

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE**

**Excessive Pricing in Pharmaceutical Markets - Note by the United Kingdom**

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More documents related to this discussion can be found at

[www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm](http://www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm)

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## United Kingdom

### 1. Introduction

1. This is not the first time that the issue of excessive pricing is discussed in this forum.<sup>1</sup>
2. Since 2011 a number of competition authorities, particularly in the European Union ('EU') but also elsewhere, have further developed significant experience in this area of the law with a particular focus in the pharmaceutical sector.
3. The Competition and Markets Authority ('CMA') is one of those authorities with a number of ongoing investigations in this area. Therefore, in this paper we will try to explain the reasons why, in certain circumstances, we have decided that intervention in the pharmaceutical sector was appropriate and share our views on the relevant legal test.

### 2. Is intervention appropriate?

4. The Background Note by the Secretariat already sets out a number of reasons in favour and against intervention<sup>2</sup> and, therefore, these will not be repeated here.
5. In the United Kingdom, there is a clear legal basis to intervene against excessive prices. Chapter II of the Competition Act 1998 (mirroring Article 102 of the Treaty on the Functioning of the European Union ('TFEU')) specifically prohibits the imposition of unfair purchase or selling prices or other unfair trading conditions as an abuse of a dominant position.
6. The CMA also considers that in certain circumstances it is important as a matter of policy to intervene directly against excessive prices.<sup>3</sup> Ensuring consumers are not exploited by unfairly high prices is at the heart of antitrust enforcement and much enforcement activity is focused on preventing companies being able to achieve the level of sustained market power that is necessary to impose excessive prices.
7. Although many of the industries that are most likely to give rise to the risk of excessive pricing (particularly the traditional utility sectors) are subject to *ex ante* regulation, this coverage is not complete. For example, as set out below, there is no *ex ante* regulation in respect of generic medicines in the United Kingdom ('UK') with the prices paid by the National Health Service ('NHS') determined by competition. However, as is set out in the following section, certain generic drug markets are characterised by high

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1 OECD (2011), Excessive Prices DAF/COMP(2011)18.

2 OECD (2018), Excessive Prices in Pharmaceutical Markets DAF/COMP(2018)12, Background Note by the Secretariat, Section 2.2.

3 This is consistent with academic research on the preparatory works associated with the initial drafting of Article 102 of the TFEU (then Article 86) which reveal that this provision was originally intended to apply only to 'exploitative' abuses and not 'exclusionary' abuses (Pinar Akman, "Searching for the Long-Lost Soul of Article 82EC", Vol. 29, No. 2 (2009) Oxford Journal of Legal Studies, page 271).

barriers to entry and expansion and inelastic demand – thereby creating the conditions where prices could potentially be increased to abusively high levels.

8. Where such gaps in the regulatory system exist there are strong public policy reasons for the CMA to intervene using its enforcement powers.

9. It is often suggested that the introduction of new specific regulatory regimes would be a preferable means of dealing with excessive prices instead of antitrust enforcement. However, this approach would often require legislative change and therefore would take time to implement. Further, this approach would only partially address the harm caused because it would be forward looking and would not address historic harm. For example, it is unlikely to mean that private actions could be taken by exploited customers to recover excesses they have may have paid as would be possible following an antitrust intervention. Also, competition law enforcement is often the trigger that leads to regulatory intervention,<sup>4</sup> such that the two approaches do not have to be mutually exclusive.

10. We are obviously alert to concerns that competition authorities may become quasi price regulators when intervening against excessive prices. We consider any intervention very carefully and would generally only intervene where there is an absence of effective regulation and where the price in question is unlikely to be competed down in a reasonable timeframe.

11. Finally, the difficulty and complexity of the analysis and the risks of false positives can also be overstated, as this is not exclusive to excessive pricing. There are several areas of competition law that are complex and difficult but where competition law intervention is less controversial.

### 3. Pharmaceutical sector

12. Generic competition has been broadly effective in the UK and resulted in substantial savings to the NHS's drugs bill.

