Europe Economics

Pfizer Fine for Excessive Pricing

A look at the recent excessive pricing cases in the pharmaceutical sector and the role of the regulatory framework.

Context

To consider a firm for excessive charging, the competition authority has to first prove market dominance. Abuse of dominance cases are extremely rare in the UK. Since 2000, there were only seven cases of abuse of dominance.[1] Among them, only one was related to excessive pricing.[2]

The reluctance of competition authorities to bring such cases stems from the difficulty in defining "excessive". In the 1978 United Brands case, the Court of Justice of the European Communities suggested a price is excessive when it bears no reasonable relation to the economic value of the product in question. Meanwhile, in the OFT's decision on Napp (2002), it stated that to prove excessive pricing, "it must be demonstrated that (i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels".

Since there does not exist a precise definition of "excessive" in competition laws, it can be difficult for competent authorities to prove the case.

The fine

On 7th December, the Competition and Markets Authority (CMA) fined pharmaceutical company Pfizer £84.2 million for excessive pricing. This is the highest fine the CMA has imposed. In addition, Flynn Pharma, the distributor of the drug, also received a fine of £5.2 million. Both Pfizer and Flynn Pharma have announced that they will appeal the decision.[3]

What did they do?

The fine is related to the price hike on the anti-epilepsy drug, phenytoin sodium capsules. Phenytoin sodium capsules were originally manufactured and sold under the brand name Epanutin by Pfizer. They were subject to the National Health Service (NHS) price regulation. In September 2012, after the patent had expired, Pfizer continued to manufacture a generic version of the product. However, the UK distribution rights were sold to Flynn Pharma, who deliberately de-branded the drug so that it was no longer subject to price regulation.

Following the de-branding, the drug price for the NHS went from £2.83 to £67.50, before reducing to £54.00 in May 2014. The price charged to the UK wholesalers and pharmacies were 2,300 per cent to 2,600 per cent higher than the price charged before de-branding.

The price hike increased the NHS' expenditure on the drug from £2 million in 2012 to about £50 million in 2013.[4] The additional expenditure is equivalent to the cost of recruiting approximately 1,300 junior doctors at £37,000.

The main points of the case

The CMA found that Pfizer and Flynn Pharma held a dominant position in the market for the manufacture and supply of phenytoin sodium capsules respectively.

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1 For a full list CA98 - infringement Chapter II case, please see this link.

2 This is the Napp Pharmaceutical Holdings Ltd: alleged abuse of a dominant position case. However, the NAPP case is different in nature from the Pfizer's case as NAPP was more related to predatory pricing which leads to exclusionary price discrimination.

3 Kate, M. (8th December 2016). Record fine given by the CMA to Pfizer for abuse of dominance. [online] Eversheds. Available at: http://www.eversheds.com/global/en/what/articles/index.page?ArticleID=en/Competition_EU_and_Regulatory/cma-pfizer-081216 [Accessed 9 Dec. 2016].

4 CMA (7th December 2016). CMA fines Pfizer and Flynn £90 million for drug price hike to NHS - Press releases. [online] Available at: https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs [Accessed 9 Dec. 2016].

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This is on the grounds that epilepsy patients who are already taking phenytoin sodium capsules should not usually be switched to other products, including another manufacturer's version of the product, due to the risk of loss of seizure control. As a result, the NHS did not have an alternative for the 48,000 patients who were already using Pfizer's version of phenytoin sodium capsules.[5]

Flynn Pharma disagreed with the CMA's conclusion on market power and argued that there were alternatives to phenytoin sodium capsules which were more expensive.[6]

On the point of excessive pricing, Pfizer argued that phenytoin sodium capsules were loss making before it was de-branded. Hence, the transaction with Flynn enabled them to secure the supply of an important drug. It claimed that when Flynn launched the product, the price was set between 25 per cent and 40 per cent less than that of an equivalent drug from another supplier to the NHS that seemed to have been accepted by the Department of Health (DH).[7]

The regulatory context for pharmaceutical pricing in the UK

Currently, there are two main pricing schemes for branded medical products in the UK: a voluntary scheme and a statutory scheme.

Prior to de-branding, Epanutin was governed by the voluntary scheme, Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is an agreement to control the prices of branded drugs sold to the NHS. It was first introduced in 1957, and is usually reviewed every five years, most recently in 2014. Currently, there are 126 companies who have joined the scheme, and Pfizer is one of them.

PPRS was negotiated – not imposed – between DH, acting on behalf of the UK Government and Northern Ireland, and the branded pharmaceutical industry, represented by the ABPI.[8] The scheme aims to ensure sustainable R&D while protecting the NHS from excessive pricing charged by the industry.

PPRS does not regulate price directly, instead, it regulates the profits that companies can achieve on sales to the NHS. The current PPRS placed a cap on the allowed growth rate for the UK medicines bill between 2014 and 2018. Any spend on medicines above the allowed growth rate must be repaid by pharmaceutical companies to the DH.

If a company chooses not to sign up to the PPRS, it is subject to the statutory reimbursement scheme. Under the statutory scheme the Government sets the discount rate.

