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**REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT**

**UPDATE ON COMPETITION ENFORCEMENT  
IN THE PHARMACEUTICAL SECTOR (2018-2022)**

**European competition authorities working together  
for affordable and innovative medicines**

# **REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**

## **UPDATE ON COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR (2018-2022)**

### **European competition authorities working together for affordable and innovative medicines**

#### **EXECUTIVE SUMMARY**

This Report provides an overview of how the Commission and the national competition authorities of the EU Member States ('European competition authorities') have enforced EU antitrust and merger rules concerning medicines and certain other medical products in the period 2018-2022 <sup>(1)</sup>. It also reports on how EU competition law served to protect undertakings and consumers during the challenging period of the Covid-19 crisis. It is a follow-up to the previously published Report covering the years 2009-2017 <sup>(2)</sup>.

In the period covered by this report, from 2018 until 2022, the European competition authorities together adopted 26 antitrust decisions related to pharmaceutical products. These decisions led to sanctions (with fines nearing EUR 780 million) or made binding commitments to remedy anti-competitive behaviour. Some of these decisions addressed anti-competitive practices that had previously not been addressed under EU competition law. These precedents give guidance to industry players on how to ensure that they comply with EU competition rules. In 2018-2022, European competition authorities also investigated more than 40 pharma cases which were closed without an infringement or commitment decision, while some 30 cases of possible anti-competitive infringements in the pharmaceutical sector are currently being examined.

To ensure that pharmaceutical markets do not get too concentrated due to mergers, the Commission reviewed more than 30 transactions in the pharmaceutical sector. Competition concerns were detected in 5 of these merger cases. The Commission cleared 4 of these mergers only after the companies offered to modify their merger transaction, while one merger was abandoned. <sup>(3)</sup>

Examples of antitrust and merger cases illustrate how close competition law scrutiny of the pharmaceutical sector and competition law enforcement help to safeguard EU patients' access to affordable and innovative medicines.

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<sup>(1)</sup> For the United Kingdom, the report covers the period until the end of 2020. The United Kingdom has withdrawn from the European Union, with the transition period ending on 31 December 2020. Since 1 January 2021, EU competition law has no longer been enforced in the United Kingdom.

<sup>(2)</sup> <https://op.europa.eu/en/publication-detail/-/publication/9cb466c8-7b71-11e9-9f05-01aa75ed71a1>

<sup>(3)</sup> The Commission additionally intervened in several non-pharmaceutical cases that relate to health or (bio-)medical technologies, most notably in prohibiting a merger regarding cancer detection tests (discussed in Sections 2.2.1 and 6.2.2).



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## 1. INTRODUCTION

This Report provides an overview of how the Commission and the national competition authorities of the EU Member States ('European competition authorities') have enforced EU antitrust and merger rules in the pharmaceutical sector in the period 2018-2022 <sup>(4)</sup>.

It is a follow-up to the previously published Report covering the years 2009-2017 <sup>(5)</sup>, serving to present the same overview of the sector for a subsequent period.

This report responds to concerns previously expressed by the Council <sup>(6)</sup> and the European Parliament <sup>(7)</sup> that patients' access to affordable and innovative essential medicines may be endangered by a combination of very high and unsustainable price levels, active business strategies by pharmaceutical companies, and the limited bargaining power of national governments against those pharmaceutical companies.

Being healthy and having access to affordable and innovative medicines and health care matters a lot to people. The societal and economic importance of the pharmaceutical sector and the healthcare sector in general became even more apparent during the Covid-19 crisis. Spending on preventive care (e.g. testing, tracing, information campaigns related to the pandemic) increased by nearly one-third, and spending growth on inpatient care reached nearly 9 % in 2020 (compared to 2019). Despite a significant reduction in GDP, per capita health expenditure increased to between 5.8 % (Luxembourg) and 12.8 % (Germany) of GDP in EU Member States in 2020. <sup>(8)</sup> Spending on pharmaceuticals constitutes a significant share of government spending on healthcare. <sup>(9)</sup> In this context, prices of medicines can pose a high burden on the national healthcare systems.

Moreover, continued efforts to innovate and invest into research and development ('R&D') are crucial to developing new or improved treatments that offer patients and practitioners a choice of state-of-the-art medication. However, incentives to innovate can also be curbed by both mergers and anti-competitive practices.

This report shows the ways in which competition law enforcement, i.e. enforcing both the EU antitrust rules and the EU merger rules <sup>(10)</sup> has helped to safeguard EU patients'

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<sup>(4)</sup> For the United Kingdom, the report covers the period until the end of 2020. The United Kingdom has withdrawn from the European Union, with the transition period ending on 31 December 2020. Since 1 January 2021, EU competition law has no longer been enforced in the United Kingdom.

<sup>(5)</sup> Competition Enforcement in the Pharmaceutical Sector (2009-2017), [https://competition-policy.ec.europa.eu/sectors/pharmaceuticals-health-services\\_en](https://competition-policy.ec.europa.eu/sectors/pharmaceuticals-health-services_en).

<sup>(6)</sup> Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, 17 June 2016, paragraph 48 (OJ C 269, 23.7.2016, p. 31).

<sup>(7)</sup> European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)), 2 March 2017.

<sup>(8)</sup> OECD (2022), *Health at a Glance: Europe 2022*, p. 132.

<sup>(9)</sup> OECD (2022), *Health at a Glance: Europe 2022*, p. 142. Pharmaceuticals sold in retail represented approximately 15 % of healthcare expenditure on average across EU countries in 2020. This figure does not include pharmaceuticals used in hospitals, which may add another 20 % to a country's pharmaceutical bill.

<sup>(10)</sup> This report does not cover the Commission's control of state aid (e.g. aid for R&D to pharmaceutical companies, or state aid in the field of health insurance) nor cases where competition is distorted due to

access to both affordable and innovative medicines. It has been drawn up in close cooperation with the national competition authorities ('NCAs') of the EU Member States (the Commission and NCAs are jointly referred to as the 'European competition authorities'). The European competition authorities closely cooperate to enforce EU competition law as well as to continuously monitor the pharmaceutical markets.

Using concrete examples, this report describes how the rules prohibiting abuses of a dominant position and restrictive agreements have been enforced to ensure that (i) price competition for pharmaceuticals is not artificially reduced or eliminated; and (ii) anti-competitive practices do not restrict innovation<sup>(11)</sup> in the sector. Scrutinising mergers of pharmaceutical companies for their possible negative impact on competition equally serves these two objectives. The report describes how the Commission's application of the EU merger control rules has in specific cases contributed to having more affordable and innovative medicines. It focuses on medicinal products for human use.

Antitrust investigations are complex and require considerable resources. This is why the European competition authorities focus their investigations on the most important cases, including those that can provide guidance to market participants and deter them from engaging in similar anti-competitive conduct. Competition law scrutiny thus helps to improve competition on pharmaceutical markets not only in terms of the specific case investigated, but also in a broader sense by guiding the industry in its future behaviour. In recent years the European competition authorities have set a number of important precedents which clarified the application of EU competition law to novel issues in pharmaceutical markets. These landmark decisions were often based on comprehensive inquiries of the entire sector. The European competition authorities continue to be committed to ensuring that competition rules are enforced in pharmaceutical markets in an effective and timely manner, including by providing guidance to companies in the context of the Covid crisis (e.g. how to discuss methods to increase the production of personal protection equipment material in a way that would not infringe competition rules).

While competition law enforcement (antitrust and mergers) contributes to securing access to innovative and affordable medicines for patients and healthcare systems, it does not replace or interfere with the legislative and regulatory measures aimed at ensuring that EU patients benefit from state-of-the-art and affordable medicines and healthcare. Competition law enforcement instead complements the various regulatory systems. It does so mainly by intervening in individual cases against specific market conduct of companies. Competition authorities occasionally also use advocacy to propose to decision-makers in the public or private sphere pro-competitive solutions to systemic market failures.

This report covers the period 2018-2022. It provides:

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special or exclusive rights granted by a Member State (e.g. complaints by private healthcare providers against potential excessive compensation of publicly owned hospitals).

<sup>(11)</sup> Innovation covers both innovation in terms of new medicines but also choice between different treatments as well as improvements of other parameters e.g. quality in terms of efficacy, safety or an improved production process. Price competition is based on choice between different closely interchangeable treatments of requisite quality.

- a general overview of competition law enforcement by the Commission and the NCAs in the pharmaceutical sector (Section 2);
- a description of the main characteristics of the pharmaceutical sector that shape the competition assessment (Section 3);
- an explanation of how competition law protected undertakings and consumers also in times of Covid-19 crisis (Section 4); and
- an illustration of how competition law enforcement contributes to affordable medicines (Section 5) and to innovation and choice in medicines and treatments (Section 6), through an analysis of (Commission and NCA) antitrust cases, and (Commission) merger cases.

## **2. OVERVIEW OF COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR**

This Section provides an introduction to the rules as well as an overview of some facts and figures on enforcement activities of the European competition authorities. Section 2.1 addresses enforcement of the antitrust rules, i.e. the prohibition of restrictive agreements and abuses of a dominant position. Section 2.2 describes the review of mergers and acquisitions to prevent concentrations that could significantly impede effective competition. Section 2.3 reports on the market monitoring and advocacy measures undertaken by the European competition authorities.

### **2.1. Enforcement of antitrust rules**

#### **2.1.1. What are antitrust rules?**

Article 101 of the Treaty on the Functioning of the European Union ('TFEU') prohibits agreements between undertakings, decisions by associations of undertakings and concerted practices which have as their object or effect the restriction of competition. Article 102 TFEU prohibits abuses of a dominant position on a given market. Regulation (EC) No 1/2003<sup>(12)</sup> empowers both the Commission and the NCAs to apply the rules contained in the TFEU to anti-competitive practices.

Companies have to assess for themselves whether their practices comply with antitrust rules. To safeguard legal certainty concerning the application of competition law, the Commission has adopted regulations specifying when certain types of agreements (such as licensing agreements) can be block-exempted and has issued guidelines that clarify how the Commission applies antitrust rules.<sup>(13)</sup>

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<sup>(12)</sup> Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ L 1, 4.1.2003, p. 1).

<sup>(13)</sup> An overview of the applicable rules is available at: [https://competition-policy.ec.europa.eu/antitrust-and-cartels/legislation\\_en](https://competition-policy.ec.europa.eu/antitrust-and-cartels/legislation_en).



### 2.1.2. Who enforces antitrust rules?

The Commission and the 27<sup>(14)</sup> NCAs share enforcement work. The NCAs are fully empowered to apply Articles 101 and 102 TFEU. The Commission and NCAs co-operate closely within the European Competition Network ('ECN'). A case can be dealt with by a single NCA, by the Commission or by several authorities acting in parallel.

If certain conduct does not affect cross-border trade, the NCAs only apply their national antitrust laws, which are often a reflection of EU law.

Besides the European competition authorities enforcing EU antitrust rules, the national courts are also fully empowered and called upon to apply Articles 101 and 102 TFEU. They do this both when reviewing decisions of NCAs and in litigation between private parties. National courts and the European competition authorities also cooperate: courts can request an authority's opinion on the application of the EU antitrust rules and authorities can participate in court proceedings by submitting their written observations.

### 2.1.3. What instruments and procedures are available?

The European competition authorities can adopt decisions that find that a certain agreement or unilateral conduct breached Article 101 and/or Article 102 TFEU. In these cases, the authority adopts a "prohibition decision" and orders the companies to cease and desist from the infringing conduct and may impose a fine, which can be substantial. Specific remedies may also be imposed. The Commission and NCAs<sup>(15)</sup> may also decide to accept the investigated firms' binding commitments to put an end to the problematic practices. Such commitment decisions do not establish an infringement or impose a fine on the companies but can be key to restoring competition in a market.

#### **Box 1: What is a commitment decision?**

The commitment decision is a formal settlement solicited by a company under investigation and agreed by the competition authority where the commitments are best suited to address its concerns.<sup>(16)</sup> If the commitments offered are accepted by the authority, the case will be closed with a commitment decision without a formal finding of infringement under Articles 101 or 102 TFEU.

Commitment decisions can be useful to craft remedies that might better address the competition concerns. The commitments can be either behavioural or structural and may be limited in time. Moreover, the Commission can reassess the situation if a material change takes place in any of the facts on which the decision was based. It is also possible for the company to ask the Commission to lift a commitment that is no longer appropriate. For an example of a commitment decision, see Box 13 below.

The commitment decision generally provides for monitoring of the commitments, and in case of non-respect of the conditions of the commitment, the competition authority can impose a fine. Periodic penalty payments are also possible until compliance with the commitments. In this period, the Romanian NCA imposed such a fine on GlaxoSmithKline (GSK). The initial

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<sup>(14)</sup> 28 until end 2020 (see also footnote 7).

<sup>(15)</sup> Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market (OJ L 11, 14.1.2019, p. 3).

<sup>(16)</sup> The formal commitment procedure of the Commission is laid down in Article 9 of Council Regulation (EC) No 1/2003.

investigation – seeking to establish whether GSK’s distribution model of the medicines Avodart, Seretide and Tyverb restricted their parallel export – had been concluded in 2017 with commitments from GSK to supply the medicines Avodart and Seretide for two years in sufficient quantities to meet patients’ needs on the domestic market. <sup>(17)</sup> However, GSK was later found to have ceased, before the expiry of the two-year period, the marketing of three forms of Seretide, a medicine indicated for the treatment of asthma and chronic obstructive pulmonary disease. <sup>(18)</sup>

The main investigative instruments of the European competition authorities include unannounced on-site inspections, requests for information, and interviews. Requests for information can be powerful investigation tools as the companies may be compelled to provide complete and correct information with the threat of fines.

### **Box 2: What are on-site inspections?**

The Commission as well as the NCAs can carry out unannounced inspections (sometimes called ‘dawn raids’) and search the premises of companies to collect evidence of suspected anti-competitive conduct. Failure to submit to an inspection or obstructing it, for example by entering a room sealed off by the Commission, can lead to hefty fines. The ECN+ Directive ensures among other things that all NCAs have the key powers and tools to investigate, including more effective inspection powers (for example, the right to search information stored on devices such as smartphones, tablets, etc.). <sup>(19)</sup>

In their proceedings, the European competition authorities safeguard the rights of defence of the investigated parties. For example, during the Commission’s administrative proceedings, the investigated parties receive a comprehensive statement of objections and access to the evidence in the Commission’s case file on the basis of which they can exercise their right to be heard before a final decision is taken. They can then reply to the objections in writing and in an oral hearing before the Commission issues a final decision.

The decisions of the European competition authorities are subject to a full and rigorous review by the courts competent to scrutinise if such decisions are well-founded in terms of substance and if all procedural rights of the parties have been respected.

Antitrust investigations are generally complex as they require a thorough investigation of a broad range of facts as well as a comprehensive legal and economic analysis. Investigations therefore require considerable resources, and it can take some years before a final decision is adopted. To ensure efficient use of resources, competition authorities may need to prioritise cases where, for instance, the market impact of the practices may be more significant or where the decision could establish a useful precedent applicable to the pharmaceutical sector or even beyond.

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<sup>(17)</sup> Decision of the Consiliul Concurentei of 28 December 2017.

<sup>(18)</sup> Decision of the Consiliul Concurentei of 11 August 2020, imposing a fine of RON 11.9 million (approx. EUR 2.5 million).

<sup>(19)</sup> See footnote 11.

### **Box 3: Can victims of anti-competitive behaviour claim damages?**

Victims of antitrust infringements are entitled to compensation. An EU Directive ensures that national laws allow for effective actions for damages before national courts.<sup>(20)</sup> Many damages actions are filed after a final decision of an EU competition authority (so called follow-on damages actions), while sometimes parties also turn directly to a court asking the court to both find an infringement of EU competition law and to award damages for the harm occurred (so called stand-alone actions).

For example, the appeal court in Venice (Italy) recently ruled on a dispute between a wholesale distributor of pharmaceutical specialties (So.Farma.Morra SpA) and its supplier GlaxoSmithKline SpA (GSK), where the distributor complained, in a stand-alone action, that GSK reduced the supply of Avodart (hyperplasia treatment) and Seretide (asthma treatment) in violation of competition law (abuse of a dominant position within the meaning of Article 102 TFEU). The plaintiff claimed compensation for loss of turnover, loss of clientele and loss of opportunity to make investments. In a judgment delivered on 4 February 2021<sup>(21)</sup>, the court found that EU competition law had been infringed and referred the case back to the first instance court to proceed with the estimation of the damage claimed by the victim (total claim of EUR 3,519,909).

#### **2.1.4. Overview of antitrust enforcement actions in the pharmaceutical sector**

In the period 2018-2022, 12 NCAs and the Commission adopted 26 “intervention” decisions (finding an infringement or accepting binding commitments) in antitrust investigations related to pharmaceuticals for human use. The complete list of the 26 cases is available on DG Competition’s website<sup>(22)</sup>.

In addition, the European competition authorities also carried out substantial investigation work on cases which were closed without an intervention decision (e.g. because the concerns were resolved during the investigation and there was no need to proceed to a formal decision), and they are currently investigating over 30 cases involving pharmaceuticals. They have also adopted 10 infringement or commitment decisions in cases concerning medical devices and 13 in cases related to other healthcare matters.

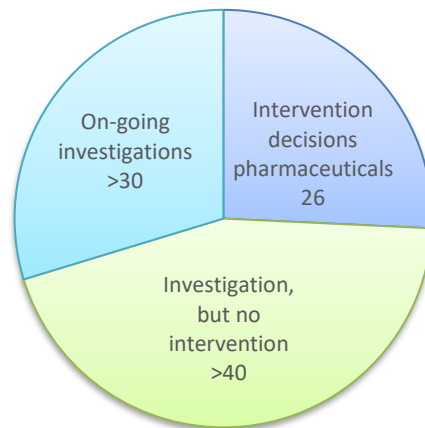
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<sup>(20)</sup> Directive 2014/104/EU of the European Parliament and of the Council of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union (OJ L 349, 5.12.2014, p. 1).

<sup>(21)</sup> Judgment of the Tribunale di Venezia of 4 February 2021 (6471/2015).

<sup>(22)</sup> In this report, the 26 antitrust cases are referred to in footnotes with the name of the competition authority and the date of the decision. The complete list of the cases is available at: [https://competition-policy.ec.europa.eu/document/552ebb75-e502-491a-9fbd-f0f9d61dac39\\_en](https://competition-policy.ec.europa.eu/document/552ebb75-e502-491a-9fbd-f0f9d61dac39_en) . This list also includes links to public information (e.g. press release, text of the decision, Court judgment).