13. However, in recent years a number of investigations have been launched in the UK into various unbranded generic drugs where the pattern of pricing behaviour has run counter to that typically associated with generic competition. Far from delivering the price reductions typically associated with generic competition, these drugs have instead produced very substantial and sustained price increases of up to several thousand percent, often adding several tens of millions of pounds to the NHS's drugs bill.

14. These drugs are generally unbranded, very old and long off patent. The price increases are not justified by cost pressures, but rather appear to be the result of competition failing, depriving tax payers of the full-benefits of generic competition.

15. Some specific circumstances of the pharmaceutical sector may explain this trend.

16. First, the pricing of generic drugs is largely unregulated in the UK as the expectation is that competition will drive prices down and deliver the best outcomes for consumers.

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<sup>4</sup> This is for instance what happened in the UK where the Government, following the CMA's investigations, introduced new legislation – Health Service Medical Supplies (Costs) Act 2017 – to extend the powers of the Department of Health in relation to the pricing of generic drugs.

17. Second, a number of generic products (often referred to as “niche generics”) are characterised by very high, non-transitory barriers to entry/expansion and inelastic demand and may provide the incumbents with substantial market power. In addition, some of these markets are small and/or in decline making new entry commercially unviable. In such circumstances, very high prices may not stimulate effective market entry meaning that the market will not self-correct within a reasonable timeframe.

18. Third, national health systems are not a single purchasing entity and have a fragmented structure, including a number of different bodies with different functions and interests. There is an important distinction between (i) the person who consumes the medicine (i.e. the patient); (ii) the person which chooses the medicine to be prescribed (i.e. the prescribing clinician); (iii) the person who dispenses a particular preparation of the medicine (i.e. the pharmacist); and (iv) the person that pays for the drug prescribed and dispensed (i.e. Clinical Commissioning Groups in the UK).

19. The split between the different roles often gives rise to a very inelastic demand, as those who benefit from the drug (patients) or play a role in deciding which one to prescribe (clinician) and dispense (pharmacist) ultimately do not have to pay for it, whereas the entity that ultimately has to fund the drug (Clinical Commissioning Groups in the UK) plays no role in deciding which medicine should be prescribed and dispensed.

#### 4. Current cases

20. In December 2016, the CMA issued infringement decisions against both Pfizer and Flynn Pharma finding that they had abused their dominant position in respect of the supply of an antiepileptic drug (phenytoin sodium capsules) in the UK by imposing excessive and unfair prices.<sup>5</sup>

21. Following the CMA’s decision, prices fell from £54 to £9 saving the NHS millions of pounds.

22. Phenytoin sodium is a very old drug. It was originally synthesised in 1908 and first marketed in the 1930s. It is long off-patent and rarely prescribed for new epilepsy patients because of its potential side effects. However, it remains an essential treatment for an estimated 48,000 patients in the UK who are either historically stabilised on the product or have not responded well to newer treatments.

23. In 2012 the drug was de-branded meaning it was no longer subject to price regulation, prices subsequently increased very substantially - by up to 2,600%. For example, the amount the NHS was charged for 100mg packs of the drug increased from £2.83 to £67.50, before reducing to £54.00 from May 2014. NHS expenditure on phenytoin sodium capsules increased from £2million a year in 2012 to about £50million in 2013. The price increases were not the result of cost pressures and the product had not been subject to any recent investment or innovation.

24. An important feature of the case was the presence of prescribing and dispensing guidance which created barriers to entry and expansion. The guidance in question has resulted in patients who are stabilised on phenytoin sodium capsules not generally being switched to other treatments, including phenytoin sodium capsules made by other

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<sup>5</sup> See CMA’s decision available at <https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products#non-confidential-infringement-decision>.

manufacturer's, due to potentially serious health consequences. The CMA found that this guidance provided Pfizer and Flynn with market power and also meant that the high prices would be unlikely to incentivise entry sufficiently effective to allow the market to self-correct in a reasonable timeframe. As a result of this, the CMA found that the NHS had no choice but to pay the substantially increased prices.