The loophole in the current regime

Both the PPRS and statutory schemes only cover licensed and branded medicines. Unbranded generics, like the one sold by Flynn Pharma after de-branding, are not covered. This is because market competition usually works well for generic drugs. Once a patent expires, the barriers to entry are reduced significantly for manufacturers. As a result, there should be more market players entering which would supposedly drive down the price and help to keep the price of generic drugs low. By de-branding the drug, it was no longer regulated.

Under the National Health Service Act 2006, the Secretary of State has power to control the price of any medicine unless the manufacturer or supplier is in the voluntary scheme. This means that price controls cannot be applied to generic drugs produced or supplied by a company that is involved in branded medicines and that has signed up to the PPRS.

The Health Service Medical Supplies (Costs) Bill, currently before Parliament, would amend the Act and

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5 CMA (7th December 2016). CMA fines Pfizer and Flynn £90 million for drug price hike to NHS - Press releases. [online] Available at: https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs [Accessed 9 Dec. 2016].

6 Flynn (December 2016). CMA issues infringement decision against Flynn. [online] Available at: http://www.flynnpharma.com/about-us/news/cma-issues-infringement-decision-against-flynn [Accessed 15 Dec. 2016].

7 Pfizer (7th December 2016). Pfizer statement on Competition and Markets Authority's infringement decision. [online] Available at: http://www.pfizer.co.uk/latest-news/2016-12-07-pfizer-statement-competition-and-markets-authority%E2%80%99s-infringement-decision [Accessed 12 Dec. 2016].

8 Department of Health (December 2016). Pharmaceutical price regulation scheme 2014. [online] Available at: https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014 [Accessed 12 Dec. 2016].

enable the Government to require companies to reduce the price of a de-branded medicine, or to impose other controls, even if the company is in the voluntary scheme.[9]

The Bill also attempts to address the pricing issue. Specifically the DH has said it would work with the industry representative bodies and the CMA to determine a price is 'unreasonably high'.

If the Bill passes through Parliament, it is most likely to come into force in the beginning of 2017.

Other pharmaceutical cases

There are currently six open cases in the pharmaceutical sector. Three (including the Pfizer case) are related to unfair pricing of similar nature.

The most recent one was related to Actavis UK (formerly Auden Mckenzie). On 16th December, the CMA issued a statement of objection accusing the company of excessive charging for hydrocortisone tablets.[10] The drug treats life-threatening conditions such as Addison's disease. It was originally manufactured by Merck Sharp & Dohme[11], which participates in the PPRS.

In 2008, Actavis de-branded the product and increased the price of 10mg hydrocortisone tablets by over 12,000 per cent. Unlike Pfizer, which only sold the distribution rights to Flynn, Actavis acquired the right to make hydrocortisone tablets. As a result of the price hike, the NHS' bill on the drug rose from £522,000 a year to £70 million a year.[12]

The other case is related to Concordia International, a generic drug company that bought the licences of patented drugs, de-branded them and raised their prices by up to 600%. The investigation includes matters that pre-date Concordia's ownership of the International segment.[13] No further detail was given on the type of drug involved in the investigation. The CMA will make a decision in February 2017 on whether or not to proceed with the investigation with Concordia.

Conclusions

The magnitude of fines imposed on Pfizer signals the CMA's determination to address the abuse of this loophole in the system. It also raises expectations on the scale of the penalties that may be imposed on other pharmaceutical companies if proven to have been charging the NHS excessively.

Going forward, once the Bill has been passed into legislation the Government will have the power to address this loophole allowing it to better control the price of expensive unbranded drugs, although the focus is likely to be on highly significant cases.

The information gathering power proposed in the Bill will also give the Government tools to access the information required in order to assess the fairness of pricing in a broader context. It will be especially useful for monitoring the price movements of future de-branded drugs.

That said, it is not entirely clear how the government would use this tool to do so. How the information would be gathered and monitored remains a question to be addressed. The Government has already expressed the intention for another consultation in spring/summer 2017 on the statutory scheme and information requirements should the Bill be passed. Hopefully, these questions will be answered following as part of the consultation.

There is still a lack of a clear definition on "excessive pricing". The criteria used in the ongoing case are likely to be significant for future investigations.

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[9] Department of Health (8th November 2016). Health Service Medical Supplies (Costs) Bill factsheet

[10] CMA (16th December 2016). Pharmaceutical company accused of overcharging NHS. Available at: https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs.

[11] BBC News (16th December 2016). Actavis UK accused of overcharging NHS for vital drug. [online] Available at: http://www.bbc.co.uk/news/business-38338359 [Accessed 16 Dec. 2016].

[12] CMA (16th December 2016). Pharmaceutical company accused of overcharging NHS. Available at: https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs.

[13] Kenber, B. (3rd June 2016). 'Extortionate' prices add £260m to NHS drug bill. [online] *The Times*. Available at: http://www.thetimes.co.uk/edition/news/extortionate-prices-add-260m-to-nhs-drug-bill-8mwtttwdk and How the loophole works [online] *The Times*. Available at: http://www.thetimes.co.uk/article/how-the-loophole-works-bhnr5q33q [Accessed 9 Dec. 2016].