

## European Commission Sets Its Sights on Allegedly Excessive Drug Prices



### IN SHORT

**The Background:** Following its 2008 pharmaceutical sector inquiry, the European Commission has largely followed through on its commitment to intensify competition law enforcement in this industry, although it has focused mainly on pay-for-delay agreements.

**The Action:** On May 15, 2017, the Commission announced the opening of a formal investigation into concerns that Aspen Pharma has engaged in excessive pricing with regards to several cancer drugs.

**Looking Ahead:** The action could signal a paradigm shift in the Commission's stated enforcement priorities in the sector and risks generating considerable uncertainty as to the legality of individual pricing practices of pharmaceutical companies.

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In the European Union, Big Pharma has been operating with a target on its back for the best part of the last decade. Eight years after the conclusion of the 2008 pharmaceutical sector inquiry, it is clear that the Commission has largely been true to its stated enforcement priorities. However, the recent announcement of an investigation into excessive drug prices marks a significant departure from past practice with potentially far-reaching consequences.

### Competition Law Enforcement of Excessive Prices Called into Question

It has been widely suggested that high prices should be condemned only where they generate exclusionary effects. The reasons for such caution are numerous. In particular, many have argued that in sectors like the pharmaceutical industry, monopoly profits are needed to carry out expensive research and development. Another relevant argument relates to the well-documented difficulties of crafting an administrable legal test, which would enable competition authorities to determine whether prices are indeed "excessive." Moreover, assuming such a test could be articulated, regulators would then be faced with the equally difficult task of designing an effective and adequate remedy.

These challenges no doubt explain why excessive pricing as a basis for regulatory intervention has been seldom used.



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### New-Found Appetite to Challenge Drug Price-Gougers

Price-gouging in the pharmaceutical industry has garnered widespread media attention and has become both topical and politicized in many jurisdictions. In Europe, the Italian (AGCM) and UK (CMA) competition authorities have been at the forefront of this issue, with fines being leveled late last year against Aspen and Flynn Pharma respectively, following sharp price increases of several debranded drugs marketed by those firms. The CMA has also issued a statement of objections against Actavis for allegedly gouging prices of its hydrocortisone tablets, and it is currently investigating Concordia International on similar charges in relation to other medicines.

Besides the UK and Italy, the Spanish competition authority (CNMC) has recently announced that it is also investigating Aspen's price increases in relation to several of its anticancer drugs.

### EU Aspen Probe

On May 15, 2017, the Commission announced the opening of a formal investigation into Aspen's pricing practices pertaining to five of its anticancer drugs. The probe will cover the entire European Economic Area, with the exception of Italy, where Aspen has already been condemned.

Assuming dominance is found, the Commission will have to determine the level at which prices became excessive. This endeavour will undoubtedly prove contentious, given the problems associated with the legal test for establishing excessive pricing under EU competition law, which looks at whether prices bear "no reasonable relation to the economic value of the product." To this end, the Commission first will have to examine whether the difference between the cost incurred and the prices actually charged are excessive. Difficulties associated with cost-price analyses notwithstanding, the Commission will then have to establish that the prices are "unfair," either in themselves or when compared to the prices of competing products.

### The Upshot

Much like its other European counterparts, the Commission appears to be setting its sights on pharmaceutical companies engaging in drastic price increases of "niche" off-patent medicines sold in low volumes. Although this new trend may prove to be confined, it is nonetheless conducive to unwarranted uncertainty as to the legality of individual pricing practices of pharmaceutical companies. Moreover, by focusing on allegedly excessive prices, the probe may signal a paradigm shift in the Commission's enforcement priorities in the sector.

### THREE KEY TAKEAWAYS

1. The Commission's probe into Aspen's allegedly excessive prices suggests that, at least in the context of the pharmaceutical industry, exploitative practices will no longer play second fiddle to exclusionary behavior.
2. Although this new trend may prove to be confined to drastic price increases of niche off-patented drugs supplied in low volumes, it is nonetheless conducive to significant legal uncertainty.
3. The probe may also signal a willingness to use competition law as a panacea to remedy the ills of other areas of the law.

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### CONTACTS



Christian B. Fulda  
Munich



Philipp Werner  
Brussels

*Amédée von Moltke, an associate in the Brussels Office, contributed to the preparation of this Commentary.*

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