

Pfizer and Flynn Pharma: The end of the road for excessive pricing cases?

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Following a substantial increase of up to 2,600 per cent in the price of the anti-epilepsy drug phenytoin sodium, the UK Competition and Markets Authority (CMA) [fined](#) Pfizer and Flynn Pharma nearly £90 million for unfair prices charged to the National Health Service (NHS). In its [judgment](#), the Competition Appeal Tribunal (CAT) has since set aside the CMA's decision and biggest ever fine,¹ demanding more from the CMA. Does this signal the end of excessive pricing cases?

The past

In 2012, the NHS spent approximately £2 million on phenytoin sodium capsules. In 2013, this figure was £50 million - a price increase of up to 2,600 per cent. The price of a 100mg pack of the drug rose from £2.83 to £67.50.² What happened?

Until 2012, Pfizer manufactured and sold capsules of phenytoin sodium (Capsules) under the brand name Epanutin. In 2012, Pfizer then sold the Capsules' distribution rights to Flynn Pharma. Now off patent, the drug was no longer subject to price regulation. After allegedly taking advantage of a loophole in price control legislation, Pfizer and Flynn Pharma raised their prices dramatically.³

Philip Marsden of the CMA [said](#) that the Companies “*deliberately exploited the opportunity offered by de-branding*” and that the “*extraordinary price rises have cost the NHS and the taxpayer tens of millions of pounds*”. The CMA concluded that both companies had abused a dominant position in their respective markets and directed both to lower their prices. To determine whether the companies' prices were excessive, the CMA had considered a benchmark of no more than a 6 per cent return on sales (ROS) to be reasonable. Both Pfizer's and Flynn Pharma's ROS were significantly, and consistently, higher than that 6 per cent.

The CMA imposed fines of £84.2 million and £5.2 million on Pfizer and Flynn Pharma respectively. Both appealed the Decision. Flynn Pharma [commented](#) that if left unchallenged “*the CMA's decision...would stunt investment in generics*”.

The present

The importance of the Decision for the CMA and the NHS is clear. Not only does the case impact a number of outstanding CMA investigations,⁴ but it directly impacts the NHS' negotiating position and any attempt to

¹ *Pfizer and Flynn Pharma vs CMA*, Judgment of the CAT dated 7 June 2018 (Judgment).

² *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, CMA decision of 7 December 2016 (Decision).

³ Pfizer's supply price to Flynn Pharma's and Flynn Pharma's selling price to the NHS.

⁴ For example: Liothyronine tablets: suspected excessive and unfair pricing, CMA investigation opened in October 2016; and Hydrocortisone tablets: suspected excessive and unfair pricing, CMA investigation opened in March 2016.

bring private actions against Pfizer and/or Flynn Pharma. That said, the CAT's resolution to set aside the Decision and refer the case back to the CMA is a significant setback for the competition authority.⁵ In a substantial judgment, the CAT found that the CMA's conclusions on abuse of dominance were simply wrong.

This was not necessarily the judgment expected. The Decision was long (over 500 pages), and contained a substantial amount of reasoning, yet the CAT concluded that the CMA's analysis needed to go further. Also, the press had heavily emphasised the significant price increase of "up to 2,600 per cent overnight" and the CMA alleged that "*the drug was deliberately de-branded*".⁶

Yet, the CAT decided that the CMA incorrectly applied the legal test for unfair pricing:⁷

- The CMA was wrong to rely solely on the cost-plus approach, which allowed for only a 6 per cent ROS. The "CMA's almost total reliance on a reasonable rate of return approach" was unconvincing, regardless of any criticism as to how the 6 per cent was reached. The CAT was clear - the CMA should not have relied on the ROS benchmark alone.
- The CMA failed to take sufficient account of other, comparable, products. The CAT concluded that "*it cannot be right that an authority can simply ignore a prima facie valid argument that a price is fair*".
- The CMA did not appropriately consider the correct economic value for the Capsules. The CAT accepted the difficulty in placing a precise monetary value on patient benefit but considered that a qualitative assessment should have been attempted.

The future

As the CAT points out, "*cases of pure unfair pricing are rare in competition law*". Authorities must avoid becoming price regulators. However, the law explicitly prohibits unfair pricing in certain circumstances. There is "*no reason in principle why competition law cannot be applied, provided this is done on the correct legal basis and the analysis of evidence is sound*". Competition authorities have the power to punish excessive pricing, but a balancing act is necessary. See Diagram 1 for the CAT's suggested framework for applying the test in *United Brands*.