25. As set out below, the CMA's decision was partially overturned on appeal by the UK's Competition Appeal Tribunal ('CAT'), which set aside the CMA's analysis of abuse and remitted it back for reconsideration in accordance with the Judgment, including any consequential matters.<sup>6</sup>

26. In addition to *Phenytoin*, the CMA has two additional cases involving excessive and unfair pricing which have reached the Statement of Objections stage:

1. In December 2016, the CMA provisionally found that Actavis UK had broken competition law by charging excessive and unfair prices for hydrocortisone tablets treating adrenal issues. The price of a packet rose from 70p to £88 between April 2008 and March 2016;<sup>7</sup> and
2. In November 2017, the CMA provisionally found that Concordia had broken competition law by charging excessive and unfair prices for liothyronine tablets, a thyroid drug. The price of a packet rose from around £4.50 to around £250 over 10 years.<sup>8</sup>

27. Although the ability of generic suppliers to extract very high prices varies on a market by market and country by country basis, the UK is not alone in experiencing high-prices for some generics or in taking enforcement action against them.

28. In May 2017, the European Commission launched an investigation into concerns that Aspen Pharma may have engaged in excessive pricing in respect of five life-saving cancer medicines.<sup>9</sup> The Commission's investigation itself followed on from the Italian Competition Authority's (the AGCM) own enforcement action against the same company for implementing price increases ranging between 250% and 1500% for the same drugs in the Italian market which resulted in a €5 million fine being imposed on Aspen<sup>10</sup> and which, so far, has been upheld on appeal.<sup>11</sup> The Danish Competition Council also recently ruled that CD Pharma had abused its dominant position by charging unfair prices for the drug

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6 Flynn Pharma and Pfizer v Competition and Markets Authority ('Flynn/Pfizer') [2018] CAT 11.

7 See press release of 16 December 2016 available at <https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs>. See also case update of 9 August 2017 available at <https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-practices#history>.

8 See press release of 21 November 2017 available at <https://www.gov.uk/government/news/drug-company-accused-of-abusing-its-position-to-overcharge-the-nhs>.

9 See press release of 15 May 2017 available at [http://europa.eu/rapid/press-release\\_IP-17-1323\\_en.htm](http://europa.eu/rapid/press-release_IP-17-1323_en.htm).

10 Decision of 29 September 2016 in case n. A480 available at <http://www.agcm.it/stampa/comunicati/8419-a480-rincari-di-farmaci-oncologici-antitrust-multinazionale-aspen-per-5-milioni-di-euro.html>.

11 Decision of the Lazio Regional Administrative Tribunal of 26 July 2017 in case n. 8948/2017.

*Syntocinon*.<sup>12</sup> As with the UK cases, the drugs which are the subject of these investigations are all old and long off patent.

## 5. Why intervention was considered appropriate

29. Unsurprisingly, intervening to prevent excessive prices in the pharmaceutical sector has not been without its critics. However, the CMA considers that intervention in these cases was appropriate for the following reasons.

30. First, the price increases of each of the drugs under investigation are, at least, several thousands of per cent in circumstances where the drugs are very old and costs have remained broadly stable. This has increased the NHS's costs of purchasing these treatments by tens of millions of GBP. This increases the NHS's overall expenditure on drugs, reduces the resources available to fund other treatments and means the taxpayer may not be getting value for money.

31. Second, the markets in these cases are often small and/or in decline and are characterised by high, non-transitory barriers to entry and expansion. This means that prices are unlikely to be competed down in the short and medium term meaning the drug suppliers effectively have a captive customer base.

32. Third, the risk of chilling research and development in the pharmaceutical sector is very low, as the CMA has not taken enforcement action against any innovative or patented product. All the drugs the CMA has investigated are very old and at the stage of the drug life-cycle where very high prices and profits would be expected to attract entry and be competed down. Nor have they been the subject of any recent innovation or investment. But for the presence of barriers to entry and expansion, the companies in question would have been unlikely to have been able to impose the prices they have been able to because generic competition should compete them down.

