Annex A: Glossary of key terms and individuals

Key terms

Term	Definition
2016 Infringement Decision	The CMA's decision dated 7 December 2016 issued to each of Pfizer and Flynn finding that their prices for the supply of Capsules were unfair between 24 September 2012 and 7 December 2016.
ABPI	The Association of the British Pharmaceutical Industry.
Act	The Competition Act 1998.
AED	An anti-epileptic drug.
AMP	Average manufacturer price (of pharmaceutical products).
API	Active Pharmaceutical Ingredient (of a pharmaceutical product).
ASP	Average Selling Price.
BGMA	British Generics Manufacturers Association.
BNF	The British National Formulary.
Boots	Boots UK Limited. Operates a pharmacy chain. Affiliated with Alliance as Alliance Boots, which acts as a wholesaler of pharmaceuticals.
Capsules	Pfizer-manufactured phenytoin sodium capsules.
CAT	The Competition Appeal Tribunal.
CCGs	Clinical Commissioning Groups who are responsible for providing and funding health services in their local areas. The equivalents to CCGs in the devolved nations are: in Scotland, Regional Boards which devolve responsibility for health service budgets to Community Health Partnerships; in Wales, Local Health Boards; in Northern Ireland, the Health and Social Care Board which works with six Health and Social Care Trusts. CCGs were preceded in England by PCTs.
Chapter II prohibition	The prohibition imposed by section 18 of the Competition Act 1998.
CHM	Commission on Human Medicines.

CMA	Competition and Markets Authority. References to the CMA should be read as referring to the OFT where they concern matters prior to 1 April 2014.
CMA8	Guidance on the CMA's investigation procedures in Competition Act 1998 cases (November 2020).
COGS	Cost of goods sold.
Continuity of Supply	The recommendation in clinical guidance that a patient who is currently taking a particular manufacturer's or MA holder's phenytoin sodium product should be maintained on that specific manufacturer's product.
Cost Plus	The costs actually incurred in the supply of a product or service plus a reasonable rate of return.
Costs Act	Health Service Medical Supplies (Costs) Act 2017.
DDD	Defined daily dose. The defined daily dose is the assumed average maintenance dose per day for a drug used for its main indication in adults.
Decision	This Decision dated 20 July 2022.
DHSC	The Department of Health and Social Care.
Directions	The directions that the CMA made to Pfizer and Flynn as set out in Annex B of the 2016 Infringement Decision.
DPS	The draft penalty statements issued by the CMA to each of Pfizer and Flynn alongside the SO on 5 August 2021.
Drug Tariff	The mechanism for determining how dispensers are reimbursed for generic drugs. It is produced monthly by NHS Prescription Services and governs the price that is reimbursed to pharmacies for fulfilling NHS prescriptions, subject to any price concessions agreed between the DHSC and the PSNC.
Drug Tariff price or Reimbursement price	The price that is reimbursed to the dispenser for fulfilling NHS prescriptions.
Epanutin	The brand name for Pfizer-manufactured phenytoin sodium capsules sold by Pfizer in other EU Member States and in the UK until 23 September 2012.
EPBU	Pfizer's Established Products Business Unit.
EU	European Union.
Exclusive Supply Agreement	An agreement between Pfizer and Flynn dated 17 April 2012 which provided for Pfizer to supply Flynn with Capsules.

Flynn	Flynn Pharma Limited and Flynn Pharma (Holdings) Limited collectively.
Flynn's Infringements	The four separate abuses of a dominant position that the CMA has found were committed by Flynn.
Flynn's Prices	Flynn's ASPs to wholesalers and pharmacies for Flynn's Products.
Flynn's Products	The four different capsule strengths (25mg, 50mg, 100mg, 300mg) of Capsules sold by Flynn as 'Phenytoin Sodium Flynn Hard Capsules'.
GEP	Pfizer's Global Established Pharma division.
GMMMG	The Greater Manchester Medicines Management Group.
GP	General Practitioner.
Infringements	Pfizer's Infringements and Flynn's Infringements collectively.
Letter of Facts	The Letter of Facts issued to each of Flynn and Pfizer on 14 April 2022.
Lloyds	Lloyds Pharmacy Limited. Operates a pharmacy chain. Owned by Celesio AG.
MA	Marketing Authorisation. Sometimes referred to as a licence. An authorisation to sell a medicine in the UK.
MHRA	The Medicines and Healthcare Products Regulatory Agency.
MHRA Guidance	The guidance issued by the Medicines and Healthcare Products Regulatory Agency in November 2013 entitled: 'Formulation switching of antiepileptic drugs: a report on the recommendations of the Commission on Human Medicines from July 2013'.
Milpharm	Milpharm Limited. A pharmaceutical company.
NHS	National Health Service.
NHS Act	National Health Service Act 2006.
NICE	National Institute for Health and Clinical Excellence.
NICE guidance	NICE Clinical Guidance CG137: The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care.
NRIM	NRIM Limited. A pharmaceutical company. Acquired by Auden McKenzie Holdings Limited in 2014.
NRIM's Product	Phenytoin Sodium NRIM Capsules (100mg).

NTI	Narrow therapeutic index.
OFT	The Office of Fair Trading. Predecessor to the Competition and Markets Authority.
Parties	Pfizer and Flynn collectively.
Party	Either Pfizer or Flynn as applicable.
PCA	Prescription Cost Analysis.
PCT	Primary Care Trust. Primary care trusts were abolished on 31 March 2013 as part of the Health and Social Care Act 2012, with their work taken over by CCGs.
Pfizer	Pfizer Limited and Pfizer Inc.
Pfizer's Infringements	The four separate abuses of a dominant position that the CMA has found were committed by Pfizer.
Pfizer's Products	The four capsule strengths (25mg, 50mg, 100mg, 300mg) of Capsules sold by Pfizer.
Pfizer's Prices	Pfizer's ASPs to Flynn for Pfizer's Products.
PPRS	The Pharmaceutical Price Regulation Scheme.
Pre-September 2012 Prices	The ASPs charged by Pfizer for the supply of Capsules up to and including 23 September 2012.
Previous Investigation	The CMA's investigation into unfair pricing in respect of the supply of phenytoin sodium capsules in the UK (Case C3/9742-13) launched in May 2013.
PSNC	The Pharmaceutical Services Negotiating Committee.
R&D	Research and development (of pharmaceutical products).
Relevant Period	The period from 24 September 2012 to 7 December 2016.
Remittal	The CMA's remittal investigation into the matters that are the subject of this Decision.
Reserve Power	The power of Secretary of State for Health and Social Care, after consulting the relevant industry body, to limit the price charged by a manufacturer or supplier for the supply of a health service medicine.
ROCE	Return on capital employed.
ROS	Return on sales.
RWM	Reduced Wholesaler Model.

Secretary of State	The Secretary of State for Health and Social Care.
SO	Statement of Objections addressed to each of Pfizer and Flynn, dated 5 August 2021.
SPC	Supplementary Protection Certificate.
Statutory Scheme	The statutory pricing regulations for controlling the cost of branded medicines to the NHS enacted under the Statutory Scheme Regulations.
Tablets	Phenytoin sodium tablets.
Teva	Teva UK Limited. A pharmaceutical company.
The 2007 Meeting	The meeting which took place between Teva and the DHSC on 16 October 2007 for the purposes of discussing Teva's supply prices for Tablets.
TLV	Dental Care and Medicines Benefits Agency in Sweden.
Tor	Tor Generics Ltd. A pharmaceutical company.
UKMF	Pfizer's UK Management Forum.
WACC	Weighted Average Cost of Capital.
Wockhardt	Wockhardt UK Limited. A pharmaceutical company.

Key individuals

Pfizer	
[Pfizer President 1]	Previously [✂].
[Pfizer Expert Witness 3]	Expert witness. Provided evidence on phenytoin dispensing practice.
[Pfizer Employee 2]	Previously [✂].
[Pfizer Director 1]	Factual witness, previously [✂]. Provided evidence on agreeing and signing off the Asset Sale Agreement and Exclusive Supply Agreement.
[Pfizer Expert Witness 2]	Expert witness. Provided evidence on market dominance, Cost Plus, and abuse.
[Pfizer Employee 1]	Previously [✂].
[Pfizer Expert Witness 1]	Expert witness. Evidence on epilepsy and its treatment.
Flynn	
[Flynn Expert Witness 3]	Expert witness. Provided evidence on generic companies and their pricing strategies, focusing on Flynn's behaviour.
[Flynn Expert Witness 1]	Expert witness. Provided evidence on benchmark analysis of Capsules' profitability.
[Flynn Director 1]	Director.
[Flynn Employee 1]	Previously [✂].
[Flynn Director 2]	Factual witness, director of Flynn since [✂]. Provided evidence on Flynn's behaviour.
[Flynn Expert Witness 2]	Expert Witness. Provided evidence on the CMA's calculation of excess, focusing on the PPRS.
Teva	
[Former Teva Director]	Factual Witness, previously [✂]. Provided evidence on Teva's meeting with the DHSC in 2007.
CMA	
[CMA Expert Witness 1]	Expert witness. Provided evidence on the Parties' costs and rates of return.

Annex B: Complaints received from CCGs and other NHS stakeholders about the Parties' prices

B.1 This Annex summarises a number of the complaints received from CCGs and other NHS stakeholders shortly after Pfizer and Flynn implemented their price increases.

Complaints received by Pfizer and/or Flynn

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
28 September 2012	[✂] Strategic Health Authority	Pfizer internal email correspondence between [Pfizer Employee 2], [Pfizer Employee] and others referring to a discussion with NHS [✂]	[Pfizer Employee] of Pfizer reports: 'At the end of the meeting, the pricing of Epanutin (phenytoin sodium) was raised. In short, and by way example, the [✂] SHA prescribing costs, like for like annual volumes, will increase by **£5.6m**.' The email noted that the new Flynn prices are an increase of 2385% per SKU.[1894]
1 October 2012	[✂] CCG	Email correspondence between [✂] and [Flynn Director 2] (Flynn), forwarding an email from [✂] CCG	'I have to say that I find this somewhat disappointing particularly as we are trying to control spending costs. I would appreciate your comments as to why the company thought this to be necessary.'[1895]

[1894] PHT00352, Email of 28 September 2012 from [Pfizer Employee 2] (Pfizer) to [Pfizer Employee] (Pfizer) (CMA document reference 00141.455).
[1895] PHT00377, Email chain of 1 October 2012 between [✂] and [Flynn Director 2] (Flynn), forwarding an email from [✂] ([✂] CCG) to [Flynn Employee] (Flynn), FW: Phenytoin Capsules (CMA document reference 00145.434).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
5 October 2012	Medicines Management Pharmacist	Email correspondence between [✂] and [Flynn Director 2] (Flynn), forwarding an email from a medicines management pharmacist	'As a Pharmacist, I was interested to see that you are taking over the manufacture and license of Epanutin from Pfizer. I have seen […] assurances are given that the Flynn Phenytoin capsules are bio-equivalent to Epanutin, and that they will actually be manufactured in the same factory and on the same production line as currently used. I have also noted that there has been a considerable price increase […]. I'd be really interested to know the rationale behind this price increase, especially as it appears that the location of production is not changing.'[1896]
7 October 2012	[✂] CCG	Email correspondence between [✂] ([✂] CCG) and [Flynn Director 2] (Flynn)	'A staggering increase, not just sizeable, of 2000% plus! A [sic] increase of £102k to [✂] alone. Some £50m nationally. Very difficult to understand. Patients and practitioners have very little option to change.'[1897]
7 October 2012		Email from [Flynn Director 1] (Flynn) to [Flynn Director 2] (Flynn)	Flynn was aware of analysis that the impact of the price increase will be 'in excess of £4 million over the next year for the West Midlands'.[1898]

[1896] PHT00378, Email chain of 5 October 2012 between [✂] and [Flynn Director 2] (Flynn), forwarding an email from [✂] (Medicines Management Pharmacist) to Flynn, FW: Epanutin / Phenytoin (CMA document reference 00145.448).
[1897] PHT00119, Email chain of 8 October 2012 between [Flynn Director 2] (Flynn) and [✂] ([✂] CCG) discussing the change in price for Phenytoin Sodium Flynn Hard Capsules: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.455).
[1898] PHT00392, Email from [Flynn Director 1] (Flynn) to [Flynn Director 2] (Flynn) dated 31 October 2012, phenytoin (CMA document reference 00145.556).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
10 October 2012	GMMMG (12 CCGs in the Greater Manchester area)	Letter from the GMMMG to the Secretary of State and others, copying Pfizer and Flynn	The GMMMG stated that the manufacturers of phenytoin sodium capsules had engaged in an 'abuse of a virtual monopoly position for purely commercial gains', noting that '[t]his change, if unchallenged will cause the NHS to pay an unnecessary and unwarranted, additional £41Million for no clinical benefit'. The letter stated that '[t]his increase in cost will provide no additional health benefit for patients' and '[t]he only pharmaceutical element which is changing is the product name'. The GMMMG urged the NHS to demonstrate that 'this unethical, anti-competitive behaviour at the expense of patient care will not be tolerated'. The GMMMG highlighted that CCGs had little alternative but to pay Flynn's prices: 'We would contend that the needs of the NHS and patients are not best served by this cynical increase in costs, as the product cannot be switched to an alternative, equivalent formulation for the majority of indications'. The GMMMG also noted that '[t]his scheme […] hinders the usual price reductions expected in a competitive generic market' and it 'places "unforeseen", unjustifiable and unacceptable "burdens" on the NHS, leading to a potentially unstable and unpredictable market in epilepsy treatment'.[1899]

[1899] PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.527).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
11-12 October 2012	[✂] PCT	Email correspondence between [Flynn Employee 1] and [Flynn Director 2] (Flynn), forwarding an email from [✂] PCT	'I've just received notification that Flynn Pharma is taking over the distribution of Epanutin and there is going to be a significant cost increase for this product. Whilst I appreciate that there may well be other factors involved in this price increase, this looks like gross profiteering and gives rise to a very poor impression of Flynn Pharma and the pharmaceutical industry in general.'[1900, 1901]
14-15 October 2012	Medicines Management Pharmacist	Email correspondence between [✂] and [Flynn Director 2] (Flynn), forwarding an email from a medicines management pharmacist	'[…] I am interested to hear the justification for such a significant price rise for a preparation of a drug identical to epanutin and manufactured at the same site. My impression is this seems an opportunity seized by Flynn pharma to extract more money out of Primary care drug budgets. For an average sized CCG this equates to hundreds of thousands [of] pounds [of] cost pressure. The only benefit for stakeholders seems to be profit [for] your company.'[1902]

[1900] PHT00379, Email chain of 12 October 2012 between [Flynn Employee 1] (Flynn) and [Flynn Director 2] (Flynn), FW: Phenytoin Sodium Flynn hard capsules (CMA document reference 00145.477).
[1901] In light of this complaint, email correspondence between [Flynn Employee 1] (Flynn) and [Flynn Director 2] (Flynn) on 12 November 2012 shows that [Flynn Employee 1] of Flynn had 'reservations about the price level agreed with the DH, see PHT00379 (CMA document reference 00145.477).
[1902] PHT00381, Email chain of 15 October 2012 between [✂] and [Flynn Director 2] (Flynn), forwarding an email from [✂] (Medicines Management Pharmacist) to Flynn, RE: Price change for phenytoin capsules (CMA document reference 00145.481).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
18 October 2012	Medicines Management customer	Pfizer internal email correspondence between [Pfizer Employee 2], [Pfizer Employee] and others referring to a complaint from a 'Meds Management customer'	[Pfizer Employee] of Pfizer reports: 'We were speaking to a Meds Management customer who was very concerned that Pfizer may be implicated in the 24x price rise that Flynn has put on this. Abuse of monopoly was an expression used!' [Pfizer Employee 2] of Pfizer responds: 'queries regarding Flynn Phenytoin Hard Capsules need to be directed to Flynn Pharma. We would ask that no one else offers comment or opinion on this matter at this time'.[1903]
22 October 2012	[✂] PCT	Email correspondence between [✂] ([✂] PCT) and [Flynn Director 2] (Flynn)	'There is no justification for increasing the cost 25x. As you will be aware it is not advisable to switch patients to the tablet formulation from the capsule so the price comparison you have made is ingenuous [sic] and misleading. It is clear that Flynn have added no value to the product and have only rebranded an existing compound in order to "justify" the cost to the NHS. It is not clear why you need to increase the price in order to maintain the drug on the market. Are you able to provide further clarification?'[1904]

[1903] PHT00355, Email chain of 18 October 2012 between [Pfizer Employee 2] (Pfizer) and [Pfizer Employee] (Pfizer) and others, RE: Epanutin and Flynn Pharmaceuticals (CMA document reference 00141.483).
[1904] PHT00207, Email chain of 22 October 2012 between [✂] ([✂] PCT) and [Flynn Director 2] (Flynn) regarding the response from Flynn with regards the increase in price of Phenytoin Sodium: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.516).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
23 October 2012	[✂] CCG	Flynn internal email correspondence between [Flynn Employee] and [Flynn Director 2] referring to complaints from [✂] CCG	[Flynn Employee] of Flynn reports: 'Today I met Dr […] from [✂] Medical Practice in [✂], who is also part of the [✂] CCG. […] he asked about Phenytoin, why Pfizer had sold it and why there was such a massive price increase. He told me that the matter had been raised within his CCG group and that the MM [medicines management] for the CCG are not at all happy.'[1905] [Flynn Employee] of Flynn subsequently adds: 'I would also like to mention that I also spoke to another member of this same CCG group/practice, highly influential also, sits on the District Prescribing Committee for [✂] […] his aside comment at the end did refer to the £600,000 cost that Phenytoin will generate!'[1906]

[1905] PHT00387, Email chain of 23 October 2012 between [Flynn Employee] (Flynn) and [Flynn Director 2] (Flynn), RE: Phenytoin (CMA documents reference 00145.523).
[1906] The prescribing newsletter from NHS [✂] states: 'This change will increase annual spend across [✂] by approximately £600,000. Approximately 1,700 prescriptions for phenytoin are dispensed in [✂] each month'. PHT00389, Medicines Management Update, NHS [✂] (CMA document reference 00145.529). See also PHT00390, Email from [✂] (3i Consultancy) to [Flynn Director 2], [Flynn Director 1] and others (Flynn) dated 24 October 2012, [✂] and Epanutin (CMA document reference 00145.536).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
12-13 November 2012	Medicines Management customers in Manchester	Pfizer internal email correspondence between [Pfizer Employee 2], [Pfizer Employee] and others referring to complaints from Medicines Management customers in Manchester	[Pfizer Employee] of Pfizer reports: 'My Medicines Management customers in Manchester are having difficulty absorbing the price hike for Epanutin which for them represents hundreds of thousands of pounds in extra costs. […] Is there any statement from us about this [as] my custoemrs [sic] feel Pfizer has 'done a deal' with Flynn which means that we have done well and the NHS has to pay the price? […] The impact globally on our reputation across Greater Manchester (Greater Manchester Medicines Management Group) may well be significant […].' [Pfizer Employee 2] of Pfizer responds: 'I am aware of the GMMMG and their position including their letter to the secretary of state etc. You should direct any customer queries regarding phenytoin capsules to the licence holder, Flynn pharma, as Pfizer is not in a position to comment on another company's assets.'[1907]
28 November 2012	[✂] PCT	Email from [Flynn Employee] (Flynn) to [Flynn Director 2] (Flynn)	A Flynn employee reported a 'rather uncomfortable conversation' with [✂] PCT in which the Flynn employee was 'bombarded with complaints regarding Phenytoin' and told that the increase in price would cost the PCT £750,000 a year.[1908]

[1907] PHT00356, Email chain of 13 November 2012 between [Pfizer Employee 2] (Pfizer) and [Pfizer Employee] (Pfizer) and others, RE: (CMA document reference 00141.518).
[1908] PHT00209, Internal Flynn e-mail of 28 November 2012 [from [Flynn Employee] to [Flynn Director 2]] re Phenytoin Complaint from [✂], [✂] PCT (Refusing Any Contact from Flynn): Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.614).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
3-4 December 2012	[✂] PCT	Email correspondence between [✂] and [Flynn Director 2] (Flynn), forwarding an email from [✂] PCT	'Epanutin cost peanuts. How dare you charge £67.50 for 84 caps of 100mg How can you justify ripping off the NHS this way?'[1909]
2-24 January 2013	[✂] PCT	Email correspondence between [Pfizer Employee 2] and [Pfizer Employee] (Pfizer), forwarding an email from [✂] PCT	'[…] we are p****d off about the epanutin situation so Pfizer won't find a friendly reception anywhere. Locally it will cost us around £240,000 per year to pay for the price hiked Flynn Pharma product.' In the subsequent email chain, [Pfizer Employee] of Pfizer notes internally: 'this has hit [✂] really hard and as you can tell, they are not pleased. [✂] sits on all things [✂] as well'.[1910]

[1909] PHT00398, Email chain of 4 December 2012 between [✂] and [Flynn Director 2] (Flynn), forwarding an email from [✂] ([✂] PCT) to Flynn, Phenytoin (CMA document reference 00145.624).
[1910] PHT00359, Email chain of 24 January 2013 between [Pfizer Employee 2] (Pfizer) and [Pfizer Employee] (Pfizer), RE: MM team [✂] FY (CMA document reference 00141.551).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
22 January 2013	Dr [✂]	Letter published in the British Medical Journal	A GP's letter was published in the British Medical Journal to which Flynn responded.[1911] Pfizer was aware of this letter.[1912] The GP's letter noted that the Parties' price increases: '…exploits the fact that the price of generic drugs is not negotiated with the Department of Health because market forces are meant to keep prices competitive, but this is not always the case. If there are safety reasons for prescribing by brand, excessive price rises may occur.' The GP's letter further stated that: '…there is no generic market for phenytoin. Pfizer is the only company to make it in the UK, and if another company started to manufacture or import it, doctors would not be able to switch on cost grounds, because of the risk of destabilising a patient's epilepsy. When a single seizure can lead to death or serious injury and a one year ban on driving, this is a risk that no doctor should take. The exploitation of this loophole has cost the NHS a serious amount of money when budgets are being reduced, has caused anxiety in people with epilepsy, and has no clinical justification whatsoever.'[1913]

[1911] PHT00210, Letters published in the British Medical Journal on 22 January 2013 (CMA document reference 00020.2).
[1912] PHT00360, Pfizer, Epanutin Capsules UK Marketing Authorisation Divestment to Flynn Pharma: External Communications Activity To Date, 7 February 2013 (CMA document reference 00141.562).
[1913] PHT00210, Letters published in the British Medical Journal on 22 January 2013 (CMA document reference 00020.2).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
4 February 2013 - 12 March 2013	NHS [✂]	Pfizer internal email correspondence between [Pfizer Employee], [Pfizer Employee] and others referring to a complaint from NHS [✂]	[Pfizer Employee] of Pfizer reports on a meeting with the Deputy Head of Medicines Management for NHS [✂] (a future CCG), noting that the Finance Director of the PCT discussed that: '[…] Pfizer had been blacklisted because of the increased cost of a medicine. Epanutin was named and stated that the organisation had incurred additional £400,000 a year cost. They indicated that one GP in particularly [sic] was unhappy and was seeking to escalate action beyond the CCG in relation to the cost increase.' In the subsequent email chain, [Pfizer Employee] of Pfizer notes internally that the customer was 'looking for the logic behind the reason Flynn would increase the price so dramatically' and 'I have a real concern around the way this is spreading between accounts. A £400K hit is significant for a PCT of this size and it feels like this is much broader in terms of the wider prescriber impact.'[1914]
Undated	[✂] NHS Trust	Flynn Pharma Med Information Request Form relating to Principal Pharmacist at [✂] NHS Trust	The form reports 'customer feedback': 'He was obviously angry re the price increase of Phenytoin. […] He was just very unhappy and could not see the justification for the price rise […].'[1915]

[1914] PHT00361, Email chain of 12 March 2013 between [Pfizer Employee] (Pfizer) and [Pfizer Employee 3] (Pfizer) and another, FW: Epanutin Caps – [✂]/CCG – Ouputs [sic] from meeting 11.03.13 (CMA document reference 00141.583).
[1915] PHT00391, Flynn Pharma Med Information Request Form relating to [✂], Principal Pharmacist at [✂] NHS Trust (undated) (CMA document reference 00145.547).

Other complaints

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
25 October 2012	Grafton Group of six CCGs	Letter from the Grafton Group to the Chief Pharmaceutical Officer of the DHSC	The Grafton Group stated they had 'grave concerns about the huge cost pressures for the NHS resulting from this change' to the price of phenytoin sodium capsules. The group noted that each CCG would have to find up to £500,000 from existing budgets to fund the product and this 'increase in cost will provide no additional health benefit for patients, but will undoubtedly compromise other services that we will not be able to afford to commission as a result.' The letter also stated that '[d]espite being the identical product, the prices for the Flynn products are approximately 24 times the price of Epanutin capsules […] There is no other equivalent preparation available for us to use.'[1916]

[1916] PHT00118, Letter of 25 October 2012 from Nene CCG to [✂] regarding Epanutin; Changes of Marketing Distribution; Impact on UK Patients: Enclosed with Nene CCG's e-mail of 10 July 2013 to the OFT about the Epanutin price increase (CMA document reference 00210.2).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
25 October 2012	[✂] CCG	Letter from [✂] CCG to [✂]	The letter noted the 'significant adverse impact' of the price increases for phenytoin sodium capsules on the CCG's prescribing budget, with an impact of around £350,000 per year. The letter stated that 'this huge price rise is a blow to all prescribers trying to meet the government's challenging targets and ensure the best possible use of NHS resources'. The letter also noted that, as phenytoin sodium has an NTI, it was vital that patients taking Capsules remain on Flynn's Products. The letter stated that Flynn 'has taken advantage of this by raising their prices by a staggering amount (24 fold) knowing that clinicians cannot switch their patients to another manufacturer'. Further, the 'drug in question is taken by a vulnerable group of patients who cannot be easily switched to another product without significant risks.'[1917]
5 January 2013	[✂] CCG	Email from [✂] to the OFT, copying others	The email stated that the price increase to phenytoin sodium capsules was 'a significant cost pressure for our local NHS services'. The individual later sent an email to the OFT and others about the 'blatant abuse of our NHS', saying 'I and very many colleagues […] are very angry and upset about this damaging and very significant cost pressure for CCGs for absolutely NO patient benefit'.[1918]

[1917] PHT00208, Letter of 25 October 2012 from [✂] Clinical Commissioning Group to [[✂] – excised in log] re Phenytoin Capsules Price Increase: Sent to OFT by [✂] Clinical Commissioning Group on 18 July 2013 (CMA document reference 00254.1).
[1918] PHT00120, Various e-mails: Email of 3 February 2013 from West Sussex PCT to the OFT discussing the price increase of Phenytoin capsules, Email correspondence dated 14 December 2012 to 3 February 2013 of 2 February 2013 between [✂] CCG and the OFT regarding the price increase of Phenytoin capsules and the cost to the NHS (CMA document reference 00014).