Despite their rarity, there have been an increasing number of excessive pricing cases in Europe recently. The European Commission is [currently](#) investigating concerns that Aspen Pharma excessively priced five cancer medicines. The Judgment represents a significant blow to the CMA's ongoing work in the pharmaceutical sector and excessive pricing cases.

The CMA may appeal the Judgment to the Court of Appeal. The outcome of this case, and the outcome of the European Commission's investigation, are highly anticipated. The CMA has "*several active investigations which may now be severely delayed*".⁸ The UK Department of Health and Social Care said that it would support the CMA in any appeal.

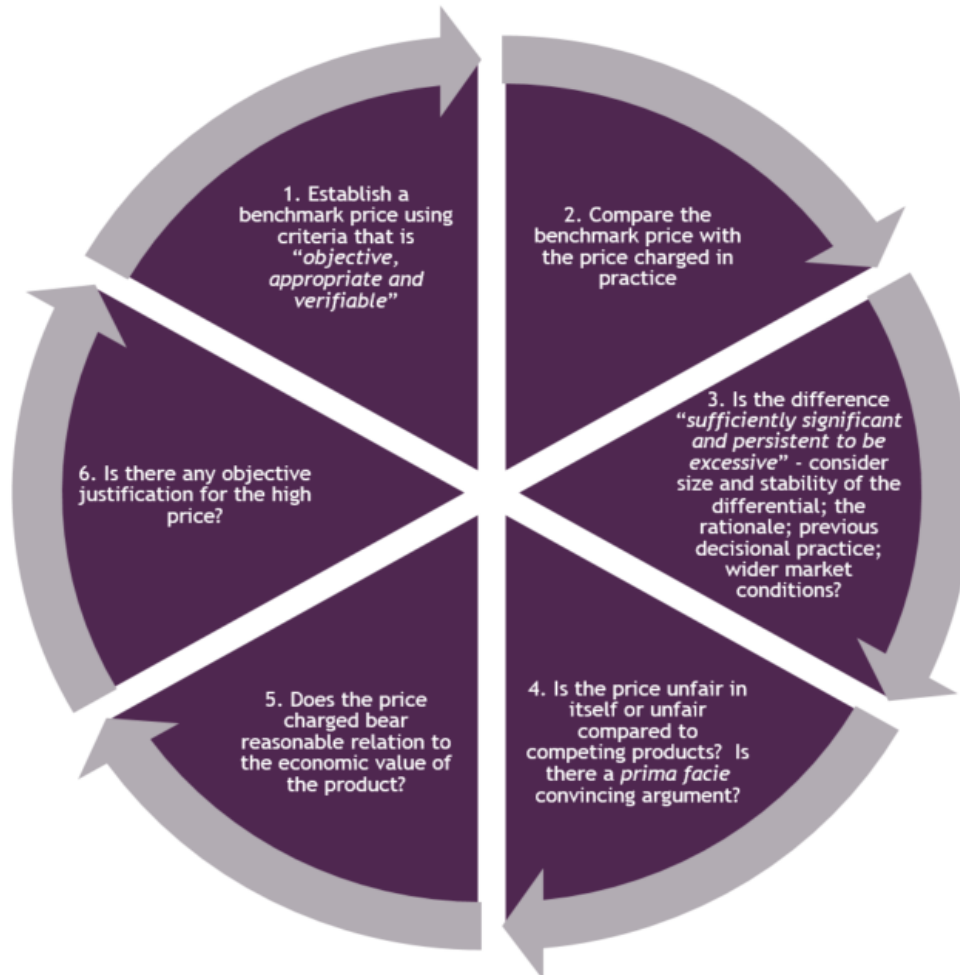
⁵ The CAT did not make a finding as to the existence of an abuse.

⁶ *CMA fines Pfizer and Flynn £90 million for drug price hike to NHS*, CMA Press Release dated 7 December 2016.

⁷ As set out in Case C-27/76 *United Brands v Commission*, Judgment of 14 February 1978, and as developed by the courts.

⁸ *Drug companies win test case on overcharging*, Billy Kenber of The Times dated 8 June 2018.

Diagram 1



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