely because of Continuity of Supply and the time and cost needed to obtain an MA and launch a product. Although we do not think this adds anything to the consideration we have already given to this issue in relation to market definition, we note that these high barriers to entry are supportive of a finding of dominance.

(7) Dominance: conclusion

251. Our conclusion is that the CMA was correct to find that Flynn and Pfizer each held dominant positions on their respective relevant markets as defined. Despite NRIM selling its capsules, Flynn was able to set and maintain high selling prices for Pfizer-Flynn Capsules over the Relevant Period. As a result of this, Pfizer was able to maintain a supply price to Flynn that was correspondingly high. We accept that Pfizer made one, significant, reduction in its supply price to Flynn and that Flynn also reduced its selling prices on one occasion. We do not think this alters the conclusion that over the Relevant Period as a whole, both supply and selling prices were high. As a consequence, both

companies earned levels of profit on their capsule sales over the Relevant Period that were consistent with being able to price relatively independently from competition. We see little sign of Pfizer's or Flynn's prices being constrained by competition either from within the relevant market, or from outside it, and conclude that they were able to an appreciable extent to behave without competitive constraint from their competitors or customers.

252. We have also found that the ability of Pfizer and Flynn to act in this way was not restrained by buyer power being exercised in practice by the DH in its capacity as overseer of the system of pharmaceutical supply and actual or potential price regulator of pharmaceutical products.

253. We agree with the other grounds relied on by the CMA in making its findings of dominance, although in some cases possibly with less emphasis. We do not see this as a market where there was normal and effective competition. Accordingly, we uphold the CMA's findings that Pfizer and Flynn each held dominant positions on their respective relevant markets as defined.

H. ABUSE

(1) Overview of the CMA's findings

254. The CMA's findings in relation to abuse of a dominant position are set out in full in Section 5 of the Decision and may be summarised as follows.

255. At paragraphs 5.7 to 5.11 of the Decision, the CMA introduced the test set out by the Court of Justice in *United Brands* for assessing whether a price is unfairly high. We discuss that test in some detail below. For the purpose of this summary, we simply note here that the CMA applied that test by first examining whether Pfizer's and Flynn's prices were excessive, and then considering whether Pfizer's and Flynn's prices were unfair. As part of its consideration of unfairness within that test, the CMA assessed the economic value of Pfizer-Flynn Capsules[46] and whether the price bore a reasonable relation to the economic value of the product. In applying the *United Brands* test, the CMA also relied at several stages of the Decision on the difference between the Pfizer-

[46] See paragraphs 269 to 272 below.

Flynn Capsule prices and the price previously charged by Pfizer for Epanutin. This was variously referred to in the course of the hearing as "the comparison over time" or the "before-and after-price". We refer to it as the "Price Comparison over Time". The CMA placed rather more reliance on this aspect of its analysis during the hearing than might be thought from reading the Decision. We therefore also highlight in this summary where in the Decision this element of the CMA's analysis arose.

256. The CMA began by assessing for each of Pfizer and Flynn whether their prices were excessive when compared to their "Cost Plus". Cost Plus in this context was composed of (a) the costs that Pfizer and Flynn each incurred in respect of each of their capsule products (to include direct costs and an appropriate apportionment of indirect, or common, costs); and (b) a reasonable rate of return for each of Pfizer and Flynn in respect of each of their capsule products.

257. For each of Pfizer and Flynn, the CMA considered that the most appropriate available method for apportioning or allocating "common costs" to Pfizer-Flynn Capsules was a volume-based method, using a sales volume by number of packs. This method involved allocating indirect costs according to total sales volumes across the relevant company's portfolio of products. Recognising that sales volumes were unlikely to be completely correlated with common costs, the CMA went on to perform a sensitivity analysis as a cross-check.

258. The CMA then determined what, in the CMA's judgment, would be a reasonable rate of return to those costs to establish the "Plus" element of Cost Plus. It examined three possible measures for each of Pfizer's and Flynn's rate of return, namely ROCE; ROS; and gross margins.

259. For Pfizer, the CMA used ROS as its primary method for determining a reasonable rate of return, and found that a ROS of 6% was a reasonable rate of return for the Pfizer-Flynn Capsule. In so doing, it accepted that there is no directly applicable and generally accepted industry benchmark within the UK for what is a reasonable rate of return for manufacturers of generic drugs. Instead, it considered the following possible benchmarks: Pfizer's internal ROS; the allowable ROS under the PPRS; and other companies' ROS rates; while taking into account the nature of phenytoin sodium

capsules, the nature of the activities undertaken by Pfizer, and the risks that Pfizer incurs with respect to its supply of its products.

260. The CMA's finding that a ROS of 6% was reasonable for Pfizer was based *inter alia* on the following considerations:

(1) A ROS of 6% was higher than Pfizer's average annual profit margins across its UK business as a whole from 2009 to 2013 (adjusted to take account of Pfizer's submissions that phenytoin sodium capsules were loss-making for some of this period). As phenytoin sodium capsules were an old drug involving no recent innovation or investment, and low risk in supply (given the established base of stabilised patients), a reasonable ROS should not be materially higher than Pfizer's average. Further, in exercising its judgment as to what would be a reasonable rate of return, the CMA had regard in particular to the interests of patients and the NHS, whilst also recognising that the interests of the supplier were important. Adopting a reasonable rate of return that was broadly in line with Pfizer's average allowed the CMA to calculate a rate of return for Pfizer that preserved its overall financial position.

(2) Pharmaceutical companies are allowed to earn a ROS of up to 6% on their portfolio of branded products within the PPRS. This rate was agreed through negotiations between the DH (on behalf of the NHS) and PPRS members and, accordingly, it strikes a balance between the sellers' and the customers' interests. The CMA recognised that there were limits to the PPRS ROS rate of 6% as an indicator of a reasonable return noting, in particular, that its purpose is to control pharmaceutical companies' profits on their portfolio of branded products rather than the prices of individual generic products, and that Pfizer could legitimately achieve a rate of return on the Pfizer-Flynn Capsule which was higher than the allowable rate of return under the PPRS without its prices being excessive.

(3) Nonetheless, the CMA considered the PPRS ROS rate to be useful and informative for determining a reasonable rate of return for the purpose of calculating Cost Plus for Pfizer's Products. The reasons for this included that (i) the Pfizer-Flynn Capsule was identical to Epanutin which had been sold as a

branded product under the PPRS; (ii) the PPRS ROS rate was the closest the UK came to an agreed industry standard for returns on pharmaceutical products, and had been agreed for branded drugs which also included new and innovative products; (iii) using the PPRS ROS rate allowed the CMA to calculate a rate of return for Pfizer that preserved its overall financial position; and (iv) a ROS of 6% was equivalent to an overall contribution margin more than four times greater than the internal target rate below which Pfizer puts a product under review.

261. The CMA rejected Pfizer's submission that it was appropriate or necessary to rely on certain other companies' ROS rates in determining a reasonable rate of return for Pfizer. Finally, it also carried out a ROCE analysis, in order to provide a cross-check against the results of its ROS analysis.

262. For Flynn, the CMA also found that ROS was the appropriate measure for determining a reasonable rate of return, and that a ROS of no greater than 6% and possibly much less would be a reasonable rate of return for the Pfizer-Flynn Capsule. As in the case of Pfizer, it accepted that there is no general industry benchmark. Instead, it considered the a number of possible specific benchmarks.

263. The CMA ultimately rejected Flynn's submission that Flynn's internal ROS rates and/or other companies' ROS rates were helpful benchmarks for the purpose of assessing a reasonable rate of return for Flynn, but acknowledged that they pointed to a ROS higher than 6%. However, the other specified factors pointed to a lower ROS than 6%. Weighing up all of these factors in the round, a 6% ROS figure was reasonable, indeed, in the CMA's view, generous.

264. The CMA's finding that a ROS of 6% for Flynn was reasonable was based *inter alia* on the following considerations:

(1) Phenytoin sodium capsules were an old drug that had been off-patent for a very long time and for which there had been no recent innovation.

(2) Flynn undertook limited activities in respect of the Pfizer-Flynn Capsule and incurred low commercial risks.

(3) Flynn paid a high supply price to Pfizer which inflated Flynn's Cost Plus figures and meant that any given percentage ROS translated into a higher absolute return for Flynn. In particular, a ROS for Flynn that was significantly lower than 6% would give it, in absolute terms, the reasonable return allocated to Pfizer based on a 6% ROS.

(4) Pharmaceutical companies are allowed to earn a ROS of up to 6% on their portfolio of branded products within the PPRS. In this regard, the CMA repeated certain of its observations made in this context in relation to Pfizer, again recognising that there were limits to the appropriateness of the PPRS ROS rate as an indicator of a reasonable rate of return.

(5) Nonetheless, the CMA considered the allowable PPRS ROS rate had some probative value for assessing what would be a reasonable return for Flynn. The reasons for this included that (i) the Pfizer-Flynn Capsule was identical to Epanutin which had been sold as a branded product under the PPRS; (ii) the PPRS ROS rate was the closest the UK came to an agreed industry standard for returns on pharmaceutical products and had been agreed for branded drugs which also included new and innovative products; (iii) Flynn's limited activities and low commercial risks in respect of the Pfizer-Flynn Capsule contrasted with those of pharmaceutical companies subject to the PPRS which engaged in a broad range of activities and bore significant commercial risks in the supply of their products. The allowable PPRS ROS rate should therefore provide a generous financial incentive for Flynn to supply the Pfizer-Flynn Capsule; (iv) the allowable PPRS ROS rate would be higher than most pharmaceutical companies earn in practice as it is a target rate which most companies do not achieve; and (v) the high supply price paid by Flynn to Pfizer meant that a 6% ROS translated into a much higher absolute return for Flynn than it would if Flynn's input costs were not inflated by Pfizer's supply price.

(6) In exercising its judgment as to what would be a reasonable rate of return, the CMA had regard, in particular, to the interests of patients and the NHS, whilst also recognising that the interests of the supplier were important.

265. For each of Pfizer and Flynn, the Decision emphasised that the CMA's findings on a reasonable rate of return were specific to the circumstances of the present case. The CMA expressly recognised that a reasonable rate of return for products other than the Pfizer-Flynn Capsule may be greater, for example in cases (unlike the present case) where substantial investment was made, substantial capital was employed or there were significant commercial risks.

266. The CMA went on to assess whether, and, if so, by what amount, each of Pfizer's and Flynn's prices exceeded Cost Plus. It referred to the relevant amount as the "excess". Following the approach taken by the Commission in the *Deutsche Post*[47] case and by the Tribunal in the *Albion Water II*[48] case, it expressed the excess as a percentage, by subtracting Cost Plus from the price and then dividing the result by Cost Plus. On this basis, the CMA found that Pfizer's prices exceeded Cost Plus by at least 29% for 25mg capsules, at least 100% for 50mg capsules, at least 705% for 100mg capsules and at least 690% for 300mg capsules. In absolute terms, the excesses ranged from just over £[…][✂] per pack for 25mg capsules to more than £[…][✂] per pack for 100mg and 300mg capsules. On the same basis, the CMA found that Flynn's prices exceeded Cost Plus by at least 133% for 25mg capsules, at least 70% for 50mg capsules, at least 31% for 100mg capsules, and at least 36% for 300mg capsules. In absolute terms, the excesses ranged from just under £[…][✂] for 50mg capsules to just under £[…][✂] for 300mg capsules.

267. The CMA then considered whether each of the excesses were, in the words of the *Albion Water II* judgment, "material" and "sufficiently large to be deemed excessive" for the purpose of the *United Brands* test, and concluded that they were. In addition to the scale of the excesses, the CMA found its conclusions for each of Pfizer and Flynn to be confirmed by the following factors: (i) the excesses were maintained for a substantial period of time (over four years); (ii) while not determinative, the excesses were above the levels found to be excessive in other cases (25% in *Deutsche Post* and 46.8% in *Albion Water II*); (iii) the results of sensitivity analyses carried out by the CMA using alternative methodologies for allocating common costs and used as a cross-check; and

[47] Commission decision COMP/36.915 – Deutsche Post AG – Interception of cross-border mail (2001) ("*Deutsche Post*").
[48] *Albion Water and Another v Water Services Regulation Authority and Others* [2008] CAT 31 ("*Albion Water II*").

(iv) the per-pack excesses for each capsule strength were considerably higher than the ASPs at which Pfizer sold Epanutin to wholesalers and pharmacies prior to September 2012 (i.e. the Price Comparison over Time).

268. In relation to Flynn, the CMA cited three further factors: (i) as the CMA had applied the maximum reasonable rate of return for Flynn, Flynn's excesses were likely to be under-estimates; (ii) Flynn's excesses were particularly material in light of its limited activities and risk with regard to the Pfizer-Flynn Capsule; and (iii) Flynn's percentage excesses were affected by the high supply prices it paid to Pfizer. The CMA rejected Flynn's submissions that its prices could not be considered to be excessive because the profitability of Pfizer-Flynn Capsules (measured through product contributions, gross margins or return on sale measures) was comparable to that of Flynn's other products.

269. Having found Pfizer's and Flynn's prices to be excessive throughout the Relevant Period, the CMA went on to consider whether those prices were unfair. It first assessed the economic value of Pfizer-Flynn Capsules. We discuss the concept of "economic value" and the CMA's analysis in detail in Section H(6) below. For the purpose of this summary, we simply note here that the approach of the CMA was to determine whether there were any non-cost related factors which would increase the economic value of the capsule product beyond Pfizer's and Flynn's Cost Plus. The CMA concluded that there were no such factors. It relied on specific characteristics of the Pfizer-Flynn Capsule including that it was an old drug which had long been off-patent, and had been superseded by other AEDs. In addition, the product had been subject to a substantial overnight price increase in September 2012 which was not the result of any material change in costs of production or supply, innovation, risk or the nature of the product itself, and no additional benefits had been created for patients. Further, customers, in this case CCGs, were paying Pfizer's and Flynn's post-September 2012 prices under protest and the DH did not consider that those prices represented value for money.

270. The CMA went on to consider and reject a number of factors put forward by Pfizer and Flynn in support of their arguments that the economic value of the Pfizer-Flynn Capsule was above Cost Plus. In particular, it rejected the submission that the economic value of phenytoin sodium capsules should take account of the therapeutic value to patients of Continuity of Supply. Nor did the value placed on tablets by the NHS, namely the Drug Tariff Price of tablets, provide a basis for assessing the economic value of

phenytoin sodium capsules. The CMA also rejected Pfizer's submission that the revenue-earning potential to Flynn of Pfizer's Products should be taken into account when determining the economic value of Pfizer's Products.

271. The CMA emphasised that its findings that the economic value of the Pfizer-Flynn Capsule was Cost Plus did not establish the upper limit of what Pfizer and Flynn could legally charge. However, their prices had to have a reasonable relation to those levels. The CMA also considered that the economic value of Flynn's Products was artificially increased by Pfizer's excessive supply prices.

272. Having established that there was no additional economic value in the Pfizer-Flynn Capsule beyond Cost Plus, the CMA went on to find that Pfizer's and Flynn's prices were unfair in themselves, as they bore no reasonable relation to the economic value of the product. In this context it had regard, in particular, to: (i) the substantial disparity between Pfizer's and Flynn's prices and the economic value of their products; (ii) the fact that competitive conditions prevailing on both relevant markets demonstrated that the relevant markets did not function in a manner that was likely to produce a reasonable relation between price and economic value; and (iii) the fact that Pfizer's and Flynn's prices had an adverse effect on the end customer (in this case the NHS in the form of CCGs) and that Pfizer and Flynn were aware of this. The CMA also relied on factors on which it had also relied in the context of excessive pricing, including the considerations relating to the age of the drug, and the substantial price increases (i.e. the Price Comparison over Time). Finally, it identified additional contextual factors to reinforce its findings that Pfizer's and Flynn's prices were unfair in themselves. In the case of both Pfizer and Flynn, contextual factors were the Price Comparison over Time and Pfizer's introduction of Flynn to the supply chain to mitigate the risk of adverse publicity and reputational damage arising from any price increase rather than genericising Epanutin itself. For Pfizer, a further such factor was that Pfizer had not implemented any similar price increases in other EU Member States. In Flynn's case, the CMA also relied on Flynn's limited activities and low commercial risk.

