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ANTITRUST AND COMPETITION

The European Commission Accepts Commitments from a Pharma Company to Stop Its Excessive Prices

On 15 May 2017, the European Commission (Commission) announced that it had opened formal proceedings to investigate whether a pharma company abused its dominant position by charging excessive prices for certain off-patent cancer medicines, in breach of EU antitrust rules.

The Commission found that the pharma company has consistently earned very high profits from its sale of these cancer medicines in Europe, both in absolute terms and when compared with the profit levels of similar companies in the industry. In fact, the company's prices exceeded its relevant costs by almost 300 percent on average without the Commission's investigation revealing any justifications for the company's high-profit levels.

To address the Commission's concerns, in July 2020, the pharma company offered commitments under Article 9 of Regulation 1/2003. The company offered to reduce its prices in the European Economic Area (the EU member states and Iceland, Lichtenstein, and Norway) for six off-patent cancer medicines by 73 percent on average, which is on average below the prices of 2012, before the company's price increases started. These prices will be the maximum that the company can charge for the next 10 years (they will start taking effect as of 1 October 2019). The company also offered to guarantee the supply of the medicines for the next five years and, for an additional five-year period, to either continue to supply or make its marketing authorization available to other suppliers.

The proposed commitments do not cover Italy, where the Italian competition authority already imposed a €5 million fine on the pharma company in 2016 for price hikes of up to 1,500 percent for these medicines.

On 10 February 2021, the Commission adopted an Article 9 Decision (Commitment Decision) that concludes that such commitments offer a fast, comprehensive, and lasting solution to the Commission's antitrust concerns. The Commitment Decision makes the proposed commitments legally binding for a period of 10 years without establishing an infringement. However, noncompliance with the Commission's Commitment Decision can entail the imposition of fines up to 10 percent of the pharma company's worldwide turnover in last financial year. In parallel, the Commission may decide to reopen the investigation that was closed pursuant to the Commitment Decision, with a view to adopting a prohibition decision against the pharma company.

Excessive pricing by pharma companies is a key area of concern for the Commission and the national competition authorities of the EU Member States. A number of national competition authorities have already

imposed heavy fines for excessive pricing behavior or are closely scrutinizing such practices. Excessive pricing is particularly concerning for critical drugs reimbursed by the social security systems of the EU Member States. For such drugs, with few available alternatives, pharma companies have significant bargaining powers and can impose high prices to national authorities, which are ultimately paid by taxpayers. As such, antitrust enforcement against excessive pricing practices should be read in the context of the Commission's objective to ensure access to safe and affordable medicines and security of supply.

The European Commission Prolongs and Expands the COVID-19 State Aid Temporary Framework

On 28 January 2021, the Commission amended, for the fifth time, the state aid temporary framework (Framework) adopted in March 2020 to support the European economy in the context of the COVID-19 outbreak. The Framework enables EU member states to support businesses hit by the outbreak under EU State aid rules, while limiting distortions to competition.

In order to address the prolonged economic effects of the ongoing pandemic crisis and to allow governments to support businesses, the Commission has decided to prolong the measures set out in the Framework until 31 December 2021. In addition, the Commission will (i) increase the company-specific aid ceilings, (ii) enable the conversion of repayable forms of aid into direct grants, and (iii) extend the temporary removal of all countries from the list of “marketable risk” countries.

The extension of the Framework includes an increased company-specific aid ceiling of € 1 million, limiting the overall maximum aid to be potentially granted to companies to € 1.8 million, contrary to the previous threshold, which was €800,000. Moreover, the Commission has also increased up to €10 million the maximum amount that an EU Member State can contribute to the fixed costs not covered by revenues for companies especially hit by the COVID-19 crisis. Previously, this limit was set to €3 million. In order to be eligible for this measure, the company should have suffered revenue losses of at least 30 percent compared to 2019.

EU Member States still enjoy the same mechanisms under the Framework's umbrella and can grant aid through direct grants, tax and payment advantages, or other forms, such as repayable advances, guarantees, loans, and equity.

