



Drug capsules are seen on the production line on March 21, 2018 | Gerard Julien/AFP via Getty Images

OPINION

Italy has set the wrong tone on excessive drug pricing

Key questions arise from an Italian court decision on Aspen Pharmacare.

By **INGRID VANDENBORRE AND STANISLAS DE VILLOUTREYS** | 10/16/18, 2:18 PM CET | Updated 10/19/18, 11:10 AM CET

On September 29, 2016, the Italian Competition Authority fined Aspen Pharmacare, a South African drug maker, on the basis that its prices for four oncology products were excessive. The lower court confirmed the authority's decision, and Aspen has now appealed that judgment with the Council of State, Italy's highest court.

Although we have had Pfizer Flynn since then, this is the first decision finding drug prices to be excessive in a competition law sense. As pricing of pharmaceuticals is at the top of the agenda of regulators and policy makers in Europe, it is useful to reflect on whether this Italian decision sets the right precedent.

We are not sure that it does. In fact, the Italian decision makes very much the same mistakes as Britain's Competition and Markets Authority did when it found Pfizer's and Flynn's prices to be excessive.

So what had happened exactly? The decision says that Aspen purchased a number of products from GSK in 2009 and wanted to increase the prices of some of them in 2013. Aspen explained to the pricing regulator that the increase was necessary to update the prices which had not been changed since their launch in the 1950s and 60s, and that the company was suffering very low and even negative margins on these products. They also wanted to align prices in Italy with those elsewhere in the European Economic Area. The difference in the price with the other member states had caused supply shortages in Italy as a result of parallel exports. The pricing regulator agreed to the company's request, but the competition authority later considered that the prices were excessive, fined Aspen €5.2 million and requested that Aspen negotiate fair prices with the pricing regulator.

There is of course a legal framework that sets out when a price is excessive in a competition law sense. The Court of Justice has said that a competition authority first has to determine whether the difference between the costs incurred and the price charged is excessive. If it is, the authority should assess whether the price level is unfair "in itself or when compared to others."

The Italian decision seems to have taken a very different approach however, causing considerable confusion, not to mention concern in the industry, somewhat similarly to the CMA's decision.

First, the decision finds that these oncology products are just too unique to be compared with anything else. So it essentially ignores the second part of the test. The authority considers the products to be the only available treatment for certain patients, and concludes that this automatically removes any possibility to compare their prices with those of any other drugs, including drugs used to treat the same type of cancer that are not based on the same molecule, or — even if they are — not already sold in Italy. The only comparison the decision makes is with the products' prior prices. The Tribunal corrected the CMA for having taken a very similar approach and for concluding that it was unnecessary to compare the Pfizer drug's price with those of comparable products.

It would have been interesting to know whether the products' prices were really out of line compared to other pharmaceuticals used for the same treatments, or when compared with their generic versions in other EU member states, as the Court of Justice has suggested. Particularly as the decision says Aspen requested the increases to bring the prices in line with those in other member states.

Second, the decision looks at the old prices as the point for comparison. Even leaving aside that the company claimed that the old prices were loss making, compounded inflation over several decades should probably have affected the use of these old prices as the only point of comparison. Based on data from the U.K. statistics office, the value of money in the U.K. has fallen by at least 94 percent since the 1960s. Just as a point of comparison, that means prices of even some everyday groceries have risen by more than 1,000 percent since then.

Third, the decision reflects no real analysis of whether other companies were blocked from supplying the products. Patents for the products had expired, so high prices would normally attract other suppliers, ultimately leading to lower prices and more choice for patients. Just like low and unprofitable prices are obviously a disincentive for companies to start to supply a generic. The decision does not assess what happened when the prices increased.

And then what is perhaps most important from an industry perspective: the decision does not assess the economic value of the products. The decision considers economic value to equal the sum of direct and indirect costs. That leaves a lot of questions for the pharmaceutical sector and other sectors where margins need to support product development as well as sustained product supply in the case of older pharmaceuticals. That questions the importance of the value patients and doctors attach to these products, and to the importance of ensuring the security of their supply, in the competition law analysis.

All eyes will be directed at how the Council of State will assess the appropriate test in this case.

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