Date	CCG/other NHS stakeholder	Correspondence	Details of the complaint/concerns raised
3 February 2013	West Sussex PCT	Email from [✂] of West Sussex PCT to the OFT, copying others	The email noted that 'this will cost the NHS approximately £50m / year with absolutely no improvement in patient care, and indeed will need disinvestment in other medical services to fund'.[1919]
23 July 2013	Somerset CCG	Letter from [✂] of Somerset CCG to the OFT	The letter noted that, following the de-branding of *Epanutin*, 'there has been a significant local and national increase in prescribing costs'. The letter also said that '[b]ecause of the complexities of epilepsy and the narrow therapeutic index of phenytoin capsules, there were really very few options open to GPs to deal with what was, in our view, manipulation of a monopoly position'.[1920]

[1919] PHT00120, Various e-mails: Email of 3 February 2013 from West Sussex PCT to the OFT discussing the price increase of Phenytoin capsules, Email correspondence dated 14 December 2012 to 3 February 2013 of 2 February 2013 between [✂] CCG and the OFT regarding the price increase of Phenytoin capsules and the cost to the NHS (CMA document reference 00014).
[1920] PHT00211, Letter received 23 July 2013 from Somerset Clinical Commissioning Group to the OFT complaining about price increase of Epanutin (CMA document reference 00279).

Annex C: Events regarding the Parties' prices and the DHSC and NHS

C.1 This Annex summarises: events regarding the Parties' prices for Capsules and interactions with the DHSC and NHS; what the Parties should have understood from these events; and the actions the Parties took (alongside observations by the CMA).

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
Pre-September 2012	The evidence adduced by Pfizer demonstrates that the DHSC had made it clear to Pfizer that Capsules did not warrant any exceptional price increase within the PPRS based on the higher Drug Tariff price of Tablets. [Pfizer Director 1] explained before the Tribunal: 'So on the one hand, it was very clear to us that from [the DHSC's] initial intervention and then subsequent acceptance of the tablet price, that that represented the value that they believed that medicine gave to the NHS. Yet at the same time, the advice I was getting from our finance team, who'd raised this subject in previous discussions with the Department, was that they would not entertain any exceptional price rise or price reset of the capsules accordingly'.[1921]	[Pfizer Director 1]'s evidence shows that Pfizer knew that the DHSC 'would not entertain' a Capsules price increase by reference to the Drug Tariff price of Tablets before it used another mechanism to implement an increase on exactly this basis. Accordingly, Pfizer was aware that the 'inference' it had drawn regarding the DHSC's views was flawed and did not reflect the DHSC's position.	The Parties continued with a plan to de-brand *Epanutin* and impose substantial price increases based on the Tablets Drug Tariff price.

[1921] PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 43, lines 14-23.

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
18 July 2012	Flynn met with the DHSC to discuss a Flynn proposals to increase the price of Capsules. Flynn told the DHSC that it intended to set its prices 10% to 30% below the Drug Tariff price of Tablets depending on whether it sold Capsules as a generic or as a branded product. Flynn's note of the meeting reflects that, '[w]hilst DH acknowledged the need for this product to remain on the market, DH expressed the difficulties in agreeing to a launch price that was significantly higher than [the prevailing price of] Epanutin' (emphasis added).[1922]	The DHSC's response clearly questions whether a significant price increase for Capsules based on benchmarking against the Drug Tariff price of Tablets was appropriate.	The Parties continued with a plan to de-brand *Epanutin* and impose substantial price increases based on the Tablets Drug Tariff price.
26 July 2012	The DHSC wrote to Flynn to inform it that the PPRS Pricing Committee had rejected Flynn's informal proposal to increase the price of Capsules in the PPRS to a price around 25% to 30% below the £30 Drug Tariff price of Tablets.	The DHSC's response should have confirmed to the Parties that the DHSC did not consider that a significant price increase for Capsules based on benchmarking against the Drug Tariff price of Tablets was appropriate or justified. This clearly undermines the Parties' proposition that the Drug Tariff price was used as a	The Parties proceeded to de-brand *Epanutin* and impose substantial price increases based on the Tablets Drug Tariff price.

[1922] PHT00047, Note of a Meeting between Flynn Pharmaceuticals and the Department of Health held on 18 July 2012 at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.9), page 1, paragraph 5.

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
		benchmark in 'good faith'.[1923] Instead, the Parties were again put on notice that the DHSC did not believe this to be appropriate.	
24 September 2012	Flynn imposed prices representing price increases for customers for 25mg, 50mg, 100mg and 300mg Capsules of between 2,366% and 2,682% overnight.		
10 October 2012	The GMMMG (made up of 12 CCGs in Greater Manchester), sent a letter to the Secretary of State for Health very shortly after the increase in prices, copying Pfizer and Flynn.[1924] The letter included a strong and reasoned critique of the Parties' strategy and pricing from the customer's perspective. The letter concluded that the Parties' price increases amounted to a 'cynical increase in costs' and were an 'abuse of a virtual monopoly position for purely commercial gains' (a point which it reiterated on five occasions). In reaching this conclusion, the letter	This letter – sent by a major NHS stakeholder directly responsible for funding the Parties' price increases – directly challenges any suggestion that these price increases were imposed in good faith and sets out a number of reasons why the increases cannot be objectively justified by factors relevant to: the underlying costs of the product; the transfer of the MA to Flynn; innovation; production; investment; and the benefits for patients. Instead, the letter makes clear that the price	The Parties maintained their high prices. This is not consistent with the claim that they proceeded in good faith. The Parties did not reconsider their approach or their reliance on the DHSC's 'willingness' to pay their prices following the concerns raised by the GMMMG. Instead, they continued to charge significantly increased prices without engaging with the points raised.[1925] Flynn met with the DHSC following the GMMMG letter and, as can be seen from the entry below, still did not provide any

[1923] Pfizer has submitted that it 'benchmarked its price in good faith by reference to what it understood to be a bespoke, lawful price agreed by the DH. As a result, the involvement of senior management in this case is a mitigating factor because there were reasonable grounds to consider the prices were fair.' See PRC03488, Pfizer's Response to the SO and DPS, paragraph 45(d)(ii).

[1924] PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.527).

[1925] [Flynn Director 2] noted in an internal email that 'we do not intend to directly reply' to the GMMMG's letter: PHT00126, Email chain of 24 October 2012 between [Flynn Non-executive Director 2] ([✂]), [Flynn Director 1] (Flynn) and [✂] ([✂]) discussing the letter re the Abuse of Monopoly – Epanutin Marketing and Distribution Changes and Flynn: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.535).

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	makes a number of highly relevant points. These include: • That Capsules will continue to be manufactured by Pfizer in precisely the same way, in the same factory and in the same way as before; and that '[t]he only pharmaceutical element which is changing is the product name'. • That the switch of the MA to Flynn and the subsequent name change to 'Phenytoin Sodium Flynn Hard capsules', far from benefitting patients, created 'considerable logistical difficulties' and 'may ultimately cause inconvenience and concern for patients'. • That the price increase imposed is 'completely unjustifiable', 'will provide no additional health benefits for patients' and 'is neither reasonable nor fair'. • That the change 'is not **Innovative**, does not **Prevent** additional epileptic seizures […] nor does it demonstrate **Productivity**, in fact it	increases are likely to have a detrimental impact on the NHS's ability to serve patients. Plainly, this letter raises a series of very explicit red flags regarding the Parties' prices. The letter would have given a clear indication to the Parties that their use of the Tablets price as a benchmark was neither appropriate nor justified. The letter also provided a suggestion for an alternative approach to simply continuing to enforce their high prices – ie that the Parties 'make a case for a **modest** price increase, but this must stand up to economical and clinical justification.'	'economic or clinical justification' for its price increases. In a Flynn internal email, a non-executive director of Flynn stated in response to the letter that 'in my view it is very difficult to argue that the allegations are a breach of Article 82 or the Competition Act'.[1926]

[1926] PHT00126, Email chain of 24 October 2012 between [Flynn Non-executive Director 2] ([✂]), [Flynn Director 1] (Flynn) and [✂] ([✂]) discussing the letter re the Abuse of Monopoly – Epanutin Marketing and Distribution Changes and Flynn: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.535).

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	is 24 time [sic] less productive than current practice.' • That, due to the price increases and '£41Million being avoidably wasted', the Parties' conduct 'may make innovative new medicines less affordable for the NHS'. • That the change, 'if unchallenged will cause the NHS to pay an unnecessary and unwarranted, additional £41Million for no clinical benefit' and that 'the NHS nationally will be adversely affected' by the increase. The letter concluded by recommending to Pfizer and Flynn that '[t]he only credible alternative is that the companies must make a case for a **modest** price increase, but this must stand up to economical and clinical justification.'		
6 November 2012	The DHSC met with Flynn.[1927] At the meeting the DHSC raised concerns over the Parties' price increases and	The DHSC made it clear that it considered the price of Capsules to be unjustified and this was the	The Parties maintained their high prices. Flynn informed DHSC that the price increases were necessary to ensure the

[1927] Flynn submitted that it requested meetings with the DHSC to discuss pricing when such matters had not been raised by the DHSC: PRC03492, Flynn's Response to the SO, paragraph 1.5 and see also PRC03903, Flynn's Response to the Letter of Facts, paragraph 3.7.3. However, Flynn requesting a meeting in July 2012 followed the DHSC requesting from Pfizer details of the divestment to Flynn (see section 2.D.II of this Decision). Prior to the November 2012 meeting, the DHSC contacted Flynn to seek details of its cost of goods (see section 2.D.III of this Decision) and this meeting was prompted by Flynn receiving a complaint about the impact of its pricing on the NHS by the GMMMG referred to in the Table above (PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 25 and PRC03492, Flynn's Response to the SO, paragraph 2.18).

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	the use of the Drug Tariff price of Tablets as a justification.[1928] The notes of the meeting[1929] show that the DHSC: • told Flynn that the GMMMG letter 'had been widely circulated in DH circles' and that the DHSC 'had received lots of representations and Parliamentary Questions had been raised and that DH needed the rationale to justify and explain the increase in cost to the NHS'; • told Flynn that it 'had never confirmed that it was content with the price of the tablets'; • told Flynn that Flynn should not 'assume that the DH and NHS	second occasion its officials informed Flynn that its benchmarking against the price of Tablets was not appropriate. Following this meeting, Flynn would also have understood that the DHSC's focus was on the overall cost of a drug to the NHS, rather than individual prices. The DHSC made it very clear at the meeting that the significant differences in volumes between Capsules and Tablets meant that the Parties' proposal would result in the cost of Capsules to the DHSC being significantly greater than the cost of Tablets.	product remained on the market, warning that it 'might have to discontinue the product if [it] didn't make sufficient margin'.[1932] However, Flynn was making substantial margins on its sales. As the CAT found in its *Phenytoin* judgment, Flynn set its selling Prices 'well above [Pfizer's supply price] and could have reduced its prices and still made a material profit.' [1933] This is not consistent with Flynn's claim that it acted in a 'constructive' and 'transparent' manner in its dialogue with DHSC. Ultimately, Pfizer and Flynn declined to provide costs information in response to the DHSC's request. Accordingly, the DHSC had no means of understanding whether or not the price increases had

[1928] Flynn submitted that between the launch of its Capsules and the 6 November 2012 meeting, the DHSC did not raise any objections to its prices, and that at the November 2012 meeting, it was a 'surprise to Flynn' that the DHSC did not consider Tablets an appropriate comparator and it was the first time the DHSC had suggested it was not happy with Flynn's prices for Capsules: PRC03492, Flynn's Response to the SO, paragraphs 2.18 and 2.19 and PRC03903, Flynn's Response to the Letter of Facts, paragraph 3.7.3. However, the DHSC had expressed concerns regarding Flynn's pricing proposals *before* the launch of its Capsules: see the Table above and see also *Phenytoin* [2018] CAT 11, paragraph 232. That the DHSC had concerns with Flynn's proposed prices and therefore, that the DHSC did not consider the comparison to Tablets to be appropriate, should have been clear to Flynn prior to the meeting on 6 November 2012. In any event, these points were also made clear by the DHSC to Flynn at the 6 November 2012 meeting, as [Flynn Director 2] accepted in his evidence before the CAT (see the Table above).

[1929] PHT00054, Note of a Meeting between the Department of Health and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16), and PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

[1932] PHT00088, Flynn File Note of 6 November 2012 of Meeting with Department of Health re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice information request of 8 May 2013 (CMA document reference 00145.585).

[1933] *Phenytoin*, [2018] CAT 11, paragraph 456.

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	are happy with the price of the tablets'; • told Flynn that 'it [the DHSC] did not consider comparisons with the table[t] relevant'; • told Flynn that whilst some price increase might be justified, 'the scale of it was the concern'; • pointed to the significant differences between the prescribed volumes of Capsules and Tablets and the related impact on total costs of the Parties' price increases for the NHS, commenting specifically that 'the much larger market share of the capsules made the total cost very difficult for them, more visible and hitting hard NHS pockets'; • told Flynn that the DHSC was 'struggling and trying to understand the justification' for the significant price increases; and	In fact, [Flynn Director 2] later accepted that the DHSC at this meeting was very unhappy with the price increases[1930] and was not happy with the use of Tablets as a benchmark for Capsules.[1931]	any cost-based justification. Again, this is not consistent with Flynn's claim that it engaged a 'constructive' 'cooperative' and 'transparent' manner in its engagement with DHSC. Flynn did not seek to contact the DHSC further after sending the letter in the row below. There is also no contemporaneous evidence showing Flynn approached Pfizer for a related price decrease. However, Flynn could, in any event, have implemented a unilateral price reduction and still made 'a material profit'.

[1930] PAD00031, [Flynn Director 2] Cross Examination, day 4, page 167, lines 13 to 14.
[1931] PAD00031, [Flynn Director 2] Cross Examination, day 4, page 158, lines 16 to 20.

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	• requested that Flynn provide a breakdown of all its costs to allow the DHSC to understand how Flynn's increased prices might be justified. At the meeting, Flynn also agreed to contact Pfizer to 'establish whether it might be possible for it to renegotiate downwards the cost of manufacturing, which would enable it to pass a lower price on to the NHS.'		
16 November 2012	Flynn wrote to the DHSC and informed it that Flynn was unable to provide information relating to its costs of supply because Pfizer had refused it permission to do so. Flynn also told the DHSC that, 'Flynn (and Pfizer) are fully aware of the Department and Stakeholder concerns in regard to the supply and pricing of this product within the UK and continue with best efforts, to pursue the strategies outlined in this letter. Flynn for its part has to ensure commercial viability and return is important, but we recognise also the legitimate concerns as to (NHS) cost and continue to		Flynn's reference to 'ensuring the commercial viability of the product' is disingenuous. It was making a significant margin and 'could have reduced its prices and still made a material profit.'[1935] Flynn also knew that Pfizer was making very significant returns on the prices it charged to Flynn. Flynn did not seek a related price reduction from Pfizer following its statements to the DHSC.[1936] Flynn's letter to the DHSC also demonstrates that there was no real belief that the DHSC could or would

[1935] *Phenytoin* [2018] CAT 11, paragraph 456.
[1936] See section 2.D.III of this Decision.

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	discuss supply pricing with Pfizer' (emphasis added).[1934]		intervene.[1937] It is also inconsistent with Flynn's claim that it conducted its discussions with the DHSC in a 'constructive', 'cooperative' and 'transparent' manner.
10 January 2013	The DHSC met with Pfizer and 'sought comments from the company in respect of the increased expenditure to the NHS' on Capsules.[1938]	The DHSC was not satisfied that the price increases for Capsules was appropriate or justified. Again, this should have led the Parties to question the appropriateness of using the Drug Tariff price of Tablets as a benchmark. Pfizer knew it was making very substantial margins and that its very high prices formed the base	The Parties maintained their prices. Pfizer later wrote to the DHSC on 26 February 2013 declining to comment on the increased price of Capsules. Pfizer told the DHSC that, '[s]ince Pfizer no longer holds the UK marketing authorisation it would not be appropriate for us to comment on Flynn Pharma's marketed product nor it's [sic] pricing strategy.'[1939]

[1934] PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DH)] re Flynn Pharma, page 6: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18).
[1937] Flynn submitted that at the November 2012 meeting with the DHSC, Flynn was led to believe that the DHSC had the power to intervene in the pricing of Capsules and at the very least thought that the DHSC might invite Flynn to join scheme M: PRC03492, Flynn's response to the SO, paragraph 2.19. The CMA does not accept this representation. Consistent with the evidence in the Table above, the CAT found that the DHSC was not exercising, or able to exercise, buyer power in a way that effectively constrained Flynn's conduct: *Phenytoin* [2018] CAT 11, paragraph 235. In relation to scheme M, the CAT also noted that [Flynn Director 2] confirmed that Flynn did not offer to join scheme M at any stage nor could the DHSC have forced Flynn to join it as it was a voluntary scheme: *Phenytoin* [2018] CAT 11, paragraph 231. Further, when responding to an email from [Flynn Non-executive Director 2] (a Flynn non-executive director) which had the subject line 'DH Arrangements for Scheme M' and following text discussing scheme M, [Flynn Director 2] agreed that '[t]he ultimate power of the Secretary of State to regulate prices seems quite useless here as they cannot force us to sell the product': PHT00393, Email of 1 November 2012 from [Flynn Director 2] to [Flynn Non-executive Director 2], copying [Flynn Director 1] (CMA document reference 00145.559).
[1938] PHT00057, Redacted Note of Meeting of 10 January 2013 between Pfizer and DH at Skipton House: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.19).
[1939] PHT00060, Email of 27 February 2013 between Department of Health Staff [[DHSC Employee 5], [DHSC Employee 1], [DHSC Employee 3] and [DHSC Employee 8] (DH)] forwarding on redacted email from Pfizer - re Outstanding actions from the Meeting with DH on 10 January 2013: Enclosed with Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.22).

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
		level against which Flynn added its own mark-up on top.	This is not consistent with the Parties approaching negotiations with the DHSC in 'good faith'.
September 2012 to February 2013	The Parties received a significant volume of complaints from CCGs and clinicians, highlighting the sheer scale of the price increases, the absence of any apparent justification and the detrimental impact on CCG budgets and patient care as set out further in Annex B. For example: • As set out above, the GMMMG stated that this was an 'abuse of a virtual monopoly position for purely commercial gains' and '[t]his change, if unchallenged will cause the NHS to pay an unnecessary and unwarranted, additional £41Million for no clinical benefit.' The letter also	This should have demonstrated that a significant number of stakeholders were unhappy about the scale of the Capsules price increases and questioned whether they were appropriate or justified. This again should have brought into question whether the prices the Parties had chosen were appropriate.	The Parties maintained their high prices. Flynn told CCGs in response that: • It 'would not have been possible' to maintain Capsules at the pre-September 2012 prices.[1943] However, as set out in this Decision, the Parties' price increases went well beyond any level that may have been necessary to ensure the drug's commercial viability.[1944] • Without its price increases to maintain Capsules' commercial viability, 'patients would have had to switch to other, more expensive formulations'.[1945] However, as noted by one clinician in response to Flynn: '[a]s you will be aware it

[1943] PHT00382, Email of 10 October 2012 from [Flynn Director 2] (Flynn) to [✂], Phenytoin (CMA document reference 00145.494); PHT00207, Email chain of 22 October 2012 between [✂] [✂] PCT and [Flynn Director 2] Flynn regarding the response from Flynn with regards the increase in price of Phenytoin Sodium: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.516); and PHT00119, Email chain of 8 October 2012 between [Flynn Director 2] Flynn and [✂] [✂] CCG discussing the change in price for Phenytoin Sodium Flynn Hard Capsules: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.455).
[1944] See section 6.B.II of this Decision.
[1945] PHT00207, Email chain of 22 October 2012 between [✂] [✂] PCT and [Flynn Director 2] Flynn regarding the response from Flynn with regards the increase in price of Phenytoin Sodium: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.516); PHT00382, Email of 10 October 2012 from [Flynn Director 2] (Flynn) to [✂], Phenytoin (CMA document reference 00145.494); and PHT00119, Email chain of 8 October 2012 between [Flynn Director 2] Flynn and [✂] [✂] CCG discussing the change in price for Phenytoin Sodium Flynn Hard Capsules: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.455).

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	noted that '[t]his increase in cost will provide no additional health benefit for patients' and '[t]he only pharmaceutical element which is changing is the product name'.[1940] • Both Pfizer and Flynn were also aware of a GP's letter which noted that 'there is no generic market for phenytoin' given the difficulties in switching patients.[1941] The letter stated that the price increases and '[t]he exploitation of this loophole has cost the NHS a serious amount of money when budgets are being reduced, has caused anxiety in people with epilepsy, and has no clinical justification whatsoever'.		is not advisable to switch patients to the tablet formulation from the capsules so the price comparison you have made is [dis]ingenuous and misleading.'[1946] • Flynn 'will look to reduce the cost of goods with a view to moderating the price'.[1947] However, the Parties did not reduce their prices and Flynn did not seek a reduction in Pfizer's supply price in response to these concerns, nor did it implement a unilateral reduction.[1948] Instead, the Parties maintained their high prices for over four years.

[1940] PHT00117, Letter of 10 October 2012 from NHS Greater Manchester to Flynn re Abuse of Monopoly - Epanutin (Phenytoin) Marketing and Distribution Changes: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.527).
[1941] PHT00210, Letters published in the British Medical Journal on 22 January 2013, (CMA document reference 00020.2). Flynn's response to this letter was also published in the British Medical Journal and Pfizer was aware of the letter: PHT00360, Pfizer, Epanutin Capsules UK Marketing Authorisation Divestment to Flynn Pharma: External Communications Activity To Date, 7 February 2013, (CMA document reference 00141.562).
[1946] PHT00207, Email chain of 22 October 2012 between [✂] [✂] PCT and [Flynn Director 2] Flynn regarding the response from Flynn with regards the increase in price of Phenytoin Sodium: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.516).
[1947] PHT00386, Email chain of 23 October 2012 between [Flynn Director 2] (Flynn) and [✂] ([✂] PCT), Re: Phenytoin Sodium Flynn Hard Capsules (CMA document reference 00145.522) and see also PHT00382, Email of 10 October 2012 from [Flynn Director 2] (Flynn) to [✂], Phenytoin (CMA document reference 00145.494).
[1948] See section 2.D.III of this Decision.

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
	• A GP's complaint to Flynn also noted that there 'is no justification for increasing the cost 25x. As you will be aware it is not advisable to switch patients to the tablet formulation from the capsule […] It is clear that Flynn have added no value to the product and have only rebranded an existing compound in order to "justify" the cost to the NHS.' [1942]		
May 2013	The CMA opened an investigation into the Parties' prices. The CMA informed the Parties that it had reasonable grounds to suspect that the Parties had infringed the Chapter II prohibition.	The commencement of a formal OFT investigation would have shown to the Parties that there were reasonable grounds to suspect that their high prices infringed the Act. This should have been a further signal that there were significant concerns about the level of prices they had imposed in the market.	The Parties maintained their high prices. It is notable the Parties did not attempt to contact the DHSC following the launch of the investigation. This may have been expected if they were acting in 'good faith' in their pricing strategy. For example, they could have engaged constructively with DHSC on price levels or (if they believed their prices were justified) asked for DHSC's assistance in managing the investigation. Neither Party approached the DHSC to discuss Capsules price levels during the course of the CMA's investigation.

[1942] PHT00207, Email chain of 22 October 2012 between [✂] ([✂] PCT) and [Flynn Director 2] (Flynn) regarding the response from Flynn with regards the increase in price of Phenytoin Sodium: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.516).

Date	Event	What the Parties should have understood (if applicable)	Parties' actions (with CMA observations)
6 August 2015	The CMA issues a Statement of Objections. Paragraph 1.58 stated: *1.58 The subject matter of this Statement was first brought to the CMA's attention by the Department of Health (the 'DH') in September 2012 and was subsequently raised with the CMA by a number of CCGs and individual complainants both prior to and during the course of the Investigation.*	This would have again shown to the Parties that the DHSC was not happy with the price level of Capsules such that it had raised the issue with the OFT. This should (once again) have brought into question whether the Parties' use of the Tablets price as a benchmark was appropriate.	The Parties did not engage with DHSC to discuss the matter further and continued to impose their high prices despite the fact it would have again been clear that the DHSC (and other stakeholders) had objected to their prices.

Annex D: Note provided by the CMA to the CAT

PHENYTOIN SODIUM TABLETS

STEPS TAKEN BY THE CMA

D.1 The CMA took the following primary steps during the administrative phase to investigate the market for phenytoin sodium tablets ('**Tablets**'):

D.1.1 At the start of the investigation, the CMA issued a number of general information requests which included reference either to phenytoin generally or to Tablets specifically. The responses to those general requests include responses from the following stakeholders. For those which are in not in the trial bundle, they are in the case file and were provided to the Appellants with the [2015] Statement of Objections:

(a) NHS England [I1/49].

(b) Dispensing Doctors Association (Document ref 00277.1).

(c) Royal College of Physicians [I1/62A].

(d) GP Society (Document ref 00261.1).

(e) Epilepsy Action (Document ref 00267 and attachment 00267.4).

D.1.2 The CMA issued a s26 Notice to Teva on 8 May 2013. The Response from Teva was on 4 June 2013 and can be found at [I1/62].

D.1.3 The CMA took the following steps in respect of the Department of Health ('DH'):

(a) The CMA issued a s26 Notice to the DH which included a section on Tablets, on 26 June 2013. The DH's response can be found at [I1/40] (see q12-15).

(b) The CMA spoke to the DH on 4 February 2013. A note of that call can be found at [J1/1] (see para 9).

(c) The CMA conducted a further meeting with the DH on 31 October 2013. Notes of that meeting are at [J1/7] and [J1/8] (see paras 53-56).

(d) The CMA conducted a further meeting with the DH on 23 February 2016. Notes of that meeting (including draft notes) are at [J2/41] (see paras 30-39) [J2/43], [J2/44], [J2/47].

(e) On 9 March 2016 the CMA issued a further s26 Notice to the DH, which asked for copies of all correspondence and/or notes of contacts between the DH and any manufacturer of Tablets. The DH's Response is at [I1/41]. There were two attachments to that response. The attachment relating to Tablets is not in the trial bundle but is in the case file under Document ref 01904.2 and was provided to the Appellants with the letter of facts.

D.1.4 Steps in relation to pharmacies:

(a) The CMA issued s26 Notices on 10th March 2016 to the ten largest pharmacy groups in the UK regarding their dispensing practices in relation to Tablets:

1. Alliance Boots [I1/20]
2. Asda [I1/5]
3. Celesio (Lloyds) [I1/32]
4. The Co-op [I1/35]
5. Day Lewis [I1/38] [I1/39]
6. Morrisons [I1/48]
7. Rowlands [I1/57]
8. Sainsbury's [I1/59]
9. Superdrug [I1/8]
10. Tesco [I1/61]

(b) The CMA also by way of s26 Notice on 10 March 2016 sought average selling prices over time of the tablets from Alliance to Boots and others customers, and from AAH to Lloyds and other customers. The Alliance data is in the trial bundle at [I1/22]. The AAH data is not in the trial bundle, but is on the case file and was provided to the parties with the letter of facts, document ref 01883A.3.

D.1.5 The CMA took the following steps in respect of the MHRA:

(a) The CMA issued a s26 Notice to the MHRA on 26 June 2013 regarding phenytoin (including Tablets). The MHRA's response can be found at [I1/42].

(b) The CMA issued a further s26 Notice to the MHRA on 18 February 2016 regarding phenytoin-based products, referring specifically to Tablets. The MHRA's response can be found at [I1/43] and included a list of all MA holders and PI licence holders which can be found at [I1/44].