**Figure 1: Antitrust investigations in the pharmaceutical sector by European competition authorities (2018-2022 and currently on-going)**



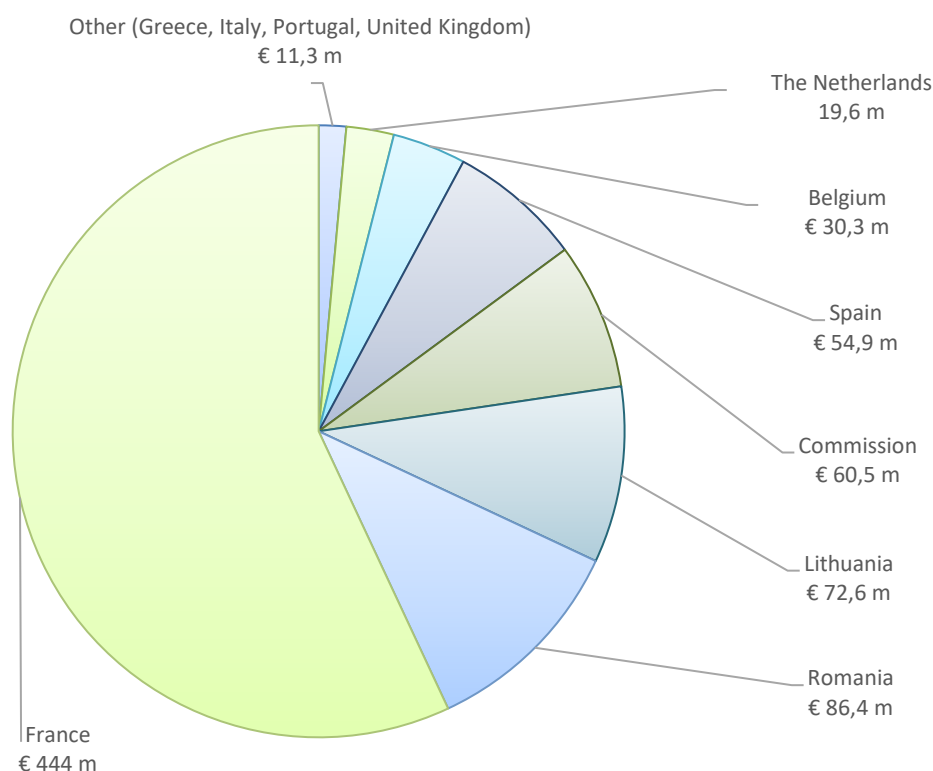
### **Competition authorities intervene and impose sanctions**

In 17 of the 26 intervention cases involving pharmaceuticals, the case was closed with a prohibition decision finding an infringement of EU competition law. Fines were imposed in 20 cases amounting to close to EUR 780 million in total for the relevant period (see Figure 2 below) <sup>(23)</sup>. In 9 cases, the investigation could be closed without finding an infringement because the competition concerns were removed by the commitments offered by the investigated companies. These were made binding by a decision of the competition authority.

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<sup>(23)</sup> The reported fines are not final as appeals are ongoing in a number of cases.

**Figure 2: Fines totalling close to EUR 780 million imposed by European competition authorities in cases involving pharmaceuticals (2018-2022)**

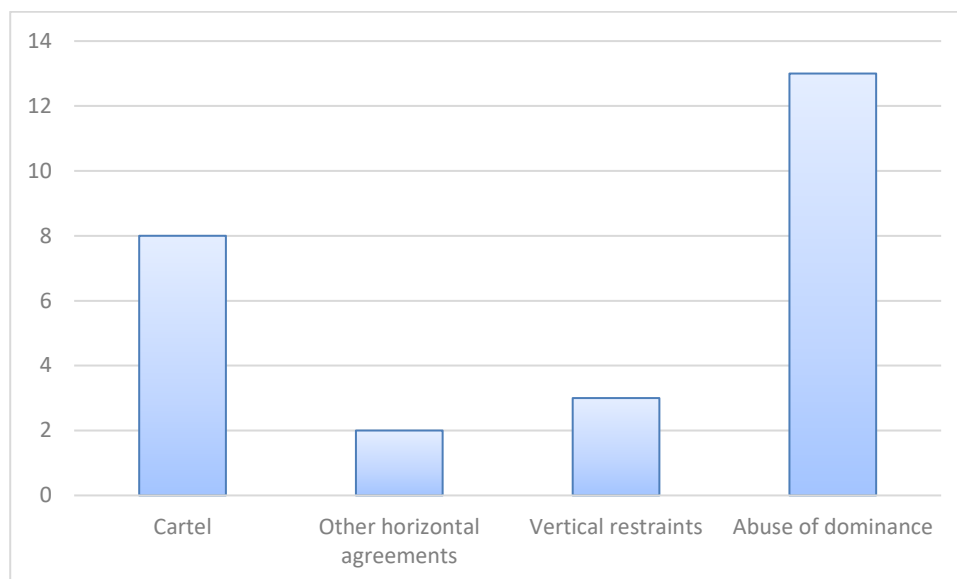


To collect evidence, unannounced inspections were carried out in 7 of the 26 investigations that led to an intervention decision. In all but one case, requests for information were used. Interviews were conducted in 8 cases.

Half of the 26 investigations were initiated *ex officio*, 9 were triggered by complaints, and 4 were initiated on other grounds (e.g. indicia gathered during a sector inquiry). The investigations related to anti-competitive practices by manufacturers of pharmaceuticals (11 cases), wholesalers (8 cases) and retail distributors (3 cases), and 4 cases related to practices involving both manufacturers and distributors. The investigations involved a wide range of medicines, for example cancer drugs (7 cases), antidepressants, hormone treatment or vaccines.

As shown in Figure 3, the most widespread type of competition concerns leading to intervention decisions are abuses of dominance (50 % of the cases), followed by different types of restrictive agreements between companies. These include (i) restrictive horizontal agreements between competitors such as pay-for-delay agreements (8 %); (ii) outright cartels (such as bid rigging) (31 %); and (iii) vertical agreements (such as clauses prohibiting distributors from promoting and selling products of competing manufacturers) (11 %).

**Figure 3: Type of competition concerns where European competition authorities intervened**



### **Competition authorities promote competition rules by carrying out investigations**

Besides those cases that ended with an intervention decision, the European competition authorities also carried out substantial investigation work on competition concerns in more than 40 cases that were closed for various reasons (in particular because the cases were no longer considered a priority after the alleged anticompetitive practices had been discontinued during the investigation<sup>(24)</sup>, or because the preliminary investigation did not find sufficient evidence). Even if no sanctions were imposed or no commitments reached in these cases, the work involved close contacts with different players in the pharmaceutical markets, which often helped to clarify the competition rules and their application in the pharmaceutical sector.

The European competition authorities are currently investigating more than 30 cases in the pharmaceutical sector.

## **2.2. Merger review in the pharmaceutical sector**

### **2.2.1. What are the EU merger rules?**

Pharmaceutical companies regularly enter into mergers or acquisitions ('mergers'). Some of these transactions aim to achieve economies of scale, extend R&D to new therapeutic areas, meet increased profit targets, etc.

Consolidation that affects the market structure can however also thwart competition. For example, the merged company may acquire market power allowing it to hike up the prices of its medicines, or to abandon the development of promising new treatments that would threaten its market position. Merger control seeks to ensure that consolidation does not significantly impede effective competition in the pharmaceutical sector.

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<sup>(24)</sup> This was, for instance, the case in two Commission's investigations. In the case AT.40731 *Quidel*: diagnostic testing kits, a long-lasting non-compete obligation concerning cardiovascular disease testing kits was removed. In the case AT.40576 *Lonza*, alleged exclusionary practices in the contract development and manufacturing of biological medicines were discontinued during the investigation.

The Commission is entrusted with reviewing mergers with an EU dimension, i.e. where the merging companies' turnovers meet the thresholds laid out in the EU Merger Regulation. This means that companies active in several EU Member States can have their transaction reviewed by the Commission, rather than separately in each relevant Member State (the "*one stop shop*" principle). If these thresholds are not met, a merger can be caught by national jurisdictional rules and reviewed by one or several NCAs.<sup>(25)</sup>

Moreover, the EU Merger Regulation includes a system of referrals from NCAs to the Commission and vice versa to ensure that the best placed authority is in charge of reviewing any transaction. <sup>(26)</sup> This includes the ability for one or more NCAs to request that the Commission reviews a merger which is not caught by the national jurisdictional thresholds, but that affects trade between Member States and threatens to significantly affect competition within the territory of the Member State or States making the request.

#### **Box 4: Commission's revised approach to referrals by Member States**

Recently, the Commission revised its approach to requests for case referrals by NCAs that do not have jurisdiction over a merger. In the past, NCAs were discouraged from requesting referrals in such cases, as it was considered based on experience at the time that the turnover-based thresholds captured all transactions that could materially impact the internal market. However, in 2016, the Commission launched a public consultation on the functioning of certain procedural and jurisdictional aspects of EU merger control, for example in relation to the notification thresholds in the pharmaceutical sector. The Commission found that while, on the whole, the existing thresholds work well, there is an increasing phenomenon of concentrations involving firms that generate little or no turnover at the time of the transaction but that already play or may develop into a significant competitive role on the market. These mergers would not be captured by the existing thresholds but could have a significant impact on competition. This is particularly relevant for the pharmaceutical sector, where innovation is a key parameter of competition and so targets with promising drug pipelines can have high valuations and significant competitive potential, even if they do not generate turnover yet and therefore fall below the relevant merger control thresholds. <sup>(27)</sup>

The Commission considers that referrals by NCAs is the most appropriate tool and a necessary safety net to capture such below-threshold transactions that could give rise to competition concerns. On 26 March 2021, the Commission adopted a Communication providing Guidance on the application of the referral mechanism set out in Article 22 of the EU Merger Regulation to certain categories of cases. The Commission clarified that it intends, in certain circumstances, to encourage and accept referrals in cases where the referring Member State does not have initial jurisdiction over the case, where the criteria of Article 22(1) the EU Merger Regulation are met. <sup>(28)</sup>

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<sup>(25)</sup> On 11 September 2020, the Commission announced a revised approach to the use of referrals for merger cases which are not notifiable at EU- or Member State-level, as described in Box 4.

<sup>(26)</sup> For example, merging companies as well as one or more Member States can ask for the Commission to review a merger falling below the EU turnover thresholds in specific circumstances (e.g. such a request may come from the merging companies provided that the merger would be reviewed in at least three Member States and these agree to the referral). Similarly, merging companies as well as a Member State can ask for a merger meeting the EU turnover thresholds to be reviewed by a NCA if the impact of the merger will be in that specific Member State.

<sup>(27)</sup> See Communication from the Commission - Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases (OJ C 113, 31.3.2021, p. 1), paragraphs 9-12.

<sup>(28)</sup> Communication from the Commission - Guidance on the application of the referral mechanism set out in Article 22 of the EU Merger Regulation to certain categories of cases (OJ C 113, 31.3.2021, p. 1).

The first application of this revised approach to referrals took place in the biotech sector (the *Illumina/GRAIL* case, see Box 16 below), and in that case the EU General Court upheld the Commission's approach to these referrals.<sup>(29)</sup> The Commission now actively monitors pharmaceutical transactions to identify concentrations that fall below the EU's and Member States' notification thresholds but nonetheless merit review by the Commission to ensure that they do not harm effective competition. This report focuses only on those merger control proceedings in which EU merger control law is applied, i.e. mergers that were investigated by the Commission.

The legal framework for the assessment of mergers by the Commission consists of the EU Merger Regulation and the Implementing Regulation<sup>(30)</sup>. In addition, there are a number of notices and guidelines which serve as guidance on how the Commission would carry out its merger review in various circumstances<sup>(31)</sup>.

When reviewing a merger, the Commission makes a prospective analysis of whether the transaction would significantly impede effective competition in the EU, in particular by creating or strengthening a dominant position. In its assessment, the Commission considers in particular (i) what behaviour the merged entity could adopt post-merger ('unilateral effects'); (ii) whether other companies would retain the incentives to compete or would instead align their commercial strategy with the merged company ('coordinated effects'); and (iii) whether access to suppliers or to customers could be denied ('vertical and conglomerate effects').

A merger review is initiated when the Commission receives notice from the companies involved of their intention to merge, often in advance of a formal notification. Parties have an obligation to notify their merger and to refrain from implementing it until the Commission has authorised it. The practice of implementing a merger before a clearance decision is commonly known as "gun-jumping".

### **2.2.2. What can the Commission do if a merger is problematic?**

If a deal raises competition concerns, for example due to the risk of a price increase for medicines or harm to innovation, and the merging companies do not propose suitable modifications, the Commission may prohibit the transaction.

To avoid this, companies can propose modifying the concentration to eliminate the competition concerns. Such modifications are commonly referred to as remedies or commitments. If proposed remedies appear fit for purpose, the Commission carries out a so-called market test by soliciting views, in particular, from competitors and customers, on whether the commitments would effectively eliminate the competition concerns. On this basis, the Commission decides whether to approve the transaction subject to the conditions and obligations of implementing the remedies either before or after the companies merge, depending on the specific circumstances of the case.

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<sup>(29)</sup> Case T-227/21 – *Illumina v Commission*. This case is currently under appeal before the EU Court of Justice (Case C-611/22 – *Illumina v Commission* and C-625/22 *Grail v Commission*).

<sup>(30)</sup> Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EU Merger Regulation) (OJ L24, 29.1.2004, p. 1) and Commission Regulation (EC) No 802/2004 of 7 April 2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (OJ L133, 30.4.2004, p. 1).

<sup>(31)</sup> An overview of the applicable rules is available at:  
[https://competition-policy.ec.europa.eu/mergers/legislation\\_en](https://competition-policy.ec.europa.eu/mergers/legislation_en) .



The Commission considers structural remedies, in particular divestitures, to be the preferred way to solve competition issues in merger cases. Accordingly, the remedies in the pharmaceutical sector often consist of a divestiture of marketing authorisations for the products for which concerns have been identified in the relevant Member State. This is usually accompanied by intellectual property and technology transfer of manufacturing and sales know-how, the transitional supply or other agreements and, where relevant, product facilities and personnel.

#### **Box 5: Examples of structural remedies**

##### ***Divestment of marketed drugs (Case M.9274 – GSK/Pfizer Consumer Healthcare Business (2019))***

GSK and Pfizer's Consumer Healthcare Business overlapped in a number of “over-the-counter” pharmaceutical product categories, including notably topical pain management (creams, gels, spays and patches to treat pain locally). The Commission was concerned that the acquisition would reduce competition for topical pain management products by creating or strengthening a dominant position, possibly leading to price increases in a number of EEA countries, including Austria, Germany, Ireland, Italy and the Netherlands.

To address these concerns, the parties offered to divest Pfizer's topical pain management business (carried out under the ThermaCare brand) globally. The divestment business encompassed all relevant assets contributing to the current operation or necessary to ensure the viability and competitiveness thereof, including (i) a Pfizer manufacturing facility located in the US (dedicated to the production of ThermaCare products), (ii) all IP rights relating to the ThermaCare products and brand, as well as (iii) products under development.<sup>(32)</sup> The divestment business was ultimately sold to Angelini, an Italian pharmaceutical group.

##### ***Divestment of a pipeline drug (Case M.9461 – AbbVie/Allergan (2020))***

In this case, the parties’ activities mainly overlapped with respect to biologic treatments for ulcerative colitis and Crohn's disease. As described further in box 15 below, AbbVie and Allergan were two of the few companies developing promising drugs to target these diseases, and the Commission was concerned that the merged entity would discontinue Allergan’s pipeline drug to avoid duplication of development efforts and the cannibalisation of sales of AbbVie’s product. The transaction would have, thus, prevented a promising drug from reaching the market, leading to a loss of innovation, potentially less choice and higher prices for patients and health systems.

The Commission approved the transaction subject to the divestment of Allergan’s pipeline drug. The divestment included notably (i) the rights to develop, manufacture and sell the pipeline drug worldwide; (ii) all IP rights, data, licences/permits, and contracts related to the drug; (iii) certain key employees of Allergan working on the pipeline; as well as (iv) a number of transitional supply arrangements to ensure a smooth transfer of the business.<sup>(33)</sup> The pipeline was ultimately divested to AstraZeneca.

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<sup>(32)</sup> Other examples of cases involving the divestment of marketed drugs include e.g. M.9517 – Mylan/Upjohn (2020).

<sup>(33)</sup> Other examples of cases involving the divestment of pipeline drugs include e.g. M.8955 – Takeda/Shire (2018); M.8401 – J&J/Actelion (2017); M.7275 – Novartis/GSK Oncology Business (2015).

### 2.2.3. Commission merger control in the pharmaceutical sector in numbers

During 2018-2022, the Commission analysed more than 30 mergers in the pharmaceutical sector.<sup>(34)</sup> Out of these, 5 were problematic from a competition standpoint.<sup>(35)</sup> The potential competition concerns identified related mainly to the risk of (i) price increases for some medicines in one or several Member States; (ii) depriving patients and national healthcare systems of some medicinal products; and (iii) diminishing innovation in relation to certain treatments developed at European or even global level. The issues identified by the Commission typically involved a small number of medicines compared to the overall size of the companies' portfolio.

Taking into account the remedies offered by the merging companies, the Commission was able to clear 4 of the mergers that raised these targeted concerns, allowing the merger to go ahead and protecting competition and consumers in Europe. One merger was abandoned as a result of the Commission having raised initial competition concerns.

As a result, the intervention rate in the pharmaceutical sector was around 17 %<sup>(36)</sup>. In comparison, the total intervention rate across all sectors during the period was 5 %.

### 2.3. Market monitoring and advocacy regarding pharmaceuticals

In addition to their direct enforcement activities – decisions and investigations on (potential) anti-competitive practices in the pharmaceutical and healthcare sectors – in 2018-2022, the competition authorities also undertook 60 market monitoring and advocacy activities. Monitoring activities include sector inquiries, market studies and surveys to identify obstacles to the proper functioning of competition that may exist in a sector. Advocacy activities are also an important (albeit sometimes less visible) part of the work of competition authorities and include consultative opinions, *ad hoc* advice and other measures that promote – for instance vis-a-vis legislative and administrative bodies – approaches and solutions that are conducive to effective and fair competition in a given sector or market. In the pharmaceutical sector, such initiatives are of particular importance given the specific challenges for competition enforcement in this area (see Section 3).

Competition authorities may conduct market monitoring where, for example, 'the rigidity of prices or other circumstances suggest that competition may be restricted or

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<sup>(34)</sup> The Commission has in addition investigated a number of mergers in the fields of biotechnology and animal health, notably prohibiting one transaction (M.10188 Illumina/GRAIL (2022)) and requiring interoperability commitments in another (M.9945 Siemens/Varian (2021)). Moreover, in 2021-2022, the Commission considered more than 10 mergers in the pharmaceutical, biotech and medical devices sectors from the perspective of possibly inviting NCAs to request a case referral to the Commission under its revised approach to referrals.