273. Having reached the conclusion that Pfizer's and Flynn's prices were unfair in themselves, the CMA considered that it was not necessary, as a matter of law, for it to reach a conclusion as to whether those prices were also unfair when compared to competing products. However, for completeness, it did consider whether such a

comparison could be conducted. It identified and assessed three potential products that could provide the basis for a comparison, namely parallel imports, NRIM Capsules and tablets. It concluded that there were no products that would provide a meaningful comparison for the purpose of assessing whether Pfizer's and Flynn's prices were unfair when compared to competing products. The CMA considered it notable in this context that Pfizer and Flynn had ignored what it saw as a more meaningful benchmark for assessing whether their prices were unfair, namely Pfizer-manufactured phenytoin sodium capsules sold by Pfizer in other EU Member States.

274. Finally, the CMA found that Pfizer and Flynn had failed to provide an objective justification for their prices.

(2) The grounds of appeal

275. For convenience, we group our description of the grounds of appeal relating to abuse[49] by broad topic, although this does not necessarily reflect their order of importance nor does it track the order in which the findings appear in the Decision.

276. Pfizer and Flynn raised a number of grounds of appeal in relation to the CMA's findings that their prices were excessive.

(1) Pfizer contended that the CMA was wrong to conclude that a Cost Plus benchmark of a 6% ROS was an appropriate benchmark based essentially on a "cut and pasted" approach from the PPRS (Pfizer Ground 3). Similarly, Flynn contended that (i) the benchmark rate of a 6% ROS derived from the PPRS rules was misconceived (Flynn Ground 5); (iii) even if a relevant benchmark could be derived from the PPRS, Flynn's prices were not excessive if the methodology for allocating costs under the PPRS was properly applied; and the permitted MOT under the PPRS rules was taken into account (Flynn Ground 6).

(2) Flynn further contended that: (i) the CMA had wrongly disregarded two key benchmarks relating to the gross margins earned by Flynn on other products in its portfolio, which showed that the margins earned by Flynn on Pfizer-Flynn Capsules were not excessive (Flynn Ground 7); and (ii) the CMA's

[49] Pfizer's Ground 4, which goes to the abuse finding, is dealt with separately in Section I below.

methodology for allocating Flynn's common costs on the basis of sales volumes produced a meaningless and arbitrary result (Flynn Ground 4).

277. Pfizer and Flynn each had an over-arching ground of appeal which took issue with the overall approach taken by the CMA in making its findings on abuse. By Ground 2 of its appeal, Pfizer contended that the CMA had misapplied the proper test for abuse by excessive pricing, namely a price that bears no reasonable relation to economic value. The CMA's conclusion that the economic value was no more than Cost Plus ignored the fact that Pfizer's supply price, and Flynn's selling price, was materially below the price of the identical phenytoin sodium tablet product. Similarly, Flynn contended by Ground 8 of its appeal that the CMA had wrongly disregarded the fact that Flynn's prices for Pfizer-Flynn Capsules had at all material times been substantially below those for phenytoin tablets as a benchmark (and were deliberately set on that basis). The tablet prices should have been the key comparator for determining whether capsule prices were excessive and/or unfair (including the assessment of economic value).

278. Finally, Flynn contended that the CMA had wrongly relied on a number of other entirely irrelevant and subjective considerations in support of its finding that Flynn's prices were unfair in themselves (Flynn Ground 9).

279. Before examining these grounds of appeal in detail, we set out our consideration of the relevant legal principles.

(3) Legal principles

(a) Overview of the case law

280. It is settled law that an undertaking which holds a dominant position "has a special responsibility not to allow its conduct to impair genuine undistorted competition" on the internal market[50]. The definition generally cited in relation to abuse of a dominant position, and which the CMA quotes in the Decision, comes from the *Hoffman La-Roche* case (at para 91):

> "The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened

[50] C-322/81 *Michelin v Commission* EU:C:1983:313, at para 57.

> and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition."

281. In practice, the law on abuse of a dominant position is most commonly applied in relation to exclusionary practices, in other words where the presence and conduct of the dominant firm may weaken competition to the detriment of consumers, even if that detriment comes about indirectly as a result of a change in market structure, or from harm done to other competitors. The abuse in the present case, however, is said to take the particular form of charging prices that are "excessive and unfair"[51], where the alleged harm to consumers is direct, to the extent that the consumer pays more for a product than would be the case under normal conditions of competition in circumstances which infringe Article 102 TFEU. The jurisprudence in relation to this category of "exploitative" abuse is not as extensive as that which covers exclusionary practices.

282. As can be seen from paragraph 88 above, Article 102 TFEU does not refer expressly to the term "excessive pricing" but rather to "directly or indirectly imposing unfair purchase or selling prices". The TFEU says nothing further on the point, but it may be observed that the reference to prices being "unfair" immediately introduces a demand side aspect to the consideration of the issue. With the exception of the cases concerning performing rights[52], which raise specific issues and are considered below, it is not common for unfair pricing to be alleged as the sole aspect of abuse. Typically, this aspect of Article 102 has been considered in conjunction with other conduct, usually exclusionary behaviour or tying.

283. The case of *Sirena v Eda*[53] ("Sirena") was cited to us by Mr Hoskins as an early example of the Court of Justice addressing unfair pricing, in particular its statement at paragraph 17 of the judgment:

> "As regards the abuse of a dominant position, although the price level of the product may not of itself necessarily suffice to disclose such an abuse, it may, however, if unjustified by any objective criteria, and if it is particularly high, be a determining factor."

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[51] See, e.g., Decision para 5.1.
[52] These cases typically relate to the rates imposed by copyright management organisations or collecting societies for licences for the public performance of copyrighted works such as music. The entities in question usually have national legal monopolies.
[53] C-40/70 *Sirena S.r.l. v Eda S.r.l. and Others* EU:C:1971:18.

284. However, that case, which was a request for a preliminary ruling, did no more than state the bare legal position that Article 102 can prohibit dominant undertakings from abusing that position through unfair pricing. The case is of little assistance when considering whether any particular conduct constitutes an infringement of Article 102. Such issues were not considered in the judgment and there was no relevant analysis. *Sirena* has not formed a material part of the analysis of this issue in subsequent cases.

285. The seminal case in which the question of how Article 102 might apply to unfair pricing is *United Brands*, to which we have already referred above, and which has remained, in the small number of cases where the issue has been considered, the critical reference point for analysis. However, the treatment of the issue is extremely limited, comprising only six paragraphs of the judgment (paragraphs 248 to 253) where the Court of Justice stated:

> "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 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"."

286. There are two immediate observations to be made in relation to the *United Brands* case. First, unfair pricing was only one of four alleged abuses.[54] Secondly, the appeal against

[54] The other alleged abuses were in relation to price discrimination, sales conditions and refusal to supply.

a finding by the Commission of abuse by unfair pricing was successful, and, although the Court of Justice laid down an approach that the Commission should have applied, there was, in fact, no finding by the Court of Justice of abuse by unfair pricing. In essence, the Commission had relied on evidence of comparative prices but the Court of Justice preferred, on the facts of that case, a more detailed, cost-based analysis which it considered would have been feasible in the circumstances, although the Court of Justice clearly anticipated that it would not always be possible to do such an exercise to the requisite standard.

287. Paragraph 248 of *United Brands* effectively restates the relevant terms of Article 102 TFEU. Paragraphs 249 and 250 provide two general principles governing the possible abuse of dominant position by unfair pricing. First, the dominant undertaking must have "reaped trading benefits" that it would not have earned under conditions of "normal and sufficiently effective" competition. Secondly, the price complained of must bear "no reasonable relation" to the "economic value" of the product supplied. The significance of these phrases is considered below, but we note here that the Court does not refer to conditions of perfect competition as the comparative situation, but instead to normal and sufficiently effective competition.

288. The Court of Justice then sets out at paragraphs 251 and 252 a two-limb test which has been considered, to a limited extent, in subsequent cases. This is that:

(1) the price must be "excessive" (in *United Brands*, it was said that this could be calculated as the difference between the cost of production of the product and the selling price ("Excessive Limb"); and

(2) the price must be "unfair" either in itself ("Alternative 1**"**) or when compared to competing products ("Alternative 2**"**) ("Unfair Limb**"**);

subject always to the reference to "other ways" in paragraph 253 and taking account of the need for an over-arching assessment under paragraphs 248 to 250.

289. That is the approach that has been cited in the subsequent jurisprudence, although it is, in our view, a deceptively simple approach and is not easily applicable to all cases in which it might be required. Further, as we discuss below, it has not actually always

been applied in practice, particularly in the performing rights cases, where the ascertainment of costs of production is impracticable and not helpful.

290. The Court clearly leaves open the possibility that an abuse of a dominant position through unfair pricing (which could have a wider meaning than simply "excessive" pricing) could be established by means other than the two-limb approach specified. This is evident from the general wording of paragraphs 248, 249 and 250 of the judgment as well as the specific reference to "other ways" in paragraph 253.

291. However, the Decision in the present case was not based on any such wider legal interpretation. Rather, it proceeded from the basis of the interpretation of *United Brands* (as set out in paragraphs 251 and 252) that is generally understood in the jurisprudence and by commentators, applying that test in a very formal and structured way. Although it was suggested by Mr Hoskins in the course of opening submissions that the Price Comparison over Time could be used as a free-standing test of abuse outside of the two-limb approach in *United Brands*, he subsequently emphasised that the CMA's primary case was that the conduct of both Pfizer and Flynn was an abuse under the two-limb *United Brands* test (with the Price Comparison over Time forming part of that test) and agreed that the Decision was not based on such a free-standing test.

292. The most comprehensive consideration in recent years, in a judicial context, of the issue of abuse by unfair pricing was contained in the Opinion of Advocate General Wahl (to which we also refer as "AG Wahl's Opinion") in C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība* EU:C:2017:286 ("*Latvian Copyright*"). This was a request from the Latvian Supreme Court for a preliminary ruling in a performing rights case, and frequent reference to the Opinion and the subsequent judgment of the Court of Justice was made by counsel for all parties in these appeals. It should be noted, however, that the Decision preceded both AG Wahl's Opinion and the judgment of the Court of Justice.[55]

293. AG Wahl's Opinion contained an authoritative review of the relevant jurisprudence and related legal and economic commentary and sought to provide a single framework

[55] As noted above, the Decision was issued on 7 December 2016. AG Wahl's Opinion was delivered on 6 April 2017 and the judgment of the Court of Justice followed on 14 September 2017.

within which the issues could be considered. The Advocate General took an expansive and holistic approach in his assessment of the questions referred.

294. AG Wahl's Opinion supports *inter alia* the following propositions:

(1) The competition authority has a wide margin of appreciation when considering excessive pricing (para 35).

(2) When exercising that margin of appreciation, the burden of proof is on the authority and the presumption of innocence must be respected (para 52).

(3) The excess has to be measured with respect to a benchmark price[56] (para 17).

(4) That benchmark price should reflect the prices that would have been set in conditions of effective competition (para 17).

(5) There is no single right way to calculate the benchmark price (paras 33 and 36). In particular, the approach referred to in *United Brands* (of using the cost of production) is not the only method of calculating the benchmark price (even assuming that cost includes a 'plus' element for a reasonable margin) (para 18).

(6) Other methods include assessing: the prices charged in other product or geographic markets by the dominant undertaking; the prices charged by other undertakings in the same or related markets; and the evolution of pricing over time (para 19).

(7) To avoid false positives and negatives, a competition authority needs to consider which approach, or combination of approaches, is most appropriate for the market it is considering and the facts that pertain (paras 42-43).

(8) Whatever that approach or combination of approaches is, it has to be objective, appropriate and verifiable (para 61). It must also be done on a consistent basis (paras 23 and 84).

[56] References to benchmark price should be taken to include a range of prices where this is appropriate (see paragraph 294(9)).

(9) It will often be appropriate to consider a number of methods in a 'triangulation' approach to seek to form a reasonable view on a benchmark price (paras 43-45) (which, by implication, although not specifically stated in the Opinion, may well result in a benchmark range rather than a benchmark price).

(10) Since competition will normally correct excessive pricing, a competition authority should move with caution and one would normally expect the circumstances for an abuse of a dominant position only to occur in markets where regulation, or some similar feature, or other barriers to entry protected the market from competition or where there was regulatory failure and the relevant regulator had not intervened (paras 48-49).

(11) Regardless of the specific situation in a given case, the method(s) applied and the other indicator(s) examined must give the authority a sufficiently complete and reliable set of elements which point in one and the same direction: the existence of a significant and persistent difference between the (hypothetical) benchmark price and the (actual) price charged by the dominant undertaking in question (para 54).

(12) The Unfair Limb is a separate test (and Article 102 is not breached merely because a price is assessed as excessive, i.e. that the Excessive Limb is satisfied) and requires an objective assessment of the dominant undertaking's behaviour and motives (paras 20-21, and 116-118).

(13) Alternative 1 is to apply where the price is so excessive that the 'abuse reveals itself'. The examples given are where nothing of value is being sold or where there is no intention to sell (paras 121-123).[57]

(14) Alternative 2 acts as a "sanity check", in essence, of the assessment made in the context of the Excessive Limb, in particular where there are elements that could not easily be factored into the Excessive Limb or where there were good reasons why the economic value would be higher than the benchmark price (paras 124-128). Advocate General Wahl thereby implicitly accepts that economic value

[57] For example as in C-26/75 *General Motors Continental* v *Commission* EU:C:1975:150 ("*General Motors*"), which is generally accepted as the first case in which the Court of Justice set out what kind of price may constitute an excessive price, albeit one where a finding of excess was rejected on the facts (see para 12).

is different from the benchmark price and that the Unfair Limb exercise is a different exercise from that of the Excessive Limb.

(15) It is open to the dominant undertaking to put forward an objective justification for the price (paras 23 and 133).

(16) A price can be qualified as an abuse under Article 102 TFEU only if it is significantly and persistently above the benchmark price (para 106); and no rational economic explanation, other than the mere capacity and willingness to use market power even when abusive, can be found for the high price applied by a dominant undertaking (para 131).

295. As would be expected, the Court of Justice gave its judgment in *Latvian Copyright* on narrower grounds (restricted to the questions posed by the referring court). Those questions focussed on the test for deciding whether the copyright management organisation in question was charging unfair prices by comparison with those applicable in other EU Member States. Although the overall judgment relates to the specific circumstances of performing rights cases, certain paragraphs are significant for present purposes.

296. The Court of Justice referred to its previous jurisprudence in this area as follows:

> "35 The abuse of a dominant position within the meaning of [Article 102 TFEU] might lie in the imposition of a price which is excessive in relation to the economic value of the service provided (see, to that effect, judgment of 11 December 2008, *Kanal 5 and TV 4*, C-52/07, EU:C:2008:703, paragraph 28 and the case-law cited).
>
> 36 In that regard, the questions to be determined are whether the difference between the cost actually incurred and the price actually charged is excessive, and, if the answer to that question is in the affirmative, whether a price has been imposed which is either unfair in itself or unfair when compared with competing products (*United Brands*, paragraph 252).
>
> 37 Nonetheless, as observed in essence by the Advocate General in point 36 of his Opinion, and as the Court has also recognised (see, to that effect, *United Brands*, paragraph 253), there are other methods by which it can be determined whether a price may be excessive."