## 6. Legal test

33. The 'seminal'<sup>13</sup> judgment in this area of the law is *United Brands v Commission*<sup>14</sup> which provides the 'critical reference point'<sup>15</sup> to determine how Article 102 TFEU might apply to unfair pricing.

34. In *United Brands*, the Court of Justice of the European Union held that:

*'It is advisable...to ascertain whether the dominant undertaking 'has made use of the opportunities arising out of its dominant position in such a way as to reap*

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12 This followed a 2,000% increase in its price (from EUR 6 to EUR 127) in the period April to October 2014. See press release of 31 January 2018 available at <https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/>.

13 *Albion Water and Another v Water Services Regulation Authority and Others* ('Albion Water II') [2008] CAT 31, paragraph 14 and *Flynn/Pfizer* [2018] CAT 11, paragraph 285.

14 C-27/76 *United Brands*, EU:C:1978:22.

15 *Flynn/Pfizer* [2018] CAT 11, paragraph 285.

*trading benefits which it would not have reaped if there had been normal and sufficiently effective competition*.<sup>16</sup>

35. A dominant undertaking reaps trading benefits that it would not have reaped if there had been normal and sufficiently effective competition if it imposes:

*'...a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse'*.<sup>17</sup>

36. These two paragraphs from *United Brands* cited above provide two general principles governing the possible abuse of dominant position by unfair pricing.<sup>18</sup>

37. Different methods and approaches may reasonably be used to establish whether a price is unfairly high.<sup>19</sup> One possible way of objectively assessing whether a price bears no reasonable relation to the economic value of the product is to determine, if the calculation is possible, the profit margin by reference to the selling price and cost of production.<sup>20</sup>

38. Under this approach a price will be abusive where the following cumulative, two stage test is met:

1. 'the difference between the costs actually incurred and the price actually charged is excessive' ('Excessive Limb'); and, if yes
2. 'a price has been imposed which is either unfair in itself or when compared to competing products' ('Unfair Limb').<sup>21</sup>

39. Other methods and approaches may however be devised for determining whether a price is abusive.<sup>22</sup> The EU and domestic courts have, for example, considered prices

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16 C-27/76 *United Brands*, EU:C:1978:22, paragraph 249. See also *Albion Water II* [2008] CAT 31, paragraphs 14 and 274; *Napp v Director General of Fair Trading* ('Napp') [2002] CAT 1, paragraph 402; and C-52/07 *Kanal 5 v STIM*, EU:C:2008:703, paragraph 27.

17 *United Brands*, paragraph 250. In this respect see also judgments in *General Motors Continental NV v Commission* C-26/75 EU:C:1975:150, paragraph 12; C-52/07 *Kanal 5 v STIM*, EU:C:2008:703, paragraph 28; and C-351/12, *OSA v Léčebné lázně Mariánské Lázně a.s.*, paragraph 88.

18 *Flynn/Pfizer* [2018] CAT 11, paragraph 287.

19 C-27/76 *United Brands*, EU:C:1978:22, paragraph 253. See also *Napp* [2002] CAT 1, paragraph 391.

20 C-27/76 *United Brands*, EU:C:1978:22, paragraph 251.

21 C-27/76 *United Brands*, EU:C:1978:22, paragraph 252. See also *Albion Water II* [2008] CAT 31, paragraph 7; *Attheraces Limited v the British Horseracing Board Limited* ('Attheraces High Court') [2005] EWHC 3015 (Ch), paragraph 294; and *Case 36568 Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004, paragraphs 102, 149, 150 and 215.

22 C-27/76 *United Brands*, EU:C:1978:22, paragraph 253 and C-177/16 *Latvian Copyright* EU:C:2017:689, paragraph 37. See also *Napp* [2002] CAT 1, paragraph 391.

charged by (a) the dominant firm at a different point in time;<sup>23</sup> (b) non-dominant firms;<sup>24</sup> and (c) the dominant firm in different geographical markets.<sup>25</sup>

40. The authority has a measure of discretion<sup>26</sup> in defining the appropriate framework for assessment.

41. In exercising its discretion, the CMA has decided to apply in its cases the two-limb test set out in *United Brands*.

