REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR (2009-2017)

European competition authorities working together for affordable and innovative medicines
Executive Summary

Following the European Commission’s inquiry into the pharmaceutical sector in 2009, competition law enforcement and market monitoring in this area have been a high priority across the EU. This report provides an overview of how the Commission and the national competition authorities of the 28 Member States (‘European competition authorities’) have enforced EU antitrust and merger rules in the pharmaceutical sector in 2009-2017. It responds to concerns expressed by the Council and the European Parliament that anti-competitive practices of pharmaceutical companies may endanger patients’ access to affordable and innovative essential medicines.

European competition authorities work closely together to safeguard effective competition on pharmaceutical markets. Since 2009, the authorities have together adopted 29 antitrust decisions against pharmaceutical companies. These decisions have imposed sanctions (with fines totalling over EUR 1 billion) or made binding commitments to remedy anti-competitive behaviour. More importantly, some of these decisions addressed anti-competitive practices that had previously not been addressed under EU competition law. These precedents give broader guidance to industry players on how to ensure that they comply with the law.

In 2009-2017, European competition authorities investigated more than 100 other cases, while over 20 cases of possible antitrust infringements are currently being examined. To ensure that pharmaceutical markets do not get too concentrated due to mergers, the Commission reviewed more than 80 transactions. Competition concerns were detected in 19 merger cases, and the Commission cleared these mergers only after the companies offered to address concerns and modify the transaction.

The pharmaceutical sector requires close competition law scrutiny and the reported antitrust and merger cases provide a range of examples of how enforcing competition law specifically helps to safeguard EU patients’ access to affordable and innovative medicines.

Access to cheaper medicines

High prices of medicines impose a high burden on the national healthcare systems, where pharmaceuticals already account for a significant share of spending.

Effective competition from generics and, more recently, biosimilars typically represents a vital source of price competition on pharmaceutical markets and significantly drives down prices (for generics, by 50% on average). This not only makes older treatments
much more accessible, but also allows some of the related savings to be redirected to newer, innovative medicines. To mitigate the impact of generic entry, which greatly reduces revenues from commercially successful medicines, originator companies often implement strategies to extend the commercial life of their older medicines. Some of these strategies and other practices that can impact price competition have attracted competition law scrutiny.

European competition authorities have vigorously investigated and sanctioned practices that lead to higher prices. In a series of decisions that build on the Commission’s 2009 sector inquiry, the authorities have targeted conduct that curbs the market entry or expansion of generics. Landmark decisions were taken by both the Commission (Lundbeck, Fentanyl and Servier cases) and the United Kingdom authority (Paroxetine case) against pay-for-delay deals. In such deals, the incumbent originator company pays the generic company to give up, or delay, its plans to enter the market. This way, the generic company ‘gets a part of [the originator’s] cake’ resulting from the artificially high prices (as one company under investigation explained in an internal document found by the Commission).

The French competition authority has pioneered several decisions that prohibit incumbents’ disparagement practices to curb the uptake of newly launched generic products. Other authorities have sanctioned incumbents that were abusing regulatory procedures to keep generics out of the market.

There have, moreover, been several recent investigations into the pricing of certain off-patent medicines (in one example, the price rose up to 2,000 %), and several authorities have found such pricing practices to be unfair and abusive, namely in Italy (the Aspen case), the United Kingdom (the Pfizer/Flynn case) and Denmark (the CD Pharma case). In addition, competition authorities have prosecuted more classical forms of misconduct, such as bid rigging cartels, or strategies to cut off rivals from access to key inputs or to customers.

Higher prices may also result from mergers of pharmaceutical companies where the pricing power of the merged company is strengthened. The Commission has intervened in a number of mergers that could have led to price increases, in particular for generic products (e.g. the Teva/Allergan case) or biosimilar products (e.g. the Pfizer/Hospira case). The Commission cleared these transactions only after the companies had committed to divest parts of their businesses to suitable buyers in order to preserve the existing degree of price competition.

**Access to innovative medicines**

Innovation is crucial in the pharmaceutical sector, with pharmaceutical companies among the leaders in investing in R&D. However, market participants may sometimes engage in conduct that affects the incentives to innovate (patenting, interventions before authorities, acquisitions of competing technologies, etc.). In doing so, they may breach competition law.

In merger control, the Commission has prevented transactions that could compromise R&D efforts to launch new medicines or to extend the therapeutic use of existing medicines. The Commission intervened to protect innovation competition in a number of cases which, for example, threatened to thwart advanced R&D projects for life-saving cancer drugs (Novartis/GlaxoSmithKline Oncology) or for pipeline insomnia medicines at an early stage of development (Johnson & Johnson/Actelion). In the Pfizer/Hospira case,
the Commission was concerned that the merger would do away with one of the two parallel projects to develop competing biosimilars. The Commission cleared all these transactions but only after the companies offered remedies to ensure that pipeline projects were not dropped and found a new operator to drive them forward.

Competition rules acknowledge that companies may work together to foster innovation. However, companies sometimes seek to frustrate rival innovation efforts or to relax competitive pressures that force them to invest in innovation. For example, action against attempts to unduly delay generic entry helps to effectively enforce the end of the innovator’s market exclusivity and therefore induce further innovation by originator companies. In addition to safeguarding innovation, antitrust enforcement also fosters patients’ choice by intervening against various exclusionary practices such as a rebate scheme designed to exclude competitors from hospital tenders or the spreading of misleading information about the safety of a medicine when used to treat conditions not mentioned in the marketing authorization (off-label use).

**Scope for further enforcement action**

The examples of cases in this report show that competition law enforcement can be very effective, within its mandate and remit, namely to investigate anti-competitive agreements, abuses by dominant firms, and mergers. However, there are limits to what competition law can do and continuous efforts by all stakeholders are needed to meet the societal challenge of ensuring sustainable access to affordable and innovative medicines.

The past enforcement record provides a solid basis for competition authorities to continue and to focus their enforcement efforts. Effective enforcement of EU competition rules in the pharmaceutical sector remains a matter of high priority and the competition authorities will continue to monitor and be pro-active in investigating potential anti-competitive situations.