297. The purpose of those observations was to establish (in the context of a performing rights case) that a comparison of prices between EU Member States is a valid method:

> "38 …according to the case-law of the Court, a method based on a comparison of prices applied in the Member State concerned with those applied in other Member States

> must be considered valid. It is apparent from that case-law that, when an undertaking holding a dominant position imposes scales of 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 (judgments of 13 July 1989, *Tournier*, 395/87, EU:C:1989:319, paragraph 38, and of 13 July 1989, *Lucazeau and Others*, 110/88, 241/88 and 242/88, EU:C:1989:326, paragraph 25). […]"

298. This view is confirmed by the Court's own citation of the *Kanal 5*[58] case (which was also a performing rights case), in which the Court was concerned to see whether the remuneration model applied by the copyright association in question was "reasonable in relation to the economic value of the service provided".[59] It was not suggested by any party in the present case that the jurisprudence of the Court of Justice in relation to these copyright cases required a test for excessive and/or unfair pricing that was based on costs of production (although the CMA submitted that this, alone, was sufficient). Moreover, it is clear, to us at least, that the comparison with prices in other EU Member States is one of the "other ways" referred to in paragraph 253 of *United Brands* itself.

299. The Court in *Latvian Copyright* went on to consider how comparisons between prices in different EU Member States should be made. Here, expressly agreeing with the Advocate General's view, the Court concluded that any comparator must be selected in accordance with "objective, appropriate and verifiable criteria" (para 41) and that comparisons must be made on a "consistent" basis (para 44).

300. We note also that the Court emphasised that the authority has a measure of discretion in defining the appropriate framework for assessment, also in line with the Advocate General's view in this regard:

> "49 It falls to the competition authority concerned to make the comparison and to define its framework, although it should be borne in mind that that authority has a certain margin of manoeuvre and that there is no single adequate method. […]"

301. Finally, the Court considered whether there was any minimum threshold of appreciability above which a difference between the disputed prices and, in that case, the prices in other EU Member States should be seen as indicative of an abuse. It concluded that there is in fact no minimum threshold (paragraph 55). The Court agreed

[58] C-52/07 *Kanal 5 and TV 4* EU:C:2008:703 ('*Kanal 5*').
[59] *Kanal 5*, at paragraphs 28-29.

with the Advocate General that the price differential must be "significant and persistent" (paragraphs 56 and 61), whilst also highlighting that it is open to the undertaking involved to justify the differential by relying on objective dissimilarities between the situations in the EU Member States in question (paragraph 57).

302. In the UK, cases involving the abuse of unfair pricing have rarely come before the national courts. Three cases are, however, worthy of mention at this stage. In *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1 ("*Napp*"), which was cited with approval in AG Wahl's Opinion, the competition authority (then the OFT) made findings of abuse by unfair pricing, in the form of predatory pricing and excessive pricing, in relation to the supply by Napp of a pharmaceutical product, oral sustained release morphine, to the hospital and community sectors respectively. The OFT considered that an abuse would be made out if a price was:

> "...above that which would exist in a competitive market and where it is clear that high profits will not stimulate successful new entry within a reasonable period. Therefore, to show that prices are excessive, it must be demonstrated that (i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be".[60]

303. The OFT's finding of excessive pricing was made by reference to a range of factors in addition to costs of production, including the profitability of other Napp products, the profitability of competitors, and the evolution of prices over time and price stability. That approach was endorsed on appeal by the Tribunal which held that:

> "Those methods seem to us to be among the approaches that may reasonably be used to establish excessive prices, although there are, no doubt, other methods."[61]

304. The second, *Albion Water II*[62] was a case concerning a refusal by the incumbent infrastructure owner, Dŵr Cymru, to allow a third party, Albion Water, to have access to part of its water system in order to compete with it for a contract for water supply to a steel mill. The Tribunal ultimately decided that the access price proposed by Dŵr Cymru was unfair in itself and therefore an abuse of Dŵr Cymru's dominant position, on the basis of a very specific cost-plus methodology and in very specific

[60] *Napp*, at para 390.
[61] *Napp*, at para 392.
[62] This was one of a series of judgments in the course of what became a complex appeal, and which also had exclusionary aspects. The Tribunal's conclusions on unfair pricing are summarised at paragraph 8 of the judgment.

circumstances. The judgment of the Tribunal in that case was relied on, before us, by the CMA to a significant extent in defence of the methodology followed by it in the Decision. However, there are a number of features of that case that mean that it is not as applicable to this case as the CMA contended. In particular, *Albion Water II* related to establishing a fair price for access to infrastructure, an exercise which had not previously been done, and there were simply no other prices available which could be used to seek to establish a benchmark. Moreover, the case was in the context of utility provision in a regulated sector with established cost and pricing methodologies. Calculating the variable cost of providing the access, allocating an appropriate share of common costs and adding on an element for the risk adjusted cost of capital was the accepted method for calculating acceptable price levels in the industry, as well as being the only method actually available in that case.

305. The question of abuse by unfair pricing has also been considered by the Court of Appeal in the context of private litigation. In *Attheraces Limited ("ATR") v British Horseracing Board Limited ("BHB")*[2007] EWCA Civ 38 ("*Attheraces*") BHB was in sole possession of pre-race data about British horse races. ATR, a broadcaster, wished to make these data available to overseas betting agencies, and complained that BHB had charged it unfair prices. The High Court held that BHB's prices were unfair, based on a cost-plus approach. This finding was overturned by the Court of Appeal on the basis *inter alia* that it was not possible to conclude that a price is abusive simply on the basis of a cost-plus approach. In relation to paragraphs 250 to 252 of *United Brands* the Court of Appeal observed that "[a]lthough it would be wrong to read this passage too literally, it must, in our judgement, be read and applied with care".

(b) The parties' submissions

306. In these appeals, there was substantial common ground as to the correct legal test for identifying an abusively high price. We note at the outset that it was not seriously suggested by any of the parties that *Latvian Copyright* represented a change in the European case law on unfair pricing. Pfizer and Flynn both submitted that AG Wahl's Opinion and the judgment of the Court relied on, and built upon, *United Brands*. The CMA also said the case law remained the same as a result of *Latvian Copyright*.

307. Mr Hoskins did, however, submit that the Court had not followed the Advocate General in all material respects. In particular, he argued that the Advocate General's interpretation of the two-limb *United Brands* test was somewhat different from how it had been put in *United Brands,* insofar as he put all of what might be referred to as the "other ways" methodologies into the Excessive Limb, and characterised the Unfair Limb as an objective justification test. By contrast, Mr Brealey submitted that the judgment of the Court was consistent with the Advocate General's Opinion. Ms Bacon's position was more nuanced. She accepted that, as is typical, the Court had not explicitly followed all of the detail of the Advocate General's analysis, and further accepted that the Advocate General had a slightly different way of looking at the two limbs of the *United Brands* test than was commonly understood. However, in her submission it was not necessary for the Tribunal to determine whether the Advocate General or the Court in *Latvian Copyright* had re-oriented the *United Brands* test, as it was clear that a set of common underlying principles underlay both the two-limb *United Brands* test and the Advocate General's version of that test. In any event, much of the Advocate General's analysis drew on established propositions. Whilst it obviously did not carry the same weight as a judgment of the Court, both the Advocate General and the Court in *Latvian Copyright* had given useful guidance as to how a court or competition authority should approach an unfair pricing analysis. We agree with Ms Bacon. We have found AG Wahl's Opinion to be very persuasive and helpful in the present case and regard his overall analysis as eminently sensible.

308. As to the legal test, the following points were not in dispute:

(1) For a price to be abusively high, it must exceed what the dominant undertaking would have obtained under "normal and sufficiently effective competition" to such a degree that it bears "no reasonable relation to the economic value of the product supplied" (*United Brands* paras 249 and 250).

(2) The difference between the disputed price and the normal competitive price must be "significant and persistent" (*Latvian Copyright* paras 55-56 and 61).

(3) One test for identifying an abusively high price as described at (1) above is the two-limb test set out in *United Brands*, and which is the test applied in the Decision. However, there may be other tests (*United Brands* paras 251-253).

(4) Comparators may be relevant to both limbs of the *United Brands* test[63]. Any such comparators must be selected in accordance with objective, appropriate and verifiable criteria, and comparisons must be made on a consistent basis (*Latvian Copyright* paras 41 and 44).

309. The principal legal issues in dispute between the parties, at least at the outset of the hearing, related to the extent to which it is *necessary* to have regard to benchmarks and/or comparators under the *United Brands* test, and in particular: (i) whether there is a need for a "normal competition" benchmark under the Excessive Limb or otherwise; and (ii) whether Alternatives 1 and 2 under the Unfair Limb are genuine alternatives, such that, as the CMA found, it is possible for an abuse to exist solely because an excessive price is unfair in itself. As these issues are more easily understood by reference to the specific context in which they arose in this case, it is more convenient to deal with the relevant issues when addressing each topic below.

(4) Excessive Limb: discussion

(a) Summary

310. For the reasons given below, we find that the CMA was (a) wrong in law to restrict its Excessive Limb assessment to a Cost Plus approach, and to exclude other methodologies, rather than seeking to establish a benchmark price (or range) that would have pertained in circumstances of normal and sufficiently effective competition using the evidence more widely available; (b) wrong in law to adopt a Cost Plus methodology that produced a result that would have pertained in circumstances of perfect or, more accurately (for the purpose of the present case), idealised competition, rather than the 'real world'; and (c) made an error of assessment by relying only on the Cost Plus approach that it selected. In saying that, we are not concluding that the benchmark price, on the right methodology, would not have given rise to a finding of excessiveness; rather we do not consider that the approach actually adopted is a sufficient basis for that finding.

[63] See paragraph 365 below.

(b) The CMA's overall Cost Plus approach

311. As noted above, the CMA arrived at its Cost Plus figures by adding what it described as a reasonable rate of return for each of Pfizer and Flynn to the costs they incurred in respect of each of their products.

312. Pfizer and Flynn each submitted that the reference to "normal and sufficiently effective competition" in paragraph 249 of *United Brands* required the authority to determine not what a theoretically reasonable maximum price for the product would be, but rather what the actual price would have been under normal competition conditions in the real world. Thus, the CMA's repeated references to the "reasonable rate of return" for phenytoin (i.e. the "Plus" in its Cost Plus figure) were incorrect if adopting the reasonable rate led to anything other than the normal competitive price. By contrast, the CMA submitted that the Excessive Limb only required the authority to establish a material difference between price and cost: contrary to the submissions of the Appellants, there was no legal requirement to compare a hypothetical benchmark price that would have been charged had there been normal and sufficiently effective competition with the price actually charged.

313. As we have set out above, the Court in *United Brands*, itself, expressly refers to a comparison of production costs and prices as an example of a method of calculating an excess, not as the only or the required method. Moreover, that approach is within the overall context of establishing whether the dominant undertaking had reaped trading benefits that it would not have earned under conditions of normal and sufficiently effective competition. We therefore agree with the Appellants on this point. There must be a benchmark for the normal competitive price to estimate the excess under the Excessive Limb. We note that this is also the approach taken in AG Wahl's Opinion.

314. Further, in our judgment, *United Brands* does not establish that Cost Plus is, in isolation, a sufficient method for establishing the excess if other methods are available and, particularly, if they suggest different results. Moreover, it is clear that an authority cannot simply choose that method of calculating the excess that was most favourable to establishing an infringement, to the exclusion of other methods. *United Brands* provides no support for such a proposition and nor would it accord with AG Wahl's

Opinion. Such an approach would run the risk of being unfair to the party alleged to have infringed and of being insufficiently robust.

315. To the extent that the CMA relies on *Albion Water II* in this context, we have described above why we think *Albion Water II* should be distinguished. In our view, that case does not establish, if it is so contended, that the adoption of the cost-plus methodology set out in *United Brands* at paragraphs 251 and 252 is either required in all cases, or necessarily sufficient in any one case. Rather it is the case that, consistent with *United Brands*, a cost-plus approach was the best suited to the particular situation at issue in *Albion Water II*. By contrast, the Tribunal in *Napp* endorsed an approach which considered whether the price was above that which would exist in a competitive market using a variety of approaches to establish that price (although neither the OFT nor the Tribunal proceeded on the basis of a formal and structured Excessive and Unfair Limb analysis in that case).

316. Thus, in our view, a "cost-plus" calculation will often form part of the methodology for calculating the excess. In some cases, it might be the only available, or overwhelmingly the best, method. But it is not sufficient to select it as the sole method when there are other valid methods available to assist the authority in establishing (on the most credible and defensible basis that can be derived from the evidence), the hypothetical counter-factual of the price that would have been established in conditions of normal and sufficiently effective competition.

317. We note Ms Bacon's submission that it is not the case that the authority has to go out there and seek out every single benchmark that might possibly exist and, moreover, that there is not likely to be any single benchmark for price or profitability, but rather that the authority should look at the available and informative benchmarks of either price or profitability and see if a comparison of those against the disputed price or disputed profit margin points clearly in the direction of there being excessive pricing. Different measures of profitability may well form part of that process of establishing the price (or range) that would apply in the counter-factual position of normal and sufficiently effective competition. But, in our view it is enough for the authority to establish a benchmark price (or range).

318. In this case, the CMA's almost total reliance on a reasonable rate of return approach is unconvincing. Quite apart from the criticism that may be made of how it arrived at a 6% ROS as a reasonable rate, which we discuss below, it is clear that the CMA's approach owes more to a theoretical concept of idealised or near perfect competition, than to the real world (where normal, effective competition is the most that should be expected). It has on the whole avoided making comparisons with other products or companies and made little significant attempt, other than by invoking the Price Comparison over Time, to place Pfizer's and Flynn's prices in their commercial context during the Relevant Period.

319. This theoretical aspect emerged from Mr Harman's evidence. Mr Harman was instructed by the CMA to assess whether it was appropriate to use the ROS measure to determine a reasonable rate of return, and whether the 6% ROS adopted by the CMA was reasonable. He concluded that both were reasonable. Pfizer's criticism of this evidence was that Mr Harman had reviewed the CMA's analysis from a "reasonableness" threshold and was not asked to consider what a proper approach from first principles would be when seeking to determine the extent of the excess for the purpose of the Excessive Limb. We should emphasise that this was not a criticism of Mr Harman himself, as he was constrained by the narrow scope of his instructions.

320. Mr Harman accepted in cross-examination that this exercise went no further than identifying the theoretical, from a finance theory perspective, economic profit, namely the return above which a company would enter a market and below which it would consider exit, without recognising any gap between the two. By contrast, Mr Ridyard had put forward empirical evidence which sought to show that the CMA's benchmark did not capture the distinction between normal and excessive returns in competitive pharmaceutical markets.

321. We agree with Pfizer that given the narrow scope of Mr Harman's instructions, and the underlying assumptions made by the CMA in its case, that his evidence is of limited assistance to us. Mr Harman's professional opinion was that, over time, in the circumstances of a competitive market, competition would drive prices down to the level of return that just reflected the risk inherent in the supply of the product, at which point, it would just be profitable for a firm to enter or remain in the market and that this represented the appropriate basis on which the CMA should calculate the profit element

for its Cost Plus analysis. This he described as, in effect, the long-term equilibrium position of a competitive market. Thus, Mr Harman's assessment of a reasonable rate of return of 6% was consistent with his instructions from the CMA to examine a reasonable rate of return within the framework of a Cost Plus approach to the Excessive Limb of *United Brands* but proceeded on the basis of theoretical or idealised competition. We do not think that is what *United Brands* requires which, rather, relates to conditions of normal and sufficiently effective competition. We, therefore, agree with Mr Ridyard that this approach does not enable a determination of the appropriate benchmark price against which to assess whether the actual prices at issue are excessive, as the law stands.

322. We also address here for completeness the ROCE cross-check exercise carried out by Mr Harman which in his opinion confirmed that a 6% ROS for Flynn was reasonable. The CMA had decided that ROS was to be preferred to ROCE as a measure as there were difficulties in valuing Flynn's capital employed. However, it had performed a broad ROCE analysis for Pfizer, to cross-check its ROS findings, and Mr Harman agreed that was a useful test. Accordingly, he carried out a ROCE analysis in relation to Flynn, describing it as "an informative cross-check", giving an indication of the minimum return investors would require on invested capital. Mr De Coninck pointed out that this type of analysis showed that many of Flynn's other products would also be earning excessive returns, and Mr Harman in response limited his opinion to confirming that his analysis showed that 6% ROS covered Flynn's working capital requirements.