(c) The CMA thereafter followed up with the MHRA in respect of Tablets by way of email on 4 March 2016 and received a response which is not in the trial bundles but was provided to the parties with the letter of facts, and is in the case file at document number 01799.

D.1.6 The CMA also sought IMS data on the volume of Tablets from IMS, and also was provided with such data by Pfizer in 2016 [J2/69]. This data was used to produce Figures 4.7 and 4.8 in the [2016 Infringement] Decision at p.240-241.

D.2 The following key documents and information (further to those provided by the Appellants) were also relevant to the CMA's analysis on Tablets:

D.2.1 NICE Guidance on AEDs, which refers to phenytoin generally [H1/14] and [H2/28].

D.2.2 MHRA Guidance on AEDs, which refers to phenytoin generally [H2/31] and [H2/32].

D.2.3 Drug Tariff Prices of Tablets, which were at relevant stages (and remain) publicly available for the preceding two years.

D.2.4 The Community Pharmacy Contractual Framework and the retained medicine margin, National Audit Office Report [H2/26].

D.2.5 2010 Scheme M [H2/25], further documents in respect of which can be found at fn 206 of the [2016 Infringement] Decision at p.73.

D.3 The CMA's primary analysis and findings in respect of the tablets market can be found in the [2016 Infringement] Decision as follows:[1949]

D.3.1 Executive summary: paras 1.5, 1.26, *1.47-1.49.

D.3.2 Phenytoin sodium: formulations at para 3.14; continuity of supply at paras 3.28-3.42 (see para 3.31 in particular); *introduction to Tablets at paras 3.46-3.49.

D.3.3 Drugs in scheme M: para 3.128-3.129; paras 3.139-3.147.

[1949] Key sections are highlighted and starred.

D.3.4 Evidence demonstrating the parties' analysis of the position in respect of tablets at relevant times: 3.211, 3.219, 3.220, 3.233, 3.254-3.261, 3.267, 3.272, 3.286, 3.294, 3.296, 3.326, 3.338, 3.339, 3.373, 3.383, 3.387, 3.391, *3.400-3.407.

D.3.5 *Tablets market (background): 3.444 – 3.492 (including introduction, the DH's complaint to the CMA regarding Tablets, Background on Tablets including pharmacy dispensing practice and the Drug Tariff Price for Tablets).

D.3.6 Market definition: paras 4.36, *4.152-4.179, 4.319-4.322.

D.3.7 *Economic value: paras 5.276, *5.284 – 5.312 (addressing the value placed on Tablets by the NHS).

D.3.8 *Unfair: paras 5.479, *5.496 -5.526.

D.3.9 Penalties: paras 7.22, 7.26, 7.37, 7.41-7.42.

Annex E: Representations on Abuse

Representations on Unfair when compared (Drug Tariff price)

E.1 Section 6.C of this Decision sets out the CMA's conclusion that the Drug Tariff price of Tablets was not a meaningful comparator.

E.2 This section of this Annex addresses representations regarding the use of Drug Tariff prices as a reference point.

E.3 Pfizer submitted that it is commonly understood that market participants use the Drug Tariff price as a reference point for pricing and that wholesalers will often seek to achieve a certain percentage discount against the prevailing Drug Tariff price.[1950] In Pfizer's view, unless the CMA disagrees with this premise, it must conclude that 'Pfizer was clearly entitled to benchmark the capsule price by reference to the tablet DT price (as in fact it did)'.[1951] Pfizer also refers to 'the legitimacy of benchmarking the capsule price on launch by reference to the DT'.[1952]

E.4 The CMA does not dispute that reimbursement prices may be used as a reference point in the industry for prices.[1953] However, this does not make all prices set by dominant undertakings by reference to prices included in the Drug Tariff immune from the application of the Chapter II prohibition.

E.5 First, whether a price is unfair for the purposes of the Chapter II prohibition will depend on all the circumstances relating to that price and any reference price adopted. The fact that other suppliers, or downstream customers, might consider reimbursement prices when setting and negotiating prices does not prevent the Parties' prices from being unfair. The Parties held dominant positions and were subject to a special responsibility to ensure that they did not abuse their market power by pricing unfairly high.[1954] This responsibility is not discharged by establishing that reimbursement prices are used as reference prices in other circumstances.

E.6 Second, as Pfizer has submitted, 'a number of categories in the DT are themselves constructed using a trailing average of market prices'.[1955] Given that the DHSC relies on competition to determine the supply prices of generic medicines, reimbursement prices will simply reflect the nature and extent of competition amongst suppliers (including where competition is ineffective). As described in

[1950] PRC03488, Pfizer's response to the SO, paragraph 11 and PRC03901, Pfizer's response to the Letter of Facts, paragraphs 6 to 8.
[1951] PRC03488, Pfizer's response to the SO, paragraph 11.
[1952] PRC03901, Pfizer's response to the Letter of Facts, paragraph 20.
[1953] This point was made a number of times in the CMA's 2016 Infringement Decision. See, for instance, paragraphs 3.59, 3.60 and 3.62(b) which refer to 'the industry's conventional discount of 12.5% off the list price', citing the OFT's 2007 Medicines distribution market study.
[1954] See section 4 of this Decision (Legal Framework).
[1955] PRC03488, Pfizer's response to the SO, paragraph 11.

section 6.C of this Decision, Teva remained the monopoly supplier of Tablets at the time of the meeting with the DHSC in October 2007 and for a number of years afterwards.

Representations on economic value

E.7 Section 7 of this Decision provides an overview of how the CMA has assessed the economic value of Capsules and the factors which have been taken into account.

E.8 This section of this Annex addresses certain representations made by the Parties which relate to the assessment of economic value. This covers representations regarding:

E.8.1 Flynn's activities and risks that it argues justify its prices;

E.8.2 portfolio pricing;

E.8.3 [Professor of Neurology]'s evidence;

E.8.4 the use of Capsules for new patients;

E.8.5 the relevance of the possible use of phenytoin in the treatment of rare epilepsies;

E.8.6 the relevance of cannabidiol, a treatment for epilepsy; and

E.8.7 the CMA's approach to the assessment of economic value and evidence the Parties argue the CMA should have gathered for the purposes of its assessment.

Representations regarding Flynn's activities for the purposes of justifying its prices

E.9 Flynn made various representations regarding its activities for the purposes of justifying its prices which are set out below along with the CMA's assessment.

E.10 The CMA considered Flynn's commercial activities and risks in supplying Capsules at the excessive and unfair limbs of this Decision. The CMA found that Flynn's commercial activities and risk were limited.[1956] Flynn's activities were limited to the ordering of stock, marketing and promotional activities, and regulatory compliance.[1957]

E.11 The CMA's view is consistent with CAT's conclusion in *Phenytoin* that:

> *Flynn took over an established product and undertook only very limited commercial activity. Admittedly it held levels of stock to keep the market*

[1956] See sections 5 (Excessive) and 6.B (Unfair in itself) of this Decision.
[1957] See section 2.D.I.d of this Decision.

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.[1958]

Risks and responsibilities of an MA holder

E.12 Flynn submitted that it bears all of the significant risks and responsibilities associated with an MA holder. Flynn identified in particular: its ultimate legal responsibilities in relation to manufacture; its responsibility to provide technical support and medical information; and its pharmacovigilance obligations.[1959]

E.13 Flynn submitted that its responsibilities as an MA holder result in Flynn's Products having greater economic value than Cost Plus.[1960] The CMA does not accept this representation for the reasons set out below.

E.14 As a general point, the returns a company can reasonably expect to earn are not based simply on the number of legal obligations the company is subject to, but the actual commercial risk incurred and the activities undertaken as a result of those obligations. Were this not the case, any dominant MA holder could be entitled to charge very high prices (relative to costs) irrespective of its activities and would be able to justify significant additional economic value just by virtue of being an MA holder. Flynn has not provided a proper explanation or quantification of the risks and activities it sought to identify. Instead, Flynn made a number of general submissions regarding its obligations and activities, and quoted from a High Court judgment relating to Flynn's enforcement of trade mark rights against parallel importers in the UK.[1961]

Legal responsibilities in relation to manufacture

E.15 Flynn did not undertake any manufacturing activities, all of which remained with Pfizer.[1962]

[1958] *Phenytoin* [2018] CAT 11, paragraph 346.
[1959] PRC03492, Flynn's response to the SO, paragraphs 1.3, 1.9 and 2.23; and PRC03631, Transcript of Flynn's Oral Hearing, page 15.
[1960] PRC03492, Flynn's response to the SO, paragraph 9.2.
[1961] *Flynn Pharma Ltd v DrugsRUs & Anor* [2015] EWHC 2759 (Ch) ('***DrugsRUs***'). The High Court in *DrugRUs* did not consider the commercial risk Flynn took on through its MA. Rather, the court considered a narrow matter related to intellectual property law, Flynn's legal obligations, and the legal distinction between Flynn and Pfizer, which the CMA does not contest.
[1962] See section 2.D.I.d of this Decision.

E.16 Flynn submitted that it had ultimate responsibility in relation to the manufacture of products that are compliant with the MA and standards of good manufacturing and distribution practices, including the specification of the products.[1963] However, Flynn did not articulate how its ultimate legal responsibilities led to commercial risk for Flynn, nor sought to provide quantification of any risks associated. For instance, Flynn has not provided any further explanation or practical examples of the financial impact of the risks it faces as an MA holder by reference to its portfolio of products and the MAs which it holds across its portfolio (and specifically for Capsules).

E.17 In fact, Pfizer manufactured the Capsules in the same manner as it had done before the Exclusive Supply Agreement. The High Court in *DrugsRUs* noted that in the Quality Agreement between Pfizer and Flynn:

> *The great majority of responsibilities relate to the manufacture of the product and are allocated to Pfizer Deutschland as the actual manufacturer of the product […] The responsibilities allocated solely to Flynn Pharma are those that relate to handling recalls of the product and to making submissions to the MHRA*.[1964]

E.18 As stated in the Quality Agreement, Pfizer was responsible, for example, for all laboratory controls, providing stability reports, performing retesting, and certifying that the product was manufactured and tested to meet specifications. The areas that Flynn was solely responsible for were fairly limited: ensuring that product labelling complied with applicable laws; preparing and submitting an annual product review; assuring a system is in place at the receiving site to manage products shipped in a non-released state; sending product complaints to Pfizer for investigation and responding to the customer; recalls; and regulatory submissions.[1965] Any other responsibilities were taken on by Pfizer Limited (and/or Pfizer Manufacturing Deutschland GmbH) or shared between the Parties.[1966]

E.19 During the Relevant Period, Flynn also delegated to a Pfizer individual the role of a qualified person who has knowledge of the MA and was responsible for releasing each batch for sale in accordance with the licence, although Flynn remained ultimately responsible for ensuring the quality of the product.[1967]

E.20 None of Flynn's ultimate legal responsibilities in relation to manufacture created any high commercial risk which might justify Flynn's Prices. Although Flynn may

[1963] PRC03492, Flynn's response to the SO, paragraph 3.5 and PRC03631, Transcript of Flynn's Oral Hearing, pages 15, 16, 20 to 23.
[1964] *DrugsRUs*, paragraph 62.
[1965] PHT00102, Quality Agreement for Supply of Phenytoin Capsules between Pfizer Limited, Pfizer Manufacturing Deutschland GmbH and Flynn Pharma Limited, Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.299).
[1966] PHT00102, Quality Agreement for Supply of Phenytoin Capsules between Pfizer Limited, Pfizer Manufacturing Deutschland GmbH and Flynn Pharma Limited, Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.299).
[1967] PRC03631, Transcript of Flynn's Oral Hearing, pages 16 to 17.

have been ultimately legally responsible for compliance with the MA, it gained significant protection through the indemnity it had with Pfizer. Under the Exclusive Supply Agreement between Pfizer and Flynn, Flynn benefited from a broad set of uncapped indemnities which would protect Flynn if it were found liable due to failures by Pfizer in the manufacturing process (which would otherwise be one of the key sources of legal and commercial risk for Flynn).[1968] The CAT in *Phenytoin* also found that this indemnity contributed to a situation whereby Flynn took 'very little business risk'.[1969] Additionally, Flynn (like most businesses) had insurance to cover liabilities it may face as a result of issues arising in connection with Capsules.[1970] The cost of Flynn's insurance premiums (the best proxy that the CMA has for the value of this risk/cover) was factored into Flynn's Cost Plus. Furthermore, Flynn merely assuming legal responsibilities that Pfizer previously assumed does not represent any additional benefit for customers or patients.

E.21 Flynn further submitted that the indemnity provided by Pfizer is a standard feature of a contract which outsources manufacturing to a third party.[1971] However, the CMA's conclusions on the relevance of the indemnity do not depend on this being non-standard. Regardless of whether this type of indemnity is standard in the industry, by outsourcing the manufacture of Capsules and benefitting from the indemnity, Flynn was insulated from financial risks stemming from its ultimate legal responsibilities.

Technical and scientific support, and medical information

E.22 Flynn submitted that it was required to provide technical and scientific support, and medical information about the products.[1972] Flynn also referred to its capabilities and resources to address the transfer of the MA and associated healthcare/patient communications.[1973] Flynn stated that the MHRA required Flynn at launch to implement a communications plan approved by the MHRA.[1974] These communications included a patient helpline.[1975] However, Flynn did not provide any quantification of any associated risks.

E.23 The CMA does not accept that these justify Flynn's Prices.

[1968] PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma (CMA document reference 00145.280).
[1969] *Phenytoin* [2018] CAT 11, paragraph 346.
[1970] PHT00101, Signed Exclusive Supply Agreement dated 17 April 2012 between Pfizer Limited and Flynn Pharma (CMA document reference 00145.280), clause 17.1.
[1971] PRC03492, Flynn's response to the SO, paragraph 2.26.
[1972] PRC03631, Transcript of Flynn's Oral Hearing, page 17.
[1973] PRC03492, Flynn's response to the SO, paragraph 2.23.
[1974] PRC03631, Transcript of Flynn's Oral Hearing page 17, and PRC03903, Flynn's response to the Letter of Facts, paragraph 6.2.
[1975] A helpline for patients established by Flynn received less than one call a day between 24 September 2012 and 31 August 2014. 385 calls were received between 24 September 2012 and 31 August 2014, with 65% of these being made by patients, relatives or carers: PHT00075, Flynn's response of 10 October 2014 to the CMA's s.26 Notice dated 15 September 2014 (CMA document reference 00872.1), question 6.

E.24 First, any costs associated with these activities have been accounted for in Flynn's Cost Plus. Flynn has not submitted that the CMA has failed to take account of any related costs incurred.

E.25 Second, in respect of healthcare communications to address the transfer of the MA, the risk of patient confusion and concern created by the arrangements between the Parties, and efforts to mitigate this, do not represent an additional benefit for patients or customers which might justify Flynn's Prices. These steps were required by the MHRA *as a result* of the arrangements entered into between the Parties.[1976] Flynn's submission is, therefore, that the DHSC should pay significantly higher prices due to steps taken by Flynn simply to maintain the status quo for patients.

Pharmacovigilance

E.26 Flynn submitted that it has obligations to keep doctors, pharmacists and patients updated with information and must notify third parties (including the MHRA) if new information comes to light regarding possible risks associated with the product.[1977] At least part of Flynn's pharmacovigilance work was outsourced to [✂], including handling the MA variation with the MHRA.[1978] Flynn did not provide any quantification of any risks associated with Flynn's activity. Flynn's staffing and other administrative costs associated with these activities are accounted for in Flynn's Cost Plus.[1979] Flynn has not submitted that the CMA has failed to take account of any related costs incurred. These activities do not create any abnormally high commercial risk of the sort that might justify Flynn's Prices.

Conclusion on MA holder responsibilities

E.27 The returns Flynn can be reasonably expected to earn are not determined by the number of nominal legal obligations it is subject to, but instead its actual commercial risk. Flynn's actual commercial risk as a result of it being an MA holder was relatively limited and not greater than the risks that any other MA holder supplying any other pharmaceutical product would face. Flynn has not provided

[1976] The MHRA had noted in a letter to Flynn that '[r]emoval of the Epanutin brand name could cause undue alarm and confusion for patients, prescribers and other healthcare professionals. There appears to have been no consideration of this and there is no indication as to how the change would be communicated to all necessary stakeholders': PHT00371, MHRA – Notification with grounds letter dated 26 June 2012 (CMA document reference 00145.309). Flynn explained that it had 'committed to introduce a helpline for patients who wish to be certain they are receiving the same product as [*Epanutin*]': PHT00104, Note of teleconference between MHRA, Flynn Pharma and [✂] held on 25 June 2012: MHRA's email of 20 August 2013 to the OFT providing its chronology of events concerning its interactions with Flynn with supporting documents (CMA document reference 00380.23). A Flynn briefing for helpline respondents noted that '[t]he objective in responding to enquiries is to provide complete reassurance that the change […] is in name only and that there are no other changes to the product, which is otherwise identical to [*Epanutin*]': PHT00375, Flynn document titled 'Question & Answer Briefing Framework for Helpline Respondents', undated (CMA document reference 00145.390).
[1977] PRC03631, Transcript of Flynn's Oral Hearing, pages 17 and 18.
[1978] See PHT00245, Email chain between [[MHRA Employee] and [MHRA Employee]] (MHRA) and others dated 15-21 June 2012 re Validated Type IB variation - Epanutin - Flynn Pharma - out of stock situation: MHRA's email of 20 August 2013 to the OFT providing its chronology of events concerning its interactions with Flynn with supporting documents (CMA document reference 00380.20).
[1979] See section 5 of this Decision (Excessive).

any further evidence or explanation to support the view that generic drugs typically command a premium due to the level of legal risk attached to being the MA holder. Instead, Flynn has simply made a series of general points without seeking to provide any specific examples or quantify the specific financial or commercial impacts of these risks.

E.28 Flynn's costs in relation to the activities above have been accounted for in the CMA's Cost Plus calculations. None of Flynn's submissions regarding its responsibilities as the MA holder indicate that it was subject to any significant risks which would justify its prices. Furthermore, none of the points above indicate any 'additional benefits not reflected in the costs of supply' or any 'particular enhanced value from the customer's perspective.'[1980]

E.29 Accordingly, the CMA concludes that none of Flynn's activities and responsibilities above justify its products having greater economic value than Cost Plus.

Ensuring continuity of supply

E.30 Flynn submitted that the CMA gives no credit for Flynn's role in ensuring the continuity of supply of Capsules.[1981] The CMA does not accept that this justifies Flynn's Prices.

E.31 First, regarding the risk of discontinuation, as set out in Annex F, the CMA finds that discontinuation during the Relevant Period was not likely.

E.32 Second, the possibility of discontinuation would not in any event justify the Parties' prices. The Parties' Cost Plus figures provide a commercially sustainable price level as these account for the Parties' costs plus a reasonable rate of return. In practice, there is a fundamental disconnect between a number of the submissions made by Flynn and the prices it imposed. Flynn has argued that the CMA's assessment:

E.32.1 'puts into question Flynn's entire business model which, in turn, threatens the supply of many drugs that require firms like Flynn to ensure their security of supply';[1982]

E.32.2 ignores the fact that some suppliers do exit the market because of falling supply prices and that, in these circumstances, Oxera has reported 'a decrease in the number of generic suppliers and an increase in price, as the market reaches a more stable long-run position';[1983] and

[1980] *Albion Water II* [2008] CAT 31, paragraphs 7 and 222.
[1981] PRC03492, Flynn's response to the SO, paragraphs 1.4, 2.23 and 9.3; PRC03631, Transcript of Flynn's Oral Hearing, pages 18 to 19; and PRC03903, Flynn's response to the Letter of Facts, paragraph 3.17.1.
[1982] PRC03903, Flynn's response to the Letter of Facts, paragraph 3.1.
[1983] PRC03903, Flynn's response to the Letter of Facts, paragraphs 3.2 and 3.3.

E.32.3 is 'not rational from a commercial perspective, as it cannot be right that prices have to stay low where there are declining volumes such that a product becomes unprofitable. There is a clear need for dealing with end-of-life products in a way that provides security of supply, which is a service that Flynn provides.'[1984]

E.33 None of these points addresses a central feature of the case, which is that the prices that the Parties imposed were significantly in excess of anything that might have been required to ensure the drug's ongoing commercial viability.[1985] Flynn makes these points in the abstract and has not articulated how they justify the specific price increases imposed in this case or the prices it actually charged for Capsules for over four years.

E.34 Further, the CMA does not consider avoided costs to the NHS if Capsules were discontinued to be a relevant factor.[1986] The CAT rejected Flynn's submissions that an assessment of economic value must take account of the avoided costs that the NHS would incur if Pfizer discontinued Capsules, which the CAT noted 'has the appearance at least of taking advantage of market power to extract more value in terms of prices'.[1987] Accordingly, the CMA does not consider this to be a relevant factor.

E.35 The CMA also does not accept Flynn's submissions:

E.35.1 that transferring the MA from Pfizer to Flynn was the only feasible way of securing ongoing supply of the product.[1988] First, as set out in section 6.B.VI.b of this Decision, each of the Parties recognised that Pfizer could have de-branded Capsules itself but for the reputational impact. Second, regardless of whether Flynn was involved in the supply of Capsules or not, the Parties could have ensured Capsules' commercial viability by charging prices that were not excessive and unfair;

E.35.2 that Flynn's actions, which it submitted prevented a stockout situation after January 2020 when NRIM experienced supply disruption, might justify its prices.[1989] Any additional costs incurred in respect of buffer stocks during the Relevant Period have been included in the CMA's Cost Plus calculation and given that Flynn's sales were virtually guaranteed, it did not incur any associated risks which might justify its prices (as set out further at paragraphs E.41 to E.42 below). Any actions Flynn took after January 2017 would have been taken following Flynn's price reductions to

[1984] PRC03903, Flynn's response to the Letter of Facts, paragraph 3.4.
[1985] See section 6.B.II of this Decision.
[1986] This responds to Flynn's representation at PRC03492, Flynn's response to the SO, paragraph 2.10.
[1987] *Phenytoin* [2018] CAT 11, paragraph 423.
[1988] PRC03903, Flynn's response to the Letter of Facts, paragraph 6.2.
[1989] PRC03492, Flynn's response to the SO, paragraphs 2.3; and PRC03631, Transcript of Flynn's Oral Hearing, pages 18 and 69.

comply with the Directions and so could not justify Flynn's Prices during the Relevant Period; and

E.35.3 that there was a 'new distribution system' which might justify Flynn's Prices.[1990] As set out in section 6.B.V.b of this Decision, the distribution of Capsules was largely the same as existed prior to September 2012 with the only relevant change being that Flynn placed orders with Pfizer.

Alternative source of API

E.36 Flynn submitted that the CMA has failed to give credit for the steps Flynn took to establish an alternative source of API.[1991]

E.37 Flynn explored without success the possibility of establishing an alternative source of API supply to Pfizer.[1992] However, Flynn did not invest any funds in pursuing an alternative source of API and no such alternative supply was established.[1993] Accordingly, there was simply no investment or improvement made by Flynn to take account of. In any event, the Exclusive Supply Agreement and Pfizer's position on alternative supplies prevented Flynn from taking alternative supplies of API that could be used to supply Capsules to Flynn.[1994]

E.38 Flynn also submitted that the CMA's Previous Investigation had a 'paralysing effect' on its efforts to establish an alternative source of API[1995] and that the CMA has failed to obtain information as to whether it is possible to change API suppliers or the site of secondary manufacture from a technical and regulatory perspective, information from the MHRA about whether there was a change to the source of API or site of manufacture for NRIM's product, or information from Accord-UK (as the current MA holder) about the work undertaken and costs to effect this change.[1996]

E.39 The relevant question for the CMA is whether, in practice, Flynn made improvements or incurred costs to establish an alternative source of API. Irrespective of whether Accord-UK changed its source of API or site of manufacture, or the impact of the CMA's investigation, it remains the case that Flynn made no investment or improvement to take account of. The CMA does not therefore consider it necessary to gather further evidence regarding the activities of other parties in this respect. In any event, as regards the impact of the CMA's

[1990] PRC03492, Flynn's response to the SO, paragraph 2.23.
[1991] PRC03492, Flynn's response to the SO, paragraphs 1.4, 2.23, 2.24 and 9.4, and see also PRC03631, Transcript of Flynn's Oral Hearing, pages 18 to 20, and 68 to 69 and PRC03903, Flynn's response to the Letter of Facts, paragraph 3.16.
[1992] See section 2.D.III.b.iii of this Decision.
[1993] PAD00031, [Flynn Director 2] Cross Examination, day 4, page 186, lines 19 to 22 and see also PRC03631, Transcript of Flynn's Oral Hearing, page 68.
[1994] See section 2.D.III.b.iii of this Decision.
[1995] PRC03492, Flynn's response to the SO, paragraphs 1.4, 2.12, 3.7 and 9.4 and PRC03631, Transcript of Flynn's Oral Hearing, page 20.
[1996] PRC03903, Flynn's response to the Letter of Facts, paragraphs 2.7.3 and 3.17.1.

Previous Investigation, in fact, Flynn continued to discuss an alternative source of API with Pfizer after the CMA launched its Previous Investigation.[1997]

Buffer stock

E.40 Flynn submitted that the CMA has failed to give credit for the steps Flynn took to build up buffer stocks.[1998]

E.41 Flynn purchased additional buffer stock.[1999] However, Flynn took very little business risk in doing so because, as the CAT also found,[2000] it was virtually guaranteed to sell these stocks. There was also little sign of Flynn's Prices being constrained by competition either from within the relevant market or from outside it.[2001] Flynn did in fact sell these stocks at a significant premium to the price it had paid to Pfizer. Further, contemporaneous documents illustrate that Flynn was not concerned by any associated risk at the time it entered into the agreements with Pfizer as it believed the arrangement would be profitable even if significant share of supply was lost.[2002] There was simply no risk incurred in purchasing these stocks which might justify Flynn's Prices.

E.42 Accordingly, the CMA's Cost Plus calculation sufficiently accounts for Flynn's buffer stocks. It includes buffer stock as part of the capital employed by Flynn in supplying Capsules (including a generous sensitivity analysis) and allows Flynn to earn a return on the capital employed in holding such stocks.[2003]

Flynn purchasing Capsules at an increased supply price

E.43 Flynn submitted that it purchased Capsules at an increased supply price which posed an additional risk to Flynn if demand had been substantially lower than foreseen and Flynn had not been able to sell its stock.[2004] Flynn also submitted that it accepted an increased supply price from Pfizer for 12 months as a result of unexpected delays in MHRA approval[2005] and that the price of the indemnity from Pfizer was taken into account in Pfizer's supply price.[2006]

E.44 The CMA does not accept that these representations justify Flynn's Prices.

[1997] PHT00169, A handwritten note of a meeting of 30 January 2014 between Pfizer and Flynn (CMA document reference 00519.4).
[1998] PRC03492, Flynn's response to the SO, paragraphs 1.4, 2.3, 2.23 and 2.24, and see also PRC03631, Transcript of Flynn's Oral Hearing, pages 18, 19, and 69.
[1999] PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 40.
[2000] *Phenytoin* [2018] CAT 11, paragraph
[2001] *Phenytoin* [2018] CAT 11, paragraph 251.
[2002] 'How much could PIs impact sales? Should be no impact on 25mg, 50mg and 300mg in the UK. These alone could be worth £15m. Even if 50% of sales of 100mg were lost to [parallel imports] the upside would still be >£20m': PHT00164, Presentation Slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.27), page 11.
[2003] See section 5 of this Decision (Excessive).
[2004] PRC03492, Flynn's response to the SO, paragraph 2.27.
[2005] PRC03492, Flynn's response to the SO, paragraph 2.17.
[2006] PRC03492, Flynn's response to the SO, paragraph 2.26.