To incentivize the use of repayable forms of aid, the Commission has also enabled EU Member States to convert repayable forms of aid, granted under the Framework, such as repayable advances, guarantees, and loans into other forms of aid, such as grants, as long as the conversion takes place by 31 December 2022 at the latest and specific conditions set in the Framework are met.

The Commission has also decided to extend until 31 December 2021 the temporary removal of all countries from the list of “marketable risk” countries under the short-term export credit insurance communication. The rationale for this measure is to account for the continued general lack of sufficient private insurance capacity to cover all economically justifiable risks for exports to countries from the list of marketable risk countries.

Finally, in relation to aid upon Article 107(2)(b) of the Treaty on the Functioning of the European Union for damage directly caused by the COVID-19 outbreak, the Commission has clarified that the aid shall compensate damage directly caused by restrictive measures precluding the beneficiary from operating its economic activity or a specific part of its activity.

Before the end of 2021, the Commission will assess whether the Framework needs to be further extended or adapted depending on the evolution of the COVID-19 outbreak over the coming months.

Dutch Authority for Consumers and Markets Publishes Study on Paid Ranking

On 2 February 2021, the Dutch Authority for Consumers and Markets (ACM) published a study on the risks paid ranking can pose to competition and consumers. The ACM examined whether paid ranking could lead to higher prices, reduced quality of products, and less relevant results being ranked higher. This was done by looking into the ways platforms inform consumers about paid ranking, what paid results are included in the ranking, and whether such information influences the consumer purchasing decisions.

The study concludes that providers taking advantage of paid ranking can generally include the extra fee in the consumer price and that payments for higher rankings reduce competition in regard to price and quality. Platforms normally rank providers based on relevance for consumers, such as review scores and repeat purchases. However, by having a paid ranking option, platforms also take into consideration their financial incentive when sorting the search results, leading to suboptimal products being ranked higher. The study also considers that consumers can in fact be misled by the search results if it is unclear that the ranking is influenced by underlying payments.

Based on the study, the ACM presented a framework for assessing the effects of sponsored ranking on consumers. This was done by identifying key factors, such as the prevalence of sponsoring, level of quality check, competition on the platform, level of consumer benefits, and paid ranking disclosure procedure. The framework has the dual purpose of showing how the ACM assessed the likelihood of harm and benefits for consumers and can also be used by online platforms that wish to evaluate the effects of their sponsored ranking procedures.

The study comes a year after the publication of guidelines on the protection of the online consumer where the ACM indicated that platforms must be transparent about paid results vis-à-vis consumers. Both publications follow the recent transparency and predictability framework established in Regulation (EU) 2019/1150 on promoting fairness and transparency for business users of online intermediation services, known as the P2B Regulation, and the Commission proposal for a Digital Markets Act (DMA). The ACM is conducting a follow-up study into the role of transparency in regard to paid ranking, following which it plans to draw up clear transparency standards and offer guidance to platforms and enforcers in complying with transparency.

DIGITAL ECONOMY

The EU Digital Markets Act – A Report From a Panel of Economic Experts

At the beginning of February 2021, the Commission released an independent economic opinion from a high-level panel of economic experts (Panel) on one of the European Union's key recent digital initiatives, the DMA.

In its assessment, the Panel noted that it is in broad agreement with the vision encapsulated in the DMA. The traditional competition policy approach is difficult and too slow to implement in the digital space, therefore the Panel agreed with the Commission's suggestion to use size thresholds for defining a gatekeeper and employ the quasi-automatic imposition of gatekeeper obligations. In this respect, the Panel remarked that some vagueness in the definition of platforms might be necessary to allow the Commission some flexibility.

The Panel endorsed an idea to create a blacklist of forbidden behaviors to which only extreme considerations would justify an exception and a grey list of practices that are in principle considered anti-competitive but for

which a justification is possible. An example of a blacklisted practice would be self-preferencing, while tying and bundling would be included in the “greylist” practices.

As for merger control, the Panel noted that while the traditional criteria for reviewing digital mergers have “little bite,” the DMA itself says very little about mergers initiated by gatekeepers, apart from the obligation to notify regarding any mergers. With respect to enforcement, the Panel suggested embedding rotating auditing teams within the platforms that may conduct behavioral experiments to evaluate the algorithm and use of the data.