323. We do not think this additional work carried out by Mr Harman added greatly to the overall picture. Finding a minimum return on capital for investors was merely another manifestation of using a Cost Plus approach to calculate the excess, and was subject to the same basic error as with finding a reasonable return on sales (of not focussing, as a start point, on the prices that would have pertained in circumstances of normal and sufficiently effective competition). Whilst, therefore, we do not disagree with it as a way of triangulating the Cost Plus approach, it is not of much assistance to us, given (a) our conclusions on the Cost Plus approach itself (that it is not necessarily sufficient) and (b) that any approach should be premised on a comparison with prices likely to have pertained in normal and sufficiently effective competition not idealised competition.

324. In summary, setting a benchmark price (or range), would have enabled the CMA to adopt a less rigid approach to its analysis. This may have meant it would have examined the various candidate comparator products and companies more carefully (using a weighted approach for relevance rather than a binary approach as to whether a comparator was helpful or not); it may also have led to less reliance being placed on the PPRS, with which we deal below. It may also have led the CMA to examine what returns might have been under normal competitive conditions, rather than, as in the case of both the Decision and Mr Harman's instructions, looking for a rate of return reflecting that which would be more appropriate to conditions of idealised competition.

325. We consider that these over-arching errors in the CMA's approach, are, in themselves, sufficient to render the CMA's findings under the Excessive Limb unsound. However, as they are just one element of the CMA's overall findings on abuse, and the Appellants have contested those findings on other specific grounds, we go on to consider these other aspects.

(c) Specific benchmarks

(i) <u>The 6% ROS and the PPRS</u>

326. Both Pfizer and Flynn objected to the CMA's reliance on the PPRS in its assessment of 6% ROS as a reasonable rate of return.

327. Pfizer pointed *inter alia* to the inappropriateness of "cutting and pasting" a single target rate of return from a regulatory scheme applying to, and negotiated in, an entirely different context, and the fact that the PPRS 6% figure related to an entire portfolio of products rather than an individual product. Further, Pfizer considered that the DH had told the CMA during the investigation that the 6% figure was not in practice the binding or operative figure under the PPRS, for reasons relating to the MOT and transfer pricing, and was not an appropriate benchmark.

328. Flynn made largely the same points and raised further detailed objections to the reliance placed by the CMA on the 6% PPRS ROS which can be grouped as follows. First, the PPRS regulated the profits of branded products, not generics; it offered no accepted industry standard for generics, and was not a standard for any individual product; Flynn's expert evidence suggested that the "standard" for generics, if it existed, was

much higher than the 6% rate suggested by the PPRS; and there was no evidence that branded products should benefit from higher rates of return than generics. Secondly, the proportion of pharmaceutical companies providing information to the PPRS was falling (Mr Williams estimated now no more than 50-60%); these were mainly multinationals, who had generally moved manufacturing operations overseas whilst leaving a limited distribution business in the UK and, hence, were not appropriate proxies for Flynn.

329. In addition, Flynn said the PPRS, itself, had developed to take account of businesses whose manufacturing operation had moved out of the UK, which, Mr Williams said, had become the typical case. The Transfer Price Profit Allowance under the PPRS had become, in effect, for UK distribution businesses, an additional profit allowance of 13%, to be added to the 6% assumed rate of return, giving a true allowable rate of return of 19% at least.

330. Flynn pointed further to the MOT of 3% allowed under the PPRS, in addition to the 6%. Mr Williams said, in practice, the MOT was routine. It was an automatic right by which companies in the PPRS were allowed to add a further 3% return on sales, allowing them to retain profits "up to 150% of target" under the 2014 PPRS.

331. Flynn was similarly dismissive of the CMA's other reasons for using the PPRS 6% rate. It maintained that not only was 6% not the rate permitted under the PPRS, it was not the rate of return that PPRS members actually made in practice.

332. The CMA submitted that the PPRS was one (and only one) of a number of different factors identified in the Decision as being relevant to a reasonable rate of return for each of Pfizer and Flynn. As such, it relied on the PPRS as a point of comparison for its chosen rate of return, not simply to set it. However, we see no obvious other source for the specific figure of 6% ROS apart from the PPRS and we consider that, in practice, the CMA did place a degree of reliance on it. Although the reference to the PPRS is placed in the text of the decision to indicate this order of priorities, the PPRS ROS appears to be the only actual source for the 6% figure, and appeared as such in the Statement of Objections ("SO").[64] Mr Harman also assumed the PPRS was the "starting

[64] A statement of objections gives parties notice of a proposed decision by the CMA that they have infringed competition law. It sets out the CMA's provisional decision, and the parties then have an opportunity to make

point" for the CMA's assessment. However, we also recognise that the CMA conducted a variety of other analyses to show why, in the CMA's view, 6% was generous to both Pfizer and Flynn.

333. Nevertheless, the substantive question is whether the PPRS does, in fact, provide a suitable benchmark for the CMA to use within the scope of its Cost Plus analysis. There are reasons for placing more limited weight on it.

334. First, the PPRS appears to have decreasing relevance as the pharmaceutical industry changes its UK orientation. Moreover, to the extent reliance can be placed on the file note of the CMA's conversation with the DH on this topic, there seems to be at least some level of official doubt, as the Appellants contend, about the continuing relevance of the 6% figure from a DH perspective. We note that Mr Williams' evidence raises the same reservations about the usefulness of the PPRS as a benchmark as those that, according to the CMA's file note, were raised by the DH.

335. Finally, we note that the PPRS applies to a portfolio of products rather than to any one product (although we are 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). All of these factors point to the need for caution in placing too simple a reliance on a PPRS 6% figure.

336. As to the MOT, it might have been helpful also to have had direct evidence from the DH in this regard. The CMA contended that the MOT was not automatically given in all cases. In the Decision,[65] the CMA referred to ABPI Guidance to the effect that the MOT was only available in certain circumstances and, together with other limits on the MOT, this meant that the MOT was therefore not "routinely available". In any event, the MOT did not undermine the reliance on 6% as a target rate. Whilst the evidence from Mr Williams was that in practice an additional 3% ROS was normally allowed, we do accept that the CMA was not looking for a maximum figure, but rather a reasonable one. We therefore agree with the CMA's approach on this point and do not

representations on the matters set out in it. The CMA then considers those representations before any final decision is made. Paragraph 5.109 of the SO in this case stated that "The CMA considers that the rate of return that should be considered reasonable for phenytoin sodium capsules is the Allowable Return as set out in the 2009 and 2014 PPRS; that is, 6%."

[65] Decision para 5.199 footnote 990.

think that the CMA, in relying on the 6% PPRS ROS figure, was obliged to increase this to 9%.

337. As to the argument relating to the Transfer Price Profit Allowance, we see this might be the case for a vertically integrated undertaking, with its manufacturing subsidiary offshore and distribution arm in the UK. On that basis, it appears that the undertaking as a whole might benefit from a 19% ROS in total, if that approach were adopted.

338. However, in this case we are dealing with separate, arm's length companies. The most that could be suggested is that the manufacturer should in some way be "allowed" a 13% ROS with the distributor retaining the 6% allowance already allocated to it. It is hard to see how this argument can lead to the distributor being allocated the full 19%. We uphold the CMA on this point and find that it was right not to adjust the PPRS allowance in this way.

339. Nevertheless, we do not think the CMA was right to place such reliance on the PPRS 6% rate of return, whether or not adjusted for the MOT or the Transfer Price Profit Allowance, as in itself confirming, far less determining, what was a reasonable rate of return for Flynn and Pfizer in this case. 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.

(ii) Flynn's other suggested benchmarks

340. Flynn put forward the following possible benchmarks for deducing a reasonable rate of return: its own products (internal ROS, gross margins and product contributions) and the ROS of other generic companies with various characteristics and profiles. Flynn relied on the expert evidence of Mr De Coninck in relation to Flynn's own products, and on that of Mr Davies and Mr Williams in relation to comparisons with various groups of other pharmaceutical businesses having generally similar characteristics to Flynn. Flynn denied that its activities and risk in relation to Pfizer-Flynn Capsules were unusually low and Mr Davies supported this view.

341. To each of these suggested benchmarks, the CMA, and its expert Mr Harman, responded that they were not suitable, either because they were not comparable as

companies, or that not enough was known about their cost structures or other aspects, or that the comparison offered was for a range of products rather than a single product, or that the products identified might not have similar characteristics to phenytoin.

342. For phenytoin, Mr Harman identified a combination of low risk, high volume and high input cost factors. In effect, this made phenytoin very unusual such that finding suitable comparator products for assessing a suitable rate of return was very difficult. Mr Harman appeared to hold the view that, as regards the performance of competitor companies rather than products, only a company with a spread of products with very similar characteristics in terms of the profile of its portfolio of products to Flynn's could offer a suitable benchmark and even then it would be difficult to be sure.

343. We observe that Flynn was concerned to place phenytoin's profitability in a commercial context and to assess what rate of return was "reasonable" or "appropriate" by reference to other products on the market. We agree that the commercial context is important (see paragraph 318 above) but it does not avoid the need for a more detailed analysis. It was not in dispute that any such comparators must be identified on objective, appropriate and verifiable criteria. Mr Harman 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 Mr Harman to that of Mr De Coninck.

344. We are particularly alert to the point that the analysis that the CMA undertook on Flynn's commercial position was extremely dependent on the very high input price from Pfizer which, on the CMA's case, was also an abusive price and which might be thought not necessarily to be a reliable part of the analysis. Mr De Coninck pointed to other products with high unit costs, but, as Mr Harman explained, these had lower volumes than phenytoin, which made them less suitable as comparators.

345. However, suitable and meaningful comparators do not have exactly to mimic the features of phenytoin, and if there were *prima facie* evidence of a meaningful

comparator which helped establish a benchmark price for Pfizer-Flynn Capsules in conditions of normal and sufficiently effective competition, it should have been examined carefully. On the various suggested combinations of other companies put forward by Flynn, whether or not their activities included manufacture, or their portfolios included or they were subject to a sufficient degree of competition, it is not apparent from the Decision (paras 5.164 and 5.193-4) that the CMA examined these fully and may have been too ready to dismiss them entirely (i.e. in a binary fashion) because of other factors such as Flynn's low level of risk and high supply price. Nevertheless, with the exception of the tablets issue discussed below and subject to our findings on the CMA's overall approach, we do not find that any of the comparators suggested to us, in themselves, presented such a clear evidential picture (given the difficulties, on the material before us, of understanding how relevant any given comparator was) that they undermined the conclusions reached by the CMA in deciding on a reasonable rate of return. We do not, however, regard the CMA's overall approach as valid (see paragraph 310 above).

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 Mr Davies' evidence in support of this view. 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.

(d) Flynn's cost allocation

347. Flynn stated in its written closing submissions that the cost allocation issues raised by its fourth and sixth grounds of appeal may be of less significance if the Tribunal accepted its arguments on benchmarks. Although we have not accepted all of Flynn's arguments on benchmarks, in light of our findings above on the CMA's overall Cost Plus approach and its reliance on the PPRS, we deal with the cost allocation issues relatively briefly, notwithstanding that there was considerable evidence and argument on the point.

348. The CMA allocated Flynn's common costs by volume rather than revenue, using costs per pack, cross-checking these allocations by defined daily dose[66] and costs per capsule.

349. Flynn argued that it did not allocate common costs to individual products and that, if it had to do so, it would have done so on a revenue not a volume basis. It took issue with the CMA's allocations and relied on expert evidence from Mr Williams and, to a lesser extent, Mr Davies, in support. Both suggested a revenue-based approach was preferable, and Mr Williams provided various models to correct for the risk of circularity (a high value product attracting more than its fair share of common costs). Mr Harman said that Mr Williams' corrective work was still insufficient, and made other criticisms of a revenue-based approach.

350. Prior to the hearing, Mr Williams and Mr Harman produced a joint statement of matters on which they agreed. They showed a good level of agreement, but still disagreed on the basic choice between volume and revenue-based allocations, and whether the corrections and cross-checks proposed by Mr Williams were sufficient to remove the circularity consequences.

351. We note Mr Davies' evidence that it is not common practice in the pharmaceutical industry, or at least in this part of it, to allocate common costs to individual products. However, it was necessary to do so for the purpose of the CMA's analysis to ascertain the profitability of individual products. The merits of different methods can be debated. It is clear, and indeed was common ground, that there is no single over-riding preferred

[66] The defined daily dose is the assumed average maintenance dose per day for a drug used for its main indication in adults. See Annex A ('Key Defined Terms'), Part B of the Decision.

method and that different methods may be used for different purposes. In the present case, Mr Harman cross-checked the CMA's overall findings by using a number of different allocation methods, more favourable to Flynn than the volume method used, which in his view confirmed that the CMA's choice of allocation methodology was reasonable. Moreover, that exercise showed that Flynn's prices materially exceeded Cost Plus regardless of the choice of allocation method. Given that Flynn does not itself allocate costs to individual products and that there is no clearly preferable method of allocation, the CMA's approach is in our view reasonable and we uphold it.

352. Flynn raised the further point that, if the CMA was correct to rely on the PPRS 6% ROS as a reasonable indication to apply to Flynn's Cost Plus calculation, then it should also use the PPRS cost allocation methodology, which was on a revenue rather than a volume basis. Given our finding (see paragraph 339 above) that the PPRS 6% ROS figure is at best one relevant factor amongst others to be examined in the course of seeking to set a benchmark price, we do not consider that the CMA was bound to follow the PPRS cost allocation methodology and we dismiss Flynn's objection.

(e) Other indicators of excessiveness

353. The CMA submitted that Pfizer's and Flynn's prices were excessive in any event, and in particular that, even if the Tribunal were to give no weight to the PPRS target rate of a 6% ROS, the other evidence would still be more than sufficient to make good the CMA's findings that Pfizer's and Flynn's prices were excessive for the purpose of the Excessive Limb. That other evidence, for Pfizer and Flynn, was that the prices were excessive on a Price Comparison over Time and, for Pfizer, by comparison with the prices of Pfizer-manufactured phenytoin sodium capsules in other EU Member States.

354. As regards reliance on the Price Comparison over Time, we explain in Section H(8) below why we do not consider this to be a sufficiently sound basis for arriving at a conclusion, either as to the amount of any excess or in the overall assessment of unfairness.[67]

355. On the price comparison with other EU Member States, this was a point on which the Tribunal raised questions with the parties in the course of the hearing. We note that

[67] We also refer to this issue at paragraph 400 below.

according to the Decision (para 5.449), the CMA had regard to Pfizer's pricing conduct in other EU Member States in its assessment of "unfairness in itself" under the Unfair Limb. Pfizer's prices were materially lower in other EU Member States in which it sold capsules, and profitable in all but one of these. In its written closing submissions, the CMA made the same point in support of its Excessive Limb case, although it accepted that some caution must be exercised in comparing prices across jurisdictions, and quite fairly did not submit that this factor was determinative. We consider this issue at paragraph 401 below.

(f) Conclusion

356. We have already set out at paragraph 310 above our over-arching reasons for finding that the Cost Plus approach adopted by the CMA was an insufficient basis, for making the findings that it did under the Excessive Limb. As such, the findings that Pfizer's and Flynn's prices were excessive for the purpose of the Excessive Limb cannot stand.

357. In Pfizer's case, we consider the CMA's theoretical approach may understate what the appropriate benchmark price for Pfizer would notionally have been under conditions of normal and sufficiently effective competition, but without further investigation we are not in a position to say whether this is the case.

