

Can drug price hikes via debranding be prevented?

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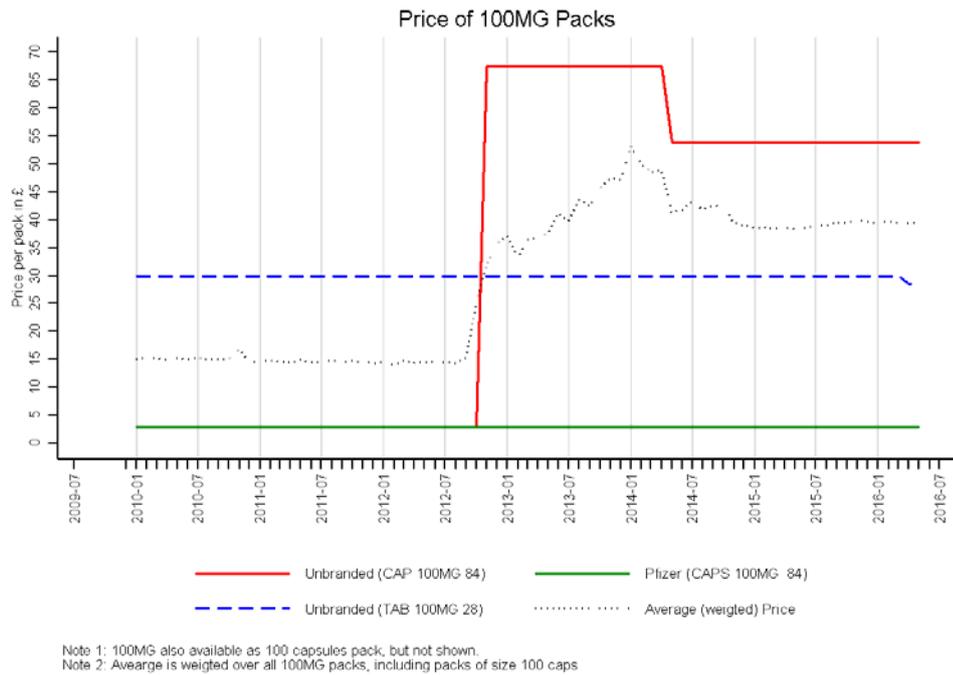
There has always been considerable media and policy attention paid to high prices for new and life-saving drugs, especially those related to cancer or hepatitis C, and to their evaluation for cost effectiveness by NICE. More recently, a series of price hikes for established older drugs has been making the headlines. In the USA, it was the sudden and large price increase in Turing's Daraprim (pyrimethamine) and Mylan's EpiPen (among others) that irked the public and law makers alike. In the UK, a similar phenomenon, where off-patent drugs have increased in price by a few thousand per cent, has drawn the attention of media, Parliament and competition authorities.

Price hikes

Examples include a price hike of over 2000% in Pfizer's antiepilepsy branded drug Epanutin (phenytoin sodium), for which the price of a pack of 84 100mg capsules went from £2.83 to £67.50 in October 2012 (see Figure 1), after the product was debranded when Pfizer sold the UK distribution rights to Flynn Pharma. The green line on the graph shows the price of the original Pfizer capsules and the red line shows the price of Flynn's generic phenytoin sodium capsules. The blue dashed line shows the price of separate generic tablets (for a smaller pack of 28 tablets). The UK's Competition and Markets Authority (CMA) found Pfizer (and UK distributor Flynn Pharma) guilty of abusing a dominant position and accordingly fined them a total of £89.5 million: £84.2 million for Pfizer plus £5.2 million for Flynn.

Similarly, Actavis UK, which increased the price of 10mg hydrocortisone tablets from £0.70 to £88.00 per pack, is now under investigation by the CMA for violating competition rules. Other companies are also being investigated for similar price hikes, including several that were identified in an article in *The Times* in June 2016 for debranding their drugs and selling them at higher prices as generics.¹ It remains to be seen whether these firms will also be found to be abusing dominance through excessive prices – something that can be difficult to prove to a legal standard.

¹ 'Extortionate' prices add £260m to NHS drug bill, June 3, 2016. See <https://tinyurl.com/jmyfonf>



Price regulation

How are these price hikes possible? Some basic economics of competition provide the essential background before we look at regulation. These price increases are generally for drugs that are off-patent, which means that any company, after filing and obtaining appropriate approval for generic medication, can enter the market. If generic formulations are truly identical, at least in the eyes of the prescribers and their patients (what we call homogenous products), then such high pricing is not sustainable. If the population base is large and there are many manufacturers of otherwise identical drugs, then competition and undercutting will prevent companies from marking the price above cost.

Product differentiation allows a degree of price premium. For example, capsules can be seen as different to tablet formulations, and the original branded drug typically retains some loyalty and can be priced at a small premium. However, there is a qualitative change in competition if the market is so small it can sustain only one generic manufacturer. It may then be able to price at the monopoly level, which is very high in the case of life-saving drugs. Beyond ethical reasons or regulation, such a monopolist is only constrained by the market if entry and exit is very quick and easy, in which case the company has to price near to cost to remain in the market.