E.45 First, as set out at paragraph E.41, Flynn was virtually guaranteed to sell its stocks at the prices it imposed. Accordingly, it is sufficient that the cost of Pfizer's supply prices have been accounted for in Flynn's Cost Plus and there is no risk incurred which might justify Flynn's Prices.

E.46 Second, whilst the CMA has taken full account of the supply prices that Flynn paid to Pfizer in Flynn's Cost Plus, Flynn's argument is that the NHS should compensate Flynn (above the level of its Cost Plus) for risks relating to the excessive supply price Flynn agreed to pay to Pfizer as part of the arrangements jointly designed between the Parties. The CMA does not accept the premise of this argument.

E.47 In respect of the 'delay' to entering into the agreement with Pfizer, Flynn's argument is that the NHS should compensate the Parties for not being able to impose significant price increases sooner than they did. This point has no foundation. This delay was also at least partly caused by Flynn's failure to give consideration to a de-branding communication plan which the MHRA deemed would result in undue alarm to patients, prescribers and other healthcare professionals.[2007]

Flynn's activities in relation to other products

E.48 Flynn submitted that the CMA has disregarded its role in maintaining the availability of medical products other than Capsules thereby providing value to the NHS, and its investment in medicines other than Capsules.[2008]

E.49 Irrespective of the merits of these activities, they cannot justify Flynn's prices for Capsules. Undertakings have a special responsibility for each product in respect of which they have a dominant position (in this case, Capsules). Flynn's activities in relation to other unrelated products are therefore not relevant in this context to the CMA's assessment of Capsules. The CAT has found that, when considering whether the pricing of a particular product is abusive, it is not appropriate to take into account the reasonableness or otherwise of the undertaking's profits on other markets unrelated to the market in which dominance exists.[2009] To do otherwise 'impermissibly directs attention away from the specific product market' which is being investigated.[2010] This applies equally to investment in other products as to profits on other products. Indeed, Flynn itself submitted that certain potential

[2007] PHT00104, Note of teleconference between MHRA, Flynn Pharma and [✂] held on 25 June 2012: MHRA's email of 20 August 2013 to the OFT providing its chronology of events concerning its interactions with Flynn with supporting documents (CMA document reference 00380.23); PHT00371, MHRA - Notification with grounds letter dated 26 June 2012 (CMA document reference 00145.309); and PHT00400 Email chain of June and July 2012 between [Flynn Director 2] (Flynn), [MHRA Employee] (MHRA) and [✂] ([✂]) and others, RE: Minutes of our telephone conference call 25/6/12 (CMA document reference 00145.728).
[2008] PRC03492, Flynn's response to the SO, paragraphs 1.3, 2.1, 2.2, 2.4, 2.11, 2.25 and 9.2; and PRC03631, Transcript of Flynn's Oral Hearing, pages 11 to 15.
[2009] *Napp* [2002] CAT 1, paragraph 413.
[2010] *Napp* [2002] CAT 1, paragraph 413. See also *United Brands*, EU:C:1978:22, paragraph 250.

activities by Flynn on other products are 'not relevant to whether Flynn's prices for phenytoin were excessive and unfair.'[2011]

E.50 In any event, evidence on the CMA's file also suggests that Flynn attempted to apply its strategy in relation to Capsules to other products where it was aware there was no generic competition.[2012] Flynn suggested arrangements to remove other drugs from the PPRS to bring about significant price increases. Whilst there is no evidence on the CMA's file that these examples went ahead, the fact that Flynn's [✂] emailed another pharmaceutical company indicates that these were serious proposals. An email from [Flynn Employee 1] of Flynn to a representative of [✂] on 27 September 2010 proposed in relation to three products that had been discussed:

> *- Add Flynn as a third party to your licenses* [sic].
>
> *- Launch a generic Flynn product for each of the brands.*
>
> *- Wind down stocks of the brands and quickly discontinue them, so that the only products available are the Flynn generics (if [✂] is sensitive about actually discontinuing the brand then it could be continued but with very little stock production)*
>
> *- The generic pricing will be 50 – 100% higher than the current ex-factory.*
>
> *- Flynn will pay [✂] a price somewhere between the old ex-factory price and the new selling price so that we both share the additional revenue from the new pricing.*[2013]

Portfolio pricing

E.51 Pfizer submitted that the CMA should consider portfolio pricing when seeking to determine the fairness of a price for a generic drug because pharmaceutical companies price their products based on a portfolio of products.[2014]

E.52 The CMA does not accept this representation for the reasons set out in paragraph E.49 above: Pfizer's pricing of other products in unrelated markets is not relevant to the CMA's assessment of Capsules in this context. Pfizer maintained both a very high market share and high prices for Capsules for many years. This was also the case in *Napp* where, in rejecting a portfolio pricing argument, the CAT noted:

> *We do not accept that, after such a long period, the price of [the product investigated] can credibly be defended on a 'portfolio pricing' theory. The*

[2011] PRC03903, Flynn's response to the Letter of Facts, paragraph 3.8.
[2012] PHT00374, Email of 27 September 2010 from [Flynn Employee 1] (Flynn) to [✂] ([✂]) (CMA document reference 00145.37).
[2013] PHT00374, Email of 27 September 2010 from [Flynn Employee 1] (Flynn) to [✂] ([✂]) (CMA document reference 00145.37).
[2014] PRC03488, Pfizer's response to the SO, paragraphs 34(f)(iii) and 37.

evidence we have is that, in the case of many pharmaceutical products, the expiry of a patent leads to competitive (often generic) market entry, with the consequence that the incumbent supplier either lowers prices, or loses market share, or both, perhaps quite rapidly […]. In the present case, however, Napp has maintained both the price of [the product investigated] and an exceptionally high market share for many years.[2015]

Representations regarding [Professor of Neurology]'s evidence

E.53 Pfizer submitted that evidence from [Professor of Neurology], as cited in this Decision, is not supported by a review of the underlying academic studies, has not been tested in court, and is relied on to challenge sworn expert evidence already accepted by the CAT.[2016] The CMA does not accept this representation for the reasons set out below.

E.54 The CAT remitted the issue of abuse and any consequential matters to the CMA for reconsideration in accordance with its judgment.[2017] The CAT's judgment noted that the CMA should have attempted a qualitative assessment of patient benefit.[2018] However, as Lord Justice Green in the Court of Appeal found, there is no suggestion in the CAT's *Phenytoin* judgment that it was directing that certain specific findings of the Tribunal were to be treated as *res judicata* ie to bind the CMA or the Parties.[2019] The CAT's *Phenytoin* judgment did not fetter 'the discretion of the CMA or the parties as to the evidence that they may adduce or consider upon the remittal.'[2020]

E.55 Accordingly, on Remittal, the CMA has assessed clinical evidence relevant to the remitted issues, including that given by [Pfizer Expert Witness 1] before the CAT, clinical guidance, and [Professor of Neurology]'s views gathered on Remittal. The CMA rejects the suggestion that it is appropriate to place no or limited weight on [Professor of Neurology]'s evidence. First, [Professor of Neurology] is a leading epilepsy clinician (see further section 1.D.III of this Decision) who provided his views to the CMA as an expert. Second, as set out in sections 2.A and 6.B.V.c of this Decision, [Professor of Neurology]'s evidence is supported in many instances by clinical guidance developed by a range of clinical experts, the evidence of [Pfizer Expert Witness 1], and also the Parties' internal documents.

Representations regarding the use of Capsules for new patients

E.56 Pfizer argued that the use of phenytoin sodium in circumstances where all other preferred treatment options have failed should be seen as justifying greater

[2015] *Napp* [2002] CAT 1, paragraph 417.
[2016] PRC03488, Pfizer's response to the SO, paragraph 24 and PRC03901, Pfizer's response to the Letter of Facts, paragraph 5(c).
[2017] *Phenytoin*, Ruling (Remittal and Permission to Appeal) [2018] CAT 12, paragraph 47.
[2018] *Phenytoin* [2018] CAT 11, paragraph 419.
[2019] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 180.
[2020] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 180.

economic value. Pfizer submitted that 'a small but significant number of new patients are stabilised on phenytoin sodium when all the other treatments have failed…[m]any or all of those patients cannot and will not shift to another drug because they do not produce the same benefits.'[2021] Pfizer did not seek to quantify the numbers of new patients in its representations.

E.57 The CMA does not accept that the patient benefit for these new patients justifies the Parties' high prices.

E.58 First, the fact that some new patients treated with phenytoin sodium might not be able to shift to another drug is a natural consequence of phenytoin sodium being the least preferred of all the treatment options due to Capsules' therapeutic limitations. The CMA does not agree that a generic drug should attract a premium for being a treatment of last resort and because, at this point, patients had no other option. As set out in this Decision, competition between suppliers of generic drugs will ordinarily drive prices down close to their costs of production, even where a drug continues to deliver significant benefits to patients.[2022] Further, customers having to pay high prices for a last-resort drug is also a situation where advantage is taken of market power to extract more value in terms of prices.[2023]

E.59 Second, in any event, even if the evidence could support some additional economic value above Cost Plus to reflect patient benefit for these new patients, the evidence suggests that any such additional value would be low and would not justify the Parties' prices.[2024] Moreover, it is common ground that the number of new patients treated with Capsules during the Relevant Period was small.[2025] Accordingly, even if significant additional economic value was justified above Cost Plus for these particular patients (which is not accepted), given the very small number of new patients, this would not be capable of justifying the high prices the Parties imposed for the vast majority of patients prescribed the drug.

Representations on the potential use of phenytoin to treat rare epilepsies

E.60 Pfizer submitted that, since the trial before the CAT following the CMA's 2016 Infringement Decision, there have been case studies showing that phenytoin sodium appears to work particularly well for rare epilepsies caused by genetic mutations (SCN8A encephalopathy and SCN2A-related disorders). Pfizer submitted that '[i]n those cases, it appears that phenytoin sodium might be the best

[2021] PRC03488, Pfizer's response to the SO, paragraph 24(b).
[2022] See section 6.B.V.a of this Decision.
[2023] *Phenytoin* [2018] CAT 11, paragraph 423.
[2024] See section 7 of this Decision (Economic value).
[2025] See section 2.A of this Decision and PRC03488, Pfizer's response to the SO, paragraph 24(b).

drug available and children with that mutation may be started on phenytoin sodium.'[2026]

E.61 The CMA does not accept that this representation justifies the Parties' prices.

E.62 First, the number of patients affected by these rare epilepsies in the UK is extremely small. SCN8A encephalopathy has had a total of around 400 cases reported *worldwide* according to a patient website.[2027] For SCN2A-related disorders, the article adduced by Pfizer indicates that this condition is extremely rare.[2028] Even if patients with these conditions were treated with Capsules during the Relevant Period, they would represent an extremely small proportion of the total number of patients taking Capsules in the UK – which numbered approximately 57,500 in total in 2012.[2029] Accordingly, even if significant additional economic value above Cost Plus was justified for any particular Capsules supplied to these patients (to reflect any particular benefit for these particular patients), this would not have a material impact on the CMA's conclusion that the Parties' prices were unfair.

E.63 Second, whilst these rare epilepsies can be particularly associated with serious symptoms including sudden death and phenytoin may be an important treatment option for patients with these rare epilepsies,[2030] treatment with phenytoin sodium may also cause severe side effects for these particular patients, especially cognitive impairment, which a study notes is particularly undesirable in patients with SCN8A encephalopathy who already suffer from a delay in cognitive development.[2031] Reflecting the balance of the drug's beneficial effects and side effects, two studies note that phenytoin sodium may be considered for patients with certain rare epilepsies caused by genetic mutations 'as a last-resort treatment'.[2032] For the reasons set out in paragraph E.58 above, the CMA does not agree that a generic drug should attract a premium for being a treatment of last resort.

[2026] PRC03488, Pfizer's response to the SO, paragraph 25 and PRC03489, Pfizer's response to the SO Exhibit. For SCN8A encephalopathy, a study adduced by Pfizer identifies phenytoin sodium as a 'possible treatment option': PRC03489, Pfizer's response to the SO Exhibit, page 1. For SCN2A-related disorders, a study adduced by Pfizer also identifies phenytoin as a possible treatment option: PRC03489, Pfizer's response to the SO Exhibit, page 23.
[2027] PAD00129, SCN8A Epilepsy Awareness Day (scn8aawarenessday.net). Pfizer submitted that the actual number of cases will be higher than the numbers reported in the scientific literature: PRC03901, Pfizer's response to the Letter of Facts, paragraph 33(b). However, Pfizer provided no evidence which indicated that the numbers of patients affected in the UK would be substantially higher. Regardless of whether there may be a very small number of additional unreported cases, the CMA considers that the evidence indicates that this condition is extremely rare.
[2028] PRC03489, Pfizer's response to the SO Exhibit, notes a calculated minimum frequency for children with an SCN2A mutation in Denmark of approximately 1 in 78,608 births, see page 13.
[2029] See section 2.A of this Decision.
[2030] PRC03901, Pfizer's response to the Letter of Facts, paragraph 33(b) and PAD00129, SCN8A Epilepsy Awareness Day (scn8aawarenessday.net).
[2031] 'Phenytoin as a last-resort treatment in SCN8A encephalopathy', Epilepsia Open, PAD00128.
[2032] 'Phenytoin as a last-resort treatment in SCN8A encephalopathy', Epilepsia Open, PAD00128 and Neurology International | Free Full-Text | 'SCN8A Encephalopathy: Case Report and Literature Review' | HTML (mdpi.com), PAD00130. Whilst these studies are based on single individual patients, the numbers of patients with these conditions are very small and these studies offer guidance to other clinicians based on this experience. The CMA therefore considers that this is relevant evidence.

E.64 In any event, Pfizer has not submitted that its Capsules were used to treat any of the very small number of patients with these rare epilepsies in the UK during the Relevant Period.[2033] Any potential use of the Parties' products after the Relevant Period cannot provide a retroactive justification for the Parties' prices during the Relevant Period.

Representations regarding cannabidiol

E.65 Pfizer submitted that cannabidiol ('**CBD**'), under the brand name Epidyolex, has recently been licensed to treat certain forms of epilepsy notwithstanding that it is considerably more expensive than Capsules were during the Relevant Period.[2034] Pfizer has not provided any additional information relating to, for example, the volumes of CBD prescribed to patients in the UK.

E.66 The CMA considers that Epidyolex is not an appropriate comparator for Capsules because it has market exclusivity for the indication approved by NICE due to its orphan designation.[2035]

E.67 Orphan designations may be provided to treatments for rare conditions where, amongst other things, there is no satisfactory existing method of diagnosis, prevention or treatment of the condition in Great Britain, or the medicine must be of significant benefit to those affected by the condition.[2036] As a result of this designation, Epidyolex has market exclusivity for the authorised indication until 23 September 2029.[2037] Epidyolex therefore gains a significant degree of protection from competition for the authorised therapeutic indication of the drug. As the CAT has found, comparisons should not be drawn with products the price of which may have been inflated by the exercise of substantial market power.[2038]

E.68 Pfizer further submitted that CBD is not a complex or novel product and it is one of the oldest forms of treatment for epilepsy, even if it has been licensed for treatment in the UK only recently.[2039] Whilst CBD may be an old product, as set out above, it

[2033] Two of the studies adduced by Pfizer were published after the end of the Relevant Period and the other was published on 9 August 2015 and so could not have affected the use of Capsules for much of the Relevant Period. See PRC03489, Pfizer's response to the SO Exhibit. Further, even if a small number of children with rare epilepsies were treated with phenytoin in the UK during the Relevant Period, an alternative formulation (such as an oral liquid) would be used rather than capsules (or tablets) before the age of around 12. Capsules are likely to be an appropriate formulation only once children become adolescents: PAD00127, Presentation - Age appropriate formulations - paediatric needs (europa.eu). See also PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 3 and PRC03901, Pfizer's response to the Letter of Facts, paragraph 33(a).
[2034] PRC03488, Pfizer's response to the SO and DPS, paragraph 34(f)(i-ii). In December 2019, CBD, under the brand name Epidyolex, was approved by NICE for use with clobazam as an option for treating seizures associated with Lennox-Gastaut syndrome. PAD00141, Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome (nice.org.uk).
[2035] Epidyolex's authorised orphan indication is for use as an adjunctive therapy of seizures associated with Lennox-Gastaut syndrome in conjunction with clobazam, for patients 2 years of age and older: PAD00136, Orphan Register, MHRA, 16 March 2022.
[2036] PAD00137, Orphan medicinal products guidance, MHRA, 22 February 2021.
[2037] PAD00136, Orphan Register, MHRA, 16 March 2022.
[2038] *Albion Water I* [2006] CAT 23, paragraph 757.
[2039] PRC03901, Pfizer's response to the Letter of Facts, paragraph 36.

has market exclusivity due to its orphan designation which the CMA considers makes it an inappropriate comparator.

E.69 In any event, the CMA considers that Epidyolex is not sufficiently similar to Capsules to allow for a meaningful comparison.[2040] First, [Professor of Neurology]'s evidence is that phenytoin sodium has a unique combination of clinical limitations which distinguishes it from other AEDs.[2041] Second, Epidyolex was recently identified by NICE as a second-line treatment for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam (in addition to also being recommended as a third-line treatment).[2042] This is a significant point of differentiation with Capsules which were only recommended as a third-line AED for a different seizure type and faced declining usage during the Relevant Period.

Representations on the evidence relevant to the CMA's assessment of economic value

E.70 The CMA has a margin of manoeuvre or discretion as to the method(s) it uses and the evidence it relies upon for the purposes of its investigation.[2043] The CMA also has a duty to evaluate the arguments and evidence advanced by the undertakings fairly and impartially. However, the CMA does not have a duty actively to carry out additional investigative steps in every case or proactively seek additional evidence regarding comparators put forward.[2044] The CMA has a margin of manoeuvre or discretion as to how it performs its duty of fair evaluation, including as to the depth and intensity of the inquiry.[2045] There is also an important evidential burden upon an undertaking being investigated and the extent of the duty on the CMA will be affected by the quality of the evidence adduced by the defendant undertakings.[2046]

E.71 The CMA has considered carefully what evidence to gather for the purposes of assessing the relationship between the Parties' prices and the economic value of Capsules during the Relevant Period. The CMA has gathered and evaluated a significant body of evidence for this purpose. This includes, for example, evidence relating to: (i) the Parties' costs, commercial activities and risks; (ii) any innovation or improvement to the product or its supply; (iii) the nature of the product and its use as a treatment for patients, including additional evidence obtained on Remittal from a clinical expert, Professor of Neurology]; (iv) the views of the DHSC and end customers around the time of the price increases and since; and (v) potential comparator products adduced by the Parties.

[2040] *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 41, 44-46 and 51. See also *Phenytoin* [2018] CAT 11, paragraphs 392 and 444.
[2041] See section 6.B.V.c of this decision.
[2042] PAD00141, Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome (nice.org.uk).
[2043] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 112.
[2044] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 113, 116 and 270 to 273.
[2045] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 113, 116 and 270.
[2046] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 114.

E.72 Both Pfizer and Flynn submitted that the CMA should have gathered more evidence and sought more views from third parties for the purposes of assessing the economic value of their products, including:

E.72.1 information and views from the DHSC on how it assesses the prices or value of medicines;

E.72.2 information relating to how NICE applies its quality adjusted life year ('**QALY**') analysis;

E.72.3 information regarding the indirect costs of epilepsy and the wider benefits of treatment to patients, carers, family members, society and the NHS;

E.72.4 further information relating to other AEDs; and

E.72.5 information regarding MA holder responsibilities.

E.73 The CMA considers, in light of the principles above at paragraph E.70 and having gathered evidence including that summarised above, that it has an evidential basis that is sufficient and appropriate to reach its conclusions on economic value as set out in section 7 of this Decision. The CMA has addressed additional related representations by the Parties below.

Additional evidence from the DHSC on how it assesses prices and value

E.74 Flynn submitted that the CMA should have sought information from the DHSC on how it assesses the prices or value of medicines. Flynn submits that, as the monopsony purchaser of medicines supplied to the NHS, the DHSC is uniquely positioned to provide information regarding what would be a reasonable rate of return because it carries out this exercise on a regular basis for branded medicines.[2047] Flynn has also submitted that the DHSC contains several bodies such as NICE whose responsibility it is to assess the prices or value of medicines and to ensure value for money for the NHS.[2048]

E.75 Flynn further submitted that the CMA should have requested information from the DHSC relating to its new powers following the Costs Act.[2049]

E.76 Pfizer submitted that the CMA should have gathered systematic evidence on how prices are set by the DHSC and in the wider pharmaceutical sector.[2050]

E.77 The CMA considers that these representations have no merit.

[2047] PRC03492, Flynn's response to the SO, paragraphs 1.14, 6.3 and 6.17.
[2048] PRC03903, Flynn's response to the Letter of Facts, paragraph 6.11.
[2049] PRC03492, Flynn's response to the SO, paragraphs 1.14 and 6.29 to 6.31. See section 2.C of this Decision for an explanation of these powers.
[2050] PRC03488, Pfizer's response to the SO and DPS, paragraph 34(c).

E.78 First, the CMA has specifically asked the DHSC for its views on the pricing and value of Capsules and Tablets, as well as for relevant internal documents on these points.[2051] The CMA does not consider that it is necessary or appropriate to seek further evidence from the DHSC regarding generic drugs *generally*, when it has obtained a significant body of evidence from the DHSC relating to the *specific* product under investigation and the main comparator put forward by the Parties.

E.79 The Parties' submissions overlook or simply refuse to accept existing evidence already gathered from the DHSC regarding its views on the Parties' prices. By way of example:

E.79.1 The CMA has gathered a significant body of evidence which shows that the DHSC did not, in practice, consider that the Parties' prices for Capsules were reasonable.[2052]

E.79.2 Whilst the DHSC's view was that it is not well positioned to determine fair prices for generic medicines[2053] (see further paragraph E.81.3 below), the DHSC told the CMA that it would expect the price of a generic, off patent, product to approach marginal cost.[2054]

E.79.3 The evidence gathered by the CMA demonstrates that the DHSC sought to understand whether the Parties' prices could be justified by reference to their costs of supply, but that Flynn and Pfizer refused to provide this information.[2055] The DHSC took the same approach with Teva when considering its PPRS application for Tablets in 2013.[2056] Flynn has submitted that the DHSC's efforts to obtain Flynn's costs 'clearly shows that the DHSC assesses the fair and reasonable price of drugs regularly'.[2057] In practice, the evidence shows the DHSC simply trying to understand the possible justification for such a large price increase.[2058] Requesting costs information in these circumstances is hardly surprising and is not evidence of the DHSC regularly determining reasonable prices for individual generic drugs.

[2051] See for example: PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1); PRC00279, the DHSC's response of 30 July 2020 to the CMA's s.26 Notice of 7 July 2020, questions 5 to 13; and PHT00040, the Department of Health's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.2), questions 1 to 6, 10 to 13, and 15.
[2052] See Annex C and section 2.D of this Decision.
[2053] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraphs 8, 9, 11 and 42.
[2054] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraph 13.
[2055] See section 6.B.IV.c of this Decision.
[2056] See section 6.C of this Decision.
[2057] PRC03492, Flynn's response to the SO, paragraph 6.13.
[2058] Flynn's note of its meeting with the DHSC in November 2012 reflects that the DHSC 'was struggling and trying to understand the justification', had 'no justification of value for money' from Flynn and was told by Flynn that it 'might have to discontinue the product if [it] didn't make sufficient margin': PHT00088, Flynn File Note of 6 November 2012 of Meeting with DHSC re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).

E.80 The CMA also does not consider that it is necessary or appropriate to gather further information relating to NICE's assessment of the cost-effectiveness of new drugs used to treat different conditions. The CMA has considered directly NICE's clinical assessment of phenytoin amongst other AEDs in NICE's guidance on epilepsy that was published in 2012 and in force during the Relevant Period.[2059] NICE categorised phenytoin sodium as a third line AED. The CMA's assessment of the therapeutic benefits of Capsules takes full account of NICE's therapeutic assessment of phenytoin sodium amongst other AEDs in this guidance.[2060] Furthermore, for the reasons set out below at paragraphs E.87 to E.89, the CMA does not consider that a QALY assessment is an appropriate way of assessing the economic value of Capsules for the purposes of the Chapter II prohibition.

E.81 Second, the concept of abuse requires an objective assessment of a dominant undertaking's conduct, not the subjective views of the DHSC.[2061] In any event, the CMA does not agree that the DHSC is 'uniquely positioned' to provide more evidence (in addition to the body of evidence already gathered) regarding what would be a reasonable rate of return for Capsules for the purposes of the Chapter II test for unfair pricing. The following support the CMA's view:

E.81.1 During the Relevant Period, the DHSC's policy was to rely on competition to determine the prices of generic medicines.[2062] The DHSC stated that it had never investigated whether the price of a generic medicine was fair or reasonable.[2063]

E.81.2 The DHSC had never used scheme M to intervene regarding generic drug prices or consider the issue of what might amount to a 'reasonable price' for these purposes.[2064]

E.81.3 Consistent with this, the DHSC submitted its view that the CMA is better placed to determine what might be a fair and reasonable price for the purposes of the CMA's assessment.[2065] The DHSC told the CMA that it did not have the capability to determine this specific question for generic drugs on an individual product level.[2066] It was also clear from the DHSC's

[2059] The NICE Guidance published in 2012 recommended eight AEDs to be used as first-line treatments or adjunctive treatments in various different combinations for focal seizure types. Phenytoin was instead recognised as a third-line treatment. See PHT00092, NICE Clinical Guidance CG137 (2012), *The Epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care* (CMA document reference PD13).
[2060] See in particular section 6.B.V.c of this Decision.
[2061] C-307/18 *Generics (UK) Ltd and others v Competition and Markets Authority*, EU:C:2020:52, paragraph 169.
[2062] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraph 13. See also section 2.C of this Decision.
[2063] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraph 11.
[2064] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraph 42.
[2065] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraphs 9, 12 and 42.
[2066] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraphs 9 and 42. Flynn has submitted that the DHSC's view in this respect is 'highly questionable'. The CMA's view is that the DHSC's view is consistent with the factors set out in this paragraph.

engagement with Flynn in 2012 that the DHSC was 'struggling […] to understand the justification' for the Parties' price increases and had 'no justification of value for money'.[2067]

E.81.4 Although Flynn has referred to the PPRS as an example of the DHSC considering drug pricing, as explained by the DHSC, while it does consider price increases for brands, 'it did not have the capability to analyse and evaluate cost data on an *individual* product level in such detail as would be required to determine whether the price charged is fair or reasonable. In particular, the method the PPRS used to evaluate a price increase application was to look at the sales and costs of a company's overall portfolio of licensed branded medicines rather than product level.'[2068]

E.82 Flynn also referred to the fact that the DHSC has been granted new powers under the Costs Act to allow it to limit the prices of generic drugs even where the manufacturer or supplier is in a voluntary scheme. Flynn suggested that the fact the DHSC considered that such powers were necessary suggests that the DHSC is, in fact, capable of determining reasonable prices for medicines. Flynn submitted that it is 'significant that it appears the DHSC has not yet exercised these new powers' and suggests that the CMA should have sought information from the DHSC on these powers.[2069]

E.83 The CMA does not accept that it is necessary or appropriate to seek this evidence from the DHSC. These powers were not available during the Relevant Period. As at the date of this Decision, the DHSC is still considering how these powers will be used and has not even consulted on how they will be used.[2070] As described above, the CMA has already gathered a significant body of evidence to inform its conclusions on the Parties' prices. Further, the DHSC's new powers do not alter the fact that the DHSC continues to generally rely on competition to determine the price of generics.