358. As to Flynn, whilst we uphold certain aspects of the CMA's approach to calculating Flynn's excess, overall the rate of return said by the CMA to be reasonable is open to question, even for the purposes of the CMA's Cost Plus analysis (which we do not consider was the right approach). The CMA should have placed less weight on the PPRS in identifying an appropriate ROS for this purpose and should have examined more closely the various comparators put forward by Flynn, amongst other factors, appropriately weighted, to establish the right benchmark price, as discussed above.

359. We note Flynn's contention that, on reasonable comparisons, its prices for phenytoin and, indeed, its profits on its sales (although that is not the relevant point) were not excessive. In the absence of a proper assessment of Flynn's actual prices in comparison with a proper benchmark price, which avoided any distortions arising from Flynn's very high input price, however, we do not think it is possible to say this.

360. As with its consideration of Pfizer, the CMA's approach to aspects of its Cost Plus analysis for Flynn is affected by its failure to set a benchmark price or range in circumstances of normal and sufficiently effective competition. If it had approached the analysis in this way, it would have examined the conditions of a competitive market more closely. That may in turn have affected the way it examined possible comparator products and companies and its view of the PPRS, and to have taken a less rigid view of what was an appropriate rate of return. It would also have put more focus on Flynn's high input price.

(5) Unfair Limb: discussion

361. The next part of the analysis relates to the CMA's findings under the Unfair Limb of the *United Brands* test. We note that, in the Decision, the CMA considered economic value at this point but we prefer to deal with it afterwards, and do so in Section H(6) below.

362. For the reasons given below, we find that the CMA has not correctly assessed whether the prices it found to be excessive under the Excessive Limb were also unfair within the meaning of Article 102 TFEU. It wrongly relied only on Alternative 1 (unfair in itself) in assessing unfairness under the Unfair Limb and therefore did not properly assess the possible impact of meaningful comparators (in particular, phenytoin tablets) for the purpose of assessing whether the prices charged were unfair.

(a) Are Alternatives 1 and 2 genuine alternatives?

363. A key issue in this case is whether Alternatives 1 and 2 of the Unfair Limb are genuine alternatives, that is whether an authority has an unfettered choice as to which one to adopt.

364. Pfizer and Flynn submitted that the CMA could not rely on Alternative 1 (unfair in itself) alone when there were meaningful comparators under Alternative 2 (unfair compared to competing products) and that the CMA was legally obliged to have regard to comparators.

365. The CMA originally submitted that it had a complete discretion at the Unfair Limb to choose between the two Alternatives. This is the clear position taken in the Decision.

There was no legal obligation to have regard to valid comparators at any stage of the *United Brands* test. In particular, there was no legal obligation to have regard to comparators in order to find that a price was unfair, and it was therefore possible for an abuse to exist solely because an excessive price was unfair in itself. However, the CMA somewhat modified its position during the hearing to accept that if there is a good comparator, account must be taken of it but said that it was immaterial whether it was considered at the Excessive Limb or the Unfair Limb (although the CMA did not explain how this approach was consistent with its claim to have adopted, in the Decision, the two-limb *United Brands* test based on a Cost Plus only assessment for the Excessive Limb). Mr Hoskins said that the CMA would always examine good comparators at some stage of the analysis and would not ignore a relevant consideration.

366. The nature of the relationship between the two Alternatives has not been specifically considered in any great detail in the jurisprudence. It is clear from the judgment of the General Court in *Scippacercola*[68] and the Commission Decision in *Scandlines*[69] that the two are alternatives, in the sense that an authority can, as a matter of law, establish a breach of Article 102 under either Alternative 1 or 2 and does not need to succeed under both. However, that is not the same as saying that the authority has an unfettered choice between the two. Nor does it mean that a breach of Article 102 can be established by selecting only one Alternative instead of the other so that an approach can be taken that gives rise to a finding under one Alternative that the pricing is unfair, when a *prima facie* argument has been raised that under the other Alternative, the pricing is fair. In particular, *Scippacercola* does not require such an interpretation. That case examined whether the Commission was obliged to apply both Alternatives cumulatively, a different question from whether an authority is entitled entirely to ignore *prima facie* evidence pointing to fairness.

367. In our view, it cannot be right that an authority can simply ignore a *prima facie* valid argument that a price is fair under one Alternative and proceed to find an infringement of Article 102 solely on the basis of the other Alternative establishing that prices are

[68] T-306/05 *Scippacercola and Terezakis v Commission* EU:T:2008:9 ("*Scippacercola*"), subsequently upheld by the Court of Justice in C-159/08 P.
[69] Commission decision *Scandlines v Port of Helsingborg* COMP/36.568 ("*Scandlines*").

unfair. That is not to say that the authority cannot find that there is an infringement where one Alternative demonstrates unfairness and the other does not since it does not need to succeed on both heads. However, the authority must consider whether a *prima facie* case of fairness under one Alternative undermines the basis for the finding of unfairness under the other Alternative and produce a reasoned basis for determining that the Unfair Limb is satisfied.

368. This is necessary not only as a matter of logic but also in order to accord with the burden of proof and respect the presumption of innocence. It also accords with the approach in AG Wahl's Opinion that Alternative 2 of Limb 2 functions as a "sanity check".[70] This is particularly the case in the context of highly imprecise tests such as 'unfairness' which need to be applied within the wider, over-arching, principles of both Article 102 and *United Brands* as summarised above (including the presumption of innocence).

(b) Alternative 1: Unfair in itself

369. We have described at paragraph 272 above the factors on which the CMA relied in coming to its conclusion that Pfizer's and Flynn's prices were unfair in themselves. These included an overall assessment that the prices bore no reasonable relation to the economic value of the product and a series of other factors. As regards the overall assessment, we consider this at paragraphs 424 to 428 below. As regards the other factors, we agree with the CMA that 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 it to weigh when considering the application of the 'unfair in itself' test, although we note that in this case the CMA also relied on several of these factors in its Excessive Limb analysis. The CMA would need to apply its discretion in the context of the presumption of innocence, but there is no intrinsic reason why it could not find the test of 'unfair in itself' met in the light of a consideration of such issues. The concern that we have with the Unfair Limb analysis is not so much the factors that were considered under Alternative 1 but, rather, the decision to select only Alternative 1 on the basis that it was an unfettered discretion for the legal reasons set out above.

[70] AG Wahl's Opinion, at para 124.

(c) Alternative 2: Unfair compared to competing products

370. The question then arises as to whether, as the Appellants contend, there were meaningful comparators giving rise to a *prima facie* case of fairness to which the CMA should have had regard under Alternative 2 of the Unfair Limb.

371. As noted at paragraph 273 above, the CMA did, "for completeness" consider whether such a comparison could be conducted. However, having considered parallel imports, NRIM Capsules and tablets, it concluded that there were no products that would provide a meaningful comparison for the purpose of Alternative 2 of the Unfair Limb.

372. By contrast, Pfizer and Flynn each contended that tablets were a meaningful comparator to which the CMA should have had due regard. In addition, Pfizer contended that other AEDs were meaningful comparators, raising this argument for the first time at the appeal stage.[71]

373. It was common ground that the words "competing products" in Limb 2 of the *United Brands* test did not mean products in the same relevant market for the purpose of competition law.[72] The key question in this context was whether the result of the comparison would be meaningful.[73]

(i) Tablets

374. Pfizer contended, in summary, that the Tribunal should be slow to find that Pfizer's price was abusively high when it was only around half of the Drug Tariff Price of tablets.[74] This was because: (i) tablets and capsules were clinically identical; (ii) they were both sold on the domestic UK market, purchased by the same ultimate buyer, the DH; (iii) the DH had specifically intervened to fix the price of tablets in 2007 and it had remained at that level for five years (including in 2012 when Pfizer set its price). It was not, therefore, a regulated price but a directly fixed bespoke price that reflected the value of the drug to the DH; and (iv) although tablets were identical to capsules, they

[71] The relevance of other AEDs had been raised in passing by Flynn at its oral hearing with the CMA. Other AEDs were not relied on by Pfizer at the administrative stage.
[72] See, e.g., the approach taken in *Scandlines*, at para 171.
[73] *Ibid.*, at para 169.
[74] As noted at paragraph 17 above, the tablet is only available in the 100mg strength. There are 28 tablets in a pack.

were not in direct competition with each other. In support of this, Pfizer relied on the evidence of Mr Ridyard who stated that:

> "So that is why in principle the tablet price is such a beautiful comparator because it is not – it does not interact competitively with the capsules as far as I can judge but it is in other ways the same product".

375. In its opening written submissions Pfizer included a table of comparative phenytoin sodium prices which showed that the September 2012 ASPs for the 100mg strength of Pfizer-Flynn Capsules were the equivalent of a 1 day treatment cost of £[…][✂] in Pfizer's case (up from £0.08) and of £[…][✂] in Flynn's case, compared with the equivalent Drug Tariff Price of tablets of £3.21. At that date, on a comparable 84 (capsule) pack basis, Pfizer's ASP to Flynn was over £[…][✂] below the Drug Tariff Price of tablets, and Flynn's ASP some £[…][✂] below it.

376. Similarly, Flynn contended, in summary, that it was entitled to take the tablet Drug Tariff Price as a benchmark because tablets comprised exactly the same drug as the capsule in tablet formulation; and were subject to a substantial price reduction during 2007-2008. Flynn submitted that the tablet price was a relevant comparator under both limbs of the *United Brands* test.

377. The CMA's reasons for rejecting tablets as a meaningful comparator were set out in the Decision at paragraphs 5.496-5.526. These reasons included that the tablet price (i.e. the Drug Tariff price) was not "cost-justified" and that the tablets market was unlikely to operate in a way that would give a reasonable relation between the price of tablets and their economic value. This was said to be because the tablet price may have been inflated by the exercise of market power. Individual tablet manufacturers were likely to possess significant market power because Continuity of Supply also applied to tablets, so that price competition between tablet suppliers was likely to be limited. Further, the tablet price had increased very significantly between 2005 to 2007, had remained significantly above the historic price even after the voluntary price reduction made by Teva in 2008, and was at a level with which the DH was "not happy". The CMA also said that tablets were only available in the 100mg strength and did not therefore provide the basis for a meaningful comparison with the other capsule strengths. Tablets also fell within Category M, rather than Category C, for pricing purposes, which made them less suitable for comparison because of the different way

in which the Category M Drug Tariff Price was calculated. The CMA considered that a better comparison would be the price of Pfizer-manufactured phenytoin sodium capsules sold by Pfizer in other EU Member States.

378. In its written closing submissions, the CMA re-iterated the points made in the Decision but placed even greater emphasis on the increase in the tablet price between 2005 to 2007 and the fact that Teva's subsequent price reduction was not expressly approved by the DH, citing Mr Beighton's evidence in this regard. Neither Pfizer nor Flynn had had any contact with Teva or the DH prior to the launch of the Pfizer-Flynn Capsule to ascertain the reasons behind the Teva price reduction. In addition, the evidence showed that Pfizer and Flynn were aware that the DH was not happy with the price of Pfizer-Flynn Capsules but had not engaged constructively with the DH about this. Further, the CMA said that tablets were in a different product market and that there was, at best, only inconclusive information as to the costs of producing and distributing tablets. Finally, the CMA developed its point about tablets and capsules being in different pricing categories by saying that if any comparison were to be made on a consistent basis, it should be between the ASPs of Teva Tablets and Pfizer-Flynn Capsules rather than their respective Drug Tariff Prices.

379. It is apparent from the above that the CMA clearly gave some consideration to the suitability of tablets as a comparator. However, it is not clear to us that it did so in sufficient depth. We emphasise that the purpose of a comparison at this stage of the analysis is to see whether what has been found to be a price influenced by market conditions where competition is restricted is unfair in the context of comparators. If the prices, and market conditions, are similar, it might suggest either that all of the prices are unfair, or that none are. Given the inherent difficulty in making assessments in this area of competition law it is all the more important to conduct a full and proper examination.

380. As to the various points made by the CMA, the fact that Pfizer and Flynn did not contact Teva or the DH about Teva's price reduction is, in our view, irrelevant as we would not seriously expect one competitor to discuss with another how its price came to be set. Secondly, we accept that, in 2007 at least, Teva was the only manufacturer/supplier of phenytoin tablets in the UK, and that Teva had managed to increase the price significantly prior to the DH's intervention. However, it appears that several other tablet

suppliers are now present, suggesting that competitive conditions may have changed, possibly very materially.[75] Thirdly, whilst the price increase brought about by Teva between 2005 to 2007 is a relevant factor, it does not in itself make the tablet wholly unsuitable as a comparator so that it is excluded from the analysis. However, the price behaviour of tablets over time seems to us to be more relevant than the 2007 price for comparison purposes. Fourthly, the fact that the tablet is not in the same product market as the capsule is in our view clearly not a determining factor, as we stated in paragraph 373. Fifthly, there is the issue of the lack of information on costs. The CMA is right that cost information may be needed to establish whether the tablet price was constructed on a similar basis to the capsule price. However, the CMA did not accept that it should obtain such information, pointing to the burden this involved; yet it is far better placed to do so than is the undertaking accused of abusing a dominant position, for which the task is virtually impossible and indeed inappropriate. Far from being a reason not to examine the tablet, this appears to be a further reason for doing so.

381. Turning to the extent to which it can be said that the tablet price was approved of or set by the DH, we have considered elsewhere the various issues associated with the tablet price, such as the DH's intervention, Mr Beighton's evidence of the meeting that took place in 2007 and Flynn being informed in November 2012 that the DH was not "happy" with the tablet price as then current. We also note that Mr Ridyard accepted that "the tablet price has its problems as [a] comparator if you do not believe that the Department of Health effectively regulated the price of the tablet". We do not think it is necessary, as Mr Ridyard contends, to find that the DH "effectively regulated" the tablet price. Indeed, Pfizer in its written closing submissions preferred to describe the tablet price as a "bespoke price" rather than a regulated one.

382. We have described the meeting between the DH and Teva at paragraphs 209 to 213 above, and the subsequent reduction in the Teva Tablet Price and consequently the Drug Tariff Price of tablets. We do not doubt that the DH would have preferred an even

[75] We note in this regard the letter from the solicitors for Pfizer of 22 November 2017, in response to a question from the Tribunal, which summarised the information on the CMA's case file relating to tablet manufacturers. That letter indicated that: by July 2009 there were two manufacturers of tablets on the UK market (Teva and Hillcross); by May 2011 there were at least three such manufacturers (Teva, Hillcross and Actavis); Teva's June 2013 Section 26 Response to the OFT specified that there were four manufacturers of tablets (Teva, Actavis, Wockhardt (although Actavis supplied Wockhardt's product) and Milpharm; and pharmacy Section 26 Responses from March 2016 referred to a number of additional manufacturers or wholesalers, namely Aurobindo, Kent and Sigma.

lower price, and note that (after the lapse of some years) it complained to the OFT to that effect. However, we think that is all part of the relevant background that the CMA should have examined and does not rule out the tablet as a meaningful comparator.

383. On the different pricing regimes, the Drug Tariff Price of Category M products includes an element intended to compensate pharmacies for their other activities. There is also a clawback element. We do not, however, think this necessarily makes any price comparison uninformative, as the CMA contends. Instead it is just one more factor to be examined and due allowance can be made for the fact that the Drug Tariff Price of Category M products may be higher than it would be without any extra element.

384. That takes us to the question whether a comparison between Teva Tablet and Pfizer-Flynn Capsule ASPs would be more informative than a comparison between their respective Drug Tariff Prices. This point was not advanced by the CMA in its pleadings or opening submissions and arose only towards the end of the hearing.

385. The dispute up to the closing stages of the hearing had been in relation to the Drug Tariff Price of tablets, which was, from 1 October 2008 to 1 April 2016 (see Decision para 3.492/Table 3.13), £30 per 28 capsule pack of 100mg tablets. However, in its written closing submissions the CMA raised the further argument that if any comparison were to be made on a consistent basis, it would require a comparison between the ASPs of Teva Tablets with the ASPs of Pfizer-Flynn Capsules. By 2013 Teva's ASPs of tablets had fallen to £[…][✂] per 28 tablet pack, which was below the Drug Tariff Price and the launch price of the Pfizer-Flynn Capsules. Over the whole Relevant Period, Flynn had charged significantly more than Teva charged for tablets, whilst 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.

