The pricing conundrum

Margaret Kyle takes a look at excessive pricing in the pharma industry

The pharmaceutical sector has attracted an increased level of scrutiny from competition authorities in recent years. While the industry touts the important contribution of pharmaceuticals to gains in health outcomes, critics point to persistently high profits, declining research productivity, and problems of access created by high prices.

Competition agencies acknowledge the need to provide incentives for risky investments in developing new drugs, but also argue that selective interventions in the sector may be necessary. Recently, enforcement action in several countries has targeted excessive pricing. This article discusses the methodologies, scope and desirability of these interventions.

Motta and de Strooel (2006) describe three conditions that justify excessive price cases: high and non-transitory barriers to entry that make it unlikely that market forces will correct the excessive price; near-monopoly or ‘super-dominant’ position attained through behaviours competition law failed to address in the past, or enjoyed as a result of special rights unrelated to quality or innovation; and the absence of a sector-specific regulatory framework, which would be better positioned to address the problem.

To date, excessive pricing cases in pharmaceuticals have concerned only generic products. In the UK, these include the Pfizer-Flynn case, as well as ongoing investigations of liothyronine tablets and hydrocortisone tablets. The Danish Competition Council concluded in January 2018 that CD Pharma had excessively priced its oxytocin injection. And in a case that prompted the European Commission to open an EU-wide investigation, the Italian First Grade Administrative Court in 2017 concurred with the competition authority that Aspen Pharmacare was guilty of excessive pricing of several off-patent cancer drugs.

By definition, expired patents no longer constitute a significant barrier. Regulatory barriers to entry should also be low following the expiration of data exclusivity; generic firms can rely on the clinical data provided by the innovator firm in order to obtain a marketing authorisation, and need only demonstrate bioequivalence to the reference product. A generic product has no brand name and marketing budgets are minimal. However, some products have barriers to entry for other reasons. For example, in the Pfizer-Flynn case, the CMA highlighted the medical recommendation that patients stabilised on a particular manufacturer’s anti-epilepsy drug (phenytoin sodium) should not be moved to any other product due to the risk of potential loss of seizure control.

Competition authorities so far have adopted the cautious approach advocated by most economists with respect to the branded, on-patent segment of pharmaceuticals. Some argue for a more aggressive stance, claiming that the existence of intellectual property does not preclude the application of competition law to pharmaceuticals: patent-protected drugs have been subject to enforcement activities including abuse of patent, pay-for-delay and parallel trade. It is worthwhile considering, therefore, how the methods and legal assessments of the generic drug cases might bear on on-patent products.

The fear of triggering an investigation may limit a firm’s willingness to increase the price of a product. Limits on future price increases – explicit or implicit – would likely increase launch prices or reduce a firm’s willingness to reduce price today. While empirical evidence on these points is scarce, given the rarity of excessive pricing cases, regulations that limit a firm’s ability to raise prices over time have had these effects.

Similarly, if low prices in other member states lead a competition authority to determine the price is excessive in its own market, firms have an incentive to sell at the same price in every country. Not only would this pricing risk reducing access in poorer countries, but widespread application of these methods could place a firm currently using country-specific pricing in a precarious situation. A country with high prices in the status quo may assert its price is excessive in comparison to other countries. In response, the firm may try to raise prices in the comparator nations used in determining international
reference prices – which could then trigger an excessive price case because of comparisons across time.

Many economists have argued that excessive pricing cases should be brought in only exceptional circumstances, if at all. From a practical standpoint, many factors (cost, quality, etc) besides the abuse of a dominant position may explain high prices, and identifying what is “excessive” is challenging. When markets work well, excessive prices should attract new entrants who compete to lower price, so the problem is temporary; if this is not the case, it is better to address the underlying barrier to competition.

Even if one believes that reining in excessive prices of branded drugs is socially valuable, is the use of competition law the best tool? The health ministry or committee responsible for pricing and reimbursement is usually better positioned to address the problem than a competition authority. If the health ministry is unable to do so, for instance because of national policies that mandate coverage of some treatments under all circumstances, lawmakers should consider changes that allow the exercise of countervailing buyer power. One such change occurred in the UK: the Health Services Medical Supplies (Costs) Act of 2017 was an attempt to correct the price-setting mechanism for generic drugs.

Elsewhere, in 2018, the US FDA listed more than 300 off-patent drugs with a single supplier in the US, which enjoys relatively robust generic competition compared to most European countries. To encourage additional entry, the regulator now prioritises its review of generic applications for drugs with little competition. European policymakers could adopt a similar approach to reduce bureaucratic barriers.

Margaret Kyle is Professor of Economics, MINES ParisTech and PSL Research University; Visiting Professor of Strategy, Northwestern University; and Research Fellow, CEPR. The views expressed in this article are solely those of the author, who would like to thank Dr Can Çeliktemur and Cornerstone Research (www.cornerstone.com) for their support in preparing this paper.