<sup>(35)</sup> M.8955 – Takeda/Shire (2018, conditional clearance with remedies), M.9274 – GSK/Pfizer Consumer Health Business (2019, conditional clearance with remedies), M.9461 – AbbVie/Allergan (2020, conditional clearance with remedies), M.9517 – Mylan/Upjohn (2020, conditional clearance with remedies), M.9547 – J&J/Tachosil (2020, abandoned after the Commission opened an in-depth investigation).

<sup>(36)</sup> The intervention rate is calculated comparing the number of merger prohibitions, merger approvals subject to remedies and withdrawals of a merger notification (during a Phase II investigation) to the overall number of cases notified to the Commission.

distorted’<sup>(37)</sup>. Generally, sector inquiries and other monitoring and advocacy activities also provide guidance to the market participants and may lead to a follow-on antitrust enforcement. Some NCAs even have far-reaching powers, allowing them for instance to conduct inquiries so they can prepare opinions on legislative projects or even impose regulatory measures that may have an impact on competition conditions in a specific sector.

Almost two thirds of the monitoring and advocacy initiatives undertaken by the NCAs are opinions – from a competition policy perspective - on draft legislation related to pharmaceuticals, pharmacies, medical devices or health services. The remainder are mainly market monitoring actions such as sector inquiries or studies, often coupled with recommendations or proposals.

Similarly, as in the period covered by the previous ECN Pharma report (2009-2017), more than one fourth of the 60 monitoring and advocacy actions focus explicitly on retail distribution of medicines and competition between pharmacies. One report – concerning online pharmacy markets – is the result of a joint initiative from the Nordic countries Denmark, Norway, Finland and Sweden. Compared to the previous period, a new important focus is pricing of (reimbursed) medicines and excessive pricing, a specific theme in about one fourth of the initiatives. A further new topic receiving special attention is biological medicines and biosimilars (a shift from generics in the previous period, see Section 3.2.1).

Complete lists of the monitoring and advocacy activities undertaken by the European competition authorities in 2018-2022, with links to the relevant reports or documents, is available on DG Competition’s website<sup>(38)</sup>.

### **3. COMPETITION ENFORCEMENT IS SHAPED BY THE PARTICULARITIES OF THE PHARMACEUTICAL SECTOR**

For competition policy and its enforcement activities in the pharmaceutical sector to be effective, they need to take account of the particularities and the resulting competitive dynamics of this sector. These particularities include, for instance, the specific structure of demand and supply involving a variety of stakeholders (Section 3.1) and the comprehensive legislative and regulatory framework in the different Member States (Section 3.2).

#### **3.1. Specific structure of demand and supply in pharmaceutical markets**

Each analysis of how a market functions and each assessment of conduct under competition law must take due account of the structure of supply and of demand. A variety of stakeholders pursue different interests in the pharmaceutical markets. The

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<sup>(37)</sup> Article 17 of Council Regulation (EC) No 1/2003, with respect to the Commission’s power to conduct a sector inquiry.

<sup>(38)</sup> [https://competition-policy.ec.europa.eu/document/34141778-9e31-4cc4-ac9e-5b8c64f798bb\\_en](https://competition-policy.ec.europa.eu/document/34141778-9e31-4cc4-ac9e-5b8c64f798bb_en) . The list includes links to public information and/or the reports itself.

demand side is characterised by consumers (patients), prescribers, pharmacies, as well as health insurance schemes and national reimbursement bodies <sup>(39)</sup>:

- *Patients* are the final users of medicines. They generally only pay – if at all – a small portion of the price of prescribed medicines, the rest being covered by the healthcare system.
- *Prescribers*, namely medical doctors, decide which prescription medicine the patient will use. They may also advise patients about which over-the-counter medicine to use. However, they do not bear the cost of the treatment they have prescribed.
- *Pharmacies* may also impact the demand for medicine. In many Member States, pharmacists are obliged or incentivised to dispense the cheapest available version of a given medicine (such as a generic version or a parallel-imported product). Pharmacists are often also the main source of advice for patients on over-the-counter medicines.
- The costs of prescription drugs are, fully or to a large part, covered by national *reimbursement bodies* or by *health insurance companies*, which are funded through taxes and/or insurance fees. In either case, they have a strong interest in containing the costs of healthcare, while ensuring through cost-efficient treatments the best overall health care for patients. Health authorities and insurers are not (directly) involved in the treatment choice made by prescribers and patients but can influence demand through price-control mechanisms.

On the supply side, there are manufacturers with distinct business models (supplying originator medicines, generic/hybrid/biosimilar medicines, or different types of products), wholesalers and different types of pharmacies: online pharmacies, mail order pharmacies, traditional ‘brick and mortar’ pharmacies and hospital pharmacies:

- *Originators* are active in research, development, manufacturing, marketing, and the supply of innovative medicines. They typically compete ‘for the market’ by trying to be the first to discover, patent and bring to the market a new medicine, but originator drugs of different active ingredients may also compete against each other ‘in the market’ on price, quality and choice.
- Manufacturers of *generic* products supply non-innovative generic versions of the originator medicine after the originators lose exclusivity, often at significantly lower prices. A generic product has the same qualitative and quantitative composition in active substance and the same pharmaceutical form (e.g. tablet, injectable) as an originator product that has already been authorised (the ‘reference medicine’), and its bioequivalence with the reference medicine has been demonstrated by bioavailability studies. <sup>(40)</sup> Since they treat the same disease as the reference medicine, generic medicines compete to win market shares from originator drugs (or from other generics already on the market), mainly through price competition. In cases where the

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<sup>(39)</sup> In some Member States, hospitals also procure medicine that is then dispensed in the hospital pharmacy.

<sup>(40)</sup> Article 10(2)(b) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use (OJ L 311, 28.11.2004, p.67).

medicinal product does not fall within the definition of a generic medicinal product (e.g. because it has a different strength, a different route of administration or a slightly different therapeutic indication compared to the reference medicine) and bioequivalence cannot be demonstrated through bioavailability studies, authorisation will depend partly on the results of tests on the reference medicine and partly on new data from clinical tests. Such medicines are called ‘*hybrid medicines*’<sup>(41)</sup>.

*Biosimilars*<sup>(42)</sup> are medicines highly similar to another biological medicine already marketed in the EU (the ‘reference medicine’), but unlike the molecules of classical medicines, which are smaller and chemically synthesised, the much more complex biological medicines<sup>(43)</sup> are extracted or synthesised from biological sources (such as living cells or organisms) in conditions that do not allow the reference product to be fully replicated (due to different cell cultures, secret process know-how, etc.). In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product<sup>(44)</sup>.

Some manufacturers supply originator as well as generic, hybrid or biosimilar products. These companies develop distinct business strategies for each type of product.

- Wholesalers organise the distribution of pharmaceuticals by purchasing pharmaceutical products from manufacturers and selling them to pharmacies and hospitals.
- The different types of pharmacies fulfil the dual role of advising patients and dispensing them the required medicines.

Member States play a significant role in this highly regulated sector – depending on the national system, various agencies may administer the granting of the marketing authorisation, pricing, procurement, reimbursement and substitution of pharmaceuticals. By setting regulations, governments aim to achieve several goals such as (i) ensuring the quality, safety, efficiency and efficacy of pharmaceuticals; (ii) making pharmaceuticals affordable to everyone by negotiating prices and setting up public health insurance

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<sup>(41)</sup> Art. 10(3) of Directive 2001/83/EC.

<sup>(42)</sup> *Biosimilars in the EU: Information Guide for Healthcare professionals*, European Medicines Agency, 2019 (Prepared jointly by the European Medicines Agency and the European Commission).

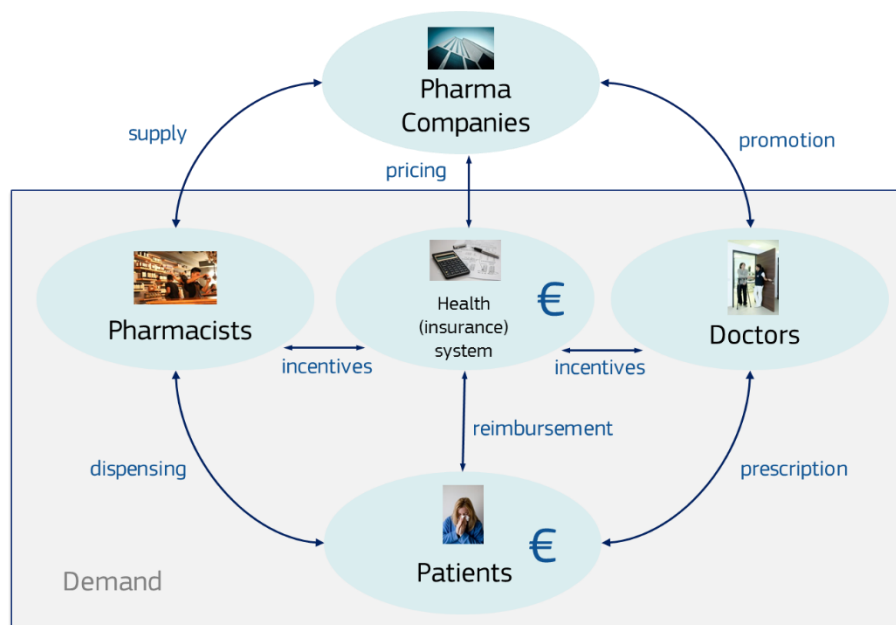
<sup>(43)</sup> Biological drugs are among the most expensive therapies, and their uptake is steadily increasing (biologics represented 35 % of medicine spending in 2022). In turn, as patent protection for some major biologicals is coming to an end, increased uptake of biosimilar medicines is expected to generate cost savings for national healthcare systems. However, for various reasons – such as inferior degree of substitution compared to generics – these cost savings seem more difficult to achieve via traditional competition mechanisms. Nevertheless, by 2022, the number of new biologic molecules with a biosimilar had doubled in five years compared to the ten years prior, and in 2022 a total of 18 molecules had direct biosimilar competition and had an average of 3.8 competitors authorised. (Source: *The Impact of Biosimilar Competition in Europe*, December 2022, IQVIA).

<sup>(44)</sup> *Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU*, 21 April 2023, EMA/627319/2022.

schemes; (iii) promoting innovation and medical research, including improving the security of supplies and prevention of shortages.

Figure 4 below illustrates the complex system of demand and supply in pharmaceutical markets.

**Figure 4: Demand and supply in pharmaceutical markets**



### 3.2. The legislative and regulatory framework shapes competitive dynamics

Competition in pharmaceutical markets depends on multiple factors, including R&D activity, marketing authorisation requirements, access to capital<sup>(45)</sup>, intellectual property rights, pricing regulation, promotional efforts, commercial risks etc. A thorough understanding of these factors is necessary to assess whether certain conduct or a specific transaction is anti-competitive. It is also key to understanding what constitutes the relevant market – a key concept in competition law analysis.

#### **Box 6: Definition of relevant markets for pharmaceuticals**

The definition of the relevant market<sup>(46)</sup> serves to identify the sources of competitive pressure that can constrain the investigated parties. The relevant market comprises both the product dimension (which other products exert effective and immediate competitive pressure on the investigated product) and the geographic dimension (the area in which the conditions of

<sup>(45)</sup> The European Investment Bank has provided total financing of more than EUR 42 billion for healthcare-related projects since it started investing in the sector in 1997. Due to Covid-19, financing has been considerably higher in recent years than it was before the pandemic. In 2022, for instance, the EIB provided EUR 5.1 billion for health and life sciences projects. The European Investment Fund (EIF), a subsidiary of the EIB Group that specialises in providing risk finance to small and medium-sized businesses, committed some EUR 400 million to funds that are expected to support the health sector. (European Investment Bank publication: *Health Overview 2023*, [https://www.eib.org/attachments/lucalli/20220314\\_health\\_overview\\_2023\\_en.pdf](https://www.eib.org/attachments/lucalli/20220314_health_overview_2023_en.pdf)).

<sup>(46)</sup> Commission notice on the definition of the relevant market (OJ C 372, 9.12.1997, p. 5-13). The Commission notice is currently being revised (see also: [https://competition-policy.ec.europa.eu/public-consultations/2022-market-definition-notice\\_en](https://competition-policy.ec.europa.eu/public-consultations/2022-market-definition-notice_en)).

competition are sufficiently similar for the effects of the conduct or concentration under investigation to be able to be assessed). To understand which medicines belong to the same market, authorities may need to assess both demand side substitution (e.g. whether prescribers, patients and payers would readily switch from one product to another) and supply side substitution (the existence, or not, of suppliers that could and would have the incentive to also start producing the medicine(s) at issue in the short term and with insignificant additional sunk costs), where appropriate).

The market definition, i.e. identifying the sources of effective and immediate competitive pressure, enables competition authorities to assess, at a second stage, whether the investigated company enjoys market power, or dominance, and whether the conduct being investigated would be likely to harm competition rather than being offset by offers from the remaining competitors.

With regard to identifying sources of competitive pressure that constrain a marketed medicine, understanding which other products are therapeutically substitutable is a necessary first step in identifying relevant competing medicines. However, it is settled case-law of the Court of Justice that “*interchangeability or substitutability is not assessed solely in relation to the objective characteristics of the products and services at issue. There must also be taken into consideration the conditions of competition and the structure of supply and demand on the market*”.<sup>(47)</sup> Only medicines that are actually able to constrain the investigated product can be considered as belonging to the same product market. For example, if the positioning of a medicine (price, quality, innovation value, promotion through marketing) is geared against losing prescriptions to another medicine with a different molecule, this would be an indication that the products based on two different molecules are likely in the same market. However, if the main competitive threat comes from generic versions of a certain molecule, which contain the same molecule, and the pressure from medicines containing other molecules is significantly weaker, this may indicate that the market is narrower and limited to the investigated molecule alone. The degree of competitive pressure faced by a medicine is naturally dynamic and may change with the entry of new products, e.g. the entry or imminent entry of a generic version of a medicine may change the competitive landscape for the originator drug.<sup>(48)</sup> The competitive landscape not only depends on the availability of substitutable medicines, but is to a large extent affected by pricing and reimbursement regulation<sup>(49)</sup>.

### **3.2.1. Product life-cycle and the evolving nature of competition driven by regulation**

The focus of competition law scrutiny, whether in merger control or in antitrust investigations, will vary depending on the stage of the product life-cycle. Life-cycles of medicines are relatively long and comprise three main phases as shown in Figure 5.

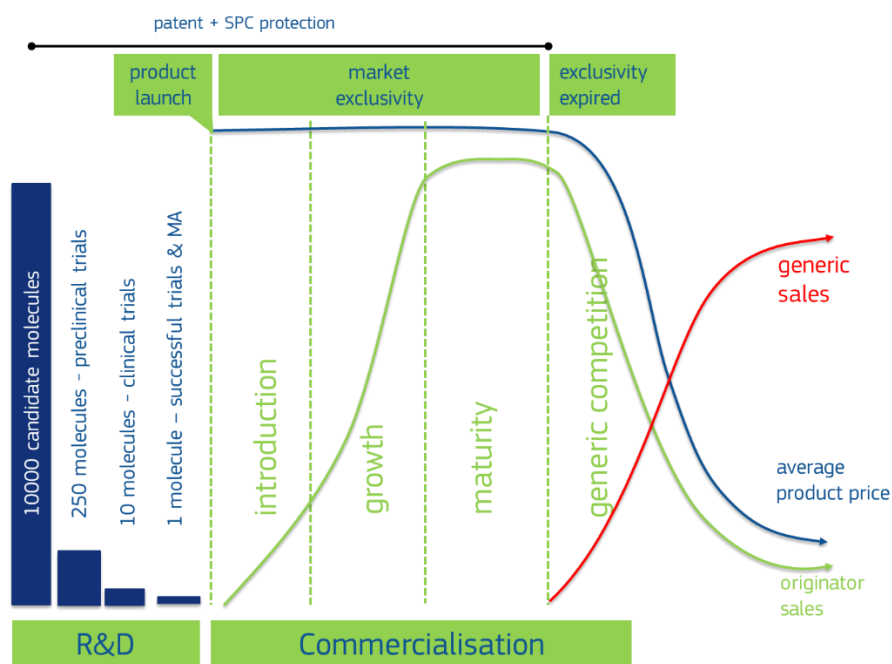
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<sup>(47)</sup> Judgment of the Court of Justice of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 129 and the case law cited.

<sup>(48)</sup> See Case C-307/18, *Generics (UK) and Others*, paragraphs 130-131.

<sup>(49)</sup> See section 3.2.2.

**Figure 5: Pharmaceutical product life-cycle**



The life-cycle of a new drug begins with a new compound (either small or large molecule, such as biologics), which is usually discovered through basic research conducted by originator manufacturers or independent research facilities (universities, specialised laboratories), often supported by public funding. Originator manufacturers then test whether a pharmaceutical product containing the candidate compound would be safe and effective. During the development stage, the candidate medicines are first assessed in laboratory tests (including on animals) in the so-called pre-clinical stage, followed by the clinical trials (on humans) which comprise three phases.

Once studies have shown that a new medicine is effective and safe, the company applies for a marketing authorisation (‘MA’) to the regulatory agency. This could be either the European Medicines Agency (‘EMA’) or a national authority.

Following approval of a medicine, further trials (phase 4 trials or ‘post marketing surveillance’) often continue to generate data to further increase understanding of the performance of the medicine. If a medicine goes on to demonstrate an unacceptable level of risks for the benefits it provides, regulatory authorities can issue warnings leading to changes in the patient leaflet or can still remove the medicine's license at this stage.

The development cycles for innovative drugs are usually risky and lengthy and entail high development costs<sup>(50)</sup>. Moreover, only a small minority of candidate molecules survive the development stage and finally make it to the market.

In pre-launch phases – both pre-clinical and clinical – developing new medicines may be a source of competitive pressure for existing medicines as well as for other medicines in

<sup>(50)</sup> Estimates suggest that the costs of bringing a medicine from the lab to the market are between EUR 0.5 billion and EUR 2.2 billion. Copenhagen Economics, *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report*, May 2018, available at: [https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals\\_incentives\\_study\\_en.pdf](https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf).



development. Once on the market, new medicines strive to secure prescriptions by either diverting demand from other medicines or by creating new demand from patients and health care professionals for that type of medicine, for example by addressing a previously unmet medical need. At this stage, competitive pressure comes primarily from other similar medicines. When the original medicine is close to losing exclusivity (e.g. loss of patent protection), pressure from generic, hybrid or biosimilar versions of the same medicine starts to build up. Upon their entry, the originator may lose significant sales volumes and average market prices may drop dramatically.