386. There was some limited evidence relating to this issue in the Decision but it was not developed. This was a potentially very important point indeed, for both the Excessive Limb (on its proper application) and the Unfair Limb. If, on a proper assessment, the Teva Tablet ASPs were considerably below the Pfizer-Flynn Capsule ASPs, there would be a materially different situation which would be relevant to much of the argument. It is unfortunate that this issue was not explored more fully in the Decision or raised earlier either in the pleadings or at the start of the hearing.

387. Pfizer and Flynn said that if this point had any validity, which they disputed, it was raised far too late in the proceedings to be given full and adequate consideration. Pfizer also pointed out that its supply price to Flynn remained below the tablet ASP at the relevant time (although this is comparing prices at different points in the distribution chain).

388. It was put to us that this represented a change in the CMA's case but we are satisfied that, although this argument was raised very late in the proceedings it is, in fact, based on material contained in the Decision. What was not clear until late in the day was what argument the CMA sought to construct based on this material.

389. It is not possible, within the scope of the present proceedings, for us to give full and adequate consideration to the competitive situation in relation to tablets during the Relevant Period. We have been given at best some isolated pieces of information, and certainly not enough to form a conclusion.

390. However, if 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 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. Assessing whether or not that remains the case, however, is clearly a matter for the CMA.

391. The Decision states (para 3.448) that the CMA had considered making a formal investigation into tablets following the DH's complaint in 2012, but decided against it on grounds of administrative priorities. This is entirely understandable. Nevertheless, in this case, the CMA should, in our view, have done a sufficient investigation into the competitive conditions surrounding the most obvious comparator product properly to inform its decision on Pfizer-Flynn Capsules. It is not an answer to state there was no obligation to conduct a full investigation. That is so in relation to the CMA's discretion in relation to the price of tablets; but it is not right in terms of obtaining sufficient evidence properly to apply Article 102 to the price of Pfizer-Flynn Capsules. As

Mr Hoskins conceded in a different context (see paragraph 365 above), no authority should leave a relevant factor unclear.

392. All this suggests to us that the phenytoin tablet as a meaningful comparator should not have been wholly rejected on the grounds relied on by the CMA. There was enough material to make it pause to consider, at the very least, whether there was a *prima facie* case of fairness under Alternative 2. We accept that there is an element of circularity in this. The authority must investigate possible comparator candidates to see if they are likely to be meaningful on objective, verifiable and appropriate criteria. On the other hand the authority has a margin of discretion as to the possible comparators that it needs to examine. How is it to know whether the comparators are likely to be meaningful unless it examines them? That difficulty does not avoid the need, in our view, for the authority, at least, to examine any *prima facie* good comparator, as the CMA accepted.

393. We also note Pfizer's point that the CMA's expert evidence, given through Mr Harman, barely touched on the issue of tablets, even though tablets appear to be almost the only product that could conform to his strict requirements for what is a suitable comparator (see paragraph 342 above). Again, we would have expected a greater degree of examination.

(ii) Other AEDs

394. Pfizer submitted that other AEDs offered a relevant comparison. Mr Brealey began the hearing with a discussion of other AEDs, referring to Professor Walker's evidence as to how different AEDs worked and what their characteristics were. Pfizer said the CMA did not seem to have considered how phenytoin fitted into the spectrum of products used to treat epilepsy and had looked at it in isolation. Pfizer said that a comparison between the cost of treatment using phenytoin and other AEDs on a monthly basis showed that its prices were not unfair.

395. Pfizer also relied on Mr Ridyard's expert evidence in which he compared the price of phenytoin with some 20 other AEDs (focussing in his second report on five 'off-patent' AEDs) which, he suggested, offered a good comparison with phenytoin. His evidence was essentially that all of these products treated epilepsy, albeit in slightly different ways, and that phenytoin's price was by no means the highest. These AEDs represented a useful range of products with differing therapeutic indices, some in Category M,

covering first, second and third line treatments with differing volumes which were still sufficient to be informative, particularly if the 2012 levels were used.

396. At the hearing, attention focussed on four of these products, the prices of which had been examined by Mr Ridyard who had regarded them as offering a meaningful comparison: they were both higher and lower than Pfizer's and Flynn's prices. Mr Ridyard said their usefulness as comparators was improved by their being subject to different competitive conditions or being outside the relevant market. It was for the CMA to show that phenytoin capsule prices were out of line with the prices of these products, but it had not done so. Higher prices for other AEDs in other markets that appeared to be competitive would suggest that phenytoin capsule prices could not be unfairly high.

397. The CMA submitted that other AEDs were not meaningful comparators, primarily because their volumes made them sufficiently different from phenytoin capsules to be good comparators, and there was no reliable information as to their costs, capital or risk, as supported by Mr Harman's evidence.

398. The argument for a meaningful comparison with other AEDs is considerably less compelling than that for tablets, mainly because they differ widely as products even though they address the same medical condition, and there is no comparative economic data, particularly as to the cost structure of those AEDs. In our view their relevance as meaningful comparators is limited to showing what the buyer is prepared to pay for a treatment that addresses epilepsy for a given patient.

(iii) Other possible comparators

399. Finally, we briefly consider two other comparisons drawn by the CMA, first, the Price Comparison over Time, and, second, in respect of Pfizer-manufactured phenytoin sodium capsules in other EU Member States, to the extent that these were also relied upon by the CMA in the context of unfairness. We mentioned these matters earlier in relation to the CMA's Excessive Limb analysis at paragraphs 353 to 355.

400. On the Price Comparison over Time, the CMA relies on this at several points of its analysis. We consider it separately in Section H(8) below. We do not consider it to be

a sufficiently sound basis for arriving at a conclusion either as to the amount of any excess or in the overall assessment of unfairness.

401. On the price comparison in other EU Member States, Flynn said in closing submissions that it was for the CMA to show why prices in other EU Member States were an informative comparator, and it had not done so. Flynn further submitted that the *Latvian Copyright* case made clear that, where a comparison is drawn between prices in different EU Member States, the authority must select the reference states in accordance with objective, appropriate and verifiable criteria which the CMA had also not done. Accordingly, the Tribunal did not have before it the evidence to determine whether capsules prices in the five EU Member States referred to in the Decision could be taken into account as comparators. Similarly, Pfizer gave detailed submissions as to why a comparison with other EU Member States was invalid in this case, including, for example, that the CMA had not taken account of detailed regulatory interventions in other EU Member States that distorted the relevant prices; that Pfizer's sales in those Member States were tiny and loss-making or only marginally profitable; and that the *Latvian Copyright* case would require parity of purchasing power to be taken into account.

402. We note that in the Decision the CMA recognised that each country has a specific regulatory regime but it went on to consider that the differences between the prices charged in the UK and those charged in other EU Member States were so significant that it was unlikely that there would be any "objective dissimilarities"[76] that could justify such differences. We think the CMA's own cautionary advice (see paragraph 355 above) should apply, namely that prices across different EU Member States should not be compared without taking account of other relevant factors such as that those prices may be kept low by governmental measures, or different economic or regulatory conditions.[77] Although we find 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, we accept Pfizer's and Flynn's submissions that the CMA has not demonstrated in the Decision that the prices of Pfizer-Flynn Capsules were either excessive or unfair by reference to prices in other EU Member States.

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[76] In this context, the CMA cited the Court of Justice in *Tournier*. See also paragraph 301 above.
[77] See in the context of the tablet comparison, Decision para 5.526.

(d) Flynn's contextual factors

403. Flynn raised as its ninth ground of appeal objections to the CMA's reliance on various "contextual" considerations. These were: (i) the Price Comparison over Time; (ii) the adverse effect of Flynn's price increases on the NHS; (iii) the alleged transfer by Pfizer to Flynn of reputational risk associated with the price increase; and (iv) the limited activities and low commercial risk assumed by Flynn.

404. We deal with the Price Comparison over Time at Section H(8) below. As regards the other factors, we considered Flynn's activities and commercial risk at paragraph 346 above in relation to excessive pricing. In our consideration of unfair pricing under Alternative 1 of the Unfair Limb (see paragraph 369 above), we said that harm to the NHS could be a relevant factor in that assessment. We do not consider the CMA has shown why the possible transfer of reputational risk should be included as an element in the assessment of unfairness.

(6) Economic value: discussion

405. We consider economic value at this point, because we believe it is the right and logical place to do so. As can be seen from paragraphs 269 to 271 above, in the Decision the CMA considered economic value before unfairness and concluded that there were no non-cost related factors which would increase the economic value of the capsule product beyond Pfizer's and Flynn's Cost Plus. At the hearing, both Mr Brealey and Mr Hoskins were reluctant to specify precisely where economic value should be dealt with in the analysis, as long as account was taken of it somewhere. Nevertheless, we think it has, consistent with the structure in *United Brands*, a clear place in the scheme of analysis and is best understood if discussed after the assessment of unfairness in the Unfair Limb. As we have set out above, one of the over-arching questions for a finding of abuse is whether the price complained of "bears no reasonable relation to the economic value of the product supplied".

406. Although the question of economic value features to an extent in one of Flynn's grounds of appeal, much of the argument on this point at the hearing came from Pfizer, with Mr Brealey placing great emphasis on this aspect of Pfizer's appeal in both his opening

and his closing oral submissions. The essence of Pfizer's key argument[78] in this regard was summarised in Pfizer's opening written submissions as follows:

> "[T]he CMA wrongly applies a purely supply-side approach based on [Cost Plus] and ignores anything to do with the demand-side, thereby erring in respect of the determination of the proper economic value of Pfizer's product. In particular, the CMA ignored the economic value of phenytoin sodium reflected in its unique, or at least important, therapeutic benefits to patients. This pure cost-based approach is simply wrong in law. […]"

407. It is clear that the term "economic value" is a legal rather than an economic concept. However, there is rather little specific guidance in the jurisprudence as to what this term means, beyond a general idea that it is what the product is worth. It can include the cost of production but also other elements of value to the purchaser. In this sense, the economic value of a product is highly fact-specific and very much a matter of judgment. This, at least, is confirmed by the jurisprudence. For example, the Tribunal stated in *Albion Water II* (at para 216):

> "…whether a given price bears 'no reasonable relation' to its 'economic value' is a matter of degree, which involves a considerable margin of appreciation, not least because the concept of 'economic value' and whether the price has a 'reasonable' relation to that value, are matters of judgment."

408. The Commission's decision in *Scandlines* where Scandlines argued that the port authority's charges were excessive and bore no relation to its costs, is often quoted in this context:

> "Moreover, the 'cost-plus' approach suggested by Scandlines only takes into account the conditions of supply of the product/service. The determination of the economic value of the product/service should also take account of other non-cost related factors, especially as regards the demand-side aspects of the product/service concerned."[79]

409. The Commission found economic value in that case to include the particular location of the port in question.

410. The issue has also been considered by the Court of Appeal. In *Attheraces*, the Court discussed (at paras 203-208) how the "critical judgment of…economic value" was to be made. In that case, the issue was deciding the value of (and hence what was a fair price for) the pre-race data owned by BHB, which cost very little to produce, but was

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[78] Pfizer also raised, as part of its fourth ground of appeal, an argument that the margin earned by Flynn on the resale of Pfizer's Products must be assessed in the economic value of Pfizer's Products. This is considered in Section I below at paragraph 458.

[79] *Scandlines*, at para 226.

clearly valuable to particular buyers. The Court rejected the idea that value was simply what the market would bear, as, on that approach, no price could ever be excessive, but observed (at para 206) that:

> "(I)t does not follow that whatever price a seller in a dominant position exacts or seeks to exact is an abuse of his dominant position."

411. In our view, although specific guidance on ascertaining economic value is limited, it is essentially a matter of judgment with appropriate weight being given to factors on both the supply and demand side. That demand-side factors can be taken into account as a matter of law was not in dispute between the parties. The question is whether the CMA was correct, on the facts of this case, to exclude from its calculation of Pfizer's and Flynn's economic value all factors other than those that formed part of the Cost Plus calculation.

412. The CMA was criticised by the parties for not considering patient benefit although it did indeed describe, in broad outline in the Decision, the nature of epilepsy and phenytoin's role in its treatment. The CMA has not, however, contested the evidence of Professor Walker and has, in effect, conceded that phenytoin remains a useful and effective treatment for a significant number of patients. That being so, we find the outright rejection of any value at all to patients surprising. The CMA seems to have placed some reliance on the age of the drug, which is irrelevant in therapeutic terms. We think there is clearly some economic value to be derived from the therapeutic benefit to patients of phenytoin capsules.

413. There is then the difficult question of whether this value is negated by the patient's dependency. In this context, the CMA relied, in particular, on the Opinion of Advocate General Jacobs in *Tournier*[80]. That Opinion arose in the context of requests for preliminary rulings in a series of cases concerning the conduct of the French copyright management society SACEM towards discothèque owners in relation to charges for music in France. The Court of Justice was requested to consider questions relating to whether the royalty rates charged were discriminatory and excessive, particularly by reference to the royalties charged in other EU Member States.

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[80] Joined cases C-395/87 *Ministère public v Jean-Louis Tournier* and C-110/88, 241/88 and 242/88 *Lucazeau v SACEM and Others* EU:C:1989:215 ("*Tournier*").

414. The Advocate General considered an argument of SACEM that instead of looking at comparisons with other EU Member States, attention should focus on *inter alia* the importance of music to the discothèques. Here he said the idea that those who need music more should pay more for it was superficially attractive, but considered that such an approach broke down when a given category of users were "completely dependent" on the supply of the music in question and there was no other possible source of supply:

> "65. The criterion of the importance of music to the business in question is superficially attractive, since it appears only logical that those who need music more should be prepared to pay more for it. However, it appears to me that the usefulness of the criterion breaks down in a situation where a given category of users is completely dependent for its functioning on the supply of music and where because of the absence of competition that category must, in effect, pay whatever price is required of it. This is the situation of the French discothèques."

415. The CMA relied on this point to argue that because patients stabilised on capsules were, for these purposes, dependent, zero value should be ascribed to patient benefit when determining the economic value of capsules. This point was illustrated during the hearing in the course of an exchange with the Tribunal as follows:

Q (Mr Lomas)	"Is the effect of your submission, Mr Hoskins, that if you start with the position whereby there's a certain value to the buyer, and therefore your economic value progressively goes up…the greater that value to the buyer becomes, and then at a certain point, based on this citation, there is a need for the buyer, whether it is music for a discothèque or a drug for someone who is stabilised on it, and at that point the economic value plunges back to zero, it is, if you like, a catastrophic event, you get to a point where your need becomes so great that the addition to your economic value to reflect that demand criteria just evaporates.
A (Mr Hoskins)	Because the language used by Advocate General Jacobs is it is completely dependent. I accept that you're right, insofar as a product or service is needed by a buyer, because it has an economic value to the person, to the buyer, then that can justify the higher price. And that's a way you can see through competition well what it's actually doing is distributing the benefits at the end of the chain because clearly the person at the start of the chain should have a say in that. But when there is complete dependency, any notion of competition breaks down, and that's what Advocate General Jacobs…that's the basis of this. You cannot then look to the value of the buyer because they're not exercising an economic choice. If that's the case for French discothèques, you can choose whether to set up business as a discothèque or not, but when you're a patient with epilepsy, our case is even stronger than this, because what is your choice other than taking the product you are stabilised on? It is the risks we've seen in the evidence.

Q (The Chairman) You discount the therapeutic value entirely because the patient has no choice?

A (Mr Hoskins) You don't ascribe any economic value to it.

Q (The Chairman) You don't ascribe economic value to the therapeutic effect because the patient has no choice.

A (Mr Hoskins) Yes."