Evidence regarding QALY analysis

E.84 Pfizer submitted that QALY analysis can provide insight into the economic value of Capsules.[2071]

E.85 Pfizer provided no analysis applying a QALY approach to this case or any evidence that would suggest a QALY analysis is appropriate. Instead, Pfizer

[2067] PHT00054, Note of a Meeting between the DHSC and Flynn at Skipton House on 6 November 2012 (DH14): Enclosed with the DHSC's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.16), and see also PHT00088, Flynn File Note of 6 November 2012 of Meeting with DHSC re Phenytoin: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.585).
[2068] PHT00082, Note of the CMA's meeting of 23 February 2016 with the DHSC (CMA document reference 02032.1), paragraph 9.
[2069] PRC03492, Flynn's response to the SO, paragraph 6.29 to 6.31.
[2070] See section 2.C of this Decision.
[2071] PRC03488, Pfizer's response to the SO and DPS, paragraph 34(f)(ii) and PRC03901, Pfizer's response to the Letter of Facts, paragraph 35.

referred to NICE's assessment of CBD (which is considered by the CMA above at paragraphs E.65 to E.69) and reserved its right to adduce evidence of a QALY analysis should the CMA issue a decision in this case.[2072]

E.86 The CMA does not accept that a QALY analysis is an appropriate way to assess the economic value of Capsules for the purposes of the Chapter II prohibition.

E.87 First, a QALY analysis is generally used to assess new treatments and concerns whether a drug should for the first time be made available for prescribing on the NHS, not whether a drug should continue to be available. In the UK, QALY is a measure which is used to support NICE's health technology appraisals. These appraisals are intended to cover 'new significant drugs and indications'.[2073] Accordingly, it is inherently not an appropriate way to assess the economic value of a product which was first synthesised in 1908 and had been long in the third stage of the drug life cycle.[2074]

E.88 Pfizer's expert [Pfizer Expert Witness 2] recognised in evidence provided to the CAT that a QALY analysis is not appropriate or useful in this case. [Pfizer Expert Witness 2] explained in response to a question from the Tribunal in relation to whether a QALY analysis was relevant to existing drugs:

> *…it is something that we did try to explore at one point but I'm afraid we could not find -- we could not find a good way of harnessing that approach to apply to the case here. It is something that my colleagues and I did some thinking about but we essentially drew a blank […] We certainly thought about it but we could not come up with an answer that was going to be robust and good enough to be useful.*[2075]

E.89 Second, a QALY analysis does not assess what is the economic value or a fair price for a particular technology or medicine. The concept that underlies QALY assessments is that of the opportunity cost of existing health interventions that could be displaced by the introduction of new technologies.[2076] NICE assesses whether, based principally on clinical outcome measures, a new technology is a cost-effective use of NHS resources compared with existing technologies.[2077] However, this takes the proposed costs of the new technology as a given rather

[2072] PRC03488, Pfizer's response to the SO and DPS, paragraph 34(f)(ii) and PRC03901, Pfizer's response to the Letter of Facts, paragraph 35(b)(2).
[2073] PAD00133, NICE, Guide to the processes of technology appraisal, April 2018, paragraph 2.1.1. See also paragraph 2.1.5 which states that the University of Newcastle 'notifies NICE about key new and emerging healthcare technologies that might be suitable for NICE technology appraisal' (emphasis added). See further PAD00134, NICE, Carrying NICE over the threshold, 19 February 2015 and PRC03901, Pfizer's response to the Letter of Facts, paragraph 35(b).
[2074] See sections 2.A and 2.B of this Decision.
[2075] PAD00030, Cross-examination of [✂], Day 5, pages 215 to 216.
[2076] PAD00135, NICE Guide to the methods of technology appraisal 2013, April 2013, paragraphs 6.2.21 and 6.3.1 to 6.3.5.
[2077] PAD00135, NICE Guide to the methods of technology appraisal 2013, April 2013, in particular paragraphs 1.3.2, 2.2.8, 3.1.2, 6.2.21 and 6.3.1 to 6.3.5.

than assessing what would be a fair price for the new technology for the purposes of the Chapter II prohibition.

Assessment of benefits to wider society

E.90 Pfizer submitted that the indirect consequences of epilepsy far exceed the direct health costs and QALY analysis may consider such indirect costs and the benefits of treatment to patients, carers, family members, society and the NHS.[2078]

E.91 Pfizer made similar submissions before the CAT regarding the indirect costs of epilepsy based on the evidence of [Pfizer Expert Witness 1].[2079] However, the CAT in its judgment did not find that the CMA should have undertaken a qualitative assessment of the indirect costs of epilepsy or wider benefits to society. Instead, the CAT noted that the CMA should have attempted a qualitative assessment of patient benefit.[2080] This is what the CMA has done in this case in section 6.B.V.c of this Decision.

E.92 As set out above, the CMA considers that a QALY analysis is not an appropriate way to assess the economic value of Capsules for the purposes of the Chapter II prohibition. The CMA also does not accept that the suggestion that it is appropriate for the purposes of its assessment to assess the economic value of Capsules by reference to indirect costs or other than by reference to customers or users of the products.

E.93 First, in respect of the NHS, the CAT found that it was not appropriate to take account of the avoided costs to the NHS of patients switching to Tablets if Capsules were discontinued.[2081] In rejecting Flynn's submissions on this point, the CAT noted that Flynn's 'argument has the appearance at least of taking advantage of market power to extract more value in terms of prices'.[2082] For the same reasons, the CMA does not consider it appropriate to consider avoided costs from the continued supply of Capsules.

E.94 Second, the Court of Appeal noted that economic value is what 'users and customers value and will reasonably pay for'.[2083] In this case, the end customers are CCGs and the NHS, and the users (or consumers) are patients. In respect of the NHS, contemporaneous evidence from the DHSC, clinicians and CCGs (ie those end customers responsible for paying for the products) clearly shows that they were strongly opposed to the prices imposed by the Parties and did not consider that the scale of the Parties' prices was justified.[2084] In respect of patients,

[2078] PRC03488, Pfizer's response to the SO and DPS, paragraphs 24(c), 34(f)(ii) and 39(d).
[2079] PRE00627, Pfizer's written closing submissions in *Pfizer v CMA* Case No 1276/1/12/17, paragraph 27(a).
[2080] *Phenytoin* [2018] CAT 11, paragraph 419.
[2081] *Phenytoin* [2018] CAT 11, paragraph 423.
[2082] *Phenytoin* [2018] CAT 11, paragraph 423.
[2083] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 171 (emphasis added).
[2084] See Annexes B and C of this Decision.

the CMA has undertaken a qualitative assessment of patient benefit in section 6.B.V.c of this Decision and finds that this does not justify the Parties' prices.

Other AEDs

E.95 In the SO, the CMA provisionally concluded that the Parties' prices were unfair in themselves. In response to the SO, Pfizer and Flynn were free to raise arguments and provide evidence relating to other AEDs which they contend show that their prices were fair.[2085] The Court of Appeal specifically clarified that Flynn was not prevented from adducing new evidence relating to comparators as part of its engagement with the CMA during a remittal.[2086]

E.96 Neither Pfizer nor Flynn put forward any additional evidence in response to the SO relating to the other AEDs already considered by the CMA in the SO or raised by the Parties pre-SO.

E.97 Flynn submitted that the CMA failed to address seven other AEDs which it put forward during its oral hearing on 27 January 2016, during the CMA's Previous Investigation.[2087] In that oral hearing, Flynn identified in a single slide the following seven AEDs and set out the 30 days treatment costs for these: eslicarbazepine acetate, pregabalin, zonisamide, lacosamide, vigabatrin, tiagabine and phenobarbital. These seven AEDs are additional to those other AEDs which the CMA evaluated as part of section 6.C.III of this Decision.

E.98 Taking into account the principles expressed by the Court of Appeal regarding the CMA's duty of fair evaluation set out at paragraph E.70 above, the CMA has not considered it necessary or appropriate to gather additional information relating to these seven AEDs for the reasons set out below.

E.99 First, the evidence does not indicate that these seven AEDs provide a meaningful comparator as they are not sufficiently similar[2088] to Capsules:

E.99.1 The CAT's view in *Phenytoin* was that other AEDs 'differ widely as products even though they address the same medical condition'.[2089] [Professor of Neurology]'s view is that phenytoin sodium exhibits a combination of unique therapeutic disadvantages.[2090] For example, phenytoin sodium is an enzyme-inducing drug. These are recognised as having a number of potential serious side effects which are not a concern

[2085] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 269.
[2086] In considering Flynn's Fifth Ground of Appeal, the Court of Appeal found that 'the Flynn Grounds of Appeal was to ensure that there was no fetter created by findings in the Judgment, upon either the ability of Flynn to adduce new evidence or the CMA to re-investigate'. See further *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 174 to 182.
[2087] See PRC03492, Flynn's response to the SO, paragraphs 8.46 and 8.47.
[2088] *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 41, 44-46 and 51. See also *Phenytoin* [2018] CAT 11, paragraphs 392 and 444.
[2089] *Phenytoin* [2018] CAT 11, paragraph 398.
[2090] PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 6.

for non-enzyme-inducing AEDs.[2091] Phenytoin sodium is the worst enzyme-inducing AED currently in use in terms of side effects.[2092] This distinguishes phenytoin sodium's product characteristics from these seven AEDs.

E.99.2 In his first expert report submitted before the CAT, [Pfizer Expert Witness 2] considered the comparability of 19 AEDs, which included these seven AEDs.[2093] [Pfizer Expert Witness 2] subsequently submitted a second report focusing on what Pfizer described as '[Pfizer Expert Witness 2]'s five, most reliable, comparator AED products'.[2094] None of the seven AEDs referred to in Flynn's slide were considered by [Pfizer Expert Witness 2] in his second report.

E.100 Second, the evidence and arguments put forward by Flynn in relation to these seven AEDs are very limited:

E.100.1 Flynn's analysis was limited to a single slide at its oral hearing on 27 January 2016 that showed the 30-day treatment cost with maintenance and maximum (recommended) doses of these seven AEDs at a static point in time for each of these drugs. In Flynn's response to the CMA's SO on Remittal, Flynn simply referred back to this slide and provided a reference to a paragraph from its response to the CMA's Statement of Objections in its Previous Investigation in which Flynn referred to other third-line treatments in the context of an argument related to market definition.[2095]

E.100.2 Flynn has not put forward any additional evidence or argument or sought to explain why these seven AEDs are, in fact, more reliable than those considered by [Pfizer Expert Witness 2] in his second report.[2096] Flynn has also not sought to make any connection between the these seven AEDs and the framework of assessment for other AEDs clearly set out in the CMA's SO.[2097] On Remittal, the CMA has gathered a significant body of evidence (including from industry and clinical guidance, as well as publicly available pricing and volumes data) for the purposes of assessing the five

[2091] PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 18 and PRE00151, First Expert Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 5.5. As it is a strong enzyme inducer, patients taking phenytoin sodium are likely to have a lower life expectancy: PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 11 and PAD00041, EMC, *Phenytoin Sodium Flynn Hard Capsules 100mg SmPC*.
[2092] PRC01817, Note of call with [Professor of Neurology] on 10 December 2020, paragraph 18.
[2093] PRE00720, The First Expert Report of [Pfizer Expert Witness 2], 7 February 2017.
[2094] PRE00627, Pfizer's Written Closing Submission, paragraph 125 and PRE00154, the Second Expert Report of [Pfizer Expert Witness 2], 19 May 2017. The CMA has assessed these five 'most reliable' AEDs in section 6.C of this Decision (Unfair when compared).
[2095] See paragraph 4.10 of PHT00231, Flynn's response to the SO in the Previous Investigation. The reference provided by Flynn in its Response to the CMA's SO on Remittal incorrectly refers to paragraph 4.16 (PRC03492, Flynn's response to the SO, paragraph 8.47).
[2096] The CMA considers that Flynn had access to publicly available data on reimbursement prices and dispensed volumes over time, as well as the applicable prescribing and dispensing guidance, which would enable Flynn to provide more information on why it considered the seven other AEDs were meaningful comparators.
[2097] As also identified in section 6.C of this Decision (Unfair when compared).

AEDs put forward by Pfizer. It was open to Flynn to seek to provide additional analysis for these seven AEDs but it chose not to do so.

E.101 Pfizer has also submitted that, in relation to the AEDs considered by [Pfizer Expert Witness 2], '[t]he CAT Judgment also noted that it would be essential to gather information in relation to the cost of those AEDs before their usefulness as comparators could be adequately assessed (CAT Judgment [389]). The CMA has not obtained any such costs data; Pfizer obviously cannot do so. Rather, the CMA has confined itself to a high-level assessment of five of the other AEDs identified in [Pfizer Expert Witness 2]'s evidence before the CAT, by reference to prices and volumes only.'[2098]

E.102 The CMA does not consider that it is necessary or appropriate to gather costs data in relation to these other AEDs for the reasons set out below.

E.103 First, the passage from the CAT's judgment on which Pfizer relies to argue that the CMA was under an absolute duty to seek costs information for other AEDs is set out below:

> *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.*[2099]

E.104 Plainly, the CAT did not say that it would be 'essential' to seek costs information relating to other AEDs.

E.105 Second, the CMA has fairly and impartially evaluated afresh the evidence put forward by [Pfizer Expert Witness 2] relating to the five 'most reliable' AEDs in his report.[2100] The CMA has also proactively gathered further information not included in [Pfizer Expert Witness 2]'s original report, including data relating to the sales volumes of the generic and branded versions of these drugs over the period 2004 to 2021. Based on this evidence, the CMA considers that it has a sufficient evidence base to conclude that these five other AEDs do not indicate that the Parties' prices for Capsules were fair.[2101] The CMA's evaluation (and related evidence gathering) goes well beyond what Pfizer describes as a 'high-level

[2098] PRC03488, Pfizer's response to the SO, paragraph 22.
[2099] CAT Judgment, paragraph 398.
[2100] See section 6.C of this Decision (Unfair when compared).
[2101] See section 6.C of this Decision (Unfair when compared).

assessment'.[2102] The CMA has explained the outcome of its evaluation, as well as the reasons for its conclusions in section 6.C.III of this Decision.

Information regarding MA holder responsibilities

E.106 Flynn submitted that the CMA should have obtained information from third parties regarding the roles and responsibilities of being an MA holder.[2103]

E.107 The CMA has considered carefully Flynn's submissions regarding its risks and responsibilities as an MA holder above. The CMA has set out its views on Flynn's submissions and provided reasons above for why it does not consider that these justify Flynn's Prices.

E.108 Having fairly and impartially evaluated these submissions, the CMA considers that further investigation would not be necessary or appropriate. This is particularly so where the CMA's assessment is concerned with the supply of Capsules by Flynn. The risks and responsibilities associated specifically with Flynn's supply of Capsules are directly relevant to the CMA's investigation – rather than the risks faced by other companies as MA holders for other drugs. Flynn has not provided a proper explanation or quantification of the risks it has identified specific to its supply of Capsules or how these might justify its prices. Instead, Flynn made a number of general submissions regarding its responsibilities and risks.

[2102] PRC03488, Pfizer's response to the SO, paragraph 22.
[2103] PRC03903, Flynn's response to the Letter of Facts, paragraphs 1.5, 2.7.4 and 3.17.2.

Annex F: Risk of discontinuation

F.1 Flynn submitted that, absent the arrangements with Flynn, discontinuation of Capsules was likely.[2104]

F.2 The CMA considers that any risk of discontinuation does not justify the Parties' prices. Even if Pfizer's pre-September 2012 prices were loss-making,[2105] the Parties could have ensured Capsules' commercial viability by increasing prices to a level that was not excessive and unfair. The CMA has found that the Parties' prices went well beyond any level that may have been necessary to ensure the drug's commercial viability.[2106]

F.3 In any event, the CMA does not accept that discontinuation of Capsules during the Relevant Period was likely for the reasons set out below.

F.4 First, the Parties have not provided any contemporaneous evidence which would suggest that Pfizer was likely to discontinue its Capsules in the absence of the arrangements with Flynn. During the Previous Investigation, Pfizer stated that there was 'considerable pressure' on management to discontinue the products or find an alternative solution to mitigate financial losses associated with the supply of the products.[2107] However, the CMA asked Pfizer to provide any contemporaneous documents which evidence this and Pfizer did not provide any such documents.[2108]

F.5 Second, the CMA finds that concerns regarding patient safety, as well as Pfizer's supply of Capsules across the European Union (all of which were manufactured at the same site as the Capsules Pfizer supplied in the UK), meant that discontinuation in the UK in the Relevant Period was not likely.

F.6 In respect of patient safety, Pfizer told the OFT in 2013 that:

> *[g]iven the potentially severe health and economic consequences associated with epileptic seizures, discontinuation of supply was considered not to be appropriate for the benefit of patients.*[2109]

F.7 Before the CAT, [Pfizer Director 1] later said he was convinced that, absent the deal with Flynn, Capsules would have been discontinued by 2017.[2110] However, he

[2104] PRC03492, Flynn's response to the SO, paragraphs 1.33 and 2.10.
[2105] PRC03901, Pfizer's response to the Letter of Facts, paragraph 27(a).
[2106] See section 6.B.II of this Decision.
[2107] PHT00172, Pfizer's response of 20 November 2015 to the CMA's 2015 Statement of Objections (CMA document reference 01622.2), paragraph 77.
[2108] PHT00077, Pfizer's response of 11 March 2016 to the CMA's s.26 Notice of 11 February 2016 (CMA document reference 01836.2), question 9.
[2109] PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.1), page 8. Pfizer also told the OFT that Pfizer's goals when considering its options were first, to ensure the identical product remained available to patients and second, to ensure commercial viability of the product; and 'divestment was the only option to meet both goals': PHT00171, Draft note of meeting of 20 August 2013 between the OFT and Pfizer (CMA document reference 00412.1), paragraphs 11 and 12.
[2110] PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 52.

also referred to patient safety concerns weighing against discontinuation. [Pfizer Director 1] was clear that a 'key driver […] was that we believed that Phenytoin capsules must continue to be available to patients across the full dose range' and he thought that Capsules should not be discontinued.[2111]

F.8 Having heard [Pfizer Director 1]'s evidence, the CAT did not find that discontinuation was a likely outcome. The CAT found that:

> *Quite apart from whether there was a real risk of discontinuation by Pfizer (and the most [Pfizer Director 1] could say about this was that he believed Epanutin would have been discontinued at some point in the future, whilst accepting that any decision to discontinue would not be taken lightly because of the patient concerns)…*[2112]

F.9 In addition to patient safety concerns themselves, the related 'pharmaco-political issues' for Pfizer stemming from the likely opposition of the DHSC to discontinuation also weigh against the likelihood of discontinuation. In Flynn's summary of its proposals to Pfizer it noted that discontinuation of Capsules in the UK would 'inevitably cause considerable pharmaco-political issues' for Pfizer.[2113] The importance Pfizer attached to avoiding 'pharmaco-political issues' (or reputational damage) in relation to Capsules is demonstrated by the fact that a key reason for bringing Flynn into the supply chain was to provide reputational protection from the criticism that would arise from the impact on the NHS resulting from the Parties' price increases.[2114]

F.10 Pfizer's supply of the products throughout Europe also weighs against the likelihood of discontinuation in the UK. Unless Pfizer discontinued *Epanutin* across Europe, it would continue to incur manufacturing costs for the products even if it ceased supply in the UK. As noted below at paragraph F.16, whilst Pfizer discontinued Capsules in Belgium and Luxembourg, the monthly sales volumes in those countries were much smaller than the UK. In fact, Pfizer's monthly sales volumes of Capsules were much higher in the UK than in any other European country excluding Spain.[2115] In respect of Spain, Pfizer had an obligation not to withdraw the supply of Capsules without the consent of the Spanish regulatory authorities, and Pfizer acknowledged the authorities would in practice not approve

[2111] PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 26, lines 10 to 15, and see also page 52, line 17 to page 53, line 13.
[2112] *Phenytoin* [2018] CAT 11, paragraph 423 (emphasis added).
[2113] PHT00193, Document entitled 'Epanutin Proposal, October 2010': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.65), page 1. In a Flynn internal document, Flynn also noted that '[Pfizer] could not increase the price under the terms of the PPRS scheme. Nor, in the interest of patients, could they discontinue it without significant damage to Pfizer's reputation': PHT00401, Flynn, *Phenytoin (2)* (CMA document reference 00145.827). Flynn later said in relation to this document that 'either the product needed to remain on the market, or Pfizer would incur reputational damage': PRC03903, Flynn's response to the Letter of Facts, paragraph 3.16.
[2114] See section 6.B.VI.b of this Decision.
[2115] See Table 2.11 of this Decision.

an application to withdraw Capsules.[2116] Pfizer could not, therefore, discontinue Capsules across Europe.

F.11 Flynn made several related submissions regarding the risk of discontinuation which are set out below along with the CMA's assessment.

F.12 First, Flynn cited a note of a meeting between Pfizer and Flynn on 8 March 2010 which stated that 'Pfizer currently makes a loss on selling Epanutin at its current prices'.[2117] This document does not suggest that Pfizer would have been likely to discontinue the drug. In fact, the document states that 'Pfizer is interested in partnerships with other companies for the older products such as Epanutin'. Indeed, Flynn itself submitted that it 'is common for some generic products to be sold at low prices, and in some cases at negative margins'.[2118]

F.13 Second, Flynn submitted that Pfizer discontinued another AED, Zarontin, in similar circumstances to Capsules in 2005.[2119] [Flynn Director 2] stated in his evidence before the CAT that, like phenytoin sodium, Zarontin was a mature product experiencing declining sales volumes.[2120] However, the circumstances of Zarontin were different to Capsules and its discontinuation does not suggest that it was likely that Capsules would have been discontinued.

F.14 Pfizer stated around the time of Zarontin's discontinuation that the reason for its discontinuation was difficulty in meeting quality standards.[2121] [Pfizer Director 1] later noted before the CAT that Zarontin had 'significant quality problems' prior to the decision to discontinue which meant the situation for Zarontin was different to that for Capsules.[2122]

F.15 Further, the evidence indicates that the patient safety concerns that would arise with the discontinuation of Capsules do not arise with Zarontin. The generic name for Zarontin is ethosuximide. It was later identified as a category 3 AED in the MHRA Guidance. These are drugs where it is usually unnecessary to ensure that patients are maintained on a specific manufacturer's product.[2123] In addition, whilst the capsule form of Zarontin was discontinued, the liquid form continued to be available.[2124] Conversely, in respect of Capsules and according to the evidence of [Pfizer Expert Witness 1], the features of Capsules that lead to concerns regarding

[2116] PHT00077, Pfizer's response of 11 March 2016 to the CMA's s.26 Notice of 11 February 2016 (CMA document reference 01836.2), questions 2(b) and 4.
[2117] PRC03492, Flynn's response to the SO, paragraph 2.6, PRC03903, Flynn's response to the Letter of Facts, paragraph 3.12, and PHT00188, Flynn Note of Meeting with Pfizer on 8 March 2010: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.8).
[2118] PRC03492, Flynn's response to the SO, paragraph 3.2.4.
[2119] PRC03492, Flynn's response to the SO, paragraph 2.7, PRC03631, Flynn's Oral Hearing Transcript, 6 December 2021, page 19 and PRC03903, Flynn's response to the Letter of Facts, paragraph 3.12.
[2120] PRE00152, First Witness Statement of [Flynn Director 2], 6 February 2017, paragraph 14.
[2121] PAD00046, Epilepsy Action, Epilepsy charity warns of 'confusion over discontinuation of medicine'.
[2122] PAD00031, [Pfizer Director 1] Cross Examination, day 4, page 85, lines 4 to 16.
[2123] PHT00093, MHRA Guidance (2013) *Antiepileptics: Changing products* (CMA document reference PD19).
[2124] PAD00046, Epilepsy Action, Epilepsy charity warns of 'confusion over discontinuation of medicine'.

switching patients between different manufacturers' phenytoin products had long been known prior to the MHRA Guidance.[2125]

F.16 Third, Flynn cited the discontinuation by Pfizer of Capsules in Belgium and Luxembourg.[2126] However, average monthly sales volumes in Belgium and Luxembourg post-September 2012 were much smaller than in the UK, at 405 compared to 19,439.[2127] The potential impact on patients of discontinuation was therefore significantly greater in the UK than in Belgium and Luxembourg. Indeed, Flynn itself suggested that products with low volumes were at greater risk of discontinuation.[2128]

F.17 Flynn further submitted that it is Flynn's perception of the risk of discontinuation that matters.[2129] The CMA rejects this suggestion: the risk of discontinuation is a factual assessment and not a matter of Flynn's perception. In any event, there is evidence that Flynn understood that Pfizer saw discontinuation as 'ethically and morally unjustifiable'.[2130]

[2125] PRE00151, First Report of [Pfizer Expert Witness 1], 7 February 2017, paragraph 6.3.
[2126] PRC03492, Flynn's response to the SO, paragraphs 2.8 and 2.9.
[2127] See Table 2.11 of this Decision.
[2128] PRC03492, Flynn's response to the SO, paragraph 3.2.5.
[2129] PRC03492, Flynn's response to the SO, paragraph 2.8 and see also PRC03903, Flynn's response to the Letter of Facts, paragraph 3.11.
[2130] PHT00204, Internal Flynn email of 26 June 2012 [from [Flynn Employee] to [Flynn Director 1], [Flynn Director 2] and [Flynn Director 4] re the need to provide MHRA with a more detailed rationale for genericisation: Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.306). See also PHT00397, Draft note of meeting between the OFT and Flynn held on 16 July 2013 (CMA document reference 00313.1), paragraph 7 and PHT00056, Department of Health email chain [between [DHSC Employee 5], [DHSC Employee 3] and [DHSC Employee] (DHSC)] re Flynn Pharma: Enclosed with DHSC's response of 15 August 2013 to the OFT's s.26 Notice of 26 June 2013 (CMA document reference 00367.18). See further PHT00164, Presentation Slides entitled 'A Specialty Care Pharma Company': Flynn's response of 21 June 2013 to the OFT's s.27 Notice of 8 May 2013 (CMA document reference 00145.27), which states that 'phenytoin capsules must continue to be available to patients'.

Annex G: Pfizer Limited's common costs

Introduction

G.1 This annex sets out the details of the common costs that Pfizer considered were in part related to Capsules[2131] and the CMA's allocation of these costs.

G.2 The CMA's approach has been to allocate common costs to Phenytoin products as a whole, using sales volumes by pack.