### **Developing new medicines – competition on innovation**

The pharmaceutical industry is one of the most R&D-intensive industries in the EU and worldwide<sup>(51)</sup>. Innovation is driven by the demand for new, more effective and/or safer treatments for patients, the life-cycles of medicines, and the threat of competition, especially generic competition after loss of exclusivity.<sup>(52)</sup> As patients are gradually switched to newer alternative treatments, or cheaper generic versions, the originator companies cannot indefinitely appropriate profits from past innovative products but need to invest in new innovative products so that they are not outcompeted by rival innovation. The continued process of investment in R&D, to which competition makes a vital contribution, therefore leads to the discovery of new or improved medicines to the benefit of both patients and society as a whole.

### **Market exclusivity for new medicines is limited in time**

Given the high development costs and the fact that, once a new medicine has been developed, it is relatively easy for rivals to copy it, legislation grants originator companies various exclusivity mechanisms that are designed to provide them with incentives to invest in new R&D projects. A common feature of these exclusivities is however that they are limited in time, and thus allow the entry of generic medicines at the end of the exclusivity.

The substance (active ingredient) in an originator medicine may be patented and such patents are often referred to as ‘compound’ or ‘primary’ patents. If this is the case, no competitor can sell a medicine containing the same active ingredient which is patent protected without the consent of the patent owner. Patent protection can be extended by supplementary protection certificates (‘SPCs’) which aim to compensate for the period of patent protection lost by the pharmaceutical innovator due to the lengthy regulatory procedures needed to obtain MA for the new medicinal product. There can also be other protection instruments granting exclusivity (see Box 7 below).

While the medicine is on the market, manufacturers may carry out further research and clinical studies to develop new medical uses for the medicine. Furthermore, they usually continue to improve their manufacturing processes, pharmaceutical form, and/or composition (different salts, esters, crystalline forms etc). Manufacturers may seek to protect these improvements by patenting them. Such patents, often called ‘secondary

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<sup>(51)</sup> In 2017, the spend on new R&D equalled 13.7 % of sales in pharmaceuticals and 24 % in biotechnology (European Commission, Industrial Research and Innovation, The 2017 EU Industrial R&D Investment Scoreboard, 2022 edition, (e.g. Table 1.2 page 11) ) [https://iri.jrc.ec.europa.eu/sites/default/files/contenttype/scoreboard/2022-12/EU%20RD%20Scoreboard%202022%20FINAL%20online\\_0.pdf](https://iri.jrc.ec.europa.eu/sites/default/files/contenttype/scoreboard/2022-12/EU%20RD%20Scoreboard%202022%20FINAL%20online_0.pdf).

<sup>(52)</sup> On exclusivities see Box 7 and the following Section.

patents', may make it more difficult for generics to enter the market soon after the active ingredient has lost its market exclusivity, as other characteristics of the originator medicine are still patented.

#### **Box 7: Patents and other exclusivities provide a period of protection**

Patents provide the innovator (originator) with an exclusive right to prevent any third party from using an invention for up to 20 years from the date of filing of a patent application. A manufacturer usually applies for the patent on a novel medicine very early in the development process so that the 20-year patent protection period starts long before the drug enters the market. SPCs can then extend the period of patent protection for a novel medicine by up to 5 years.

Originator medicines can also benefit from market and data exclusivity. During this data exclusivity period, generic or biosimilar producers cannot apply for an MA for the generic or biosimilar version of the same medicine by way of a MA procedure, which relies in part on the data submitted for the originator medicine.

To encourage research, development and commercialisation of treatments for rare diseases, the pharmaceutical regulations provide for market exclusivity for so called orphan medicines, which means that similar medicines for the same therapeutic indication cannot apply for nor be granted a marketing authorisation, for a specified period (and as a result enter the market), which may run either in parallel or not with a patent protection. When medicines are adapted to meet the medical needs of children (paediatric medicines), this may also be rewarded by an additional period of exclusivity (SPC, data or market exclusivity).

#### **Loss of protection and generic or biosimilar competition**

The limitation in time of all protection instruments is fundamental for dynamic competition, as it balances the incentives to innovate from market exclusivity and the subsequent threat of generic or biosimilar competition with increased access to cheaper medicines after loss of exclusivity. Competitive pressure from generics or biosimilars may be significantly different and stronger than pressure from other originator medicines.

Most Member States have regulatory mechanisms to encourage the prescription and/or dispensing of generic or biosimilar medicines instead of the more expensive originator medicine. Once a generic or biosimilar medicine enters the market, these mechanisms lead to stronger price competition from generics or biosimilars and to important shifts in volumes of product sold from the originator to the generic/biosimilar, potentially even threatening the entire patient population of the originator. As a result, the entry of cheaper generics/biosimilars tends to slash the sales of the originator medicine and average prices, and is a key driver of cost savings for healthcare systems and of greater access to medicines for patients. For various reasons as explained below, such cost savings seem more difficult to achieve for biosimilars than for generics. Nevertheless, by 2022, the number of new biologic molecules with a biosimilar had doubled in five years compared to the ten years prior. <sup>(53)</sup>

Unlike competition between medicines based on different molecules, a generic medicine contains the same active ingredient, is marketed in the same dosages, and treats the same indications as the originator medicine, and thus competition is between homogeneous products.

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<sup>(53)</sup> In 2022 a total of 18 molecules had direct biosimilar competition and had an average of 3.8 competitors authorised. (Source: *The Impact of Biosimilar Competition in Europe*, December 2022, IQVIA).

While the competitive dynamics between original biological medicines and biosimilars is similar to that between originator medicines and generic medicines, biological products have a number of distinctive features which may lead to a more limited uptake or lesser price reductions compared to generics. As explained above in Section 3.1, biosimilars are not exact copies of reference medicines. Due to the inherent differences in all biological medicines, there is also room for differentiation strategies and non-price competition between distinct biosimilars of the same molecule. This complexity leads to higher barriers to entry for biosimilars compared to classical generics. In 2023, the EMA emitted a general statement on the scientific principle highlighting that biosimilars can be used interchangeably and detailing the scientific references supporting this position.

**Box 8: Interchangeability of biosimilar medicines in the EU**

The EMA and the national Heads of Medicines Agencies ('HMA') have emphasised that biosimilars approved in the EU are interchangeable from a scientific viewpoint, meaning that a biosimilar can be used instead of its reference biologic product, or vice versa.<sup>(54)</sup> A biosimilar can likewise be used in place of another biosimilar of the same reference product. Any interchange should, however, only take place after careful consideration of the product information.

EU experts consider that when approval for a biosimilar is granted in the EU, additional systematic switch studies are not required to support the interchangeability. Considering the available scientific evidence and the successful experience with biosimilars in clinical practice over the years, the HMA and the EU experts Working Party on biosimilar medicines support that medicines approved as biosimilars in the EU may be prescribed interchangeably. This will allow more patients to have access to biological medicines necessary for treating diseases such as cancer, diabetes and rheumatic diseases. Member States will continue to decide which biological medicines are available for prescribing in each territory and whether automatic substitution is allowed at pharmacy level.

In addition to stimulating price competition, generic and biosimilar entry also helps to foster innovation. First, after the expiry of various exclusivities (such as patents, SPC, market and data exclusivity), the knowledge behind the innovation (disclosed in patent applications and MA files) can be freely used by other innovators to develop and commercialise new products. Second, the entry of cheaper generic or biosimilar products disrupts the innovators' ability to benefit from high revenues owing to market exclusivity and will therefore encourage the originator company to continue investing in R&D for pipeline products in order to secure future revenue streams. Generic/biosimilar competition therefore not only results in lower prices for older medicines, but also acts as a disciplining force that compels originator companies to continue to innovate.

Companies may occasionally attempt to misuse the regulatory system which grants patent or exclusivity protection to gain additional time before competing products can enter the market. In addition to judicial and regulatory control, competition authorities also have a role to play in such scenarios to ensure that incentives to innovate are not distorted and that healthcare systems are not worse off as a result of companies unduly obstructing competition to protect their revenues. Finally, it is important for generics and biosimilars manufacturers to be able to anticipate when patents and other exclusivities protecting an originator drug expire in order to viably enter and compete on a given market.

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<sup>(54)</sup> *Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU*, 21 April 2023, EMA/627319/2022.

### **3.2.2. Pricing and reimbursement rules strongly impact competition between medicines**

In most Member States, the manufacturers must undergo pricing and reimbursement procedures before marketing prescription medicines. Pricing and reimbursement rules and policies remain an exclusive competence of Member States. Regulation, public procurement and related negotiations influence the price of a medicine. This goes both for originator, generic or biosimilar medicines.

Member States have opted for different pricing schemes that are typically based on negotiations between healthcare bodies of the Member States and manufacturers. These in turn may be coupled with (i) references to the price of the medicine in other Member States; (ii) considering the additional benefit brought about by the medicine as assessed following a 'health technology assessment'; or (iii) a combination of the above. Even where initial prices are not subject to specific mechanisms, medicines will in general only be reimbursed up to a certain amount.

To tap into the potential for cost savings, most Member States introduce measures to encourage price competition between equivalent medicines. For instance, dispensing cheaper generic or biosimilar products can be stimulated by rules that require generic prescriptions by physicians (prescribing a molecule rather than a specific brand) and/or by authorising pharmacists to dispense the cheapest (generic) version of the medicine. In genericised markets, health insurers may also organise tenders to select the cheapest supplier for a given medicine.

The regulator can facilitate price competition between therapeutically substitutable medicines, for example by only reimbursing the costs of the cheapest product in a therapeutic class (i.e., groups of medicines which have different active ingredients but are used to treat the same condition) and thereby spark a higher degree of economic substitution (switching patients to interchangeable but less costly medicines). Such measures may profoundly transform the nature and intensity of competition for alternative medicines, as suppliers are no longer protected from price-driven competition from therapeutic alternatives.

### **3.2.3. The reform of the EU pharmaceutical legislation and Pharmaceutical Strategy for Europe**

On 26 April 2023, the European Commission adopted a 'pharmaceutical package'<sup>(55)</sup> proposing to the Council and the European Parliament to revise the EU's pharmaceutical legislation, based on preparatory work in the period since the adoption of the Pharmaceutical Strategy for Europe in 2020<sup>(56)</sup>. The package is composed of proposals for a new directive and a new regulation, which would replace the existing pharmaceutical legislation, including the legislation on medicines for children and for

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<sup>(55)</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en)

<sup>(56)</sup> Communication from the Commission, Pharmaceutical Strategy for Europe (COM/2020/761 final).

rare diseases. The package also contains a Council recommendation to step up the fight against antimicrobial resistance <sup>(57)</sup> and a communication <sup>(58)</sup>.

The proposed revision of the pharmaceutical legislation aims at making medicines more accessible (in all Member States), available (to address risks of shortages), and affordable (to national health systems and patients), while supporting competitiveness of the EU pharmaceutical industry, combatting antimicrobial resistance, and ensuring higher environmental standards of medicines.

The proposals include measures that promote patient access to medicines in all Member States, a long-standing request from the Council. This would notably be done through a system of modulation of incentives. The reform aims to support the development of medicines by incentivising all innovative medicines with a set of standard incentives (data and market protection for all innovative medicines and data exclusivity for medicines for rare diseases) that remain internationally competitive. In addition, it would reward companies with additional periods of data protection when the medicine is supplied in all Member States in which the marketing authorisation is valid. The proposed reform does not affect the EU's system of intellectual property rights or supplementary protection certificates which remain an essential element of protection of innovation in the EU.

The proposals also include measures to promote innovation in the areas of unmet medical need. Medicines addressing an unmet medical need would receive an additional period of data protection and EMA would also provide early regulatory and scientific support to companies for promising medicines under development addressing an unmet medical need.

The revision also addresses medicines shortages and enhances security of supply, at all times, building on and strengthening the systems and processes that were established in the EMA's extended mandate Regulation.

Affordability for healthcare systems and patients in the EU would be enhanced through different measures. First, the reform would facilitate earlier market entry of generics and biosimilar medicines by speeding up market entry after the expiry of the patent protection of the originator (the extended and harmonised so-called *Bolar* exemption <sup>(59)</sup> and the change in orphan market exclusivity rules making filing of application possible before market exclusivity expires), which increases competition and reduces prices. It also aims to incentivise the generation of comparative clinical data through an additional period of data protection to support Member States to take timely and evidence-based decisions on pricing and reimbursement. It moreover contains measures on transparency around public funding for medicine development, which will support Member States in their

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<sup>(57)</sup> Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01 (OJ C 220, 22.6.2023, p. 1).

<sup>(58)</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance (COM/2023/190 final).

<sup>(59)</sup> The EU Bolar exemption (laid down in Article 10(6) of Directive 2001/83/EC and Article 41 of Regulation (EU) 2019/6 (formerly Article 13(6) of Directive 2001/82/EC)) states that, under certain conditions, procedures such as production of samples which are necessary for regulatory approval do not infringe the existing patent right or protection certificate for medicinal products.

negotiations with pharmaceutical companies and ultimately make medicines more affordable.

The pharmaceutical package is the biggest building block of the Pharmaceutical Strategy for Europe adopted in November 2020 and composed of 55 action points. The Pharmaceutical Strategy for Europe aims at creating a future-proof and patient-centred pharmaceutical environment in which the EU industry can innovate. The Pharmaceutical Strategy for Europe is also taking non-legislative actions to support cooperation among Member States on pricing, reimbursement, and procurement policies through exchange of information and best practices through the group of National Competent Authorities on Pricing and Reimbursement and Healthcare payers.

Both the reform of the EU pharmaceutical legislation and the Pharmaceutical Strategy are central pillars of a strong European Health Union<sup>(60)</sup>. They will complement other key initiatives, including the reinforcement of the EU health security framework with the new legislation on cross-border threats to health and stronger mandates for EU health agencies, the establishment of the Health Emergency Preparedness and Response Authority (HERA) as well as Europe's Beating Cancer Plan and the European Health Data Space.

#### **4. COMPETITION LAW PROTECTS UNDERTAKINGS AND CONSUMERS ALSO IN TIMES OF COVID CRISIS**

From March 2020 through to 2022, businesses within the EU faced particular challenges due to the consequences of the Covid-19 pandemic. However, many of these businesses were in a position to play a crucial role in mitigating the effects of the crisis. The exceptional circumstances and the related challenges sometimes triggered a need for companies to cooperate with each other in order to ensure the supply and fair distribution to all consumers of essential and possibly scarce products and services.

In response to this need, the Commission, the NCAs and the EFTA Surveillance Authority issued on 23 March 2020 a joint statement on the application of the EU antitrust rules during the Covid-19 pandemic, explaining how competition authorities could help companies deal with the crisis.<sup>(61)</sup> The statement clarified that the ECN would not actively intervene against necessary and temporary measures put in place in order to avoid a shortage of supply, but that it would, however, not hesitate to take action against companies taking advantage of the crisis situation by cartelising or abusing their dominant position. In this context, the ECN pointed out that the existing rules allowed manufacturers to set maximum prices for their products, which could prove useful to limit unjustified price increases at the distribution level.

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<sup>(60)</sup> [https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union\\_en](https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en).

<sup>(61)</sup> [https://competition-policy.ec.europa.eu/system/files/2021-03/202003\\_joint-statement\\_ecn\\_corona-crisis.pdf](https://competition-policy.ec.europa.eu/system/files/2021-03/202003_joint-statement_ecn_corona-crisis.pdf). A similar statement by the International Competition Network was published on 8 April 2020: <https://www.internationalcompetitionnetwork.org/wp-content/uploads/2020/04/SG-Covid19Statement-April2020.pdf>.

#### **4.1. Commission guidance on antitrust rules to companies cooperating in response to the Covid-19 outbreak**

During the Covid-19 period, the Commission was available to provide guidance to companies, associations and their legal advisors regarding specific cooperation initiatives with an EU dimension that needed to be swiftly implemented during the coronavirus pandemic, and where there was uncertainty about whether such initiatives were compatible with EU competition law. On 8 April 2020, the Commission adopted a Temporary Framework Communication<sup>(62)</sup>, setting out the main criteria for assessing cooperation projects aimed at addressing a shortage of supply of essential products and services during the coronavirus outbreak. The document also foresaw the possibility of providing companies with written comfort (via ad hoc “comfort letters”) on specific cooperation projects falling within the scope of the Temporary Framework<sup>(63)</sup>.

During the Covid-19, crisis two comfort letters were adopted under the Temporary Framework. The comfort letter sent on 8 April 2020 to “Medicines for Europe”<sup>(64)</sup>, an association of pharmaceutical manufacturers, concerned a voluntary cooperation to address the risk of shortages of critical intensive care medicines for the treatment of Covid-19 patients by significantly increasing the production capacity of Covid-19 medicines. The temporary cooperation appeared justifiable under EU antitrust law, in view of its objective – jointly to increase rather than to decrease output – and the safeguards put in place to avoid anticompetitive concerns.

On 25 March 2021, the Commission issued a further comfort letter<sup>(65)</sup>, addressed to co-organisers of a pan-European matchmaking event, which aimed at addressing bottlenecks in the production of Covid-19 vaccines and accelerating the use of additional available capacities across Europe. The comfort letter identified the conditions under which exchanges of information between the companies, including direct competitors, could take place in compliance with the EU competition rules.

#### **4.2. Commission coordination and initiatives of national competition authorities**

In the spirit of the common ECN statement described above, the European competition authorities took numerous initiatives and provided guidance to businesses to safeguard access to essential medical products and services while ensuring compliance with competition rules. The initiatives described below are just a few examples of their intense activity, frequently in coordination with the Commission, during the challenging Covid-19 crisis.

Following media reports, the *Dutch NCA* in 2020 launched an investigation into Roche Diagnostics in connection with expanding test capacity in the Covid-19 crisis. According to the information in the media reports, Roche withheld the recipe for its lysis buffers used for its PCR Covid-19 tests, making it difficult for laboratories to make their own

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<sup>(62)</sup> Commission Communication on Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak (OJ C 116I, 8.4.2020, p. 7).

<sup>(63)</sup> [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_20\\_618](https://ec.europa.eu/commission/presscorner/detail/en/IP_20_618).

<sup>(64)</sup> [chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://competition-policy.ec.europa.eu/system/files/2021-03/medicines\\_for\\_europe\\_comfort\\_letter.pdf](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://competition-policy.ec.europa.eu/system/files/2021-03/medicines_for_europe_comfort_letter.pdf).