416. We do not disagree with the Advocate General's assessment in *Tournier* generally, but the facts here are a little different. Whilst it is clear that the concept of a competitive market is difficult to apply where there is only one supplier and the buyer is medically dependent, to a degree, on the supply, it does not follow that the value to be attributed to the demand side is zero and we do not think this is what the Advocate General was suggesting. Moreover, on the facts in this case, it was common ground that for patients already stabilised on a particular formulation of phenytoin it may be clinically undesirable to switch to a different formulation. But we have seen that the reality may be less absolute. It seems that the CMA may be confusing the conclusion of its analysis of markets and dominance with a medical assessment that any given patient is completely dependent on the particular formulation. Professor Walker's evidence shows that to be not necessarily correct in all or even a majority of cases. As he said in his second expert report, to the extent that the CMA has described patients as "completely dependent" on phenytoin sodium by reason of Continuity of Supply, the CMA has used Continuity of Supply out of context.

417. We therefore do not think this is a binary issue but more one of degree. We of course accept the Court of Appeal's view in *Attheraces* that charging what the market will bear does not automatically point to abuse of a dominant position. There is clearly some economic value to be derived from the significant contribution of phenytoin to treating epilepsy in a significant number of patients. Some allowance must be made for the extent to which the choice of switching from phenytoin may be restricted, which decreases the value as measured in terms of patient benefit.

418. At the hearing, Mr Hoskins further submitted that if there were economic value to be derived from patient benefit, this should go mainly to Pfizer rather than Flynn. He suggested that in view of Pfizer's large price excess, this would be insufficient to render

Pfizer's prices fair and that the small amount attributable to Flynn would be similarly insufficient. He suggested further that the Tribunal could allocate these amounts itself, and would not need to remit the decision to the CMA. Pfizer and Flynn disagreed with this proposal. Whilst it may appear superficially attractive for the Tribunal to proceed in this way, we do not find it appropriate to do so in this case. We are in no position to make assessments or allocations of value of this nature on the evidence before us.

419. In light of the above, our finding is that the Decision was defective in its treatment of the economic value that may be derived from patient benefit. Placing a precise monetary value on patient benefit is not straightforward but it appears to us that a qualitative assessment would be possible and should have been attempted by the CMA rather than simply assessing this value as nil.

420. Separately, Pfizer and Flynn contended that the Drug Tariff Price of tablets was relevant for assessing the economic value of the product. We have discussed comparator products in Section H(5)(c) above in our consideration of unfairness and do not repeat that discussion here. However, whilst we think that the issue of comparators is similar in relation to the two instances (the Unfair Limb and economic value), there is a slightly different emphasis.

421. In considering economic value, the relevance of comparators is in helping to assess what the product "is worth" by reference to the supposed value of other similar or comparable products. In considering whether a price found to be excessive is also unfair when compared with competing products, the question is whether the prices of those other products are "fair" and if so on what basis. The questions to be asked are broadly similar but we note this different perspective of the two analyses.

422. Without repeating the discussion under unfairness, we note that in that context we found the CMA's consideration of tablets as a meaningful comparator to have been insufficient and that finding applies here also.

423. Finally, Flynn also contended that any assessment of the economic value to the NHS of the continued supply of capsules had to take account of the avoided costs of patients switching to tablets (i.e. the costs that the NHS would incur if Pfizer discontinued the capsules). This point was also taken by Pfizer at the investigative stage and rejected by the CMA for the reasons set out at 5.313 to 5.319 of the Decision. We do not accept

this argument. Quite apart from whether there was a real risk of discontinuation by Pfizer (and the most Mr Poulton 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), this argument has the appearance at least of taking advantage of market power to extract more value in terms of prices. As to the possibility of Flynn discontinuing the capsules, we have already discussed this in Section G(6)(a) above.

(7) Overall assessment of unfairness

424. Having considered economic value, we now examine whether the CMA made an appropriate overall assessment of unfairness.

425. If economic value is a matter of judgment, particularly so is whether there is a reasonable relation between the price charged and the economic value of the product or service in question. Here, there is little or no guidance as to what a reasonable relation should be, and we consider that this question has to be assessed by a competition authority taking into account the nature of the product or service, together with all the surrounding circumstances. Simple percentages expressed as absolute mark-ups are not sufficient.

426. The CMA found Pfizer's and Flynn's prices to be unfair by reference to the fact that they bore no reasonable relation to the economic value of the product and allowed the dominant undertakings to reap trading benefits that they would not have reaped if there had been normal and effective competition.

427. We agree that these are the assessments that need to be made, but, from their location in the framework of the Decision, the CMA appears to have made them mainly as part of its consideration of unfairness "in itself" under the Unfair Limb, rather than as an over-arching assessment, as we think it should have done. Where the CMA does attempt a more general assessment, this is expressed more in terms of the Price Comparison over Time, as an assessment of the price increase involved, rather than as a comparison of the current price with economic value. As a consequence, any overall assessment is heavily dependent either on this comparison or on the CMA's calculation

of economic value, which, as we have seen, it rated as no more than the value of Cost Plus. For this reason it is likely to be defective.

428. It is not, in our view, open to the CMA to re-present its findings under the Excessive Limb to justify a finding of unfairness. The disparity between the Cost Plus figure found under the Excessive Limb and the respective prices charged by Pfizer and Flynn was a significant feature of the CMA's excess finding. Treating this Cost Plus figure as the same as the product's economic value and using the same data to conclude that the price bore no reasonable relation to the economic value of the product does express those findings in terms consistent with the *United Brands* approach; but it renders largely otiose the clearly separate Unfair Limb under that approach.

(8) Price Comparison over Time

429. The CMA said at the hearing[81] that we could consider the Price Comparison over Time either as part of its application of the two-limb *United Brands* test, or as a separate basis for finding the prices were unfair, as one of the "other ways" referred to in paragraph 253 of *United Brands* (although that was not the basis on which the Decision proceeded).

430. The comparison being drawn is between the ASPs for Epanutin sold by Pfizer on the UK market prior to September 2012, and the ASPs for Pfizer-Flynn Capsules, at launch and in the period between May 2014 to June 2016.[82] The price increase initially was (at its maximum) 27-fold. Even allowing for the price reduction made by Flynn in April 2014, the price increase was very large, and still standing at a 22-fold increase following the price reduction.

431. In this context, the CMA relied *inter alia* on the *Sirena* judgment of the Court of Justice, which pre-dated *United Brands*. However, as set out at paragraphs 283 to 284 above, we have found that case to be of little assistance.

432. We accept that in theory, the Price Comparison over Time could provide a basic underpinning for a finding of abuse that puts into context the more technical arguments over which test should be used to decide whether a price is abusive. It is for this reason,

[81] The CMA also provided a note of its position on this point in the course of the hearing.
[82] See, for example, Tables 1.1 and 1.2 at paras 1.17-1.18 of the Decision.

we presume, that the CMA placed emphasis on it, and why Mr Hoskins invited us to rely on it, if necessary, as a new ground for our own decision, outside the framework of the CMA's findings in the Decision itself. Pfizer and Flynn disputed that it was open to the CMA to rely on the Price Comparison over Time as a free-standing test of abuse at the appeal stage.

433. Pfizer further submitted that the legal basis for regarding this as a separate test was weak.[83] The Epanutin price had been eroded by the operation of the PPRS to a loss-making level. The Price Comparison over Time added nothing to the CMA's existing analysis as the CMA's benchmark figure of Cost Plus was essentially an adjusted version of Pfizer's "before" price that took Pfizer's relevant costs and added a reasonable rate of return. Finally, placing weight on the price increase in this way also reversed the burden of proof, requiring the accused party to justify its price increase, rather than requiring the authority to prove an infringement.

434. Flynn made similar submissions, arguing *inter alia* that to be a realistic point of comparison, the "before" price had to be a normal competitive price, whereas the Epanutin price had been suppressed through the operation of the PPRS. While the size of the price increase could be a relevant factor this was as part of any overall assessment of unfairness under *United Brands* and not as a separate criterion.

435. Whether or not the CMA's argument is correct in theory, and whether or not it is open to the CMA to rely on a free-standing test at the appeal stage when it did not do so in the Decision, in the present case we do not think it is right to regard the Price Comparison over Time as a stand-alone ground for finding an infringement of Article 102 on the basis of unfair prices. The CMA has woven this comparison into a number of aspects of its case on appeal, as it did in the Decision. We are able to consider whether it is right to see the "before" Epanutin price as a useful point of comparison and whether the scale of the price increase is any more than a prejudicial factor as and when the point arises in the analysis. The observations that follow are applicable to the Price Comparison over Time wherever the point is relied on by the CMA.

[83] Pfizer cited *General Motors* and C-226/84 *British Leyland v Commission* EU:C:1986:421 which it had identified as the only EU cases which had considered a similar "before and after" point.

436. We referred earlier to the observations of Advocate General Wahl and the Court in *Latvian Copyright* on the question of whether there was a threshold above which a price differential could be seen as appreciable, and therefore likely to be an abuse of dominant position. Both considered that there was no settled amount or size of differential that could be applied as a rule or standard, and both emphasised that any difference would have to be significant and persistent. The Court also explained that there is no minimum threshold for appreciability.

437. The Advocate General also emphasised that deciding what was significant and persistent was not easy; neither existing case law, nor the national authorities' practice nor economic literature gave any precise guidance. He stated, perhaps self-evidently, that the greater the difference between the benchmark price and the price charged and the longer it was sustained, the more likely was it that there was an abuse (AG Wahl's Opinion paragraphs 109-112).

438. In the present case, we have a price increase implemented by Pfizer and Flynn that was very substantial by comparison with the price previously charged by Pfizer. There were factors associated with the "before" price, arising from the operation of the PPRS in relation to Pfizer's brand portfolio, that mean an adjustment would be needed before that price could be considered a suitable point of comparison, and no-one in this case has suggested that the "before" price was a price that represented normal competitive conditions.

439. We agree that a large price rise, sustained over a considerable period, may be indicative of an abuse of a dominant position that needs to be examined, and we understand the weight that the CMA placed on this matter. However, whilst this may be a valid reason for a competition authority to investigate a case, it should not be confused with the test for unfair pricing itself.

(9) Abuse: conclusion

440. For the reasons we have given, we find the CMA's findings on abuse to be defective.

441. In overturning the CMA's findings of abuse of dominance we are not saying that no finding of abuse could be made in this case. The correct application of the *United Brands* test, involving the establishment of a benchmark price, a careful assessment of

whether the prices charged were excessive, followed by an assessment of unfairness that took appropriate account of the various factors we have mentioned, including an overall judgment on price and economic value, could of course lead to such a conclusion particularly given the size of the increase that occurred in this case.

442. We recognise the difficulties inherent in seeking to formulate a generally applicable framework or test for abuse by unfair pricing, and we are conscious that, as *United Brands* itself states, there may be other ways than the two-limb test set out in that case for establishing an abuse. Nonetheless, if an authority chooses to proceed to apply the two-limb test in a structured way, as the CMA has purported to do in this case, a sensible framework would, in our view, and in light of the requirements and factors we have already set out above, be as follows.

443. In our assessment, to apply Article 102 through the two-limb test of United Brands, in circumstances where the only alleged infringement is one of excessive pricing and the dominance of an undertaking in a given market has been established, a competition authority should:

(1) consider a range of possible analyses, reflecting market conditions and the extent and quality of the data that can be obtained, to establish a benchmark price, or range, that reflects the price that would pertain under conditions of normal and sufficiently effective competition. On the facts of a particular situation, there might be only one basis of analysis that was credible, but the authority is not entitled to select one basis of analysis and ignore others that are also credible. The criteria for selection and application must be objective, appropriate and verifiable. The analysis must also be done on a consistent basis;

(2) compare that price (or range) with the price that has been charged in practice and determine whether that is excessive;

(3) for that purpose, form an assessment, for the purpose of the Excessive Limb, of whether that differential is sufficiently significant and persistent to be excessive, as a matter of its own discretion, exercised fairly and reasonably, in the light of such factors as:

(i) the absolute size and stability of that differential;

(ii) the reasons for it, taking account of the fact that the conditions for excessive pricing will only usually occur where the market is one where regulation, or some similar feature, or other barriers to entry, protect it from competition, or where there is regulatory failure and the relevant regulator has not intervened;

(iii) previous decisions finding other differentials excessive, weighted for the markets applicable in those cases;

(iv) the wider market conditions, including the evolution of pricing over time.

(4) where there is a conclusion that the differential is excessive, then proceed to consider whether it is unfair under the Unfair Limb;

(5) be free to use either Alternative 1 (unfair in itself) or Alternative 2 (unfair compared to competing products) to determine unfairness but give due consideration to any *prima facie* convincing argument that the pricing is actually fair under either Alternative and take that into account in reaching a decision under either Alternative 1 or 2;

(6) if there is a finding of unfairness under the Unfair Limb, assess what is the economic value of the product, and whether the price charged in practice bears no reasonable relation to it;

(7) give appropriate consideration to any objective justification advanced by the dominant undertaking;

(8) make a finding of an infringement of Article 102 if all the conditions above are fulfilled; and:

(i) the price bears no reasonable relation to the economic value;

(ii) the dominant undertaking is reaping trading benefits that it would not reap under conditions of normal and sufficiently effective competition.

444. It is for the competition authority to determine, when considering comparators, either for the application of Alternative 2 or for considering whether there are *prima facie*

issues raised under Alternative 2 that need to be considered before proceeding under Alternative 1, or indeed if they are relevant to the Excessive Limb, what weight to be applied to them in the light of market conditions and their suitability, as comparators, for the product concerned. In making that determination, it must, but need only, act in a manner which is objective, appropriate and verifiable. It has a substantial margin of appreciation, but must recognise the presumption of innocence in favour of the undertaking under investigation.

I. PFIZER'S POSITION AS SUPPLIER

445. Pfizer's fourth ground of appeal also challenged the CMA's abuse findings but as it is a separate and specific ground we think it appropriate to consider it in a separate section. It is grounded both on legal arguments and specific factual issues.

446. 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 Decision that Pfizer abused Flynn's market. Pfizer so submitted for a number of reasons including that:

(1) first, its prices were freely agreed with, and acceptable to, Flynn (and did not prevent Flynn making a profit - they reflected the product's economic value to Flynn);

(2) second, if Flynn had chosen to sell at a price close to cost plus 6% there would have been no abuse by Flynn (on the CMA's Cost Plus approach) so there can have been no abuse by Pfizer since nothing would have changed, had that occurred, in relation to Pfizer's behaviour or prices (which cannot, thus, constitute a free-standing abuse);

(3) third, competition law does not interfere in the competitive setting of margins at different levels in the supply chain (relying on the Court of Appeal's judgment in *Attheraces*); and

(4) fourth, Pfizer did not set Flynn's price in its (downstream) market nor did its supply price create a floor price for Flynn (which had plenty of 'headroom' and

could adjust its pricing as it saw fit) not least because it could, and indeed did, reduce its supply price to Flynn.

447. It is not entirely clear whether Pfizer advanced Ground 4 on the basis that it admitted, for that purpose, that it was dominant in the market, as defined by the CMA, or otherwise in the alternative to its other grounds of appeal. However, logically, as may reflect its position in the order of Pfizer's appeal arguments, Pfizer does not need Ground 4 unless it has already been held to be dominant in its market.

448. In Pfizer's view, the pricing of its product in the downstream market was driven by market conditions in that (i.e. Flynn's) market as opposed to Flynn's pricing being driven by Pfizer's pricing strategy and, accordingly, Pfizer could not be engaging in an abuse by unfair pricing.

449. In written and oral submissions, Pfizer spent some time explaining what alternative cases that the CMA had considered and not pursued.[84] We find that to be irrelevant. Rather, the issue is whether Pfizer has a valid appeal against the case that the CMA did, in fact, pursue.