The DMA is currently in the preparatory phase of the legislative procedure.

ECONOMIC AND FINANCIAL AFFAIRS

European Supervisory Authorities Agree on the Regulatory Technical Standards on Amendments to the Key Information Document

On 3 February 2021, the Joint Committee of the European Supervisory Authorities (watchdogs for insurance, securities, and banking) submitted to the Commission the Regulatory Technical Standards (RTS) on the presentation, content, review, and revision of a standardized key information document (KID) and the conditions for fulfilling the requirement to provide a KID as required by the Packaged Retail and Insurance-based Investment Products Regulation (PRIIPs).

The RTS includes proposals to:

- Introduce new methodologies to calculate appropriate performance scenarios and a revised presentation of these scenarios.
- Revise the summary cost indicators and changes to the content and presentation of information on the costs of PRIIPs.
- Modify the methodology to calculate transaction costs to address practical challenges that have arisen when applying the existing rules and address issues regarding the application to certain types of underlying investments.
- Refine the rules for PRIIPs offering a range of options for investment reflecting experience of challenges regarding the clarity and usefulness of the information, in particular to identify the product's full cost implications.
- Integrate existing provisions applying to investment funds into the PRIIPs framework, given the expiry of the exemption in Article 32 of the PRIIPs on 31 December 2021. PRIIPs provides a temporary exemption for management and investment companies and persons advising on, or selling, Undertakings for Collective Investment in Transferable Securities (UCITS) from the obligation to produce and provide a PRIIPs KID. For such funds, a key investor information document is currently provided to investors in accordance with the UCITS directive.
- Require for certain types of investment funds and insurance-based investment products to publish information on the past performance of the product and refer to this within the KID so that the availability of this information is known and the information is published in a standardized and comparable format.

In the draft RTS report, the European Supervisory Authorities (ESAs) have also made recommendations for targeted amendments to the PRIIPs regulation itself. Meanwhile, in a letter dated 29 January 2021, the Commission outlined how it sees the broader review of the PRIIPs regulation. This review is a priority for the Commission, and it will take place as soon as possible, taking into account the results of the cross-sectoral study on "Disclosure, Inducements and Suitability Rules for Retail Investors" launched in September 2020 and due by end of 2021.

As for next steps, the ESAs' draft RTS are now subject to adoption by the Commission and will be afterwards subject to scrutiny from the Council of the European Union and the European Parliament.

European Securities and Markets Authority Calls for Appropriate Regulatory Requirements to Ensure the Quality and Reliability of ESG Ratings

On 29 January 2021, the European Securities and Markets Authority (ESMA) published a letter it had written to the Commission sharing its views on the main challenges in the area of environmental, social, and governance (ESG) ratings and assessment tools. ESMA's letter builds on its response to the Commission's consultation on the Renewed Sustainable Finance Strategy in July 2020, where specific issues in relation to the ESG ratings and assessment tools were raised.

Against this backdrop, ESMA's letter outlines certain regulatory concerns that the Commission should take into account in the context of its forthcoming Renewed Sustainable Finance Strategy, namely:

- The development of a common legal definition for an ESG rating that captures the broad spectrum of assessment tools that are currently available in the market.
- The need to require any legal entity whose occupation includes the issuing of these ESG ratings and assessments to be registered and supervised by a public authority.
- The development of a regulatory framework in this area, which would ensure that larger, more systemic entities are subject to a full suite of organizational and conflict-of-interest requirements that reflect their growing importance in sustainable finance.
- Given the high level of consolidation in the market for ESG ratings and ESG rating providers, ESMA sees merits in being the authority entrusted with direct supervisory responsibilities for these actors.

This is not the first time ESMA has called for regulation of ESG rating firms. In February 2020, ESMA Chair Steven Maijoor noted that "where ESG ratings are used for investment purposes, ESG rating agencies should be regulated and supervised appropriately by public sector authorities." Some national regulators have also taken position on this issue. In December 2020, the French securities regulator and its Dutch counterpart issued a joint position paper calling for new legislation that would grant ESMA supervisory powers over ESG data providers.

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