<sup>(65)</sup> [https://competition-policy.ec.europa.eu/document/5cfbb468-decb-4ca5-b583-f3764773209f\\_en](https://competition-policy.ec.europa.eu/document/5cfbb468-decb-4ca5-b583-f3764773209f_en)

reagent solution to use in Roche’s PCR testing machines. Upon information requests and discussion with the NCA, government agencies and experts, Roche committed to the NCA to doing everything it could to enable hospitals and laboratories to carry out as many tests as possible and to eliminate any obstacles as much as possible. In this process, the NCA worked closely together with the Commission. <sup>(66)</sup>

The *Greek NCA* set up a special Covid Task Force and took action against potential price fixing:

- In March 2020, the Greek NCA set up a “Covid-19\_Competition Task Force” to fight anticompetitive practices. <sup>(67)</sup> Its task was to provide businesses and citizens with information about the application of competition rules and inform the public about the investigations and procedural matters carried out by the NCA. One of the primary objectives of this Task Force was to create a hub collecting questions raised by different institutions and businesses, concerning the initiatives they intend to take and their compatibility with competition law, as well as to ensure immediate response thereto.
- In September 2021, the Government set price caps for Covid-19 diagnostic tests carried out in private diagnostic laboratories, private clinics, pharmacies, and other retail outlets. However, the Panhellenic Pharmaceutical Association (“PPA”) issued guidelines to its members (i.e. local associations of pharmacists) which suggested that the price cap for rapid tests set by the Government at EUR 10 was a fixed price, thus possibly removing competition to offer the tests at a lower price. Instead of opening an investigation, the Greek NCA sent a warning letter to the PPA which reiterated that the price caps imposed by the Government should be understood as maximum and not as fixed prices and instructed the PPA to (a) publicly repeal its guidelines, (b) distribute the NCA’s letter to its members and post it on its website. The NCA also made a public statement which clarified that the price caps imposed by the Government represented the maximum, but not a fixed price, and invited citizens to report any anti-competitive conduct that would come to their attention. <sup>(68)</sup> Pursuant to the NCA’s instructions, the PPA sent letters to its members and published modified guidelines.

In March 2021, the *German NCA* gave the green light for the participation of full-line pharmaceutical wholesalers in the “VCI Emergency Platform for Vaccination Equipment”. The platform was launched with the NCA’s approval to better coordinate the supply of vaccination equipment (syringes, cannulas, and NaCl solution). The B2B platform enabled the federal Länder and manufacturers of vaccination equipment to exchange information on their current supply situation and their capability to deliver. This transparency was supposed to help better coordinate the supply chain in order to prevent shortages or misallocation of vaccination equipment. The platform did not allow for the provision of any details on the prices and quantities of the suppliers and its duration was limited to the emergency situation at that time.

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<sup>(66)</sup> <https://www.acm.nl/en/publications/acm-has-confidence-commitments-made-roche-help-solve-problems-test-materials>

<sup>(67)</sup> <https://www.epant.gr/en/enimerosi/press-releases/item/858-press-release-covid-19-task-force-to-fight-anticompetitive-practices.html>.

<sup>(68)</sup> <https://www.epant.gr/en/enimerosi/press-releases/item/1604-press-release-pricing-of-pcr-and-rapid-tests-in-the-greek-market.html>.



The *Polish NCA* conducted several Covid-19-related preliminary investigations, which did however not result in an infringement decision. The investigations related to (i) complaints about shortage and price increase of ethanol used for manufacturing magistral drugs (drugs prepared in pharmacy), (ii) shortage of medical oxygen, and shortages in the field of personal protective equipment. The Polish NCA found that the shortages were not linked to anticompetitive behaviour but were rather the result of a sudden increase in demand for the products. The Polish NCA also investigated whether Qiagen abused its dominant position as a distributor of diagnostic reagents but found no evidence of the alleged refusal to deal, tying or exclusive contracts, and found that delays in fulfilment of orders were again due to demand-driven shortages arising from the Covid-19 pandemic.

## **5. COMPETITION PROMOTES ACCESS TO AFFORDABLE MEDICINES**

Competition law enforcement activities that contribute to continuous efforts to deliver affordable medicines to European patients and healthcare systems include, in particular, actions against practices that hinder or delay the market entry of medicines and the resulting price competition (Section 5.1), and against excessively high prices of medicines when they amount to an abuse of dominant position by a pharmaceutical company ('unfair' prices) (Section 5.2). In addition, the European competition authorities have also addressed a number of other anti-competitive practices capable of hindering price competition (e.g. refusal to supply, resale price maintenance, bid rigging, market sharing and exchange of commercially sensitive information) that either directly or indirectly lead to higher prices of medicines (Section 5.3). Finally, the Commission's merger control in the pharmaceutical sector has concentrated on facilitating and protecting market entry of generic and biosimilar medicines, especially through remedies (Section 5.4).

### **5.1. Antitrust enforcement supports swift market entry of cheaper medicines**

Effective generic or biosimilar competition typically represents an important source of price competition on pharmaceutical markets and drives prices down significantly. For example, an economic study prepared for the Commission<sup>(69)</sup> found that prices of innovator medicinal products drop by 40 % on average in the period after generic products enter the market. It also showed that when generic medicinal products enter the market, their price is on average 50 % lower than the initial price of the corresponding originator product.<sup>(70)</sup> On the one hand generic and biosimilar entry brings benefits to patients and national healthcare systems while on the other it significantly reduces the originator companies' profits from their product, which no longer enjoys patent protection or another form of exclusivity.

To mitigate the impact of generic or biosimilar entry, originator companies often devise and implement a variety of strategies to artificially extend the commercial life of their innovative medicines and hinder market entry of competitor products. Examples of

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<sup>(69)</sup> *Copenhagen Economics*, see footnote 45.

<sup>(70)</sup> Examples from the Commission's enforcement practice show that price reductions can be even more drastic in the case of blockbuster medicines. For instance, in the *Lundbeck* case the Commission found that prices of generic citalopram dropped on average by 90 % in the United Kingdom compared to Lundbeck's previous price level within 13 months of the generic products entering the market on a wide scale (Commission Decision of 19 June 2013 in case COMP/AT.39226 – *Lundbeck*, paragraph 726).

illegitimate practices such as patent misuse and vexatious litigation, anti-competitive agreements to delay market entry, disparagement of competitor products, abusive rebates and predatory pricing, as well other practices hindering market entry, are described below.

### 5.1.1. Patent misuse and vexatious litigation

Given the regulatory framework characterising the pharmaceutical sector and the key role played by patents, the use of certain rights and privileges conferred on dominant undertakings may in certain cases be qualified as falling outside the scope of competition on the merits and may have an anticompetitive effect, thereby constituting a potential violation of Article 102 TFEU. Indeed, the abusive nature of a certain conduct under Article 102 TFEU is in general unrelated to that conduct's compliance with other legal rules<sup>(71)</sup>, including the regulatory framework characterising the pharmaceutical sector.<sup>(72)</sup> An example of when otherwise legitimate patent conduct by a dominant undertaking could be considered as an abuse of dominant position is provided by the preliminary findings in the ongoing *Teva Copaxone* case.

#### **Box 9: The *Teva Copaxone* case**

On 10 October 2022, the Commission adopted a Statement of Objections reaching the preliminary conclusion that Teva may have abused its dominant position in the markets for glatiramer acetate, a treatment for multiple sclerosis, in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain. According to the Commission's preliminary findings, Teva engaged in two types of conduct, with an overall objective of artificially prolonging the exclusivity of Teva's blockbuster drug Copaxone by hindering the market entry and uptake of competing glatiramer acetate medicines.<sup>(73)</sup>

In particular, one of the two potentially abusive conducts identified in the Commission's Statement of Objections consists in the misuse of patent procedures.<sup>(74)</sup> In essence, in the Commission's preliminary view, Teva's potentially abusive behaviour would have consisted in the staggered filing before the European Patent Office of applications for divisional patents<sup>(75)</sup> with largely overlapping content. Teva would have then subsequently obstructed the legal review of its patents by withdrawing the parent patent applications (but leaving pending the divisional patent applications) once legally challenged by competitors who were trying to "clear the way" for their market entry. As a result, Teva's competitors could have been forced to legally challenge essentially similar Teva patent claims multiple times (one for each divisional patent), with the result that legal uncertainty was artificially prolonged to the benefit of Teva, and market entry of generic or generic-like medicines was effectively blocked or delayed, amongst others due to interim injunctions.

The Commission's preliminary views as to the potential qualification of Teva's conduct as abusive under Article 102 TFEU are yet to be confirmed, and the issuance of a Statement of Objections addressed to Teva does not prejudice the outcome of the Commission's investigation.

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<sup>(71)</sup> Judgment of 12 May 2022, *Servizio Elettrico Nazionale et al. v AGCM*, C-377/20, EU:C:2022:379, paragraph 67.

<sup>(72)</sup> Judgment of 6 December 2012, *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 132.

<sup>(73)</sup> Press release: [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_22\\_6062](https://ec.europa.eu/commission/presscorner/detail/en/IP_22_6062).

<sup>(74)</sup> See Section 5.1.3 for the other type of potentially abusive conduct identified in the Commission's Statement of Objections.

<sup>(75)</sup> Divisional patents are patents derived from earlier patent applications (so-called "parent patents"), and whose subject matter is already contained therein.

In some instances, companies may file claims before a Court not to assert their rights but merely to harass the opposing party as part of a plan to eliminate competition. In such exceptional circumstances, where it can be established that the legal action by a dominant company is objectively baseless, the practice of “vexatious litigation” may constitute an abuse of dominance. The practice can also be relevant in the pharmaceutical sector, where a company may for example request preliminary injunction from courts not as a means to protect its proprietary rights but with the sole objective to halt a competitor from launching a product and thereby eliminate competition.

In a case investigated by the Spanish NCA, the pharmaceutical company Merck Sharp & Dohme GmbH (‘MSD’) enjoyed patent protection for the first vaginal contraceptive ring, Nuvaring from 2002 to 2018. Meanwhile, the competitor Insud Pharma developed an alternative (also patent protected) vaginal ring with different characteristics. The product was launched in June 2017 under the name Ornibel. MSD filed legal action claiming patent infringement and requested a Spanish court to order fact-finding to support its claims, and subsequently to adopt interim measures in proceedings without hearing Insud Pharma (so called *ex parte* proceedings). The court issued interim measures which effectively halted the manufacture and sale of the Ornibel ring in Spain from September until December 2017, when the court annulled the interim measures following Insud Pharma’s appeal.

The Spanish NCA considered that when alleging patent infringement and requesting fact-finding and interim measures, MSD deployed a strategy to mislead the court in order to hinder the market entry of a competitor, withholding relevant factual and technical information and providing misleading information to the court. The Spanish NCA established that the real purpose of MSD’s legal actions was to foreclose competition rather than to enforce their patents reasonably and legitimately. As the only factory producing Insud Pharma’s rings was located in Spain, the halt in production affected distribution and sales in all the countries where the rings had started to be marketed. Consequently, MSD's conduct affected competition in several EU countries. The NCA concluded that the lack of transparency of MSD's conduct vis-à-vis the court was contrary to competition on the merits and imposed a EUR 38,93 million fine on MSD.<sup>(76)</sup>

### **5.1.2. Pay-for-delay agreements**

Pay-for-delay agreements encompass a variety of arrangements between originator and generic companies, whereby the generic company agrees to restrict or delay its independent entry onto the market in exchange for significant benefits transferred from the originator. In other words, the originator company pays its competitor, the generic company, to stay out of the market for a period of time that may be shorter or longer – whereby even short delays may come at a high cost to the society at large.

A pay-for-delay agreement may be advantageous for both the originator, who reaps extra profits from extended market exclusivity, and the generic company, who can receive a windfall profit from the originator. If the profit that the originator hands over to the generic company is significantly lower than the loss in originator profits in the case of independent entry, then the originator can afford to pay off one or several generic companies to prevent their entry. A generic company may also find a pay-for-delay

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<sup>(76)</sup> Decision of the Comisión Nacional de los Mercados y la Competencia of 21 October 2022.

agreement attractive since it can make significant earnings without even entering the market, by sharing part of the originator's profits from exclusivity.

In such a scenario, these two players (originator and generic would-be entrant) benefit at the expense of healthcare systems and taxpayers. Patients and healthcare systems suffer as result of pay-for-delay agreements as they forego the savings that would result from the timely independent generic entry, and which instead provide extended profits for the originator and generic companies. Considering the scale of price reductions brought about by generic entry, even short delays can have a significantly negative impact on competition.

Pay-for-delay agreements can also have a detrimental effect on innovation. Competition from generics stimulates pharmaceutical companies to focus their efforts on developing new drugs rather than on maximising income streams from their old drugs by artificially preserving market exclusivity. <sup>(77)</sup>

Since pay-for-delay agreements involve coordination between competing companies they fall under Article 101 TFEU (and equivalent provisions in national competition laws). The anti-competitive nature of pay-for-delay agreements does not depend on the form in which they are concluded. Such arrangements are often entered into in the context of disputes between originator and generic companies concerning the validity and/or infringement of the originator's secondary patents. In such pay-for-delay deals the originator induces the generic company to stay out of the market either by cash payments or any other commercial arrangement that essentially serves to buy a competitor out of the market.

In January 2020, the Court of Justice issued its first ever ruling concerning pay-for-delay agreements ('Generics UK judgment') based on a number of questions referred from the United Kingdom Competition Appeal Tribunal ('CAT'). <sup>(78)</sup> The judgment confirms that 'pay for delay' agreements have the object of restricting competition and may constitute an abuse of a dominant position. The CAT then delivered a final judgment in May 2021 dismissing all of the remaining grounds of appeal but lowered the fine from GBP 44.99 million (approximately EUR 51.8 million) <sup>(79)</sup> to GBP 27.1 million (EUR 31.9 million). <sup>(80)</sup>

Then, in May 2021, the CAT upheld the NCA decision <sup>(81)</sup> that GlaxoSmithKline and some generic suppliers of the anti-depressant paroxetine broke competition law. In its 2016 decision, the NCA had found that GlaxoSmithKline abused its dominant position

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<sup>(77)</sup> See, *mutatis mutandis*, Judgment of the General Court of 1 July 2010, *AstraZeneca AB and AstraZeneca plc v European Commission*, Case T-321/05, EU:T:2010:266, paragraph 367: "misuse of the patent system potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator."

<sup>(78)</sup> Judgement of the Court of Justice of 30 January 2020 in Case C-307/18, paragraph 87.

<sup>(79)</sup> All EUR countervalues in this report are calculated against the European Central Bank average exchange rate in the year of the NCA's decision.

<sup>(80)</sup> Judgment of the Competition Appeal Tribunal of 10 May 2021. The reasoning behind this reduction is the question of novelty of the case and the lapse of time between the infringements and the start of the investigation.

<sup>(81)</sup> Decision of the Competition and Markets Authority of 12 February 2016.

by inducing, through payments and other benefits, three potential generic competitors (IVAX, Generics (UK) and Alpharma) to delay their potential independent entry into the paroxetine market in the United Kingdom. In March 2018, the CAT already dismissed a number of the companies' grounds of appeal against the NCA's decision and referred the remaining grounds to the Court of Justice for a preliminary ruling on various questions of EU law. <sup>(82)</sup>

In the Generics UK judgment, the Court of Justice pointed to the central role for the assessment of value transfers. It concluded that pay-for-delay agreements restrict competition by their very object "*when it is plain from the analysis of the settlement agreement concerned that the transfers of value provided for by it cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits.*"

In the latest Commission case concerning pay-for-delay agreements, the *Cephalon* case, Cephalon induced Teva not to enter the market with a cheaper version of its drug for sleep disorders in exchange for a package of commercial side-deals and some cash payments. <sup>(83)</sup>The General Court confirmed the Commission's decision in its entirety <sup>(84)</sup>.

**Box 10: The *Cephalon* case**

On 26 November 2020, the Commission fined Teva and Cephalon EUR 30 million and EUR 30.5 million respectively for agreeing to delay for several years the market entry of a cheaper generic version of Cephalon's drug for sleep disorders, modafinil, after Cephalon's main patents had expired. The infringement lasted, for almost all EU Member States and EEA countries, from December 2005 to October 2011, when Teva acquired Cephalon and they became part of the same group.

Modafinil is used to treat excessive daytime sleepiness associated with narcolepsy. It was Cephalon's top-selling product under the brand Provigil for years, accounting for 40 % of Cephalon's worldwide turnover.

Teva held its own patents relating to modafinil's production process, was ready to enter the modafinil market with its own generic version, and it had even sold its generic in the United Kingdom for a short period in 2005. Shortly after Cephalon introduced a patent infringement action against Teva, Cephalon and Teva signed a settlement agreement. The parties agreed to terminate the litigation, while Teva also committed not to enter the market and not to challenge Cephalon's patents. Teva committed to stay out of the modafinil markets, not because it was convinced of the strength of Cephalon's patents, but because of the substantial value transferred to it by Cephalon. The value transfer was mainly embedded in a number of commercial side-deals, which Teva would not have achieved without committing to staying out of the market. These included a distribution agreement, the acquisition of a licence on certain Teva modafinil patents by Cephalon, a lucrative supply contract, and granting by Cephalon of access to clinical data that were highly valuable for another medicine in Teva's portfolio.

On 18 October 2023, the General Court fully upheld Commission's decision, accepting the Commission's reasoning that the side deals would not have been carried out at all or under the same conditions favourable to Teva had Teva not agreed to the non-compete and no-challenge

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<sup>(82)</sup> C-307/18, *Generics (UK) Ltd., GlaxoSmithKline Plc, Xellia Pharmaceuticals APS, Alpharma LLC, Actavis UK Ltd. and Merck KGaA vs. Competition and Markets Authority*.

<sup>(83)</sup> Commission Decision of 26 November 2020 in case COMP/AT.39686 – *Cephalon*.

<sup>(84)</sup> Judgement of the General Court of 18 October 2023.

clauses in the settlement agreement. The Court also rejected all of the appellants' individual claims on the basis of a factual analysis of each of the side deals. Following the principles set out in the Generics UK judgment the Court thus confirmed that the only plausible explanation for each of the commercial transactions was to induce Teva to accept the restrictive clauses and thus to refrain from competing with Cephalon on the merits. In addition, the judgment confirmed that a licence to Teva to enter the modafinil markets before the expected expiry of Cephalon's secondary patents (so called "*early entry agreement*") did not fulfil stringent criteria set in the Generics UK judgment and could not be qualified as a pro-competitive element preventing the characterisation of the Settlement Agreement as a "by object" restriction. Finally, the Court fully rejected the appellant's objections to the Commission's "*by effects*" analysis.

Pay-for-delay agreements were found to be anti-competitive in various other circumstances. In the *Lundbeck* decision of 2013 the Commission imposed fines on pharmaceutical companies for entering into agreements that delayed the market entry of generic citalopram. <sup>(85)</sup>.