450. The CMA's (limited) reply to this ground of appeal included the following main points. If Pfizer's argument were correct, it would be open to any dominant firm to interpose a distributor, outside its own corporate organisation, and then claim that any alleged abuse was the responsibility of the distributor and, absent any proven conspiracy, could not give rise to any infringement by the dominant supplier. The supply price charged by Pfizer did set a floor for the prices charged by Flynn; accordingly, it was not open to Pfizer to deny that its pricing impacted prices in Flynn's market. The market in this case was not competitive at the retail level, and consumers' interests were not thereby protected. On the contrary, the CMA's findings were that Flynn's prices were excessive and competition was not working effectively.

451. We find Pfizer's reliance on *Attheraces* to be misplaced, on the facts of this case. In *Attheraces*, the downstream market was competitive and the Court of Appeal chose not to interfere with the upstream pricing and the margin allocation thereby set between parties at different levels in the distribution chain in that context. In this case, we have

[84] See paragraph 67 above.

already found that the downstream market is characterised by dominance and therefore not one in which competition was operating effectively. Accordingly, the constraint (and benefits) of competitive price-setting that were observed in *Attheraces* with regard to the downstream market (with the consequence that the relationship between BHB and ATR could be construed as a contest as to how those parties shared the margin available from a competitively set pricing structure) do not apply in this case.

452. We were not attracted by Pfizer's argument that if Flynn had priced at around cost plus 6% there would have been no abuse (on the CMA's theory of harm) and hence Pfizer's pricing to Flynn (which it was assumed would have remained unchanged) could not have been abusive. Although we have already determined that the CMA's Cost Plus approach was incorrect as a matter of law in this case (see paragraphs 310 to 325 above), this submission by Pfizer illustrates the general difficulty with its argument under Ground 4. In such a case, Pfizer would, in effect, be determining the general level of pricing in the downstream market (because Flynn could only add on a small amount for common costs and profit, which would not be materially variable over the medium term) through the medium of its supply price to Flynn. Pfizer did not explain why that would not be an even more problematic position for it were that price to bear no reasonable relation to economic value.

453. 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% (£[…][✂]).[85]

454. Pfizer's submission has the consequence, as the CMA pointed out, 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-

[85] See Decision Tables 1.3 and 1.4 at para 1.34.

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.

455. 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. Indeed, Mr Ridyard, Pfizer's own expert did not support that wider position and merely commented that, in his view, the CMA had not done enough to tie down the causal links between Pfizer's prices and Flynn's.[86] Pfizer was not clear, at the hearing, on why this argument also protected it if the downstream price were held to be abusive (as was the case in the Decision) although, logically, Ground 4 is of little use to Pfizer unless it also applies in that circumstance.

456. This argument by Pfizer, however, also demonstrates that the Pfizer supply price did, in practice, constitute, at least at some level, a price floor for phenytoin sodium capsules in the UK market. We saw no evidence that Flynn would have chosen to price below its acquisition cost from Pfizer (at all, and certainly not for any material period – this was not a 'loss-leader' type product or situation). On the contrary, it was clear from the oral evidence given by Mr Walters that the Pfizer supply price (plus relevant costs) was a floor below which Flynn would not price – albeit that Flynn was, in practice, pricing well above this level and could have reduced its prices and still made a material profit.

457. Finally, and critically, the evidence consistently showed that the strategy, which was jointly evolved between Pfizer and Flynn, to remove phenytoin sodium capsules from the PPRS and to price them at a much higher level (close to the then Drug Tariff Price of tablets), was based on a clear-sighted view, by both, of the increased profit that would flow to each from that arrangement: indeed that was the admitted purpose. Pfizer and Flynn expressly discussed a percentage split of that benefit, ultimately reaching a

[86] For example, in his second expert report Mr Ridyard stated that "It is not clear that Pfizer's supply price was the driver of the downstream price…".

commercial solution based on a supply price which provided each with a satisfactory share of the increased profit. They did so, irrespective of the fact that Flynn was left free as a matter of contract law to determine precisely what price (above the Pfizer supply price and appropriate other costs) it actually set. Pricing was an integral part of the strategy radically to improve the profitability of the capsules.

458. We therefore reject this ground of appeal. We should add by way of completeness that it follows from this that we do not accept Pfizer's argument, made in the context of the assessment of economic value, that the margin earned by Flynn on the resale of Pfizer's Products must be assessed as part of their economic value.

J. PENALTIES

459. In view of our decision on abuse of dominance, we have considered whether it is necessary for us to come to a decision on the financial penalties imposed by the CMA in this case, and have concluded that it is not, notwithstanding that the matter was fully argued before us.

460. We make no findings on any of the matters raised in argument, particularly on whether the Appellants' conduct in this case was intentional or negligent or whether infringements of Article 102 are in principle more or less serious than infringements of Article 101, other than to state our general view that the gravity of the infringement will normally depend on the facts of the case rather than the categorisation of the infringement.

461. Having listened carefully to the submissions made by each party and, for present purposes, we make one specific point, however. Had we upheld the CMA's findings on abuse, we would likely have regarded the very substantial uplift for deterrence applied to Pfizer as, on its face, difficult to justify and not required by the CMA's own penalty guidance[87] (which we would naturally and by law have been obliged to take into account if we were ourselves required to decide on the level of fines to be imposed). 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,

[87] As at the date of the Decision and hearing, the relevant guidance was OFT 423 OFT's guidance as to the appropriate amount of a penalty (September 2012), as adopted by the CMA Board. A revised version of this guidance was published in April 2018 (CMA73).

particularly having regard to the new price control powers of the DH that have recently been passed into law.

K. OUR OVERALL DECISION

462. Cases of pure unfair pricing are rare in competition law. Authorities find them difficult to bring and are, rightly, wary of casting themselves in the role of price regulators. Generally, price control is better left to sectoral regulators, where they exist, and operated prospectively; *ex post* price regulation through the medium of competition law presents many problems. However, the law prohibits unfair pricing in certain circumstances and in such cases there is no reason in principle why competition law cannot be applied, provided this is done on the correct legal basis and the analysis of evidence is sound.

463. In this case, there is much in the Decision with which we agree. For example, we agree with the CMA's narrow definition of the market and that Pfizer and Flynn each held dominant positions over the Relevant Period. This was essentially on the grounds that they were able to set and sustain high prices for phenytoin capsules throughout the Relevant Period and that they did not face sufficient competitive pressure, whether from within or from outside the relevant market, to constrain their behaviour. We also did not find their conduct to be effectively constrained by countervailing buyer power on the part of the DH. We also do not accept Pfizer's claim under Ground 4 of its appeal that the law on abuse of dominant position could not be applied to it in this case.

464. However, we find the CMA's conclusions on abuse of dominance were in error (recognising that a material relevant case (*Latvian Copyright*) which would have contained useful guidance for the CMA was decided after the Decision and before the hearing of the appeals). The CMA did not correctly apply the legal test for finding that prices were unfair as laid down in the *United Brands* case, which was the test that the CMA expressly adopted and purported to apply, as subsequently developed and interpreted both by the EU courts and also by domestic courts, including the Tribunal. It did not appropriately consider what was the right economic value for Pfizer-Flynn Capsules; and it did not take sufficient account of the situation of other, comparable products, in particular of the phenytoin sodium tablet. This means that the CMA's overall findings on abuse of dominance are not well founded as a matter of law and

assessment and cannot be upheld. For these reasons, we come to the conclusion that the Decision must be set aside in part.

465. The importance of this case for the public interest makes it desirable to rectify the errors we have found. In a matter as important for government, for the public as patients and as taxpayers, as well as for the pharmaceutical industry itself, the law should be clear and any decisions made should be soundly based on proper evidence and analysis. It is important that there is a good legal foundation for any future action in this area.

466. As a Tribunal, we have the power to come to a new decision on abuse ourselves, and we were invited to do so by the CMA if necessary. We accept, of course, that one advantage of an appeal "on the merits" is that errors can be corrected by the Tribunal and further cost and delay can be avoided. In many cases, that is entirely proper and we would have followed that course had we felt that it was properly and responsibly available to us.

467. In the present case, however, although our essential finding is that the CMA misapplied the test for unfair pricing, the correct application of that test as we have described it would involve detailed consideration of further information, some of which may need to be obtained and properly tested, and the careful assessment of what normal competitive conditions might have been. A particular example is a better understanding of the evolution of the tablet market and tablet pricing. These are not things that the Tribunal is, in practice, in this case, in a position properly to do.

468. We therefore confirm the Decision save for that part of it that relates to abuse (and any consequential findings, including penalties). That part we set aside. Our provisional view is that we will remit the matter, insofar as it deals with abuse, to the CMA for further consideration as it sees fit. However, before making an order to that effect, we will invite written submissions from the parties on whether to remit the matter to the CMA and the scope of any such remittal.

469. We wish to emphasise that this Judgment does not imply any finding by the Tribunal as to whether there has been an abuse by Pfizer or Flynn of their respective dominant positions.

470. This Judgment is unanimous.

471. We should like to express our thanks to all counsel involved for the thorough and courteous way in which the case has been presented and argued before us and in responding to our many questions; also to the CMA staff and to the parties' solicitors and other advisers for their careful preparation of this case.

Peter Freeman CBE QC (Hon) Chairman

Paul Lomas

Prof. Michael Waterson

Charles Dhanowa OBE QC (Hon) Registrar

Date: 7 June 2018

CMA Guidance	OFT 403, Market definition, originally published by the OFT in 2004 and adopted by the CMA Board	§112
Commission	European Commission	§90
Continuity of Supply	Patients who are stablised on a particular manufacturer's phenytoin sodium capsule are generally maintained on that manufacturer's capsule and should not be switched to another manufacturer's capsule	§24
Cost Plus	Comprised of the costs that Pfizer and Flynn each incurred in respect of each of their capsule products and a reasonable rate of return for each of Pfizer and Flynn in respect of each of their capsule products	§68(5)(i) /§256
Court of Justice	Court of Justice of the European Union (formerly the European Court of Justice)	§90
CRA	Charles River Associates	§77(2)
Decision	CMA Decision of 7 December 2016 entitled "Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK"	§10
DH	Department of Health	§34
Draft Heads of Terms	Proposed heads of terms between Flynn and Pfizer drawn up by Flynn at Pfizer's request	§56
Drug Tariff	Sets out the reimbursement that pharmacies can claim from the NHS when fulfilling NHS prescriptions	§20/§33-34
Drug Tariff Price	The basic price minus any clawback discount at which a pharmacy is reimbursed for medicines dispensed	§33
DTP	Direct to pharmacy model	§20
Excessive Limb	Limb 1 of the *United Brands* two-limb test: the price must be "excessive' (in *United Brands*, it was said that this could be calculated as the difference between the cost of production of the product and the selling price)	§288(1)
Exclusive Supply Agreement	Agreement dated 17 April 2012 pursuant to which, *inter alia*, Pfizer agreed to supply what were then Epanutin capsules, which it would continue to manufacture, to Flynn	§57(2)
Flynn	Flynn Pharma Limited and Flynn Pharma (Holdings) Limited	§10
Flynn's Products	The four different capsules strengths of Pfizer-manufactured phenytoin sodium capsules sold	Fn 2

	by Flynn as "Phenytoin Sodium Flynn Hard Capsules"	
Kantar	Kantar Health UK	§76(2)
MA	Marketing authorisation	§19
MHRA	Medicines and Healthcare Products Regulatory Agency	§19
MHRA Guidance	Guidance entitled "Antiepileptics: changing products" published by the MHRA in November 2013	§29
MOT	Margin of tolerance	§38
MPS	Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000	§47
NHS	National Health Service	§21
NHS Act 2006	National Health Service Act 2006 (as amended)	§36
NICE	National Institute for Health and Care Excellence	§24
NICE Guidance 2012	Guidance (CG137) entitled "Epilepsies: diagnosis and management" published by NICE in January 2012	§26
NRIM	NRIM Limited	§17
NRIM Capsule(s)	Phenytoin sodium capsules in the 100mg strength manufactured and supplied by NRIM	§17
NTI	Narrow therapeutic index	§16
OFT	Office of Fair Trading	
Pfizer	Pfizer Limited and Pfizer Inc.	§10
Pfizer-Flynn Capsule(s)	The capsule form of phenytoin sodium manufactured by Pfizer, but supplied by Flynn since September 2012 and available in four different capsule strengths (25mg, 50mg, 100mg, 300mg)	§17
Pfizer's Products	The four different capsule strengths of Pfizer-manufactured phenytoin sodium capsules	Fn 2
Price Comparison over Time	The difference between the Pfizer-Flynn Capsule prices and the price previously charged by Pfizer for Epanutin	§255
PPRS	Pharmaceutical Price Regulation Scheme	§37
PSNC	Pharmaceutical Services Negotiating Committee	§34

Relevant Period	The infringement period found by the CMA to last from 24 September 2012 to at least 7 December 2016 i.e. the date of the Decision	§68(1)
ROCE	Return on capital employed	§38
ROS	Return on sales	§38
RWM	Reduced wholesaler model	§20
Scheme M	Non-contractual voluntary scheme for manufacturers for setting the Category M Drug Tariff Price, agreed between the DH and the BGMA	§34/§40-§44
Scheme W	Non-contractual voluntary scheme for wholesalers of Category M generic products	§41
Section 26 Responses	Evidence obtained by the CMA in response to notices it issued usings its powers under section 26 CA 98	§83
SSNIP test	A test which considers whether, in response to a small but significant non-transitory increase in price, typically of 5-10%, by a hypothetical monopolist supplying the product in question, sufficient consumers would switch to an alternative product so as to render that price increase unprofitable. If so, the alternative product is part of the same relevant market.	§96/fn 24
SO	Statement of Objections	§334
Teva	Teva UK Limited	§17
Teva Tablet(s)	Phenytoin sodium tablets in the 100mg strength manufactured and supplied by Teva	§17
TFEU	Treaty on the Functioning of the European Union	§10
Top 10 Spreadsheet	Data from Alliance setting out its sales of NRIM Capsules to its top 10 customers from June 2013 to February 2016	§145
Tor	Tor Generics Limited	§53
Transfer Price Profit Allowance	An allowance granted under the PPRS where products are purchased from an affiliate of the PPRS member	§39
TWM	Traditional wholesale model	§20
Unfair Limb	The second limb of the United Brands two-limb test: the price must be "unfair" either in itself ("Alternative 1") or when compared to competing products ("Alternative 2")	§288(2)

18 July Meeting	Meeting between the DH and Flynn on 18 July 2012	§63
6 November Meeting	Meeting between the DH and Flynn on 6 November 2012	§66/219
	Defined terms: case law / Commission decisions	
AG Wahl's Opinion	Opinion of Advocate General Wahl in *Latvian Copyright*	§292
Albion Water II	*Albion Water and Another v Water Services Regulation Authority and Others* [2008] CAT 31	§267
Attheraces	*Attheraces Limited v British Horseracing Board Limited* [2007] EWCA Civ 38	§305
ATR	Attheraces Limited	§305
BHB	British Horseracing Board Limited	§305
Deutsche Post	Commission decision COMP/36.915 – Deutsche Post AG – Interception of cross-border mail (2001)	§267
General Motors	C-26/75 *General Motors Continental* v *Commission* EU:C:1975:150	Fn 57
Hoffmann-La Roche	C-85/76 *Hoffmann-La Roche v Commission* EU:C:1979:36	§116
Kanal 5	C-52/07 *Kanal 5 and TV 4* EU:C:2008:703	§298299
Latvian Copyright	C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība* EU:C:2017:286	§292
Napp	*Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1	§302
National Grid	*National Grid plc v Gas and Electricity Markets Authority* [2009] CAT 14	§201
Scandlines	Commission decision *Scandlines v Port of Helsingborg* COMP/36.568	§366
Scippacercola	T-306/05 *Scippacercola and Terezakis v Commission* EU:T:2008:9	§366
Sirena	C-40/70 *Sirena S.r.l. v Eda S.r.l. and Others* EU:C:1971:18	§283
Tesco	*Tesco v OFT* [2012] CAT 31	§83
United Brands	C-27/76 *United Brands v Commission* EU:C:1978:22	§117