We can now look at current regulation in the light of this economic analysis. The NHS publishes tariffs for all approved drugs on the basis of which it reimburses pharmacists for dispensing prescriptions. The method of determining these prices is different for branded (ie patented and new medicines) and generic drugs. When a new drug is launched, a manufacturer can set any price, and due to lack of competition, this can be quite high. The justification for allowing such high prices is that it compensates companies for undertaking risky and

expensive drug development, and without such compensation, new drug development may not be as rapid. For instance, the pharmaceutical industry reportedly invested £4.5bn in research in 2007 in the UK alone.²

Nonetheless, pricing for branded drugs is not completely unregulated. Increasing the price of a drug can be difficult. Under the Pharmaceutical Price Regulation Scheme (PPRS), which was introduced in 1957, and whose terms are updated roughly every five years, the government imposes a cap on profits from prescription drugs sold to the NHS after making allowances for research and development expenditures. Thus, a company can increase the price of its branded drug, but only as long as the total profit from the portfolio of drugs for the company does not go above the maximum allowed profit. In reality, it may even mean that to increase the price of one drug, a manufacturer has to decrease the price of another drug in its portfolio.

Generic drugs, on the other hand, are not covered by the PPRS and are priced using a different set of rules. Generics are those drugs whose patents have expired, and potentially have multiple manufacturers producing them. For these drugs, the government samples generic prices via wholesalers, computes an average price for each drug, and then sets a reimbursement rate based on that average value, while also allowing for a dispensing fee for the pharmacist. The logic behind this mechanism is that the pharmacists will always try to purchase from the cheapest generic provider and this will keep prices low for the NHS.

The Pfizer case

We can now apply the economic analysis to the Pfizer debranding example. Pfizer sold the rights of distribution in the UK of its branded drug, Epanutin, to Flynn Pharma and withdrew its original brand from the UK. Sales to a third party do not fall under the two price schemes described above, so Pfizer could supply its off-patent branded drug to Flynn at roughly 25 times the original price. Flynn, in turn, hiked the price further and sold it as a generic, under the new name, Phenytoin Sodium Flynn Hard Capsules, to the NHS. Because Flynn was the only supplier of *this specific strength and form, ie 100mg capsules*, Flynn could charge the monopoly price – recall that generic price regulation is an average price, and the average over one manufacturer is simply the price of the single supplier.

This is a fundamental problem with the regulatory rules in particular circumstances, but it should not be used to throw out the whole system. Two features meant entry by other generics did not take place despite the price hike.

First, phenytoin has a very narrow therapeutic index because of manufacturing difficulties. The UK Medicines and Healthcare products Regulatory Agency (MHRA) classifies this drug as a category 1 antiepileptic, and specifically advises doctors not to switch their patients to other manufacturers' products. Its advice is based on safety and quality concerns of a drug, as it should be, rather than competition concerns. Nonetheless, whether generics by other manufacturers are identical or of lower quality, it is likely that such a strong advisement from the MHRA will keep most prescribers from switching to other manufacturers, even if their drug is much cheaper. In turn, other generic manufacturers are not likely to enter this market despite such high prices, as there is no guarantee of sale and the process of filing for, and gaining, marketing approval for a bioequivalent generic comes at a cost.

Second, wholesalers tried to import the original branded drug from Europe, where Pfizer was still manufacturing and distributing Epanutin at a much lower price. Given the MHRA advisement, the wholesalers

² House of Parliament, Parliamentary Office of Science and Technology, Post Note, Number 364, October 2010. See <https://tinyurl.com/gvpdbnw>

also wanted to change the name from Epanutin to the one under use by Flynn Pharma. However, this was blocked by Flynn Pharma as an infringement of trade name.

Another feature of the market raises a question about how excessive the price hike actually was. As Figure 1 shows, there were also generic 100mg phenytoin sodium tablets on the market at the same time (produced by several manufacturers) and the NHS tariff was £30 for a smaller 28 pack. In fact, this makes them more expensive than the Flynn capsules if we consider a capsule to be equivalent to a tablet.

Are they valid substitutes? Our data analysis indicates that volume shares of 100mg capsules and tablets were roughly equal prior to the debranding and price hike by Pfizer/Flynn, but that the change in price of capsule did not result in an increase in the shares of the tablets, as one would expect if they were substitutes. This may well be because the two drugs are not medically equivalent, hence patients cannot switch that easily between them.

Can price hikes be prevented?

Clearly the actions of Pfizer/Flynn are not to be condoned. They found a loophole in the price regulation and took advantage of it. Other pharma companies appear to be doing the same, so what should be done about it? Currently, this is left to the CMA to apply its powers in relation to the abuse of a dominant position under general UK and EU law. These powers are generally used to address business strategies that prevent entry without benefiting consumers. They are only very rarely used (anywhere in the world) to address excessive pricing because it is so difficult to benchmark a genuinely competitive price and because price signals are an important feature of the workings of the market system.

Furthermore, even if prosecutions under competition law can be made to stick, the maximum penalty that can be imposed is 10% of worldwide turnover. This could be painful for a major multinational, but many of these cases involve smaller specialist 'entrepreneurs' or private equity. If £10m revenues can be increased to £100m by a price hike, then the prospect of a 10% fine is little disincentive – pay a £10m fine to 'buy' an extra £90m revenue (although litigation for damages would change this calculation). The appropriate way forward is to address the loophole in the PPRS directly and urgently. This could save the NHS hundreds of millions of pounds every year.

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