42. This two-limb test has been consistently affirmed by the Court of Justice;<sup>27</sup> the European Commission;<sup>28</sup> the Court of Appeal;<sup>29</sup> the CAT;<sup>30</sup> and competition authorities of other Member States of the EU.<sup>31</sup>

43. On appeal the CAT upheld the CMA's findings on market definition and dominance and agreed with much in the decision,<sup>32</sup> but it found that the CMA's analysis of abuse had been defective.

44. In relation to the Excessive Limb that CAT found that the CMA:

1. 'was wrong in law to restrict its Excessive Limb assessment to a Cost Plus approach, and to exclude other methodologies, rather than seeking to establish a benchmark price (or range) that would have pertained in circumstances of normal and sufficiently effective competition using the evidence more widely available;
2. was wrong in law to adopt a Cost Plus methodology that produced a result that would have pertained in circumstances of perfect or, more accurately, idealised competition, rather than the 'real world'; and
3. made an error of assessment by relying only on the Cost Plus approach that it selected.'

45. With regard to the Unfair Limb, the CAT found that the CMA 'did not appropriately consider what was the right economic value for Pfizer-Flynn Capsules; and it did not take

23 Case 226/84 *British Leyland v Commission* EU:C:1986:421, paragraphs 27–30.

24 Case 30/87 *Bodson v SA Pompes funèbres des régions libérées* EU:C:1988:225, paragraph 31; *Napp* [2002] CAT 1, paragraph 392.

25 Case 395/87 *Tournier* EU:C:1989:319, paragraph 38; cases 110/88, 241/88 and 242/88 *Lucazeau* EU:C:1989:326, paragraph 326; C-177/16 *AKKA/LAA* EU:C:2017:689 ('Latvian Copyright'), paragraph 38.

26 *Flynn/Pfizer* [2018] CAT 11, paragraph 300.

27 For a recent example see Case C-177/16 *Latvian Copyright*, paragraph 36.

28 Case 36568 *Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004, paragraphs 98-103 and 145-152.

29 *Attheraces Limited v British Horse Racing Board Limited* ('Attheraces Court of Appeal') [2007] EWCA Civ 38, paragraphs 114-119.

30 *Albion Water I* [2006] CAT 23, paragraphs 308 and 314; *Albion Water II* [2008] CAT 31, paragraphs 14-15 and 20-21; *Napp* [2002] CAT 1, para 387.

31 See e.g. *Aspen Italian NCA* decision of 29 September 2016 and *CD Pharma Danish NCA* decision of 31 January 2018.

32 *Flynn/Pfizer* [2018] CAT 11, paragraph 463.

sufficient account of the situation of other, comparable products, in particular of the phenytoin sodium tablet.<sup>33</sup>

46. Consequently, the CAT ordered the issue of abuse and any consequential matters to be remitted to the CMA for reconsideration in accordance with the Judgment.<sup>34</sup>

47. The CMA is currently seeking permission to appeal this Judgment before the UK's Court of Appeal and, therefore, at the date of this submission these proceedings are still ongoing.

## 7. Conclusion

48. Excessive pricing is a complex area of competition law and competition authorities ought to consider carefully the need for intervention, not least to avoid the risk of overenforcement.

49. However, these risks and complexity can be overstated and should not result in underenforcement where intervention is appropriate. In particular, intervention may be appropriate where there is an absence of effective regulation and where markets conditions are such that very high prices are unable to stimulate effective entry allowing the market to properly self-correct in a reasonable timeframe.

50. Some of these features may be present in specific sectors of the pharmaceutical industry, in particular generics markets which are often characterised by the absence of effective regulation, the existence of high, non-transitory barriers to entry/expansion and fragmented national health systems.

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33 Flynn/Pfizer [2018] CAT 11, paragraph 464.

34 Ruling (Remittal and Permission to Appeal) of 25 July 2018 [2018] CAT 12, paragraph 47.