The litigation concerning the Commission's *Servier* decision <sup>(86)</sup>, which concerned five pay-for-delay agreements, is still pending before the Court of Justice. At first instance, the General Court confirmed the Commission's findings concerning four agreements but annulled the decision as far as it concerned the agreement between Servier and Krka, as well as the Commission's findings concerning the relevant product market and dominance and consequently the conclusion that Servier also abused its dominant position in violation of Article 102 TFEU. <sup>(87)</sup>

### 5.1.3. Disparagement

Over the last ten years, investigations of disparagement in the pharmaceutical industry have been on the rise. In these cases, dominant incumbents disparage (denigrate) their competitors - usually new entrants - to hinder the uptake of competing products.

The Court of Justice already clarified that dissemination of misleading information to the authorities, healthcare professionals and the general public can raise concerns under the EU competition rules. Specifically, in a judgment concerning restrictive agreements under Article 101 TFEU, the Court ruled that companies may not collude to disseminate, in a context of scientific uncertainty, misleading information relating to adverse reactions resulting from the off-label use of one product with a view to reducing the competitive pressure it exerts on another product. <sup>(88)</sup>

The French NCA pioneered the enforcement in this space with a series of decisions against companies engaged in disparagement practices <sup>(89)</sup>, three of which have been

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<sup>(85)</sup> Commission decision of 19 June 2013. See also 2019 Report on competition enforcement in the pharmaceutical sector.

<sup>(86)</sup> Commission Decision of 9 July 2014.

<sup>(87)</sup> Judgment of the General Court of 12 December 2018. See also Opinion of Advocate General Kokott of 14 July 2022.

<sup>(88)</sup> Judgment of the Court of Justice of 23 January 2018, *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, C-179/16.

<sup>(89)</sup> See also the 2019 Report on Competition enforcement in the pharmaceutical sector: the *Plavix* decision (Decision of the Autorité de la concurrence of 14 May 2013), the *Subutex* decision (Decision of the Autorité de la concurrence of 18 December 2013), the *Durogesic* decision (Decision of the Autorité de la concurrence of 20 December 2017), and the *Avastin Lucentis* decision (see Box 11).

confirmed by the French highest courts. In the *Durogesic* case, by way of a judgment of 11 July 2019, the Paris Court of Appeal, while rejecting the appellants' claims seeking the annulment of the decision, lowered the fine from EUR 25 million to 21 million.<sup>(90)</sup> This was confirmed on 1 June 2022 by the Court of Cassation.<sup>(91)</sup> In the *Avastin-Lucentis* case, the appeal procedure is pending before the Court of Cassation.

**Box 11: The *Avastin-Lucentis* cases: misleading information about use of pharmaceutical**

Several NCAs investigated a case related to an agreement between Hoffmann-La Roche and Novartis aiming at discouraging and limiting off-label use of Hoffmann-La Roche's oncology medicine Avastin for treatment of Age-related Macular Degeneration ('AMD'). AMD is the main cause of age-related blindness in developed countries. Avastin (authorised for the treatment of tumorous diseases) and Lucentis (authorised for the treatment of eye diseases) are medicines developed by Genentech, a company which belongs to the Hoffmann-La Roche group. Genentech transferred the commercial exploitation of Lucentis to the Novartis group by way of a licensing agreement, whereas Hoffmann-La Roche markets Avastin for cancer treatments. Nonetheless, the active ingredient in both medicines being similar (though developed in different ways), Avastin was frequently used off-label (i.e. without authorisation by a medicines agency) to treat eye diseases instead of Lucentis because of its significantly lower price.

The *Italian NCA* found in 2014 that Novartis and Hoffmann-La Roche had colluded to artificially differentiate Avastin from Lucentis and disseminate alarmist messages.<sup>(92)</sup> The arrangement sought to disseminate information raising concerns about the safety of Avastin used in ophthalmology to shift demand towards the more expensive Lucentis. According to the NCA, this illicit collusion was capable of hindering access to treatment for many patients and caused the Italian healthcare system additional expenses estimated at EUR 45 million in 2012 alone. In the second-instance appeal procedure against the NCA's decision, the Italian State Council sent a preliminary reference to the Court of Justice on several questions concerning the interpretation of Article 101 TFEU. In its answers the Court of Justice clarified, amongst others, that (i) in principle, a medicine used off-label can be considered as competing with medicines authorised for that use and that (ii) communication of misleading information regarding the safety of an off-label medicine to the authorities, medical professionals and general public may constitute a restriction of competition by object<sup>(93)</sup>. Following this referral, the Italian State Council in 2019 upheld the NCA's decision<sup>94</sup> with a judgment confirmed both by the Italian Supreme Court of Cassation in 2021<sup>(95)</sup> and by the same Italian State Council in 2023 during a review proceeding that called for an additional preliminary ruling of the Court of Justice<sup>(96)</sup>.

Regarding the same medicines, the *French NCA* fined Novartis, Roche and Genentech for a total of EUR 444 million in 2020.<sup>(97)</sup> However, the French NCA did not find an anticompetitive agreement in this case but an abuse of collective dominant position of these three undertakings aiming at preserving the position and the price of Lucentis by curbing the off-label use of Avastin. The NCA established that Novartis disparaged Avastin, since it unjustifiably

<sup>(90)</sup> Judgment of the Cour d'appel de Paris of 11 July 2019.

<sup>(91)</sup> Judgment of the Chambre commerciale de la Cour de cassation of 1 June 2022.

<sup>(92)</sup> Decision of the Autorità Garante della Concorrenza e del Mercato of 27 February 2014.

<sup>(93)</sup> Judgment of the Court of Justice of 23 January 2018, *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, C-179/16.

<sup>(94)</sup> Judgment of the Italian State Council of 15 July 2019.

<sup>(95)</sup> Judgment of the Italian State Council of 8 May 2023.

<sup>(96)</sup> Judgment of the Court of Justice of 7 July 2022, *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, C-261/21.

<sup>(97)</sup> Decision of the Autorité de la concurrence of 9 September 2020.

exaggerated the risks associated with its off-label use in comparison with Lucentis for the same purpose. This communication campaign targeted ophthalmologists, patient associations and the general public in order to discredit the off-label use. Moreover, the NCA found that Novartis, Roche and Genentech unduly interfered with the French healthcare authority's initiatives to encourage this off-label use by engaging in obstructive behaviour and disseminating alarmist or misleading information in this regard. In 2023, the Paris Court of Appeal annulled the NCA's decision, ruling that no anti-competitive practice had been established against the three undertakings. <sup>(98)</sup> An appeal against this judgment is pending before the Court of Cassation.

The *Belgian NCA* followed the same reasoning and imposed a fine of EUR 2.78 million on Novartis for abusing its collective dominant position held together with the Roche group. <sup>(99)</sup>

In its Statement of Objections addressed to Teva in the Copaxone case (see Box 9 above), the Commission expressed preliminary concerns about a possible anticompetitive and systematic disparagement campaign targeting healthcare professionals and casting doubts about the safety and efficacy of a competing glatiramer acetate medicine and its therapeutic equivalence with Teva's Copaxone.

#### **5.1.4. Abusive rebates and predatory pricing**

Dominant pharmaceutical suppliers must ensure that the discounts they give do not amount to an abuse of their dominant position. Even if, at first sight, such discounts may seem to benefit society through decreasing overall costs for medicines, they may in the medium-term lead to negative effects if, for example, they hinder competitors to grow or even exclude competitors from the market.

In 2019, the Dutch NCA launched an investigation into the discounts that AbbVie had offered hospitals for its drug Humira (prescribed for rheumatism, psoriasis, and Crohn's disease among other conditions). The patent on the active ingredient of Humira had expired and other drug manufacturers produced and marketed biosimilars of Humira. Under the AbbVie discount scheme, hospitals could only get a significant discount if all existing patients continued to use Humira and did not switch to a biosimilar.

Based on its investigation, the NCA concluded that AbbVie, as former patent owner, sought to make it harder for biosimilar manufacturers to enter the market. Following this, AbbVie dropped the conditions of its discounts and indicated that it would not oblige hospitals to purchase exclusively or to a large extent from AbbVie through discount schemes or rebate programs. In light of these assurances, , the NCA closed its investigation. <sup>(100)</sup>

In another case, also concerning anti-rheumatic biologics, the Dutch NCA received information in autumn 2021 that Pfizer was using a discount scheme for its anti-rheumatic drug Enbrel that could discourage hospitals from switching to other competing biosimilar drugs. The NCA's investigation revealed that, in various contracts with hospitals, Pfizer had included a clause that enabled Pfizer to significantly reduce the discount applied to future volumes if the purchased quantities decreased by more than a

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<sup>(98)</sup> Decision of the Cour d'appel de Paris of 16 February 2023.

<sup>(99)</sup> Decision of the Autorité belge de la concurrence / Belgische Mededingingsautoriteit of 23 January 2023.

<sup>(100)</sup> <https://www.acm.nl/en/publications/acm-closes-investigation-drug-manufacturer-abbvie-competitors-get-more-room-now>.



pre-specified percentage. This created the risk of a substantial financial barrier emerging for hospitals to switch drugs.

On the basis of its preliminary investigation, the NCA informed Pfizer of its findings that the pricing structure that Pfizer used seemed to be at odds with competition rules. In reaction, Pfizer removed the discount clauses from its Enbrel contracts. Consequently, the NCA decided not to further investigate the case. <sup>(101)</sup>

Continuation of the above conduct could have been particularly harmful to drug affordability, since despite rebates offering lower prices for hospital in the short term, they can result in foreclosure of cheaper generic drugs, and in reduced investment incentives for biosimilar manufacturers. Both cases show that the NCA's intervention, although not resulting in a final decision, could enable hospitals, patients, and insurance systems to benefit from the improved market-entry opportunities for biosimilars.

Another example of abusive discounting is the predatory pricing in the Austrian temozolomide case.

#### **Box 12: The Austrian *temozolomide* case**

In 2016 the Commission conducted inspections in Merck Sharp & Dohme's ('MSD') premises in Vienna, for a suspected abuse of a dominant position through predatory pricing in relation to Temodal. The drug with the active ingredient temozolomide is used in oncology to treat brain tumours such as glioblastoma (the most frequent type of brain tumour in adults). Following the Commission's inspection, the case was transferred to the Austrian NCA which started an investigation in 2018, and concluded it in 2021 after receiving commitments from MSD that dispelled its competition concerns. <sup>(102)</sup>

Patients were usually given their first dose of Temodal as in-patients at the hospital where they were being treated. For subsequent doses, treatment continued on an out-patient basis, with the medicine being prescribed by specialist doctors in their practices. These doctors are usually the same doctors that treated the patients at the hospital.

After the expiry of patent protection for Temodal, MSD followed a strategy of foreclosing generic manufacturers' access to hospitals. This was a key point for competitive entry because the prescription made in the hospital would also determine the prescription once the patient left the hospital. MSD's prices to hospitals were allegedly set below cost, with free samples made available. In some cases, hospitals were at times only given free samples for the initial dispensing. This allegedly barred generics not only from supplying the hospitals, but also from competing in pharmacies, as out-of-hospital patients had prescriptions only allowing the pharmacists to dispense branded Temodal. This precluded generic drug manufacturers from entering the market during the period of the alleged infringement, effectively harming competition through predatory foreclosure measures.

Hospitals benefited from lower costs when prescribing the medicine for the first time. However, when the more expensive drug continues to be prescribed by doctors in their practices, society will pay more in the medium-term. This ultimately means less price competition and therefore overall higher costs for the healthcare system.

Due to the structure of this system, the NCA assumed strong lock-in effects in favour of the first prescription. Lock-in effects mean that customers remain loyal to a particular product and are

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<sup>(101)</sup> <https://www.acm.nl/en/publications/drug-manufacturer-pfizer-discontinue-its-steering-pricing-structure-enbrel-following-discussions-acm>.

<sup>(102)</sup> Decision of the Bundeswettbewerbshörde of 2 April 2021.

unlikely to switch to another one. In this case, hospital doctors had no incentive to prescribe other products containing temozolomide.

MSD agreed to stop its aggressive pricing strategy vis-à-vis hospitals and to set up a compliance program including commitments (i.e. not to distribute below costs any longer).

### **5.1.5. Other practices hindering market entry**

In addition to the cases described above, the European competition authorities also detected and pursued a number of other anti-competitive practices carried out by originator companies designed to prevent or delay generic or biosimilar entry. All of these practices prevented price reductions from generic or biosimilar entry and therefore directly harmed patients and healthcare systems.

In December 2019 <sup>(103)</sup>, the Romanian NCA found that, in the period from 2017 until 2019, Roche Romania SRL had implemented a strategy to prevent the sales of competing cheaper generic medicines to protect its medicine Tarceva (a medicine used for the treatment of lung cancer and pancreatic cancer). Roche's strategy included directing patients to their most expensive product, Tarceva, through the Roche Patient Card and the Roche Call Center and covering the price difference that patients would have had to pay when purchasing Tarceva, in order for them not to buy another similar medicine. This type of behaviour can lead to exclusion of competitors in the medium term. For this practice, Roche Romania SRL was fined RON 15,799,839 (EUR 3.34 million).

In a separate case, the Romanian NCA also fined Roche Romania SRL RON 59,967,944 (approx. EUR 12.8 million) for adopting a commercial strategy aimed at eliminating competition and at delaying the entry of competing biosimilar medicines for several oncological treatments. <sup>(104)</sup> To avoid monopolisation of medicines distribution, Romanian legislation obliged market authorisation holders to wholesale their medicines to at least three distributors (which could therefore independently participate in public procurement procedures). Roche participated in a Romanian centralised public procurement procedure within the Romanian National Oncology Program and in several tenders organized at hospital level. However, Roche supplied its rituximab, trastuzumab and bevacizumab medicines to the wholesalers with whom it was competing in tenders at prices higher than its own bid. This way, Roche squeezed the wholesalers' margins and eliminated the competition in the auction. Roche thus also limited the wholesalers' ability to replace, under a tender that they would have possibly won, Roche's products with cheaper soon-to-be-authorised or already available biosimilar alternatives. As a result, Roche's actions strengthened its dominant position and harmed competition by creating barriers to market entry and delaying the uptake of cheaper biosimilars.

## **5.2. Enforcement against dominant firms charging unfairly high prices (excessive prices)**

European competition authorities have been investigating several cases where a company imposed excessive prices on patients and healthcare systems by abusing its dominant position. Exploitative conduct by way of unfair pricing (sometimes referred to as 'excessive pricing') is prohibited under EU competition rules (Article 102(a) TFEU). The

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<sup>(103)</sup> Decision 91 of the Consiliul Concurentei of 16 December 2019.

<sup>(104)</sup> Decision 92 of the Consiliul Concurentei of 16 December 2019.

Court of Justice has laid out a set of conditions under which a dominant company's prices can be found as unfair, and thus in breach of Article 102 TFEU which prohibits abuses of a dominant position. <sup>(105)</sup>

In investigating potentially unfair high prices, competition authorities need to carefully balance rewards for possible dynamic efficiencies and innovation against the burden such prices inflict on consumers and society. Moreover, they consider whether high prices and profits may result from excellence, risk taking and innovation and whether prices can be kept in check by market forces, namely the threat of new entry or expansion attracted by high prices.

That said, competition authorities have not hesitated to intervene where necessary to ensure effective competition. Recent investigations and enforcement in the EU, leading to several decisions concerning excessive pricing, show that a heightened degree of vigilance under competition law is merited with respect to possible excessive pricing practices by dominant companies in the pharmaceutical sector.

**Box 13: Commitments to significantly reduce prices in the Commission's *Aspen* case**

In 2021, the Commission adopted a commitments decision in its first excessive pricing investigation in the pharmaceutical sector. <sup>(106)</sup> The decision set out the Commission's concerns about the pricing practices of Aspen Pharmacare, a South African pharmaceutical company, regarding six of its off-patent cancer medicines mainly used in the treatment of leukaemia and other haematological cancers in several EU Member States (excluding Italy) and EEA countries.

The Commission's assessment followed the framework of analysis set out by the Court of Justice in the *United Brands* judgment. <sup>(107)</sup> In particular, Aspen's accounting data on revenues and costs revealed that, after the price increases, Aspen consistently earned very high profits from the sales of these cancer medicines in Europe, when compared to the profit levels of similar companies in the industry. In certain cases, high profit margins can be explained by, for example, the need to reward significant innovation and commercial risk-taking. However, the Commission's assessment did not reveal any such justifications for Aspen's very high profit levels.

By accepting and declaring Aspen's final commitments binding, the Commission was satisfied that these commitments removed its concerns of excessive pricing. In particular, the commitments ensured that: (a) Aspen reduced its prices across Europe for all six cancer medicines under investigation by, on average, approximately 73 %; (b) these new prices (which started taking effect retroactively, as of October 2019, when Aspen first approached the Commission with a commitment proposal) were the maximum that Aspen can charge for the coming ten years; and (c) Aspen guaranteed the supply of these medicines for the next five years, and, for an additional five-year period, would either continue to supply itself or make its marketing authorisation available to other suppliers.

These commitments have delivered to patients and national health systems concrete and tangible benefits at a moment when there were and still are widespread concerns about companies withdrawing from supplying some Member States (a concern also highlighted in the Commission's Pharmaceutical Strategy for Europe, see Section 3.2.3 above).

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<sup>(105)</sup> Case 27/76 - *United Brands v Commission*, judgment of the Court of Justice of 14 February 1978; and Case 177/16 – *AKAA/LAA*, judgment of the Court of Justice of 14 September 2017.

<sup>(106)</sup> Commission decision of 10 February 2021.

<sup>(107)</sup> Judgment of the Court of Justice of 14 February 1978.