G.3 Where only the totals of a cost category (for example employment costs) are known and the CMA considers that a cost may reasonably be allocated to the production of Capsules in respect of that cost category,[2132] then the total cost attributable to that cost category has been treated as relevant (ie used as the starting point for the allocation calculation), with the exception of certain specific costs, as explained below.

Pfizer Group structure and reorganisation prior to 1 December 2013

G.4 Common costs are incurred both at a company level and at a business unit level.

G.5 Pfizer's UK operations are conducted by Pfizer Limited. As part of these operations it incurs costs which are in part related to the sale of Capsules in the UK.

G.6 Before 1 December 2013, Pfizer was organised into seven operational business units: Primary Care, Specialty Care, Oncology, Established Products, Emerging Markets, Animal Health and Consumer Healthcare. Capsules were included within the Established Products Business Unit ('EPBU'). The EPBU managed 'human prescription pharmaceutical products that had lost patent protection or marketing exclusivity in certain countries and/or regions'.[2133] EPBU common costs were only shared across the products within that business unit.

G.7 With effect from 1 December 2013 Pfizer was reorganised into three units which resulted in Capsules moving into the Global Established Business Unit. It is important to note, however, that Pfizer's activities were not materially altered by the restructuring.

G.8 Table G.1 and Table G.2 below show the common costs ('SI&A expenses') and the CMA allocations using sales volumes split by EPBU and Pfizer Limited for the financial years ending 30 November 2012 and 2013.

[2131] PHT00140, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.4).
[2132] Given the lack of detail provided by the Parties, the CMA has only had limited scope to assess to what extent the Parties' costs have been efficiently incurred.
[2133] PAD00029, Appendix A of Pfizer's 2012 Financial Report.

Table G.1: Pfizer, common costs (Sales, Informational and Administrative) allocation to Capsules for the year ended 30 November 2012

£	Business unit costs		Company costs		Total costs
	EPBU costs	Allocated to Phenytoin*	Pfizer Ltd costs	Allocated to Phenytoin**	
Advertising and promotion	451,484	17,052	-	-	17,052
Field selling	607,361	22,939	-	-	22,939
Other marketing expense	3,426,000	172,529	-	-	172,529
Distribution expense	8,484,935	-	-	-	-
Total marketing & distribution	12,969,780	212,520	-	-	212,520
Bad debt	33,573	1,691	(510,490)	-11,019	- 9,328
Depreciation	-	-	7,160,017	154,551	154,551
Employee costs	-	-	43,887,492	947,322	947,322
IT expenses	-	-	3,825,257	82,569	82,569
Management recharge expenses	480,408	24,193	517,979	11,181	35,373
Management recharge income	-	-	(90)	-2	-2
Marketing	-	-	67,143,861	1,086,987	1,086,987
Office expenses	-	-	5,556,610	119,941	119,941
Other	504,746	25,418	7,006,896	151,246	176,664
Professional/consulting services	(2,557)	(129)	31,325,639	676,172	676,043
Restructuring	-	-	29,546,820	637,775	637,775
General and administrative	1,016,168	51,173	195,459,990	3,856,722	3,907,895
Total SI&A expenses	13,985,948	263,693	195,459,990	3,856,722	4,120,415

Source: PHT00140, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.4), Annex B.
Note: The CMA has allocated nine months of advertising and marketing costs in 2012 to Capsules, reflecting that Pfizer divested the *Epanutin* brand in September 2012.
* The total number of phenytoin sodium packs sold (1,026,499) make up 5.0% of the EPBU's total sales volume (20,383,788).
** The total number of phenytoin sodium packs sold make up 2.2% of Pfizer Limited's total sales volume (47,555,593).

Table G.2: Pfizer, common costs (Sales, Informational and Administrative) allocation to Capsules for the year ended 30 November 2013

£	Business unit costs		Company costs		Total costs
	EPBU costs	Allocated to Phenytoin*	Pfizer Ltd costs	Allocated to Phenytoin**	
Advertising and promotion	-	-	-	-	-
Field selling	-	-	-	-	-
Other marketing expense	5,346,999	165,923	-	-	165,923
Distribution expense	10,310,456	-	-	-	-
Total marketing & distribution	15,657,455	165,923	-	-	165,923
Bad debt	-	-	-	-	-
Depreciation	-	-	5,563,628	133,666	133,666
Employee costs	-	-	41,149,433	988,611	988,611
IT expenses	-	-	3,591,280	86,280	86,280
Management recharge expenses	390,662	12,123	687,901	16,527	28,649
Management recharge income	-	-	-48,061	-1,155	-1,155
Marketing	-	-	47,007,299	-	-
Office expenses	-	-	4,957,919	119,114	119,114
Other	-	-	10,279,574	246,966	246,966
Professional/consulting services	-	-	18,925,112	454,674	454,674
Restructuring	-	-	10,194,220	244,915	244,915
General and administrative	390,662	12,123	142,308,305	2,289,598	2,301,720
Total SI&A expenses	16,048,117	178,046	142,308,305	2,289,598	2,467,643

Source: PHT00140, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.4), Annex B.
* Costs were allocated on the ratio of the total number of phenytoin sodium capsule packs sold (1,065,015) divided by EPBU's total sales volume (34,320,949).
** Costs were allocated on the ratio of the total number of phenytoin sodium capsule packs sold (1,065,015) divided by Pfizer Limited's total sales volume (44,329,624).

EPBU common costs

G.9 The treatment of each cost category is described below:

G.9.1 Advertising and Promotion and Field Selling - costs represent 'spending aimed at specific customers and channels which may have served to benefit the product pre-divestment but not afterwards'.[2134] Pre-divestment refers to the date on which Pfizer divested its MAs to Flynn: on 24 September 2012. None of these costs were attributable to Pfizer's costs in respect of Capsules after 24 September 2012. That being so, the CMA has not allocated any common costs to Capsules after that date.

G.9.2 Other Marketing expenses - Pfizer stated that these costs relate to 'services such as demand management and customer service and an element of management resources. These are not product specific, but rather underlie its operations across all of its products'.[2135] Pfizer argued that a proportion of these costs should be allocated to Capsules on the

[2134] PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question 6.
[2135] PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question 6.

basis that they continued to be incurred after the Agreements.[2136] The CMA considered that it is more likely than not that at least some of the costs within this category were common to Capsules and therefore should be allocated. The information provided by Pfizer did not enable the CMA to determine whether all of the costs within this category should be apportioned to Capsules. In accordance with the CMA's approach as set out in paragraph D.3, these other marketing expenses were allocated on a sales volume basis for both years with no adjustment for the period after Flynn acquired the MAs.

G.9.3 Distribution expenses - Pfizer provided the CMA with specific distribution expense figures for supplying Flynn with Capsules. The actual distribution costs provided by Pfizer have been included within direct costs and therefore the CMA has excluded the EPBU distribution charge from its common cost allocation exercise.

G.9.4 Management recharges, bad debts, 'other' expenses and professional and consulting fees - The information provided by Pfizer did not enable the CMA to ascertain accurately their nature and as such whether they related in part to Capsules. These costs were however apportioned to Capsules in line with the approach summarised in paragraph G.3 above.

Pfizer Limited common costs

G.10 The information provided by Pfizer in response to the CMA's requests for information did not enable the CMA to carry out a detailed analysis of Pfizer Limited's common costs. Pfizer did not propose the inclusion or exclusion of any of Pfizer Limited's costs or make submissions on which allocation method would be most appropriate to use.

G.11 Only one adjustment was made to Pfizer Limited's common costs before apportioning them to Capsules: the exclusion of general marketing expenses.

G.12 Pfizer submitted to the CMA that it had wrongly excluded general marketing expenses from its cost analysis. It was said this category of cost included expenses such as business analytics and stock option costs, which applied across multiple product lines and were therefore applicable to Capsules.[2137] The CMA rejects the inclusion of these costs for two reasons. The first reason is that the CMA has calculated costs in respect of Capsules after Pfizer divested its MAs to Flynn, ie since 24 September 2012. It follows that general marketing expenses should be excluded from the CMA's common cost allocation exercise.

[2136] PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question 4.
[2137] PHT00172, Pfizer's response of 20 November 2015 to the CMA's 2015 Statement of Objections (CMA document reference 01622.2), paragraphs 326 and 327.

G.13 The second reason is that the CMA's approach to allocating common costs to Capsules has been generous to Pfizer.[2138] This means that any risk of understating any indirect costs attributable to Capsules from this category will be offset by the likely overstating of other cost categories.[2139] Finally, Pfizer has only provided very high level data with regards to its common costs, despite the CMA requesting more detailed information,[2140] and Pfizer has made no attempt in any of its submissions to quantify the size of these costs or the impact that their inclusion would have on the CMA's assessment. As such, the CMA considers that the exclusion of general marketing expenses from this analysis is both appropriate and unlikely to affect materially the estimation of Pfizer's costs.

[2138] As demonstrated by the common cost to direct cost ratios outlined in Annex I.
[2139] For instance, the CMA has allocated employee costs of £1.0 million per year to phenytoin sodium capsules. The CMA considers that this is a very generous allocation, particularly as it is a product with only one customer submitting its product orders once every fortnight.
[2140] PHT00131, Annex 1 of Pfizer's response of 16 April 2014 to the OFT's s.26 Notice of 5 March 2014 (CMA document reference 00519.2); PHT00133, Pfizer's draft response of 4 July 2014 to the CMA's draft s.26 Notice of 6 June 2014 (CMA document reference 00664.1); and PHT00134, Annex A of Pfizer's response of 7 October 2014 to the CMA's s.26 Notice of 16 September 2014 (CMA document reference 00863.1).

Annex H: Flynn's common costs

H.1 This annex sets out the details of Flynn Pharma Limited's common costs that Flynn considered were in part related to Capsules,[2141] and the CMA's allocation of these costs.

H.2 The CMA's approach has been to allocate common costs to Capsules as a whole, using sales volumes by pack.

H.3 Where only the totals of a cost category (for example employment costs) are known and the CMA considers that a cost may reasonably be allocated to the production of Capsules in respect of that cost category,[2142] then the total cost attributable to that cost category has been treated as relevant (ie used as the starting point for the allocation calculation), with the exception of certain specific costs, as explained below.

H.4 Table H.1 shows the common costs (administrative expenses) and the amounts the CMA allocated to Capsules between 1 April 2012[2143] and 23 January 2017.[2144] The total value of common costs allocated to Capsules is £3.4m (£3,440,487) over this period. The figures for each financial year were provided to the CMA split into the categories shown in the table.

[2141] PHT00153, Spreadsheet re Breakdown of Flynn Pharma's Administrative Expenses (Q4): Annex 4 of Flynn's response of 19 June 2014 to the CMA's s.26 Notice of 6 June 2014 (CMA document reference 00607.2); PHT00112, Final Trial Balances at 31 January 2015: Annex 2.2 of Flynn's response of 17 August 2016 to the CMA's s.26 Notice dated 2 August 2016 (CMA document reference 02115.4); and PHT00242, Draft Trial Balance at 31 March 2016: Annex 2.3 of Flynn's response of 17 August 2016 to the CMA's s.26 Notice dated 2 August 2016 (CMA document reference 02115.5).

[2142] Given the lack of detail provided by the Parties, the CMA has only had limited scope to assess to what extent the Parties' costs have been efficiently incurred.

[2143] Common costs from 24 September 2012 to 31 March 2013 were accounted for within the financial year ending 31 March 2013. Although this covers a period over which Flynn was not selling phenytoin sodium capsules in the UK, the CMA has allocated these common costs using sales volumes across Flynn's entire portfolio of products for the 12 months from 1 April 2012. Therefore, the CMA considers that this methodology leads to a reasonable proxy for the level of common costs that would have been attributed to phenytoin sodium capsules if data between 24 September 2012 up to 31 March 2013 were available.

[2144] Financial data for the period to 23 January 2017 was provided to the CMA during its Remittal, split into varying categories of administrative costs. The CMA collected data to 23 January 2017 as the Relevant Period proposed in the SO began on 24 September 2012 and ended on 23 January 2017 (being the date from which the Parties were directed to revise their selling prices): see SO, paragraphs 6.8–6.11. In this Decision, the CMA has now reverted to a Relevant Period ending on 7 December 2016 (the date on which the 2016 Infringement Decision was issued). Although data to 23 January 2017 covers a period after the Relevant Period (ie the period between 7 December 2016 and 23 January 2017), the CMA has allocated common costs using sales volumes across Flynn's portfolio for the period to 23 January 2017. Therefore, the CMA considers that this methodology leads to a reasonable proxy for the level of common costs that would have been attributed to phenytoin sodium capsules if data for the period to 7 December 2016 were available.

Table H.1: Flynn Pharma Limited's total common costs (administrative expenses) and allocation to Capsules

	Flynn Pharma Limited	Allocated to Phenytoin*
Employee costs	£11,598,023	£2,503,681
Premises and utilities costs	£409,753	£78,232
Development costs	£196,251	£0
Computer and Telephone	£148,539	£28,466
Depreciation and Amortisation	£3,564,071	£51,973
Insurance	£543,540	£104,298
Stationery, printing and sundry expenses	£1,301,529	£234,396
Sales force and Promotion activities	£14,640,329	£35,427
Other expenses	-£236,828	£21,919
Consultancy fees	£1,306,500	£249,579
Legal and Professional	£642,905	£132,516
Total Administrative expenses	**£34,114,612**	**£3,440,487**

Source: PHT00153, Spreadsheet re Breakdown of Flynn Pharma's Administrative Expenses (Q4): Annex 4 of Flynn's response of 19 June 2014 to the CMA's s.26 Notice of 6 June 2014 (CMA document reference 00607.2); PHT00112, Final Trial Balances at 31 January 2015: Annex 2.2 of Flynn's response of 17 August 2016 to the CMA's s.26 Notice dated 2 August 2016 (CMA document reference 02115.4); and PHT00242, Draft Trial Balance at 31 March 2016: Annex 2.3 of Flynn's response of 17 August 2016 to the CMA's s.26 Notice dated 2 August 2016 (CMA document reference 02115.5), PHT00251, Trial balance for the period to the end of August 2014: Annex 3 of Flynn's response of 10 October 2014 to the CMA's s.26 Notice of 15 September 2014 (CMA document reference 00872.5).

H.5 The CMA considered that the following administrative expenses could reasonably be expected to have been incurred as part of Flynn's activities when it sold Capsules during the Relevant Period - Premises and Utilities costs, Computer and Telephone, Insurance, Stationery and Printing expenses and Consultancy, Legal and Professional costs. For this reason, no adjustments were made to any of these cost categories before they were allocated to Capsules.

H.6 The CMA has made certain adjustments to the following administrative expenses:

H.6.1 Flynn paid bonuses amounting to £868,235 in FY2014 to a number of staff relating to the signing of the MAs for Capsules. These bonuses were in addition to their annual performance bonuses and were based solely on this agreement being signed. The CMA consider that these bonuses were discretionary and as such, the bonuses were excluded from the total employee costs to be allocated.

H.6.2 The salaries of [✂] ([✂]) and [✂] ([✂]) - these salaries have been allocated in full to Flynn's costs of selling Capsules. Flynn stated that 'initially, both [✂] and [✂] committed all of their time to activities relating to Capsules. However, both individuals became involved in other projects more and more as time passed'. The CMA has been unable to obtain

sufficient detail regarding the length of these periods. Adopting an approach that is favourable to Flynn, the CMA has apportioned all of this cost to Capsules up until the 31 March 2014. The remaining employee costs, including [✂] and [✂] after the 31 March 2014, have been allocated to Capsules using the volumes-based approach.

H.6.3 Depreciation and amortisation of £3.6 million, include an amortisation charge of £3,277,600. Flynn's financial statements stated that this charge related to the write-off of brand names, knowhow and licences on consolidation. As Flynn acquired Pfizer's MAs for Capsules for only £1 the CMA does not consider that this charge related to Capsules. For this reason, the charge has been excluded from the allocation of Flynn's common costs.

H.6.4 Development costs were excluded as Flynn stated that these costs related to the development of Penicillin Potassium Injections.[2145]

H.6.5 Irish office costs were excluded from sundry expenses because these were not applicable to Capsules.

H.6.6 Flynn provided specific 'Sales force and Promotion expenses' figures for Capsules of £34,552.[2146] All of these costs were allocated to Capsules.

H.6.7 'Other expenses' were said to include offsetting balances for 'Management Charges to Inresa' and licence fees. Flynn explained that Management Charges to Inresa 'comprise cross charges for the provision of services by Flynn's staff to its subsidiary in Germany. The amount shown represents an apportionment of staff salaries, charged at cost with no margin earned. They do not relate to Phenytoin'.[2147] In light of that explanation, the CMA has offset this credit against employee costs to make sure that costs relating to activities not applicable to Capsules were not allocated to this product. Licence fees however have been removed from these charges as a nominal £1 fee was paid to acquire the MAs from Pfizer.

[2145] PHT00252, Schedule re Trial Balance as at 31 March 2014: Annex 5.3 of Flynn's response of 19 June 2014 to the CMA's s.26 Notice of 6 June 2014 (CMA document reference 00607.6).
[2146] PHT00252, Schedule re Trial Balance as at 31 March 2014: Annex 5.3 of Flynn's response of 19 June 2014 to the CMA's s.26 Notice of 6 June 2014 (CMA document reference 00607.6); and PHT00253, Schedule re Trial Balance as at 31 March 2013: Annex 5.3 of Flynn's response of 19 June 2014 to the CMA's s.26 Notice of 6 June 2014 (CMA document reference 00607.7).
[2147] PHT00075, Flynn's response to 10 October 2014 to the CMA's s.26 Notice dated 15 September 2014 (CMA document reference 00872.1), question 8.

Annex I: Alternative approaches to common cost allocation

Introduction

I.1 This annex sets out the CMA's consideration of various methodologies that may be adopted when allocating common costs as part of a Cost Plus assessment.

I.2 It considers the appropriateness of each methodology in the circumstances of this case and explains why the CMA considers that output-based cost drivers (and specifically sales volumes per pack) provide the most appropriate basis for allocating Pfizer's and Flynn's common costs.

I.3 For completeness, this annex also sets out the CMA's testing of the effect of adopting various alternative approaches to common cost allocation (other than sales volumes per pack) and the effect of each on the excessiveness of Pfizer's Prices and Flynn's Prices.

Approach to allocating common costs

I.4 The OFT's *Profitability Assessment Report* (produced by the economic consultancy Oxera) states that broadly there are three types of cost driver that can be used separately or in combination to allocate common costs:

I.4.1 input-based cost drivers, where indirect costs are allocated to a particular line of business based on other known inputs employed in the production of that line of business, such as labour employed, raw-material, or costs of floor space used;

I.4.2 output-based cost drivers, where indirect costs are allocated using output indicators, such as production or sales volumes; and

I.4.3 value-based cost drivers, where indirect costs are allocated based on demand factors, such as prices, revenues or consumers' willingness to pay.[2148]

I.5 The Inter-Regulatory Working Group[2149] identified four principles upon which cost allocation approaches should be based.[2150] Of these, the CMA considers that the following principles are most relevant in the context of this case and should

[2148] PAD00037, Oxera, *Assessing profitability in competition policy analysis*, OFT 657, July 2003, paragraph 6.16.
[2149] The Inter-Regulatory Working Group was established to identify and develop areas of consistency within published regulatory accounts.
[2150] These principles are described in PAD00032, a paper from the Inter-Regulatory Working Group (2001), 'The Role of Regulatory Accounts in Regulated Industries: A Final Proposals Paper', by the Chief Executive of Ofgem, Director General of Telecommunications, Director General of Water Services, Director General of Electricity and Gas Supply (Northern Ireland), Rail Regulator, Civil Aviation Authority, and Postal Services Commission.

therefore be taken into account when seeking to identify an appropriate cost allocation methodology:[2151]

I.5.1 Cost causality – Costs should be allocated in accordance with the activities that cause them.

I.5.2 Objectivity – Costs should be allocated on an objective basis, not unduly benefiting any particular party.

I.5.3 Transparency – The method should be clear to all interested parties with the underlying data (costs, revenues, asset values, etc) all being clearly identifiable.

Input-based cost drivers

I.6 The CMA considers that input-based cost drivers can be an appropriate way of allocating common costs where suitable and reliable data is available. Input-based cost drivers allocate common costs based on the underlying inputs which cause those costs to be incurred.[2152] This approach is often referred to as 'activity-based costing' and is consistent with the cost causality principle for allocating common costs. However, such an approach can only be adopted where the available data permits it to be applied correctly and objectively.

I.7 In this case, Pfizer and Flynn have not been able to provide sufficiently detailed information to enable cost drivers to be quantified and related to the categories of indirect costs.[2153] The CMA considers that the limitations in the data obtainable from the Parties render an input-based approach insufficiently objective and transparent to be adopted in this case.

Output-based cost drivers

I.8 Output-based cost drivers, where indirect costs are allocated on the basis of output indicators such as production or sales volumes, are a recognised approach to allocating common costs.

I.9 Based on the principles set out in paragraph I.5, the CMA considers that using an output-based cost driver would be appropriate in this case. This is because:

[2151] The other criterion identified by the inter-regulatory working group in the Profitability Assessment Report is 'consistency'. This is less relevant in the context of this case as it relates more specifically to its application in regulatory accounts where it is important to ensure the same method is used from year to year.
[2152] For example, floor space may be an appropriate basis for allocating heating costs.
[2153] For example, PHT00140, Spreadsheet detailing Pfizer's Common Costs Sales and costs for 2011-2013: Annex B to Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.4), shows that 88% to 94% of all of Pfizer's common costs are classified within an 'other' category between 2011 and 2013 and in PHT00132, Flynn's response of 19 June 2014 to the CMA's s.26 Notice of 6 June 2014 document 00607.1, question 6, Flynn notes that it could not provide data on the number of orders received from its customers.

I.9.1 It is transparent and practical to allocate common costs using output-based cost drivers because data on the number of packs sold are readily available.

I.9.2 Using volume (number of packs sold) to allocate common costs ensures that the cost allocation is objective and does not unduly benefit any particular product of Pfizer's or Flynn's.

Value-based cost drivers

I.10 As regards value-based cost-drivers, the CMA considers that this approach can be transparent and practical. However, the use of value-based cost drivers can sometimes result in allocations which fail to be objective. This means they are often considered inadequate for the assessment of pricing abuses under competition law.

I.11 For example, sales revenues are an example of a value-based cost driver. By using sales revenues, a greater proportion of indirect costs would be allocated to higher priced products, which is circular when assessing whether prices are excessive. This is because an excessive price attracts a disproportionate share of common costs, reducing the observed profitability of the product and potentially 'hiding' the excessiveness.

I.12 These proble were recognised by the CAT in Genzyme where it confirmed that the OFT was right to reject 'Healthcare at Home's submission that certain costs should be allocated solely according to turnover: such an approach would allocate an unduly high proportion of overheads to Genzyme, because of the high cost of the drug'.[2154] The same issue was also noted by the CAT in Socrates v Law Society, where the CAT noted that 'the method of cost allocation (whereby an increase in revenue automatically generates a corresponding increase in attributable cost) [is] an unreliable basis for any fair assessment of the profitability of the scheme'.[2155, 2156]

I.13 For these reasons, the CMA has rejected using a value-based cost driver, such as sales revenue, as a potential cost allocation methodology for the purposes of its analysis.

Conclusion on approach to allocating common costs

I.14 For the reasons above, the CMA considers that output-based cost drivers provide the most appropriate method for allocating indirect costs in this case. The CMA has

[2154] *Genzyme Remedy* [2005] CAT 32, paragraph 268.
[2155] *Socrates v Law Society* [2017] CAT 10, paragraph 83.
[2156] The issues with revenue-based allocation were also recognised by the CAT in *Phenytoin*. See *Phenytoin* [2018] CAT 11, paragraphs 351 to 352.

therefore used sales volumes (number of packs sold) to allocate Pfizer's and Flynn's respective common costs.

I.15 In the following section, the CMA has nonetheless tested the effect of adopting various alternative approaches to common cost allocation and the effect of each on the excessiveness of Pfizer's Prices and Flynn's Prices.

Alternative approaches to allocating common costs

Volume-based approaches

I.16 The CMA has considered the effect of adopting alternative volume-based cost drivers, other than sales volume by number of packs.[2157] The CMA has tested the effect of allocating the common costs of each Party on the basis of:

I.16.1 sales volume by number of capsules; and

I.16.2 sales volume on a defined daily does (DDD) basis for phenytoin sodium.[2158]

I.17 The CMA has tested these alternative volume-based approaches because an outcome of the sales volume per pack methodology is that all capsule strengths incur the same common cost per unit (ie per pack). This has a distortionary effect on the smaller capsule strengths, which also have the lowest prices, as they incur a higher proportion of indirect costs to total costs. This results in lowering overall margins for the lower capsule strengths relative to the higher capsule strengths.[2159]

I.18 The main effects of adopting sales volume by number of capsules, or sales volume on a DDD basis (compared with sales volume per pack) are:

I.18.1 Sales volume per capsule shifts common costs from all other capsule strengths towards the 100mg packs, to reflect their larger pack size (ie 84 capsules per pack compared with 28 capsules per pack for all other capsule strengths).

I.18.2 Sales volume per DDD allocates costs across capsule strengths based on the assumed average maintenance dosage of a product. The effect, for instance, is that four 25mg capsules are treated as equivalent to one 100mg capsule for the purposes of this calculation. Therefore, twelve

[2157] These alternative allocation methods are applied after common costs are first allocated to phenytoin sodium capsules as a whole using sales volumes. Ratios are then calculated using the number of capsules and DDD of each pack. These ratios are then used to allocate the common costs across the different capsule strengths.
[2158] The CMA requested order and transaction data from the Parties. However, this data was not ultimately pursued as it would have been a significant undertaking for both Pfizer and Flynn to collate and submit and would not necessarily have provided a meaningful allocation. See, for example, PHT00133, Pfizer's draft response of 4 July 2014 to the CMA's draft s.26 Notice of 6 June 2014 (CMA document reference 00664.1), question 5.ii; and PHT00132, Flynn's response of 19 June 2014 to the CMA's s.26 Notice of 6 June 2014 (CMA document reference 00607.1), paragraph 6.2.
[2159] While the CMA considers sales volumes by pack to be the most appropriate methodology for allocating common costs, it recognises that sales volumes are unlikely to be completely correlated with common costs.

packs of 25mg should have as much common cost allocated to it as one pack of 100mg (given that 100mg packs contain 84 capsules whilst 25mg packs contain 28 capsules). The effect is the same as taking a per mg of API per pack approach.

Other approaches

I.19 The CMA has also tested the effect on each Party's common cost allocation, and the resultant excesses, of adopting an equi-proportionate mark-up (EPMU) approach to allocating common costs. The EPMU approach allocates common costs in proportion to each product's directly attributable costs.

I.20 Additionally, as the approach to common cost allocation is more likely to affect the level of Flynn's excesses than Pfizer's excesses,[2160] the CMA has calculated Flynn's excesses under a number of additional approaches to common cost allocation.

I.21 Specifically, the CMA has considered the level of common costs to be allocated to each of Flynn's Products, and how this impacts the excessiveness of Flynn's Prices, under the following common cost allocation methodologies:[2161]

I.21.1 Revenue-based approach: whereby common costs are allocated in proportion to the revenues generated by Flynn's Products.

