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Pfizer and Flynn Pharma Fined £90 Million for Charging "Excessive Prices" for Epilepsy Medicine

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The UK Competition and Markets Authority (the CMA) announced on 7 December that it had fined pharmaceutical manufacturer Pfizer and its UK distributor Flynn Pharma a total of £90 million. According to the CMA, the companies abused their dominant positions in, respectively, the markets for the manufacturing and wholesale of phenytoin sodium capsules in the UK by charging "excessive and unfair" prices, contrary to the Chapter II prohibition of the UK Competition Act 1998 (CA98) and Article 102 of the Treaty on the Functioning of the European Union (TFEU). The CMA imposed a record fine of £84.2 million[1] on Pfizer, whereas Flynn Pharma was fined £5.2 million.

Background

Phenytoin sodium is used in the treatment of epilepsy to prevent and control seizures. According to the CMA's press release announcing the decision,[2] Pfizer manufactured and sold phenytoin sodium capsules to UK wholesalers and pharmacies under the brand name Epanutin prior to September 2012. Under the UK's medicines pricing regime, the price of the drug was regulated as long as it was sold under this brand. In September 2012, Pfizer sold the UK distribution rights for Epanutin to Flynn Pharma, which immediately de-branded (or 'genericised') the drug, meaning that it was no longer subject to price regulation.

At that point, the CMA states that Pfizer increased its wholesale price for what was now a generic un-branded product to Flynn Pharma by between 780% and 1,600%. Flynn Pharma then sold the products on to UK wholesalers and pharmacies at prices that were between 2,300% and 2,600% higher than those they had previously paid for the drug. Put another way, the price of a 100mg pack of the drug increased from £2.83 to £67.50.

Reflecting the UK's state healthcare system, these higher prices were then reimbursed by the National Health Service (NHS). The CMA has calculated that, as a result of the price increases, NHS expenditure on phenytoin sodium capsules increased from about £2 million a year in 2012 to about £50 million in 2013. The CMA has noted that, although other generics exist to treat epilepsy, patients who are already prescribed phenytoin sodium capsules may suffer serious health consequences if swapped to a clinically equivalent medicine. As a result, it seems that clinicians had no alternative in this case than to pay what the CMA describes as "extraordinary price rises".

The CMA also ordered both companies to reduce their prices. As the full decision is not yet available, it is not possible to assess the CMA's methodology for establishing when prices become unlawfully excessive or to establish how prescriptive it is being in terms of the parties' new prices. Although the CMA press release provides limited detail, it does note that both companies will continue to be able to charge prices which are "profitable". While the CMA notes that Pfizer argued that Epanutin was loss-making before it was de-branded, the CMA claims that, according to Pfizer's own figures, all such losses would have been recovered within only two months of the price rises.

Both Pfizer and Flynn Pharma have announced that they will appeal the decision to the Competition Appeal Tribunal.

Commentary

Although businesses are generally free to set prices as they see fit, dominant companies have a "special responsibility" under EU and UK competition law not to abuse their dominant position. Charging "unfair selling prices" is specifically listed as an abuse in section 18 CA98 and Article 102 TFEU. Nevertheless, cases concerning excessive prices are rare, since competition authorities are understandably reluctant to second guess companies in differentiating between "fair" and "unfair" prices and thereby become price regulators.

The substantial increase in pricing in this case, coupled with the particular dynamic of the UK healthcare sector in which the State is the largest customer, seems to have persuaded the CMA to abandon such reluctance. The CMA and its predecessor the OFT have form in this area, however. Indeed, the pharmaceutical sector has accounted for a significant portion of the UK's abuse of dominance caseload and abusive excessive pricing by a pharmaceutical company was the subject of one of the OFT's very first decisions under the CA98, in the *Napp Pharmaceuticals* case.[3] The CMA has four other live pharmaceutical investigations open at the time of the writing and earlier this year it fined GlaxoSmithKline and generics manufacturers a total of £45m for anti-competitive behaviour relating to the sale of paroxetine, an antidepressant.[4]

The decision will not be the last act in this drama. In its press release the CMA confirms that the NHS (and presumably any other parties that purchased may have suffered loss or damage) can rely on the CMA's infringement decision for damages actions. Assuming that their appeals are unsuccessful, the parties are therefore likely to face claims from UK healthcare providers looking to claw back money spent on the drug since September 2012. Any damages claim will need to determine what constitutes an "excessive" price. In this context, Pfizer and Flynn Pharma may find setting prices difficult going forward, since a price that is too high may breach the CMA's direction, but a low price could potentially increase the level of any damages it has to pay to third parties.

It is interesting to note that the practice of drugs companies dramatically raising the price of medicines is not unique to this case. Last September, a US companies decision to increase the price of a medicine for treating parasitic infections from $13.50 per tablet to $750 triggered media and political attention in the US. This new CMA decision is therefore a reminder of the fact that there remains material divergence between the US and EU positions on this critical issue. Whether other European agencies now follow the CMA's lead remains to be seen. While such dramatic price increases in the U.S. may bring scrutiny, under U.S. antitrust law, the mere fact of raising prices cannot be the basis of a monopolization claim (the U.S. analogue to abuse of dominance in Europe). Rather, the FTC, state attorneys general, or private plaintiffs must prove that there has been exclusionary conduct – such as cornering the market on a key ingredient or obtaining a patent through fraud on the Patent Office. As the U.S. Supreme Court explained a few years ago, "The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system.

Notes

1. The fine is indeed a record for UK competition law enforcement. Although the CMA's predecessor, the Office of Fair Trading (OFT), issued a fine of £112.3 million against Imperial Tobacco in 2010, the OFT's case collapsed on appeal to the Competition Appeal Tribunal and the original decision fining Imperial Tobacco was overturned. Although the fine on Flynn was smaller than Pfizer's in absolute terms, it is notable that, at 10% of Flynn's global revenues, it represented the maximum possible fine that the CMA could impose.
2. Available at **https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs**

3. Available at https://assets.publishing.service.gov.uk/media/555de4bf40f0b669c4000169/napp.pdf
4. See https://www.gov.uk/cma-cases/investigation-into-agreements-in-the-pharmaceutical-sector

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