### ***The Italian Aspen case***

Before the conclusion of the Commission's *Aspen* case (see Box 13 above), the Italian NCA imposed in September 2016 a EUR 5.2 million fine on Aspen for abusing its dominant position by setting unfair prices in Italy for four cancer medicines.<sup>(108)</sup> The NCA also ordered Aspen to put in place measures aimed at, among other things, setting new fair prices for the medicines concerned. Following the NCA's order and after protracted negotiations, Aspen reached an agreement on pricing with the Italian Medicines Agency. On 13 June 2018 the NCA determined that Aspen was compliant with its order and estimated that the concluded agreement would save the Italian National Health Service EUR 8 million annually. The NCA decision was upheld by the Administrative Regional Court<sup>(109)</sup> in 2017 and an appeal by Aspen against this judgment was rejected by the Italian State Council in 2020.<sup>(110)</sup>

### ***The Danish CD Pharma case***

By its decision of January 2018<sup>(111)</sup>, the Danish NCA found that CD Pharma (a pharmaceutical distributor) abused its dominant position in Denmark by charging Amgros (a wholesale buyer for public hospitals) unfair prices for Syntocinon. This medicine contains the active ingredient oxytocin, which is given to pregnant women during childbirth. From April 2014 until October 2014 CD Pharma increased the price of Syntocinon by 2,000 % from DKK 45 (EUR 6) to DKK 945 (EUR 127). The NCA established that the difference between the costs actually incurred and the price charged by CD Pharma was excessive. In addition, the NCA compared CD Pharma's price with the economic value of Syntocinon, historical prices for Syntocinon, prices charged by CD Pharma's competitors and the prices charged outside Denmark. As a result, the NCA found that prices for Syntocinon were unfair and, therefore, CD Pharma had abused its dominant position. On 29 November 2018<sup>(112)</sup>, the Danish Competition Appeal Tribunal upheld the Danish NCA's finding that CD Pharma held a dominant position on the Danish market for the sale of oxytocin on the basis of its very high market share and an exclusive distribution agreement, which guaranteed supply of Syntocinon and provided a competitive advantage in comparison to its competitor Orifarm. As regards the nature of the abuse, the Tribunal further upheld the Danish NCA's finding that CD Pharma abused its dominant position by charging excessive prices on the basis of CD Pharma's profit margin amounting to 80-90 %. In addition, the Danish NCA reported CD Pharma to the Public Prosecutor for Serious Economic and International Crime (SØIK) for the purpose of criminal prosecution and fine.

The Competition Appeal Tribunal decision was subsequently brought before the Maritime and Commercial High Court, which in March 2020 upheld the rulings of the NCA and the Competition Appeal Tribunal.<sup>(113)</sup>

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<sup>(108)</sup> Decision of the Autorità Garante della Concorrenza e del Mercato of 29 September 2016.

<sup>(109)</sup> Judgment of the Tribunale Amministrativo Regionale per il Lazio of 26 July 2017.

<sup>(110)</sup> Judgment of the Consiglio di Stato of 13 March 2020.

<sup>(111)</sup> Decision of Konkurrence- og Forbrugerstyrelsen of 31 January 2018.

<sup>(112)</sup> Judgment of Konkurrenceankenævnet of 29 November 2018.

<sup>(113)</sup> Judgment of Sø- og Handelsretten of 2 March 2020.

### ***The Lediand cases***

Lediand's pricing policy for a rare disease treatment has led to a series of decisions by NCAs<sup>(114)</sup>. The Dutch, Italian and Spanish NCAs in 2021-2022 adopted decisions finding that Lediand abused its dominant position by charging excessive prices for its prescription medicine Chenodeoxycholic Acid Lediand ('CDCA'). CDCA treats an extremely rare disease (cerebrotendinous xanthomatosis, 'CTX') that, if untreated, can lead to dementia and death. It has been used "off label" for the treatment of CTX for several decades. Lediand acquired CDCA and relaunched it as an orphan drug (see Box 7) in 2017 after the Commission granted Lediand an orphan designation and a marketing authorisation on a recommendation from the EMA. This gave Lediand market exclusivity for ten years in the EU for CDCA-based drugs for the treatment of CTX. Lediand then imposed huge price increases for CDCA (up to 20 times).

Lediand was also found to have imposed an exclusivity clause on the only authorised supplier of the active pharmaceutical ingredient able to supply CDCA in sufficient quantities and quality (preventing the emergence of alternative medicines, both industrial and in the form of magistral formulations). Free of constraints from competition or customers, this in turn enabled Lediand to charge or maintain excessive prices. The decisions of all three NCAs consider the price charged by Lediand in their respective national markets to amount to an abuse of dominance. The decision of the Spanish NCA, in addition, also considers the exclusivity agreements with the supplier to amount to an abuse of dominance.

***In the Netherlands***, Lediand offered since 2008 a CDCA-based drug Chenofalk (not developed by Lediand itself but acquired from another manufacturer). The maximum price at the time was EUR 46 per pack. In late 2009, Lediand changed the name of the drug into Xenbilox, and raised the price up to almost 20 times the original price. In 2014, Lediand again increased the price of Xenbilox (to up to EUR 3,103). In June 2017, Lediand released CDCA on the Dutch market under the trade name CDCA-Lediand and stopped selling CDCA under the old name Xenbilox. As from then, Lediand charged EUR 14,000 per pack. Based on the aforementioned criteria, the Dutch NCA found that the prices were abusive and imposed a fine of 19.6 million Euro. <sup>(115)</sup>

***In Italy***, Lediand (at that time Sigma-Tau) started selling Xenbilox at the beginning of 2016 at the price of EUR 2,900 per pack (until then patients were administered CDCA-based magistral preparations at the final price of around EUR 70 per pack). When Lediand obtained the orphan drug designation and market authorisation in 2017, it launched the CDCA-Lediand at the price of EUR 15,507 per pack. At the same time Xenbilox became unavailable. In December 2019, Lediand and Agenzia Italiana del Farmaco (AIFA) agreed on a price of EUR (between 5,000-7,000) per pack, which entered into effect as of March 2020. The Italian NCA found that the investigated conduct constituted an abuse of a dominant position and decided to impose a fine of EUR 3.5 million on Lediand.

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<sup>(114)</sup> Decision of the Autoriteit Consument en Markt of 1 July 2021, decision of the Autorità Garante della Concorrenza e del Mercato of 31 May 2022, and decision of the Comisión Nacional de los Mercados y la Competencia of 10 November 2022. These decisions are still subject to appeals with the relevant national courts. In first instance, the decision of the Italian NCA was confirmed in appeal by the TAR Lazio on 20 July 2023. The Belgian NCA initiated proceedings but decided not to grant priority to pursuing this case.

<sup>(115)</sup> Decision on administrative appeal on 22 June 2023 in which it reduced the fine to EUR 17 million.

*In Spain*, Leadiant withdrew the CDCA-based drug it had been marketing since 2010 (Xenbilox) from the Spanish market, and reformulated it in order to launch it on the market as an orphan drug under a different brand name (CDCA-Leadiant) at a price 14 times higher. The only drug available in Spain for the treatment of CTX went from costing EUR 984 per pack in September 2010 to EUR 14,618 per pack in June 2017. In November 2022, the Spanish NCA imposed a fine of EUR 10.25 million on Leadiant.

Concerning the assessment of excessive pricing, the NCAs coordinated their methodology and based their assessment on the two-step legal test as established by the Court of Justice in the case *United Brands*.<sup>(116)</sup>

In the first step, they established that Leadiant's CDCA prices were excessive. The NCAs found that the internal rate of return on investment, based on the costs and internal risk estimates of Leadiant, was vastly superior to the weighted average of cost of capital considered reasonable for this investment.

In the second step, the NCAs also established that Leadiant's CDCA prices were unfair in themselves. The NCAs examined mainly qualitative criteria, such as: nature of the product (CDCA-Leadiant, the product with the orphan drug designation, is equivalent to Leadiant's predecessor product, Xenbilox, also CDCA-based and used off label to treat CTX, which did not have an orphan drug designation); low investments in research and development and low commercial risks entailed by Leadiant.

Importantly, the NCAs took into account the context of the orphan drug designation and marketing authorisation (Leadiant registered CDCA for CTX but did not introduce any innovative product, since the Leadiant product had no therapeutic added value compared to the previous CDCA-based drugs). The NCAs found that the unfairness of CDCA-Leadiant's prices was also apparent from the fact that this price was far higher than the prices of Chenofalk and Xenbilox a few years earlier, even though they were chemically identical.

### ***The Pfizer Flynn case***

In 2016, the United Kingdom NCA found that Pfizer and Flynn had each abused their respective dominant position by imposing unfair prices for phenytoin sodium capsules (an epilepsy medicine) manufactured by Pfizer in the United Kingdom<sup>(117)</sup>. Pfizer and Flynn had entered into agreements under which Pfizer transferred its marketing authorisations for Epanutin to Flynn but continued to manufacture and supply the product to Flynn for distribution in the United Kingdom. However, Pfizer's supply prices to Flynn were between 780 % and 1,600 % higher than what Pfizer had previously charged distributors. In turn, Flynn hiked up prices to distributors by up to 2,600 %, compared to previous price levels when the medicine was sold branded. This was possible because Flynn started selling Epanutin under its generic name phenytoin sodium (without the brand name) taking advantage of a loophole in the law at the time which did not subject generic medicines to any price limits (contrary to branded medicines). The NCA fined Pfizer GBP 84.2 million (EUR 99.2 million) and Flynn GBP 5.16 million (EUR 6.08 million).

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<sup>(116)</sup> Case 27/76 - *United Brands v Commission*, judgment of the Court of Justice of 14 February 1978.

<sup>(117)</sup> Decision of the Competition and Markets Authority of 7 December 2016.

In 2018, the United Kingdom Competition Appeal Tribunal (‘CAT’) upheld several findings of the NCA (i.e. the narrow market definition and that Pfizer and Flynn each held dominant positions), but found that the NCA conclusions on abuse of dominance were in error, ultimately deciding to remit the case back to the NCA for further consideration.<sup>(118)</sup> Both the NCA and Flynn appealed this ruling through proceedings where the Commission intervened as *amicus curiae*.<sup>(119)</sup> The Court of Appeal handed down its judgment in March 2020, partially upholding the NCA’s appeal and entirely dismissing Flynn’s appeal.<sup>(120)</sup> Following this judgment, the NCA adopted a new infringement decision in 2022, imposing a fine on Pfizer amounting to GBP 63.3 million (EUR 73.2 million) and a fine on Flynn amounting to GBP 6.7 million (EUR 7.7 million).<sup>(121)</sup> Pfizer and Flynn have appealed that decision to the CAT and the hearing was scheduled to take place in November and December 2023.

### **5.3. Other anti-competitive practices capable of hindering price competition**

European competition authorities also intervened against various other anti-competitive practices that hinder price competition amongst medicines. Some of these practices are specific to the pharmaceutical sector and driven by its economic and regulatory features, while others are known from other sectors as well, but can nonetheless have strong effects on prices of medicines.

In some instances, companies have artificially reduced the competitive pressures that normally restrain their pricing power. The practices concerned range from cartel or cartel-like infringements of competition law (e.g. bid rigging, price fixing and market sharing), to abuses of a dominant position, and restrictions in relations between suppliers and their customers. What these practices, illustrated by examples below, have in common is that they have a direct impact on the prices of medicines paid by European patients and healthcare systems.

Collusion in tenders, price fixing and other types of coordination between competitors belong to the well-known, and at the same time the most reprehensible, violations of competition law.

A series of decisions by European competition authorities sanctioned conduct aimed at excluding competitors or limiting their ability to compete, typically by shutting out pharmaceutical suppliers’ access to either customers or production inputs, thus affecting their long-term ability to sell cheaper medicines.

#### ***Limiting or interrupting supply of immunoglobulin***

In December 2021, the Romanian NCA sanctioned five suppliers of immunoglobulin and other medicines derived from human plasma – Baxalta GmbH, CSL Behring GmbH,

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<sup>(118)</sup> Judgment of the Competition Appeal Tribunal of 7 June 2018.

<sup>(119)</sup> Pursuant to Article 15(3) of Regulation 1/2003, the Commission, acting on its own initiative, may submit written observations ("*amicus curiae*" observations) to courts of the Member States where the coherent application of Article 101 or 102 TFEU so requires. With the permission of the court in question, it may also make oral observations.

<sup>(120)</sup> Judgment of the Competition Appeal Tribunal of 10 March 2020.

<sup>(121)</sup> Decision of the Competition and Markets Authority of 21 July 2022. This decision is currently again under appeal before the Competition Appeal Tribunal.

Biotest AG, Kedrion Spa and Octapharma AG – as well as the representative association of the producers of plasma protein therapies (‘PPTA’), with fines amounting to a total of RON 353,393,694 (approx. EUR 71 million).<sup>(122)</sup> Immunoglobulins are medical products that treat severe inflammatory and autoimmune diseases.

The Romanian competition authority found that, in the period 2015-2018, the five undertakings, which gathered in a task force organised by the PPTA, coordinated their actions to limit and even disrupt the supply of immunoglobulin to the Romanian market. Companies colluded to put pressure on the authorities to suspend the clawback tariff (taxation to be paid by producers/suppliers of reimbursed medicines) on medicines derived from human blood or human plasma. In this way, the undertakings aimed to improve their profit margins.

During the infringement period, the immunoglobulin producers gradually decreased the volume of immunoglobulin supplied in Romania and then completely stopped the supply, endangering the lives of some patients.

Following the investigation by the NCA initiated in 2018 and governmental measures, almost all producers resumed the supply with immunoglobulins in Romania, and in 2019, the total volume of immunoglobulin supplied increased with about 130 % compared to 2018, and further increased in 2020.

### ***Resale price maintenance (‘RPM’)***

The Portuguese NCA sanctioned Farmodiética – Cosmética, Dietética e Produtos Farmacêuticos, S.A. for fixing the resale prices of its products in Portugal, both through direct and indirect means, implementing a monitoring system and creating incentives for the implementation of such fixed prices.<sup>(123)</sup> The NCA found that such behavior is amounted to a serious breach of Article 101(1) TFEU, and sanctioned Farmodiética with a fine of EUR 1,258,900 (after a 30 % reduction as the company agreed to settle the case).

In May 2021, the Italian NCA opened an investigation upon a complaint that SOFAR S.p.A., a producer of probiotics, would have required online retailers to charge to its customers fixed resale prices for the product Enterolactis Plus, and would have admitted only a few dealers to its distribution network to sell the product on e-commerce platforms. To address the concerns expressed by the NCA, SOFAR offered commitments which the NCA considered suitable to restore competition and made binding through a commitment decision<sup>(124)</sup>. The company committed to not apply any minimum resale prices, to not restrict the freedom of its dealers to sell the SOFAR products on any trade channels and to communicate this in a memorandum to its dealers.

### ***Coordination between pharmacies and pharmaceutical companies***

In 2017, the Lithuanian Ministry of Health decided to assess the need to change the retail and wholesale margins of pharmaceuticals laid down in Lithuanian law and thus asked the Lithuanian Pharmacy Association (‘LPA’) to submit proposed margins based on

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<sup>(122)</sup> Decision of the Consiliul Concurentei of 20 December 2021.

<sup>(123)</sup> Decision of the Autoridade da Concorrência of 15 November 2022.

<sup>(124)</sup> Decision of the Autorità Garante della Concorrenza e del Mercato of 3 December 2021.



economic calculations. However, the Lithuanian NCA found that the proposed margins of reimbursable pharmaceuticals were coordinated between the LPA and 8 pharmaceutical companies, and covered not only the costs incurred by the companies, but also ensured additional profits to the competitors. In the NCA's view, a coordination of undertakings' proposals and data with a view of distorting the market infringes competition law, as in the absence of that collusion, the Ministry could have taken its decision based on a set of different submissions. The competitors were fined more than EUR 72 million. <sup>(125)</sup> The NCA invited the Ministry and the Government to re-evaluate and, if appropriate, to amend the established legal framework, as well as to set new wholesale and retail margins for reimbursable pharmaceuticals.

### ***Vaccine cartel***

In February 2022, the Belgian NCA adopted a settlement decision by which it sanctioned two pharmaceutical wholesalers, Febelco CV and Pharma Belgium-Belmedis SA, for having participated in a cartel involving direct sales from pharmaceutical companies to pharmacists and flu vaccines. <sup>(126)</sup> The wholesalers had agreed to apply the same commercial conditions for the distribution of pharmaceutical products via a 'direct sales to pharmacists' system and for sales of flu vaccines to pharmacists during the pre-sales periods. In particular, the companies agreed not to grant discounts to pharmacists and not to accept returns of unsold vaccines ordered during the pre-sale period. The NCA imposed a total fine of EUR 29,8 million on Pharma Belgium-Belmedis. Febelco was granted immunity from fines for having disclosed the existence of the cartel.

### ***Bid rigging, market sharing and exchange of commercially sensitive information***

The Spanish NCA fined the two main suppliers of PET radiopharmaceuticals, Advanced Accelerator Applications Ibérica (AAA) and Curium Pharma Spain for sharing the market for supply contracts for this drug for at least four years. AAA and Curium adopted a two-fold strategy. Instead of competing, they agreed on bid rigging in tenders (e.g. not submitting an offer or making errors in the tender process in order to not win the tender) and afterwards to subcontract the service to each other at lower prices. The NCA imposed a fine of EUR 5.76 million on the two pharmaceutical companies and also fines of EUR 46,000 on two of their managers, after finding them directly responsible for the infringements. <sup>(127)</sup>

The United Kingdom NCA fined King, Lexon (UK) Ltd and Alissa Healthcare Research Ltd for illegally sharing commercially sensitive information in an attempt to keep nortriptyline prices up. Between 2015 and 2017, when the cost of the drug was falling, the three suppliers exchanged information about prices, the volumes they were supplying, and Alissa's plans to enter the market. The NCA imposed fines totalling GBP 1,47 million (EUR 1.73 million). <sup>(128)</sup>

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<sup>(125)</sup> Decision of the Konkurencijos taryba of 9 December 2022.

<sup>(126)</sup> Decision of the Autorité belge de la concurrence / Belgische Mededingingsautoriteit of 18 February 2022.

<sup>(127)</sup> Decision of the Comisión Nacional de los Mercados y la Competencia of 2 February 2021.

<sup>(128)</sup> Decision of the Competition and Markets Authority of 4 March 2020 (information exchange). This decision was appealed to the Competition Appeal Tribunal and upheld on appeal.

In a separate decision, the NCA also found that King Pharmaceuticals Ltd and Auden Mckenzie (Pharma Division) Ltd shared out between them the supply of nortriptyline to a large pharmaceutical wholesaler. From September 2014 to May 2015, the two companies agreed that King would supply only 25mg and Auden Mckenzie only 10mg tablets. The firms also colluded to fix quantities and prices. As a result, the NCA fined King and Accord-UK GBP 75,573 (EUR 88,915) and GBP 1,882,238 (EUR 2.2 million) respectively. On top of this, Accord-UK and Auden Mckenzie have agreed to make a GBP 1 million (EUR 1.17 million) payment to the British National Health Service (NHS) in connection with the case. <sup>(129)</sup>

The United Kingdom NCA further fined three pharmaceutical companies for taking part in an illegal arrangement in relation to the supply of life-saving medicine fludrocortisone, a prescription-only medicine mainly used to treat adrenal insufficiency. The NCA found that the companies Amilco and Tiofarma had agreed to stay out of the fludrocortisone market so that Aspen could maintain its position as the sole supplier in the UK. In exchange, Amilco received a 30 % share of the increased prices that Aspen was able to charge, and Tiofarma was given the right to be the sole manufacturer of the drug for direct sale in the UK. Following the agreement, and as a result of this collusion, the price of fludrocortisone supplied to the NHS increased by up to 1800 %. The investigation resulted in fines totalling almost GBP 2.3 million (EUR 2.5 million) and a payment of GBP 8 million (EUR 8.7 million) directly to the NHS. <sup>(130)</sup>

### ***Other practices aimed at excluding competitors***

A series of decisions by European competition authorities sanctioned conduct aimed at excluding competitors or limiting their ability to compete, typically by shutting out pharmaceutical suppliers' access to either customers or production inputs, thus affecting their long-term ability to sell cheaper medicines.