I.21.2 Standalone: a standalone approach to cost allocation allocates all common costs of a company to the product under assessment. The standalone approach therefore represents the maximum amount of common costs which could theoretically be allocated to Flynn's Products.

I.21.3 Incremental: under this approach, all common costs are allocated to other products in the company's portfolio (ie zero common costs are allocated to the product under assessment). While this approach is likely to be too strict for use in a Cost Plus assessment, the CMA considers that it remains informative as part of a sensitivity analysis as it represents the lower bound for Flynn's Cost Plus.

I.21.4 Equal allocation: whereby common costs are allocated equally across Flynn's products (ie each of Flynn's 14 products recovers an equal share of common costs).

[2160] Flynn's excesses over Cost Plus are significantly lower than those of Pfizer, largely as a result of Flynn's high direct costs.
[2161] This analysis was performed an independent expert appointed by the CMA. See PRE00708, First Expert Report of [CMA Expert Witness 1], prepared for the CMA and dated 4 April 2017, paragraphs 3.56 to 3.62.

Pfizer's common costs and excesses under alternative approaches to allocating common costs

Volume-based approaches

I.22 Table I.1 below shows the level of common costs that would be allocated to each of Pfizer's Products using the alternative volume-based allocations of per capsule and per DDD, and how each compares against a sales volume per pack approach.

Table I.1: CMA analysis of common costs allocated to Pfizer's Products, September 2012 to December 2016

	Sales volume (per pack)		Sales volume (per capsule)		Sales volume (DDD)	
	Total common cost	Common cost per pack	Total common cost	Common cost per pack	Total common cost	Common cost per pack
25mg	£1,238,838	£2.32	£698,331	£1.31	£164,109	£0.31
50mg	£2,503,683	£2.32	£1,411,322	£1.31	£663,328	£0.61
100mg	£2,288,129	£2.32	£3,869,444	£3.92	£3,637,314	£3.68
300mg	£1,535,712	£2.32	£865,678	£1.31	£2,441,237	£3.68

I.23 An impact of adopting either a per capsule or per DDD approach is to increase the common costs allocated to the 100mg capsule strength.

I.24 Using the per capsule sales volumes method, common costs are allocated towards the 100mg packs and away from all other capsule strengths, reflecting the fact that 100mg packs contain more capsules. The impact is significant for the 25mg, 50mg and 300mg packs for which common costs are £1.31 per pack rather than £2.32 per pack.

I.25 Using DDD, the common costs allocated to the 25mg and 50mg packs are lower at £0.31 and £0.61 respectively whilst the common costs allocated to the 100mg and 300mg packs are higher at £3.68 per pack.

I.26 Table I.2 below shows how each approach to allocating Pfizer's common costs affects the excess on each of Pfizer's Products.

Table I.2: CMA analysis of Pfizer's excesses on Pfizer's Products under various volume-based cost allocation methodologies, September 2012 to December 2016

	Sales volume (per pack)		Sales volume (per capsule)		Sales volume (DDD)	
	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)
25mg	£0.88	24%	£2.00	80%	£3.11	223%
50mg	£3.20	91%	£4.32	181%	£5.09	314%
100mg	£32.67	667%	£30.89	463%	£31.15	486%
300mg	£32.10	653%	£33.22	875%	£30.58	476%

I.27 Table I.2 shows that the excesses vary according to the choice of cost allocation methodology. For example, there is a significant increase in the excesses for packs of 25mg and 50mg capsules when either a per capsule or per DDD approach is adopted. Using DDD, for example, the percentage excess for 25mg capsules goes up to 223% and for 50mg to 314%. Conversely, the excess on the 100mg capsules falls, although it remains at 486%. Compared to a per pack approach, the excess on the 300mg capsules is lower using the DDD method, due to its high dosage strength, but is higher using the volumes by capsules method due to its lower pack size.

I.28 The CMA considers that each of the excesses set out in Table I.2 is material and sufficiently large to be deemed excessive under the Excessive Limb of the United Brands Test. The CMA's common cost sensitivity testing therefore reinforces its provisional conclusion that each of Pfizer's Prices is excessive.

Other approaches

I.29 As above, in addition to the per capsule and per DDD approaches, the CMA has calculated how much common cost would have been allocated to Pfizer's Products under the EPMU approach. This approach uses Pfizer's average direct costs to common costs ratio instead of the sales volumes per pack basis.

I.30 The common cost to direct cost ratio across Pfizer Limited's entire business was 35% in 2013 (ie a ratio of direct:common costs of 1:0.35). Under this alternative methodology, the total amount of common costs allocated to Pfizer's Products between September 2012 and December 2016 would be £1.7 million; significantly lower than the balance allocated to Pfizer's Products by the CMA, which is £7.6 million.[2162]

I.31 Consequently, the CMA's approach to common cost allocation results in around twice the level of overall costs (direct and indirect) being allocated to Pfizer's

[2162] This alternative approach would reduce the amount of common cost per pack of phenytoin sodium capsules from £2.32 across capsule strengths to £0.33 and £0.30 per pack of 25mg and 50mg phenytoin sodium capsules respectively and £0.73 and £0.74 per pack of 100mg and 300mg phenytoin sodium capsules.

Products than would have been the case had the CMA allocated Pfizer's common costs in line with Pfizer Limited's average common costs to direct costs ratio. The approach adopted by the CMA therefore results in lower excesses for each of Pfizer's Products than would be the case if an EPMU approach were to be adopted.

I.32 The CMA considers that this highlights the generous approach, which is favourable to Pfizer, that the CMA has taken to allocating common costs to Pfizer's Products.

Flynn's common costs and excesses under alternative approaches to allocating common costs

Volume-based approaches

I.33 Table I.3 below shows the level of common costs that would be allocated to each of Flynn's Products using the alternative volume-based allocations of per capsule and per DDD, and how each compares against a sales volume per pack approach.

Table I.3: CMA analysis of common costs allocated to Flynn's Products, September 2012 to December 2016

	Sales volume (per pack)		Sales volume (per capsule)		Sales Volume (DDD)	
	Total common cost	Common cost per pack	Total common cost	Common cost per pack	Total common cost	Common cost per pack
25mg	£554,068	£1.05	£345,882	£0.65	£80,675	£0.15
50mg	£1,114,757	£1.05	£695,897	£0.65	£324,627	£0.31
100mg	£1,015,307	£1.05	£1,901,443	£1.96	£1,773,996	£1.83
300mg	£681,095	£1.05	£425,180	£0.65	£1,190,044	£1.83

I.34 Using the per capsule sales volumes method, common costs are allocated towards the 100mg packs and away from all other capsule strengths to reflect their smaller sizes. The impact is significant for the 25mg, 50mg and 300mg packs for which common costs fall from £1.05 per pack to £0.65.

I.35 Using DDD most significantly affects the 25mg and 50mg packs, with common costs falling to £0.15 and £0.31 respectively, while the common costs allocated to the 100mg and 300mg packs rise to £1.83 per pack.

I.36 Table I.4 below shows how each approach to allocating Flynn's common costs affects the excess on each of Flynn's Products.

Table I.4: CMA analysis of Flynn's excesses on Flynn's Products under various volume-based cost allocation methodologies, September 2012 to December 2016

	Sales volume (per pack)		Sales volume (per capsule)		Sales Volume (DDD)	
	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)
25mg	£8.26	139%	£8.65	156%	£9.16	182%
50mg	£6.27	77%	£6.67	86%	£7.02	95%
100mg	£14.55	37%	£13.64	33%	£13.77	34%
300mg	£16.30	42%	£16.70	43%	£15.52	39%

I.37 Table I.4 shows that both the percentage excess and excess per pack figures for the 25mg and 50mg capsule strengths increase under a per capsule approach or per DDD approach, while the excesses for 100mg capsules are slightly lower. The excesses for 300mg capsules are slightly lower on a DDD basis and slightly higher on a sales volume per capsule basis.

I.38 The CMA considers that the excesses on each of Flynn's Products in Table I.4 are material and sufficiently large to be deemed excessive under the United Brands test, thus bolstering the CMA's conclusion that Flynn's Prices are excessive.

Other approaches

I.39 As above, in addition to the per capsule and per DDD approaches, the CMA has calculated how much common cost would have been allocated to Flynn's Products under a range of cost allocation methodologies, and how the level of excesses across each of Flynn's Products would be affected.

I.40 Table I.5 below sets out the value of common costs that would be allocated to each of Flynn's Products under various different allocation methods. Each of these methods and their relative merits and suitability in this case are described in more detail in the following paragraphs.

Table I.5: CMA analysis of common costs allocated to Flynn's Products on a per pack basis, September 2012 to December 2016

Cost allocation methodology	25mg	50mg	100mg	300mg
Volume-based	£1.05	£1.05	£1.05	£1.05
Revenue-based	£0.93	£0.94	£3.56	£3.61
EPMU	£0.43	£0.63	£3.52	£3.42
EPMU (adjusted for Pfizer excesses)	£0.64	£0.61	£0.81	£0.72
Incremental	£0.00	£0.00	£0.00	£0.00
Standalone (volume-based)	£4.85	£4.85	£4.85	£4.85
Standalone (revenue-based)	£1.98	£2.01	£7.60	£7.71
Equal allocation	£0.53	£0.26	£0.29	£0.43

Revenue-based cost allocation

I.41 A revenue-based approach to cost allocation most significantly affects packs of higher capsule strengths, with common costs increasing from £1.05 per pack to £3.56 per pack for 100mg capsules and to £3.61 per pack for 300mg capsules. Common costs per pack fall slightly for 25mg capsules and for 50mg capsules.

I.42 The CMA explained in Chapter 5 that a revenue-based approach is likely to introduce a circularity into the analysis, whereby a potentially excessively priced product is allocated a higher proportion of common costs as a result of its allegedly excessively high price. In turn, this increases Cost Plus and reduces the scale of the measured excesses. The CMA considers that such circularity concerns are likely to be present in this case as Capsules are among Flynn's highest priced products.[2163]

I.43 While the CMA considers that a revenue-based cost allocation approach is inappropriate in this case for these reasons, it has nonetheless included this method in its analysis, to test the impact of allocating common costs to Flynn's Products in this way.

EPMU approach

I.44 An EPMU approach has a similar impact to allocating common costs on the basis of revenues. That is, common costs allocated to 100mg and 300mg packs increase considerably, and common costs allocated to 25mg and 50mg packs are reduced. This is because the EPMU approach allocates common costs in proportion to each product's directly attributable costs. Therefore, the EPMU approach allocates a high share of common costs to the 100mg and 300mg packs as a direct

[2163] PHT00129, Annex 1 of Flynn's response of 16 March 2016 to the CMA's s.26 Notice of 9 March 2016 (CMA document reference 01856.2).

consequence of the high input prices that Flynn pays to Pfizer for these products.[2164] As a result, and as with a revenue-based approach, the EPMU method gives rise to a circularity problem, with the effect that excessiveness by Pfizer may mask excessiveness by Flynn. For this reason, the CMA does not consider that an EPMU approach to cost allocation is appropriate for Flynn in this case. The CMA has included this approach in its analysis for completeness only.

I.45 However, the CMA has carried out additional analysis which follows the EPMU approach, but which adjusts Flynn's direct costs for the level of Pfizer's excesses, thereby controlling for the problem identified in paragraph I.44 above (the results of this analysis are referred to as 'EPMU (adjusted for Pfizer excesses)' in Table I.5).

I.46 A comparison of the common costs in Table I.5 to be allocated under an unadjusted EPMU approach and an EPMU that is adjusted for Pfizer's excesses demonstrates that the distortion caused by Flynn's high input price is significant for 100mg and 300mg capsule strengths. When adjusted to control for excessiveness in the supply price charged by Pfizer to Flynn, the EPMU approach allocates a considerably lower amount of common costs to packs of 100mg capsules and packs of 300mg capsules.

I.47 The CMA's chosen method of allocating common costs by sales volumes per pack allocates a greater amount of common costs to each of Flynn's Products than under an EPMU approach which takes account of Pfizer's excesses.

Incremental and standalone approaches

I.48 The incremental approach allocates all of Flynn's common costs to other products in Flynn's portfolio (ie all products other than Capsules), while the standalone approach allocates all of Flynn's common costs to Capsules.[2165] The two approaches therefore represent the lower and upper bounds for common cost allocation to Flynn's Products, with the incremental method reflecting the strictest possible approach and the standalone method reflecting the most favourable methodology to Flynn.

I.49 While both approaches clearly have limitations,[2166] the CMA considers that they are informative as part of its analysis as they allow a consideration of the extent to which the CMA's findings are justifiable under a broad range of common cost allocation methods.

[2164] PRE00155, Second Expert Report of [Flynn Expert Witness 1], Figure 2 which demonstrates that Flynn's input price for these products is several times greater than the cost of a number of Flynn's other products.
[2165] The allocation across capsule strengths can then be undertaken on the basis of sales volumes or revenues. The CMA has included both approaches in its analysis and in Table I.5.
[2166] In particular, the incremental approach assumes zero common cost recovery and the standalone approach attributes all common costs to the products under investigation. Neither of these assumptions are likely to be consistent with the United Brands test which allows for the recovery of common costs which can reasonably be attributed to the relevant products.

I.50 The incremental approach allocates zero common costs to Flynn's Products. When using sales volumes, the standalone approach increases the amount of common costs allocated to Flynn's Products from £1.05 per pack to £4.85 per pack. Using sales revenues, the standalone approach increases common costs allocated to each pack of 25mg capsules and 50mg capsules from £1.05 per pack to £1.98 per pack and £2.01 per pack respectively. Common costs allocated to 100mg and 300mg packs increase more considerably as a consequence of the higher prices (and therefore higher revenues) that Flynn charges for these products. Common costs allocated to 100mg capsules increase to £7.60 per pack, and to £7.71 per pack for 300mg capsules.

Equal allocation

I.51 The equal allocation method allocates Flynn's common costs equally across all products in Flynn's portfolio.[2167] This approach results in a lower amount of common costs being allocated to all capsule strengths than under the CMA's chosen method. The impact is more significant for 50mg packs and 100mg packs, where common cost allocations fall from £1.05 per pack to £0.26 and £0.29 respectively. Common costs allocated to 25mg packs fall to £0.53 and to £0.43 for 300mg packs.

Flynn's excesses under other common cost allocation approaches

I.52 Table I.6 below shows how each approach to allocating Flynn's common costs affects the excess on each of Flynn's Products.

Table I.6: CMA analysis of Flynn's excesses (%) on Flynn's Products under various cost allocation methodologies, September 2012 to December 2016

Cost allocation methodology	25mg	50mg	100mg	300mg	Total
Volume-based	139%	77%	37%	42%	47%
Revenue-based	144%	80%	28%	33%	40%
EPMU	167%	87%	29%	34%	41%
EPMU (adjusted for Pfizer excesses)	157%	87%	37%	43%	49%
Incremental	191%	103%	40%	46%	54%
Standalone (volume-based)	46%	21%	25%	29%	27%
Standalone (revenue-based)	107%	58%	17%	21%	27%
Equal allocation	163%	96%	39%	44%	52%

I.53 As described in the above analysis, each of the alternative approaches to common cost allocation set out in Table I.6 should not be considered to have equal merit. In

[2167] A share of 1/14 of Flynn's total common costs is allocated to phenytoin sodium capsules and, of this amount, one quarter is allocated to each of the four capsule strengths.

particular, a revenue-based approach and the unadjusted EPMU each suffer from circularity problems, while the incremental and standalone approaches are too extreme for adoption in a Cost Plus assessment. The CMA notes however that, even under a standalone approach (which allocates all of Flynn's common costs across its entire business to Capsules), Flynn's prices remain considerably in excess of Cost Plus.[2168]

I.54 In the CMA's view, an EPMU approach which is adjusted to control for Pfizer's excesses and the equal allocation method are more likely to represent reasonable alternatives to the CMA's chosen methodology. Each of these methods allocates a lower amount of common costs to Flynn's Products than the CMA's approach and results in greater levels of excess on each of Flynn's Products.

I.55 For these reasons, the CMA considers that an analysis of alternative common cost allocation methodologies supports a conclusion that:

I.55.1 the CMA's chosen methodology for Flynn, to allocate common costs by sales volumes per pack, is reasonable; and

I.55.2 under any reasonable approach to common cost allocation, the excesses on each of Flynn's Products are material and sufficiently high to be deemed excessive under the United Brands test.

I.56 The CMA considers therefore that this analysis bolsters its conclusion that Flynn's Prices are excessive.

[2168] PAD00037, The economic consultancy Oxera stated in paragraph 6.12 of its report for the OFT on *Assessing Profitability in Competition Policy Analysis*: 'If the allocation is carried out on the basis of the stand-alone cost, and the estimated [internal rate of return] still exceeds the cost of capital, this represents prima facie evidence of excessive profits. This is because the stand-alone cost is the maximum amount of cost that would be borne by the business.'

Annex J: Pfizer's direct costs

J.1 This annex sets out the components of Pfizer's direct costs in the manufacture and transport of Capsules and the internal transfer prices incurred by Pfizer Limited.

J.2 Pfizer provided the CMA with a breakdown of its standard manufacturing costs of each capsule strength by component.[2169]

J.3 Pfizer stated that 'the Active Pharmaceutical Ingredient ("API") is manufactured in Kalamazoo in the US by Pfizer. The Capsules are manufactured and turned into finished goods in Freiberg, Germany in a Pfizer facility. The capsules are then transported to the [✂] ("[✂]")'.[2170] The main change in the supply chain following the transfer of marketing rights to Flynn is that 'the ownership of the capsules transfer from Pfizer to Flynn at the [✂] warehouse. Flynn is then responsible for the distribution of the capsules in the UK'.[2171] This distribution is still performed by [✂].

J.4 The main change in cost terms for Pfizer is a reduction in distribution costs as the transportation from [✂] to pharmacies is now the responsibility of Flynn.

J.5 Pfizer's direct costs for Capsules are calculated on a standard costing basis. To calculate the actual direct costs it is necessary to adjust the standard cost for actual costs incurred. Pfizer stated though that 'actual costs are not tracked at stock keeping unit level, and variances to standard costs are only tracked at total plant level, so it is not possible to provide an accurate answer on variances relating to Capsules'.[2172] As such standard costs represent the best proxy for actual costs.

J.6 Pfizer stated that 'standard costs are generally below its internal transfer prices, known as the corporate COGS, as the internal price should include a contribution charge for 'unallocated global common costs'.[2173] Pfizer submitted that 'the corporate cost of goods sold is therefore a much better measure'[2174] of direct costs

[2169] Pfizer's manufacturing costs for Capsules are calculated on a standard costing basis. To calculate the actual direct costs it is necessary to adjust the standard cost for actual costs incurred. Pfizer stated though that 'actual costs are not tracked at stock keeping unit level, and variances to standard costs are only tracked at total plant level, so it is not possible to provide an accurate answer on variances relating to phenytoin sodium capsules', PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question. As such standard costs represent the best proxy for actual costs.
[2170] PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.1), question 1.
[2171] PHT00081, Pfizer's response of 29 May 2013 to the OFT's s.26 Notice of 8 May 2013 (CMA document reference 00086.1), question 1.
[2172] PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question 1.
[2173] As explained in PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question 1, 'corporate COGS are the costs that Pfizer Ltd must cover and therefore, in effect, the inter-company adjustment implicit within these costs constitutes its (entire) contribution towards Pfizer's Inc's common costs'.
[2174] PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question 1.

as it is more representative of the price Pfizer would have to pay a third-party manufacturer to produce these products.

J.7 Table J.1, Table J.2, Table J.3 and Table J.4 outline Pfizer's direct costs, including the breakdown of the various standard costs, the contributions to overheads and the distribution costs. These figures are presented on a per pack basis.

Table J.1: Direct cost per pack, 28 x 25mg capsules

	Year ended 30 November 2012	6 months ended 31 May 2013	6 months ended 30 November 2013	Year ended 30 November 2014
Raw material: API	£0.062	£0.060	£0.060	£0.061
Raw material: Excipients	£0.057	£0.062	£0.062	£0.065
Labour cost	£0.086	£0.043	£0.052	£0.047
Packaging material	£0.322	£0.104	£0.117	£0.117
Equipment/OH/Quality	£0.345	£0.410	£0.523	£0.509
Total manufacturing cost	£0.873	£0.679	£0.813	£0.799
Global overhead contribution	£0.027	£0.221	£0.087	£0.101
Corporate cost of sales	£0.900	£0.900	£0.900	£0.900
Distribution costs	£0.395	£0.050	£0.050	£0.050
Total direct costs	**£1.295**	**£0.950**	**£0.950**	**£0.950**

Table J.2: Direct costs per pack of 28 x 50mg capsules

	Year ended 30 November 2012	6 months ended 31 May 2013	6 months ended 30 November 2013	Year ended 30 November 2014
Raw material: API	£0.120	£0.116	£0.116	£0.118
Raw material: Excipients	£0.056	£0.062	£0.062	£0.070
Labour cost	£0.066	£0.030	£0.041	£0.034
Packaging material	£0.257	£0.101	£0.502	£0.106
Equipment/OH/Quality	£0.279	£0.296	£0.426	£0.387
Total manufacturing cost	£0.779	£0.604	£1.146	£0.715
Global overhead contribution	£0.021	£0.196	-£0.346	£0.085
Corporate cost of sales	£0.800	£0.800	£0.800	£0.800
Distribution costs	£0.419	£0.050	£0.050	£0.050
Total direct costs	**£1.219**	**£0.850**	**£0.850**	**£0.850**

Table J.3: Direct costs per pack of 84 x 100mg capsules

	Year ended 30 November 2012	6 months ended 31 May 2013	6 months ended 30 November 2013	Year ended 30 November 2014
Raw material: API	£0.721	£0.689	£0.689	£0.670
Raw material: Excipients	£0.178	£0.208	£0.208	£0.218
Labour cost	£0.118	£0.053	£0.077	£0.068
Packaging material	£0.227	£0.135	£0.558	£0.574
Equipment/OH/Quality	£0.556	£0.596	£0.804	£0.778
Total manufacturing cost	£1.800	£1.681	£2.336	£2.338
Global overhead contribution	£0.250	£0.369	-£0.286	-£0.182
Corporate cost of sales	£2.050	£2.050	£2.050	£2.050
Distribution costs	£0.423	£0.050	£0.050	£0.050
Total direct costs	**£2.473**	**£2.100**	**£2.100**	**£2.100**

Table J.4: Direct costs per pack of 28 x 300mg capsules

	Year ended 30 November 2012	6 months ended 31 May 2013	6 months ended 30 November 2013	Year ended 30 November 2014
Raw material: API	£0.741	£0.712	£0.712	£0.722
Raw material: Excipients	£0.069	£0.075	£0.075	£0.079
Labour cost	£0.210	£0.094	£0.094	£0.089
Packaging material	£0.069	£0.075	£0.075	£0.091
Equipment/OH/Quality	£0.573	£0.698	£0.698	£0.774
Total manufacturing cost	£1.661	£1.653	£1.653	£1.755
Global overhead contribution	£0.409	£0.417	£0.417	£0.315
Corporate cost of sales	£2.070	£2.070	£2.070	£2.070
Distribution costs	£0.412	£0.050	£0.050	£0.050
Total direct costs	**£2.482**	**£2.120**	**£2.120**	**£2.120**

J.8 Table J.5 outlines Pfizer's weighted average standard manufacturing cost between October 2012 and September 2014. These figures are presented on a per pack basis.

Table J.5: Weighted average standard manufacturing costs between October 2012 - September 2014

	Capsule strength			
	25mg	**50mg**	**100mg**	**300mg**
Sales volume				
P10, P11 and P12 FY2012	38,105	56,520	79,472	39,167
FY2013	135,308	325,215	412,160	192,332
Up to P10 FY2014	121,464	244,198	173,230	147,598
Total products sold	294,877	625,933	664,862	379,097
Average standard cost per pack				
FY2012	£0.8728	£0.7785	£1.8004	£1.6611
FY2013	£0.7463	£0.8754	£2.0087	£1.6534
Up to P10 FY2014	£0.7985	£0.7146	£2.3379	£1.7545
Weighted average standard manufacturing cost	**£0.7842**	**£0.8039**	**£2.0696**	**£1.6936**

J.9 As shown in Table J.1 and Table J.2, the API costs of the packs of 25mg and 50mg of Capsules are proportional to the capsule strength. However, equipment costs of the 25mg packs are greater than those of the 50mg packs and this additional cost exceeds the lower additional API cost. Pfizer explained that this reflects economies of scale as 'the 50mg production order size is much higher than the 25mg. As a result costs for line set up and cleaning (fixed times per production order) are spread over a higher quantity and the costs per pack are lower than the 25mg presentation.'[2175]

J.10 The 100mg and 300mg packs have very similar direct costs per pack, although the components of these costs vary greatly. As shown in Table J.3 and Table J.4, the 100mg packs incur higher excipient costs[2176] and packaging costs. 100mg packs contain three times as many capsules as the 300mg packs, which drives the excipient requirements, and 100mg capsules are packaged in bottles which are more expensive than the blister packs which are used to package the 300mg capsules. However, these increased costs are offset by lower equipment costs, as a result of higher production volumes, which lowers the overhead cost per unit.

J.11 The figures in Table J.1 to Table J.5 also show that Pfizer's standard manufacturing costs for the 50mg and 100mg capsules rose significantly in June 2013 and exceeded the internal price (COGS) charged to Pfizer Limited. However, no changes were made to the COGS, which also remained the same in 2014. In response to this observation, Pfizer explained that 'if there is a shortfall between the direct costs incurred by Pfizer Manufacturing Deutschland GmbH and the price

[2175] PHT00134, Annex A of Pfizer's response of 7 October 2014 to the CMA's s.26 Notice of 16 September 2014 (CMA document reference 00863.1), question 3.
[2176] Excipients are the inactive substances that serve as the vehicle or medium for a drug or other active substance (such as phenytoin sodium).

it charges to Pfizer Ltd, then it would absorb this difference'.[2177] Since these differences are not material, the CMA considers it reasonable to continue using Pfizer's COGS as the measure of Pfizer's manufacturing cost of Capsules.

[2177] PHT00136, Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), Annex A, question 2.i.

Annex K: The CMA's calculation of Pfizer's capital employed

Introduction

K.1 The first step in carrying out a ROCE assessment in relation to Pfizer's Products is to estimate the capital employed by Pfizer in the production and supply of Pfizer's Products. An estimate of the WACC is then applied to this capital employed balance to calculate a reasonable rate of return for Pfizer's Products.

K.2 This annex sets out the CMA's estimate of the capital employed by Pfizer in the supply of Capsules.

Capital employed

K.3 Pfizer submitted that it employs capital at four stages of its supply chain:[2178]

K.3.1 Assets associated with the production of API in Kalamazoo (US);

K.3.2 Assets at the Freiburg production facility (Germany);

K.3.3 Assets supporting the management functions in the UK; and

K.3.4 Working capital.

K.4 The API is manufactured by Pfizer in Kalamazoo and purchased by the manufacturing facility in Freiburg where it is used in the production of Capsules. In its response to the CMA, Pfizer did not provide details of the capital employed to produce the API at Kalamazoo.[2179] As such the CMA has assumed that the charge to the Freiburg facility of purchasing their API from Kalamazoo follows Pfizer's typical process of being 'set with reference to the direct costs, with an inter-company adjustment'.[2180] The inter-company adjustment represents a margin which should satisfy Kalamazoo's return on capital requirement. Therefore, the CMA's ROCE analysis starts from the point at which the data was made available: the Freiburg facility.

[2178] PHT00141, Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.1), and PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).
[2179] PHT00141, Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.1), and PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).
[2180] PHT00136, Annex A to Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), question 2.

K.5 Pfizer stated that 'Freiburg is a multi-purpose plant that produces several products and there is no dedicated line for phenytoin or any other product'.[2181] As such, it believed that a bottom-up approach of its phenytoin production assets was not possible. It also stated that there were no dedicated parts of the Freiburg facility for Capsules. Therefore, Pfizer proposed, and produced, a capital asset valuation based on a top-down approach.

K.6 The asset figures were provided to the CMA on both a Gross Book Value (GBV) basis and Net Book Value (NBV) basis, as recorded within Pfizer's financial statements.[2182]

K.7 The CMA considers that the NBV of assets provides a more accurate measure of the current replacement cost of the relevant assets, as the inclusion of depreciation reflects the fall in value of the relevant assets and reflects Pfizer's assessment of the useful economic life of its assets. As Pfizer did not produce a bottom-up valuation of its assets, the CMA has used NBV in its calculation of Pfizer's capital employed. However, the CMA recognises that NBV is sensitive to Pfizer's choice of depreciation policy and that this can have a significant impact on the value of its capital employed.

K.8 The NBV of the Freiburg site assets was provided by Pfizer for the years ending 30 November 2012 and 2013 and is set out in Table K.1.[2183]

K.9 Pfizer submitted that there has been no material change to the value of these assets since 2013 which would materially affect the CMA's estimate of the average capital employed by Pfizer in the production and supply of Capsules in the UK.[2184] On that basis, the CMA considers that it is appropriate to treat these asset values as representative of the NBV of the relevant assets during the entire Relevant Period. The CMA therefore allocated these assets to all Capsules produced at this facility based on the proportion of phenytoin sodium capsule equipment hours at Freiburg compared with all other products, detail of which are provided in Table K.2.[2185]

K.10 Once this amount was attributed to Capsules as a whole, the UK's allocation was then calculated using the number of Capsules sold in the UK as a proportion of the

[2181] PHT00141, Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.1); and PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).
[2182] NBV takes account of accumulated depreciation, subtracting this from the original asset value.
[2183] PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).
[2184] PHT00143, Pfizer's response of 26 August 2016 to the CMA's s.26 Notice of 2 August 2016 (CMA document reference 02129.1), question 4, and PRC00490, Pfizer response to CMA's.26 Notice dated 12 August 2020, question 7.
[2185] PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).

total number of capsules produced at the Freiburg facility. These volumes are provided in Table K.3 and the results of this allocation are outlined in Table K.4.

K.11 Pfizer did not provide any specific data in respect of its capital assets employed in supporting the management functions in the UK. The CMA therefore adopted a similar approach to that suggested by Pfizer to assign the Freiburg facility assets to Capsules. The CMA reviewed Pfizer Limited's financial statements and attributed capital to Pfizer's Products using the NBV of Pfizer Limited's fixed assets for the years ended 30 November 2012 and 2013 which are provided in Table K.5. These assets were allocated to Capsules using the sales volume figures of Pfizer Limited, outlined in Table K.6. The results of this allocation are provided in Table K.7. This is also the approach adopted by the CMA for allocating common costs.

K.12 Pfizer's fixed assets are tangible, intangible and financial. The tangible assets of Pfizer Limited as set out in its financial statements include freehold land and building, leasehold improvements and plant and equipment. All these categories of fixed assets are included in the CMA's assessment.

K.13 Pfizer Limited's intangible assets include concessions, patents, licenses and trademarks. The CMA considers that no assets of this nature are applicable to Pfizer's Products as the products are off-patent and have been de-branded. As such, assets of this type have been excluded from the CMA's assessment. Similarly, given that Pfizer has not invested in development activities nor made recent innovations in relation to the supply of Capsules,[2186] the CMA does not consider there to be any relevant research and development expenditure which should be included in the assessment.[2187]

K.14 Financial fixed assets comprise shares in group undertakings, partnerships and joint ventures. The CMA considers that none of these assets are applicable to Capsules and, as such, these assets are excluded from its analysis.

K.15 As regards its working requirement, Pfizer only included stock in its calculation of working capital. It stated that whilst Capsules stock is separately identified within its management accounts, other elements of working capital (eg debtors and creditors) are not. Pfizer's stock calculation included: API (Kalamazoo), Work in Progress/Finished Product (Freiburg) and Finished Products (UK). The first two categories have been allocated to the UK using total production volumes. The final category is fully allocated to the UK.

K.16 Pfizer stated that debtor and creditor balances would be too difficult to produce. The CMA considers that as a result of the price charged to Flynn, debtors are likely

[2186] See Chapter 4 of this Decision.
[2187] Research and development expenditure may not meet the accounting criteria for recognition as an asset on the balance sheet. In such circumstances, potentially relevant expenditure would not be captured by the asset data provided by Pfizer nor by the CMA's review of Pfizer Limited's financial statements. In this case, the CMA does not consider there to be any relevant research and development costs to be added to its assessment.

to exceed creditors. This would increase the capital employed figures and therefore the reasonable return on capital.

K.17 However, the CMA considers that Pfizer's debtor balance (which relates solely to Flynn, as the only customer of Pfizer's Products in the UK) would need to be reduced as part of the calculation of its capital employed. This is because its debtor balance would be inflated by the allegedly excessive selling price charged to Flynn. This leads to a circularity problem in the analysis whereby the high price charged to Flynn would increase Pfizer's capital employed and reasonable return on capital, consequently increasing Pfizer's Cost Plus and reducing the scale of any excesses.

K.18 In addition, the CMA understands that all debtor balances are settled within one month. The CMA therefore considers that the impact of excluding debtors from the calculation of working capital is unlikely to be material. The exclusion of creditors, which reduces working capital and therefore capital employed, is favourable to Pfizer.

K.19 Pfizer's working capital figures (which, for the reasons above, are limited to stock balances and exclude debtors and creditors) and the amounts allocated to Capsules are outlined in Table K.8.

K.20 Based on all of the above, Table K.9 sets out the CMA's calculation of Pfizer's total capital employed in the production and supply of Pfizer's Products. Throughout its analysis, the CMA has used the average capital employed over FY2013. Fixed asset data was not made available after December 2013. The CMA considered using capital employed as of the 31 November 2013, however due to the risks associated with picking an asset value at a specific moment in time, the CMA deemed it more appropriate to use the only available average as representative over the full period.

Freiburg fixed assets

Table K.1: Fixed assets at Freiburg facility as at the 30 November 2012, 30 November 2013 and on average between these two dates

Fixed Assets: Freiburg	YE 30.11.2012	YE 30.11.2013	Average FY2013
	NBV (£)	NBV (£)	NBV (£)
Land	1,147,825	1,147,825	1,147,825
Buildings	23,815,544	22,883,087	23,349,315
Manufacturing equipment	26,944,949	27,162,394	27,053,672
Other Assets*	7,554,513	9,640,011	8,597,262
Total tangible assets	59,462,831	60,833,317	60,148,074

Source: PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).
* Other Assets includes: office equipment & furniture, building services equipment, laboratory instruments, computer equipment, software.

Table K.2: Total and Phenytoin Equipment hours at Freiburg facility during the year ending 30 November 2013

	YE 30.11.2013
Total Freiburg Equipment Hours	295,175
Phenytoin equipment hours	9,025
Phenytoin's portion of Freiburg Equipment Hours	3.06%

Source: PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).

Table K.3: Total Phenytoin volumes produced at Freiburg and sold in the UK during the year ended 30 November 2013

	YE 30.11.2013
Freiburg Production Volumes: Phenytoin*	225,000,197
Phenytoin sodium capsule products sold in UK	52,901,380
UK % of Freiburg production	23.5%

Source: PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).

Table K.4: Fixed assets from Freiburg facility allocated to UK phenytoin

Fixed Assets: Freiburg	Average in FY2013
	NBV (£)
Freiburg Fixed assets allocation to UK Phenytoin*	396,809

Source: PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).
*These assets are allocated to the UK using the Phenytoin equipment hours figures above followed by the UK's PS production volumes relative to Freiburg total PS output.

UK fixed assets

Table K.5: UK Fixed assets as at the 30 November 2012, 30 November 2013 and on average between these two dates

UK Fixed assets per UK financials	YE 30.11.2012 £'000	YE 30.11.2013 £'000	Average in FY2013 £'000
	NBV (£)	NBV (£)	NBV (£)
Freehold land and buildings	39,788	49,969	44,879
Leasehold improvements	2,363	2,162	2,263
Plant and equipment	24,633	24,601	24,617
Payments on account or AICC	4,319	11,598	7,959
Total tangible assets	71,103	88,330	79,717

Source: PAD00057, Pfizer's financial statements for the year ended 30 November 2013.

Table K.6: Total sales volumes of Pfizer Ltd and of Capsules by Pfizer Ltd during the year ended 30 November 2013

	YE 30.11.2013
UK total sales volume	44,329,624
UK's phenytoin sodium capsule sales volume	1,065,015
% of total volumes	2.4%

Source: PHT00136, Annex A to Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1).

Table K.7: Average value UK fixed assets allocated to Phenytoin in the UK during the year ended 30 November 2013

Fixed Assets: UK	Average in FY2013
	NBV (£)
Fixed assets allocated to Capsules*	1,915,181

Source: PHT00136, Annex A to Pfizer's response of 30 July 2014 to the CMA's finalised s.26 Notice of 6 June 2014 (CMA document reference 00725.1), and PAD00057, Pfizer's financial statements for the year ended 30 November 2013.
*These assets are allocated using the UK's total sales volumes.

Working capital

Table K.8: Working capital figures and allocation to UK Phenytoin at the 30 November 2012, 30 November 2013 and on average between these dates

	YE 30.11.2012	YE 30.11.2013	Average FY2013
	GBP	GBP	GBP
API (Kalamazoo)*	100,838	563,509	332,174
WIP/Finished Product (Freiburg)	1,875,000	1,875,000	1,875,000
Total Working Capital Inventory	1,975,838	2,438,509	2,207,174
UK % of Freiburg production	31.8%	23.5%	27.0%
Freiburg WC allocated to UK	627,705	573,335	518,944
Finished Product (UK)	336,890	1,032,986	684,938
Total UK WC	964,595	1,606,321	1,203,882

Source: PHT00142, Annex A of Pfizer's response of 28 October 2014 to CMA Questions in relation to Reasonable Return and Information Relating to the PPRS Annual Financial Return (CMA document reference 00903.2).
* Assumed that all API from Kalamazoo is delivered to Freiburg for the production of Capsules. This is likely to overstate the level of API.

Total capital employed

Table K.9: Pfizer's total capital employed in the production and supply of Capsules

	Average FY2013
Freiburg fixed assets (NBV)	£396,809
UK fixed assets (NBV)	£1,915,181
Working capital	£1,203,882
Total Capital employed	**£3,515,873**

Annex L: The effect of the Parties' price changes on their respective excesses

Introduction

L.1 At the beginning of 2014, Pfizer and Flynn decreased their respective prices of Capsules. In February 2014, Pfizer decreased its prices retrospectively for all sales from January 2014 and going forward. A rebate was also provided for all stock held by Flynn based on the new supply price. Subsequently, Flynn decreased its supply price to wholesalers from April 2014.

Pfizer

L.2 From February 2014, Pfizer lowered the price of the 50mg, 100mg and 300mg Capsules it sold to Flynn. The new prices were set retrospectively for all sales from 1 January 2014 and for all stock held by Flynn as of 31 December 2013. The CMA believes that Pfizer's Prices remain excessive after the price change but has decided to present the Parties' results for the different time periods. Since the price changes were backdated to 1 January 2014, the CMA believes Pfizer has two relevant time periods:

L.2.1 First period: September 2012 to 31 December 2013, which includes the rebate on all stock held as at 31 December 2013.

L.2.2 Second period: 1 January 2014 to 7 December 2016, from the date these sales were backdated.

L.3 The CMA has calculated the value of Pfizer's rebate on the stock held by Flynn as at 1 January 2014. The approach taken was to apply the prices from 1 March 2014 to the volumes sold during January and February 2014 to determine what the revenue figures would have been over this period if they had been applied as of 1 January 2014. This calculation is outlined in Table L.1.

Table L.1: Pre-January 2014 rebate value

	25mg	50mg	100mg	300mg	Total
Post February 2014 price	£4.50	£6.53	£34.21	£34.39	N/A
January and February 2014 sales volumes	18,536	39,120	10,044	21,900	89,600
January and February 2014 revenue at new prices	£83,412	£255,438	£343,585	£753,189	£1,435,623
Actual January and February 2014	£83,412	£238,550	-£420,694	£579,870	£481,139
Rebate on stock held at 31.12.2013	**£0**	**£16,887**	**£764,278**	**£173,319**	**£954,484**

L.4 As shown above, under the new prices, the sale of 89,600 packs of Phenytoin should have led to revenue of £1,435,623, yet only £481,139 was recorded. As such, the CMA concludes that the rebate on all stock held at 31 December 2013 was valued at £954,484. This rebate has been included in the first period as it applied to all sales before 1 January 2014.

L.5 Using the rebate adjustment set out in Table L.1, Pfizer's excesses during the periods of September 2012 to December 2013 (prior to some of Pfizer's Prices decreasing) and between January 2014 to December 2016 (subsequent to Pfizer's Prices decreasing) are set out in Tables L.2 and Table L.3 respectively.

Table L.2: Pfizer's excesses on sales of Capsules between September 2012 and December 2013 (prior to some of Pfizer's Prices decreasing)

	Capsule strength (mg)				
	25mg	**50mg**	**100mg**	**300mg**	**Total sales**
Revenue	£798,277	£2,752,959	£20,130,202	£9,843,929	£33,525,368
Cost Plus	£642,266	£1,373,101	£2,406,614	£1,159,007	£5,580,989
Excess (revenue)	£156,011	£1,379,858	£17,723,588	£8,684,922	£27,944,379
Price per pack	£4.50	£7.04	£40.95	£41.76	N/A
Excess per pack	£0.88	£3.53	£36.05	£36.85	N/A
Excess (%)	24%	100%	736%	749%	501%

Table L.3: Pfizer's excesses on sales of Capsules between January 2014 and December 2016 (after some of Pfizer's Prices decreased)

	Capsule strength (mg)				
	25mg	**50mg**	**100mg**	**300mg**	**Total sales**
Revenue	£1,607,776	£4,501,203	£16,963,937	£14,688,961	£37,761,878
Cost Plus	£1,293,604	£2,419,523	£2,427,537	£2,100,196	£8,240,860
Excess (revenue)	£314,172	£2,081,680	£14,536,400	£12,588,765	£29,521,018
Price per pack	£4.50	£6.53	£34.21	£34.39	N/A
Excess per pack	£0.88	£3.02	£29.31	£29.47	N/A
Excess (%)	24%	86%	599%	599%	358%

L.6 While Pfizer's excesses were lower following the price decreases than they had been prior to then, the CMA considers that each of those excesses are nevertheless both *material* and *sufficiently large to be deemed excessive* in the context of the Excessive Limb of the United Brands Test.

Flynn

L.7 Flynn subsequently introduced its own price decreases in April 2014, although they were not backdated and did not include any rebate. As such, Flynn's two relevant time periods are:

L.7.1 First period: September 2012 to 31 March 2014.

L.7.2 Second period: 1 April 2014 to 7 December 2016.

L.8 Table L.4 sets out what Flynn's excesses are for the period of September 2012 to March 2014 (prior to some of Flynn's Prices decreasing), and Table L.5 sets out Flynn's excesses between April 2014 to December 2016 (subsequent to some of Flynn's Prices decreasing).

Table L.4: Flynn's excesses on sales of Capsules between September 2012 and March 2014 (prior to some of Flynn's Prices decreasing)

	Capsule strength (mg)				
	25mg	**50mg**	**100mg**	**300mg**	**Total sales**
Revenue	£2,819,688	£6,030,165	£29,920,318	£15,392,199	£54,162,369
Cost Plus	£1,235,437	£3,656,847	£21,863,614	£11,241,080	£37,996,979
Excess (revenue)	£1,584,251	£2,373,318	£8,056,704	£4,151,118	£16,165,390
Price per pack	£13.83	£14.10	£59.53	£59.32	N/A
Excess per pack	£7.77	£5.55	£16.03	£16.00	N/A
Excess (%)	**128%**	**65%**	**37%**	**37%**	**43%**

Table L.5: Flynn's excesses on sales of Capsules between April 2014 and December 2016 (after some of Flynn's Prices decreased)

	Capsule strength (mg)				
	25mg	**50mg**	**100mg**	**300mg**	**Total sales**
Revenue	£4,680,302	£9,287,721	£22,780,514	£20,489,245	£57,237,783
Cost Plus	£1,892,202	£4,982,962	£16,815,958	£14,069,096	£37,760,218
Excess (revenue)	£2,788,100	£4,304,760	£5,964,556	£6,420,149	£19,477,565
Price per pack	£14.41	£14.60	£48.87	£52.48	N/A
Excess per pack	£8.58	£6.77	£12.79	£16.44	N/A
Excess (%)	**147%**	**86%**	**35%**	**46%**	**52%**

L.9 As can be seen, due to the fall in Pfizer's Prices and the change in Flynn's distribution model, Flynn's percentage excesses in the second of these periods actually increased in total and for 25mg, 50mg and 300mg capsules. Excesses on 100mg capsules fell by only 2% in the second period.

L.10 Flynn's excesses on 25mg, 50mg and 300mg capsules are greater in the second period than its percentage excesses across the whole of the Relevant Period. Its excesses on 100mg capsules are only 2% below its excesses across the whole of the Relevant Period. Accordingly, the CMA considers that Flynn's excesses remain excessive by any reasonable measure.

Annex M: Summary of key evidence relating to the meeting between the DHSC and Teva on 16 October 2007

Contemporaneous email correspondence between the DHSC and Teva[2188]

M.1 In response to a request for internal documents issued during the course of the Remittal, Teva provided a series of emails exchanged between the DHSC and Teva immediately following their meeting on 16 October 2007. These emails record an agreement reached between Teva and the DHSC at the meeting to a phased reduction in the Drug Tariff price of Tablets to £30 by the end of 2008.[2189]

M.2 The initial email from the DHSC to Teva summarised the agreement as being for a phased reduction in the Drug Tariff price to £40 from 1 January 2008 to £35 from 1 April 2008 and to £30 from 1 July 2008.

M.3 In response, Teva asked for the reduction to £30 to be implemented later in 2008. The DHSC's response confirmed its agreement that the £30 Drug Tariff price would be implemented on 1 October 2008, asking for Teva's final agreement.[2190] Teva confirmed later the same day.

M.4 The initial follow-up email from the DHSC official on 17 October 2007 refers to the discussions resulting in 'a conclusion which is of value to the NHS patients'. However, the DHSC official also refers twice to the anticipation of further reductions below £30.

M.5 The DHSC official refers to the outcome of the meeting (ie a reduction in the Drug Tariff price to £30) as being 'with a view to a further reduction'. In a subsequent email in the same chain, the DHSC official sets out that 'the reimbursement price will fall to £30 from 1 October 2008 and we will anticipate further reductions thereafter'.

M.6 The CMA has not seen any evidence of further discussions between the DHSC and Teva regarding pricing for the supply of Tablets. The Drug Tariff price remained at £30 from October 2008 until April 2016.

[2188] PRC00458, Emails between [DHSC Employee 1] (DHSC) and [Former Teva Director] (Teva) dated 17 October 2007 and 18 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020.
[2189] PRC00458, Email from [DHSC Employee 1] (DHSC) to [Former Teva Director] (Teva) dated 17 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020, which stated 'Just to summarise our agreement: the reimbursement price of Phenytoin sodium 100mg tablets* 28 will reduce to £40.00 from 1 January 2008, then to £35.00 from 1 April 2008 and then to £30.00 from 1 July 2008'.
[2190] PRC00458, Emails between [DHSC Employee 1] (DHSC) and [Former Teva Director] (Teva) dated 17 October 2007 and 18 October 2007, Teva's response of 4 September 2020 to the CMA's s.26 Notice of 31 July 2020.

Teva's internal documents from 2007

M.7 A Teva 'Internal briefing note' from 27 November 2007 reported internally on the outcome of the meeting with the DHSC.[2191] The briefing note acknowledged that the supply price of Tablets had been increasing and that this had caused the reimbursement price to rise to '113.62 for 28 in the latest list for Q4 2007'.

M.8 The briefing note reports that Teva 'have been working with the Department of Health (DH) on how to bring some stability to the situation, including looking at pricing and whether or not Phenytoin should remain in Category M or should move to Category A or C, which are reimbursed using different models'. It goes on to note, '[i]n the meantime, we are working to reduce the list price for phenytoin, as DH is changing the way that phenytoin will be reimbursed from January 2008. From January the drug tariff price will be based on the list price, and so reimbursement for the dispenser will be based on the new list price of £40.'

M.9 The briefing note also sets out a number of 'Frequently asked questions' and answers, including the following response clarifying that the new list price was not imposed on Teva by the DHSC:

> *Have we been told to do this?*
>
> *No, we have been discussing with DH for some time about the impact that an unintended consequence of the Category M model has been having and we have been working closely with them to work for the benefit of patients and customers.*[2192]

M.10 An internal Teva 'Staff briefing' document also included an explanation of the outcome of the meeting with the DHSC, as follows:[2193]

> *A little bit of the shine came off Phenytoin Sodium in Quarter 4. As you know the price of phenytoin had been rising throughout 2007, to the point where it was becoming our single most profitable product. In a commodity market you're at the mercy of the markets to a very great degree, and both we and the Department of Health felt that the market 'chasing up' the price of phenytoin was unsustainable. So we have worked with DH to stabilise the situation – on our part we have reduced the price to £40 from its peak of over £113, and for its part DH has changed reimbursement to a fixed £2 margin for the pharmacist on that to stop people 'speculating'. The up side is that the situation is now sustainable and stable – the down side is that with all the calculations for us, we will make less margin on phenytoin in*

[2191] PRC00461, Internal briefing note Phenytoin Sodium 100mg, 27 November 2007: Teva's response of 4 November 2020 to the CMA's s.26 Notice dated 31 July 2020.
[2192] PRC00461, Internal briefing note Phenytoin Sodium 100mg, 27 November 2007: Teva's response of 4 November 2020 to the CMA's s.26 Notice dated 31 July 2020.
[2193] PRC00463, Teva Staff briefing Quarter 4, 2007: Teva's response of 4 November 2020 to the CMA's s.26 Notice dated 31 July 2020.

2008 than we expected so this is a bit of a hole in the 2008 workplan before we really start.

DHSC email from 2013[2194]

M.11 In response to a request for internal documents issued by the CMA as part of its investigation on Remittal, the CMA received an internal DHSC email chain from July 2013 in which one of the DHSC attendees sets out his recollection of the circumstances surrounding the DHSC's meeting with Teva on 16 October 2007:

> *The department of health introduced a new method of calculating the drug tariff for the most commonly used generic medicines in April 2005. This new method was called category M.*
>
> *Category M concerned itself not with setting individual prices which represented the true transaction costs arising from the operation of the market. Rather it set a relative reimbursement level driven by, but not determined by, the average net price charged by manufacturers. The calculation of category M contained a deliberate opacity to hinder reverse engineering as this was thought to be potentially damaging to the market. The overall price level was set by reference to a target spend on all category M medicines. This target was reviewed under the pharmacy contract: a significant element of the cost of pharmacy was met by retail pharmacies retaining part of the margin secured through competition.*
>
> *When first introduced, the category M reimbursement level was around three times the average factory gate price. In the case of phenytoin, there was a single supplier which took advantage of its position to increase the factory gate price in the knowledge that the subsequent reimbursement prices would increase. This led to a spiralling price which through the operation did not increase overall costs to the NHS, but which greatly distorted the true cost of acquisition. All that was happening was increased expenditure on phenytoin was balanced by reduced reimbursement prices across the rest of category M products. Nonetheless, the distortion was an irritation and at a meeting with Teva it was agreed to reduce the reimbursement price over a period of several quarters. The alternative of ejecting the company from membership of Scheme M and then enforcing a maximum price by direction of the Secretary of State was considered a less attractive option.*
>
> *On reflection, the classification of phenytoin as a generic and its subsequent inclusion in category M was not a good idea. The company was quite open about the process, it saw an opportunity and exploited it. It could*

[2194] PRC01233, Email from [DHSC Employee 1] (DHSC) to DHSC colleagues dated 16 July 2013 (DHSC009.253), DHSC response of 22 December 2020 to the CMA's s.26 Notice of 7 July 2020.

have done the same under the previous category A process, but did not notice until the introduction of category M.

Evidence provided by [Former Teva Director] before the CAT

M.12 [Former Teva Director], one of the Teva staff in attendance at the meeting between the DHSC and Teva in October 2007, provided evidence to the CAT following the Parties' appeal of the CMA's 2016 Infringement Decision.

M.13 [Former Teva Director]'s recollection of the meeting was that the DHSC said that it wanted the price of Tablets to be reduced and Teva identified a reduced price.[2195] [Former Teva Director] could not recall the precise price tabled by Teva[2196] but did recall that the DHSC wanted Teva to implement a phased reduction in Tablet prices to a lower level.[2197]

M.14 [Former Teva Director] gave evidence that DHSC officials told Teva in the meeting that the Secretary of State had the power to reduce the price of Tablets if an agreement was not reached,[2198] although he could not recall reference being made to any specific powers.[2199]

M.15 [Former Teva Director] explained that Teva proposed in the meeting to reduce its price to £40 and that the DHSC officials wanted a phased reduction to £30.[2200]

M.16 Regarding the agreement reached to reduce the Drug Tariff price to £30, [Former Teva Director] noted that '[i]t 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'.[2201] [Former Teva Director] also said that the 'original price' of Tablets was 'around the same price as Phenytoin capsules, historically. So I think about £3'.[2202]

M.17 [Former Teva Director] also provided his view that the overall cost of a drug to the NHS is more relevant to the possibility of intervention than the pricing of individual drugs. [Former Teva Director] confirmed in his response to questions that the overall cost to the NHS would have to be 'pretty eye watering' to attract regulatory intervention.[2203]

[2195] PRE00625, First Witness Statement of [Former Teva Director], 6 February 2017, paragraphs 6 and 7.
[2196] PRE00625, First Witness Statement of [Former Teva Director], 6 February 2017, paragraphs 6 and 7.
[2197] PRE00625, First Witness Statement of [Former Teva Director], 6 February 2017, paragraph 7.
[2198] PAD00030, [Former Teva Director] Cross Examination, day 5, page 19, lines 18-22.
[2199] PAD00030, [Former Teva Director] Cross Examination, day 5, page 23, lines 19-20.
[2200] PAD00030, [Former Teva Director] Cross Examination, day 5, page 20, line 12, to page 21, line 10.
[2201] PAD00030, [Former Teva Director] Cross Examination, day 5, page 38, lines 3-6.
[2202] PAD00030, [Former Teva Director] Cross Examination, day 5, page 44, lines 7-9.
[2203] PAD00030, [Former Teva Director] Cross Examination, day 5, page 37, lines 14-16.