In 2019, the Belgian NCA adopted a decision condemning the Order of Pharmacists for attempting to hinder the MediCare-Market group's uptake and development using disciplinary proceedings against pharmacists belonging to the group. According to the Ordre des Pharmaciens, MediCare-Market's business model would create confusion between pharmacy and parapharmacy goods, both of which are found in MediCare-Market stores (although there is a physical separation between the two). In 2020, the Court of Appeal annulled the decision insofar as it set the amount of the fine at EUR 1 million, while confirming the infringement and the very principle of imposing a fine. <sup>(131)</sup>

In a separate case, the Belgian Order of Pharmacists was also fined EUR 225,000 for some of its decisions limiting the ability of pharmacists to advertise. <sup>(132)</sup> The NCA reached a settlement with the Order of Pharmacies which committed among others to adapt its Code of Ethics and to regularly review the explanatory code on advertising and

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<sup>(129)</sup> Decision of the Competition and Markets Authority of 4 March 2020 (market sharing).

<sup>(130)</sup> Settlement Decision of the Competition and Markets Authority of 3 October 2019 and infringement Decision of 9 July 2020.

<sup>(131)</sup> Decision of the Autorité belge de la concurrence / Belgische Mededingingsautoriteit of 26 March 2021. In 2021 the Belgian NCA adopted a final decision lowering the fine to EUR 245,000.

<sup>(132)</sup> Decision of the Autorité belge de la concurrence / Belgische Mededingingsautoriteit of 16 October 2019.

commercial practices in view of avoiding restrictive interpretations of competition by the disciplinary bodies.

The Greek NCA fined the Karditsa Pharmaceutical Association EUR 2,096 for preventing a number of pharmacies of Karditsa from operating during the extended opening hours of pharmacies regulation that was applicable at that time. <sup>(133)</sup>

In 2020, the United Kingdom NCA launched an investigation upon concerns that Essential Pharma would discontinue supply of its drug Priadel - used to treat bipolar disorder - in circumstances where the potential alternative drugs for patients were more expensive and where the process of switching may have resulted in significant harm to patients. Immediately following the opening of the investigation, Essential Pharma paused the withdrawal of Priadel and entered into price negotiations with the British Department for Health and Social Care, resulting in a new price being agreed. It then offered binding commitments to the NCA for a period of 5 years to ensure continued supply of Priadel, which were accepted by the NCA. <sup>(134)</sup>

#### **5.4. Merger control and affordable medicines**

Competition law enforcement against abuses of dominant position and anti-competitive coordination is complemented by the review of mergers that could result in market structures that free companies from competitive constraints and may thus result in higher prices for medicines.

##### **5.4.1. How do mergers affect the pricing of medicines?**

Mergers of pharmaceutical companies can create or increase the market power of the merged entity by eliminating competitive pressure between the merging parties and reducing competitive pressure in the market. The greater the market power arising from a merger, the more likely it is that it results in higher prices and harm to patients and healthcare systems.

A key objective of merger control in the pharmaceutical sector is to ensure that the changes in the market structure due to a merger do not result in higher prices. This leads to scrutiny irrespective of whether a merger concerns originator, generic or biosimilar competition. For example, a merger between an originator and a generic company may significantly impede price competition between the originator's products and their cheaper generic versions. Generics are normally full substitutes of the originator product and competition takes place mostly on price <sup>(135)</sup>.

The negative price effects of mergers can be significant. Reduced competitive pressure may enable the merged company to raise its own prices (directly or by reducing rebates, discounts, by renegotiating increased prices with national healthcare authorities, by withholding the launch of a cheaper generic etc.) but can also lead to an increase of prices in the market as a whole <sup>(136)</sup>.

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<sup>(133)</sup> Decision of the Επιτροπή Ανταγωνισμού of 2 December 2020.

<sup>(134)</sup> Decision of the Competition and Markets Authority of 18 December 2020.

<sup>(135)</sup> The Commission refers to the homogeneous nature of generic in a number of decisions, for example in M.7559 - Pfizer/Hospira.

<sup>(136)</sup> These are the so-called 'non-coordinated or unilateral effects' on price.

#### 5.4.2. How does merger control prevent price increases from mergers?

EU merger control rules mandate the Commission to intervene where the merger is likely to adversely affect competition. An illustrative example is the *Mylan/Upjohn* case, where the combination of Mylan, one of the top five generic suppliers in the EEA, with Upjohn, which marketed Pfizer's off-patent branded and generic medicines, threatened to eliminate competition in a number of markets.

##### **Box 14: The *Mylan/Upjohn* case (April 2020)**

The transaction related to a merger between the global pharmaceutical company Mylan and Upjohn, a business division of Pfizer, which operated Pfizer's off-patent branded and generic medicines, including well known products under the brands Viagra, Xanax and Lipitor. Already prior to the merger, Mylan was one of the five largest suppliers of generic medicines in the EEA.

The Commission investigated the market impact of the transaction by gathering evidence from the parties, including a detailed review of their business documents, and from their customers and competitors. This process revealed that there was direct competition on prices between all versions of a given off-patent molecule (including generics and the off-patent originator product). The Commission found that the merger would harm competition for 12 molecules by giving the merged entity a strong position in several Member States and removing a source of competitive pressure.

These areas of concern related to various areas such as cardiovascular, musculoskeletal, nervous system and urinary tract diseases. For example, the Commission found that in Greece, Iceland, Ireland, Italy and Portugal the deal would harm competition for alprazolam, which is used to treat anxiety and panic disorders (it was sold by Upjohn under the brand name Xanax, while Mylan supplied an unbranded version). Prior to the merger, Upjohn was in most cases already the leading supplier, and the deal would strengthen its market power, in some cases leading to a near-monopoly with few credible alternatives to put pressure on prices.

To address the Commission's concerns, including the risk of price increases, the companies offered remedies. Specifically, they committed to selling Mylan's business for those products where a concern was identified, including marketing authorisations, contracts and brands. This resulted in various medicines in over 20 countries throughout the EEA and the United Kingdom being sold to four different purchasers, who could actively develop these businesses in a way that competes with and puts pricing pressure on with Mylan/Upjohn.

The *Mylan/Upjohn* case is one instance where, thanks to the Commission's investigation, concerns, including over possible price increases, were identified and addressed through proposed divestitures. In recent years, the Commission has tackled this risk in a broad range of markets, spanning from over-the-counter pharmaceutical products for pain management (*GlaxoSmithKline/Pfizer's consumer health business*) to irritable bowel disease (*AbbVie/Allergan, Takeda/Shire*). In one case involving haemostatic patches to manage bleeding during surgery, the parties decided to terminate the merger after the Commission identified concerns that the deal could keep prices high (or reduce choice or innovation) by preventing the entry of a new product in Europe (*Johnson & Johnson/Tachosil*).

In cases where the Commission intervenes and the companies offer a commitment to fix the identified concerns (conditional clearance), the Commission's role does not end with its decision. The Commission remains active to ensure that the remedies are properly implemented in practice. In particular, the Commission, with the help of monitoring trustees, vets the process of selecting a suitable buyer for the divested business and ensures that the viability and competitiveness of the entire divested business is not compromised until its transfer to the buyer. Also, once the divested business has been sold to the purchaser, the Commission may continue to monitor transitional agreements

up until the business becomes fully independent of the merged entity (i.e. transfer of the marketing authorisations, production transfer to the buyer's own manufacturing plant etc.).

## **6. COMPETITION DRIVES INNOVATION AND INCREASES THE CHOICE OF MEDICINES**

As described in Section 3.2.1, innovation is of key importance in the pharmaceutical sector with the most prominent healthcare benefits flowing from R&D into novel treatments. This R&D may lead to new medicines for previously untreated conditions or to medicines which may treat given conditions more effectively and/or with fewer side effects. It can also lead to the discovery that an existing medicine can be used for other conditions for which it has not previously been prescribed.

In addition, innovation may also reduce the cost of treatments, for example, by developing production processes that make it viable for cheaper medicines to be commercially produced. Innovation may also create new, more efficient technologies that lead to higher quality medicines being produced. Therefore, while innovation remains a particularly significant competitive force in pharmaceutical markets, the companies active in these markets may use various practices to ease the pressure of having to constantly innovate (e.g. defensive patenting which aims to interfere with a competing R&D project). Such practices may in specific circumstances be anti-competitive and be particularly harmful for patients and national healthcare systems.

### **6.1. Antitrust enforcement fosters innovation and choice**

This Section 6.1 describes how enforcement contributes to improving patients' choice and access to innovative medicines by intervening where companies, unilaterally or jointly, relax competitive pressures that force them to innovate further or prevent others from innovating, Section 6.2 then explains how the Commission, under merger control rules, may prevent mergers that are likely to reduce or harm innovation, and, in its assessment, take into account possible positive effects of mergers on innovation <sup>(137)</sup>.

#### **6.1.1. Enforcement against practices preventing innovation or limiting patient choice**

Market participants do not always welcome innovation. It can disrupt or even entirely undermine their markets. There might not be much they can do to stop innovation by competitors. However, they can make it hard for innovative products to reach consumers. Antitrust enforcement can help ensure that companies do not abuse their power or enter into arrangements that hold back innovation.

In 2022 the Commission opened a formal antitrust investigation to assess whether Vifor Pharma has restricted competition by illegally disparaging one of its closest competitors for the provision of intravenous iron treatment, Pharmacosmos. <sup>(138)</sup> Vifor Pharma's conduct appears to be aimed at hindering competition against its blockbuster high-dose intravenous iron treatment medicine, Ferinject, from another innovator medicine,

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<sup>(137)</sup> The Commission has commissioned a study to analyse the impacts of mergers and acquisitions on innovation in the pharmaceutical sector. Publication of the results is due in 2019.

<sup>(138)</sup> [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_22\\_3882](https://ec.europa.eu/commission/presscorner/detail/en/ip_22_3882).

Monofer. Approximately 1.8 million patients suffering from iron deficiency are currently being treated with high-dose intravenous iron products annually in the EEA. The Commission is concerned that Vifor Pharma may have been disparaging Pharmacosmos' product Monofer by spreading misleading information regarding its safety, primarily targeting healthcare professionals. If the Commission's concerns are proven, Vifor Pharma's behaviour may amount to an abuse of dominant position and infringe Article 102 of the TFEU and Article 54 of the EEA Agreement. The opening of formal proceedings does not in any way prejudge the outcome of the investigation.

### **6.1.2. Competition rules support procompetitive co-operation on innovation**

Competition authorities need to be mindful not only of the potentially negative effects that a practice under investigation may have on the market, but also of the possible positive effects competition law enforcement should preserve, and ideally improve. Numerous competition rules acknowledge that companies' behaviour may result in synergies that could further encourage innovation (for example from combining complementary assets required to engage in R&D or from technology licensing). These rules also help companies to design their co-operation projects so that they comply with competition law and avoid enforcement from the competition authorities. In 2019, the Commission started an evaluation of the EU 2010 Block Exemption Regulation on R&D agreements<sup>(139)</sup> and adopted on 1 June 2023 the revised Horizontal Block Exemption Regulations on R&D and Specialisation agreements ('HBERs')<sup>(140)</sup>, accompanied by revised Horizontal Guidelines<sup>(141)</sup>. The HBERs exempt R&D and specialisation agreements from the prohibition in Article 101(1) of the TFEU, subject to certain conditions. The rules thus provide for a safe harbour where certain agreements are block-exempted from the competition rules.

### **6.2. Merger control preserves competition on innovation for medicines**

The Commission's control of pharmaceutical mergers ensures not only that healthy price competition is maintained for the benefit of patients and national healthcare systems, but also that R&D efforts to launch new medicines, or to extend the therapeutic use of existing medicines, are not diminished as a result of a merger.

Several recent pharmaceutical mergers investigated by the Commission show the possible impact of mergers on the incentives for pharmaceutical companies to continue developing parallel R&D programmes after a merger. In some of these cases, the Commission required appropriate remedies to approve a proposed merger that would have otherwise threatened to halt or hinder the development of a promising new medicine.

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<sup>(139)</sup> Commission Regulation (EU) No 1217/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements (OJ L335, 18.12.2010, p. 36).

<sup>(140)</sup> Commission Regulation (EU) 2023/1066 of 1 June 2023 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements (OJ L 143, 2.6.2023).

<sup>(141)</sup> Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (OJ C 259, 21.7.2023).

### **6.2.1. How can mergers harm innovation in the pharmaceutical sector?**

Consolidation in an industry may have a neutral impact on competition, or may even be pro-competitive if it combines the complementary activities of the merging firms, and as a result strengthens the ability and incentive to bring innovation to the market. This can be true even of large acquisitions: for instance, during its the 2019 investigation into the acquisition by BMS of Celgene, one of the largest pharmaceutical acquisitions in history with a value of USD 74 billion, the Commission carefully assessed the competitive landscape to ultimately conclude that transaction could be cleared as it would not result in any loss of competition within the EEA.

Conversely, mergers may also curb the scale or scope of innovation, and patients and physicians may have a more limited choice of future innovative treatments. For example, this may be the case where one merging company's pipeline product would be in competition with another company's marketed product, and thus be likely to capture significant revenues from the other company's competing product. If this is the case, the merged company may be inclined to discontinue, delay or redirect the competing pipeline project in order to increase the profits of the merged entity. Similarly, merging firms may be working on competing R&D programmes, which would divert profitable future sales from each other in the absence of the merger. By bringing two competing firms under a single ownership, a merger may reduce the incentives to engage in parallel R&D efforts.

Reducing competition on innovation means that patients and healthcare systems would forego future benefits from innovative and affordable medicines. Harmful effects may include a loss of potentially better treatments, reduced future variety of medicines on the market, delayed access to medicines needed for the treatment of their conditions, and higher prices.

### **6.2.2. How can merger control preserve conditions for innovation?**

Merger control seeks to ensure that the transaction does not significantly impede competition, including on innovation<sup>(142)</sup>, ultimately leading to higher prices or less choice for patients. Where innovation concerns are detected, the Commission can prohibit the transaction unless the companies offer appropriate remedies designed to preserve the ability and incentives to innovate and restore effective competition in innovation. Such remedies may include a divestment of pipeline products, or underlying R&D capabilities.

Innovative medicines were the focus of several recent merger investigations, highlighting the Commission's efforts in preserving innovation in relation to originator chemical drugs and biological and biosimilar medicines. In some instances, the Commission acted to preserve competition from medicines in the early stages of product development. It can also act to ensure that a merger does not result in a company having a monopoly of R&D resources and capabilities in a given pharmaceutical field.<sup>(143)</sup>

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<sup>(142)</sup> On the possible impact of a merger on innovation, see in particular Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, 2004/C 31/03, paragraph 38.

<sup>(143)</sup> The Commission's practice is to investigate four 'layers' of competitive overlap between the merging parties' activities: (i) whether their marketed products compete, (ii) whether the marketed products of one player compete with the pipeline drugs in development of the other, (iii) whether the parties' pipeline drugs compete, and (iv) the extent of overlap in R&D capabilities more generally. Recently,

In 2022, the Commission launched an ex-post evaluation study<sup>(144)</sup> into the phenomenon of “killer acquisitions” in the pharmaceutical sector – that is, transactions that likely had as their object or effect the discontinuation of overlapping drug research and development projects (including both pipeline-to-pipeline overlaps and marketed-to-pipeline overlaps) to the detriment of competition. The study assesses transactions, whether in the form of concentrations or of agreements such as IP acquisitions and licensing, occurring in the period 2014-2018 and will devise both a typology of the phenomenon’s manifestations in practice and a workable methodology that will help the Commission to better identify such transactions in the future.

The Commission intervenes where a merger between two originator companies would result in less competition to innovate and bring new or improved treatments onto the market. For example, the drive to develop effective treatments for irritable bowel disease has led to consolidation in the industry, which required the Commission to intervene in two recent cases which were both resolved with a remedy (*AbbVie/Allergan* and *Takeda/Shire*). In *AbbVie/Allergan*, for instance, the Commission’s concerns came from the fact that one company already marketed a treatment for a particular condition, while the other was developing a drug for the same purpose.

**Box 15: The *AbbVie/Allergan* case (January 2020)**

AbbVie is a global pharmaceutical company with a broad portfolio, which was developing several biologic drugs for ulcerative colitis and Crohn’s diseases (together referred to as irritable bowel diseases (“IBD”)). IBD are lifelong autoimmune diseases that involve inflammation of the digestive tract and for which there is no cure.

At the time of the transaction, Allergan was also developing a treatment for IBD. Both parties’ drugs belonged to a promising class of biologics called “IL-23 inhibitors”, and the Commission found that these two pipelines were expected to be close competitors, facing limited competition as there were only two other competing pipelines being developed worldwide. As a result, the acquisition would lead to duplicate clinical programmes in AbbVie’s portfolio.

The Commission was concerned that AbbVie would not have continued to develop Allergan’s product, as it could have taken sales away from the alternative product that AbbVie was developing. In its assessment, the Commission took into account the expected benefits of having both of these two innovative drugs available for patients and healthcare systems, especially given that there were few close alternatives being developed.

To restore the conditions needed for continued innovation concerning this pipeline project, AbbVie offered to sell Allergan’s pipeline product, including the rights to develop, manufacture and sell the product worldwide, to a suitable purchaser. This purchaser would ensure that the development of this drug is continued, removing the Commission’s concerns. Ultimately, AbbVie proposed to sell this drug to AstraZeneca, which the Commission approved.

Without this remedy, Allergan’s drug would probably have been discontinued to avoid a duplication in pipelines. Therefore, it is likely that the remedy has helped to maintain innovation and competition in the treatment of IBD. These conditions are important, so as to deliver a wider choice of innovative treatments and better care for patients.

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the Commission has investigated cases looking at pipelines at an early stage of development or even in appropriate instances at pre-clinical stage (see, for example, cases M.9294 BMS/Celgene, M.10165 AstraZeneca/Alexion, M.10629 CSL/Vifor).

<sup>(144)</sup> COMP/2021/OP/0002 – Ex post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector leading to the discontinuation of overlapping drug research and development projects. The Final Report of the study is due 30 January 2024.



Merger control also involves making sure that M&A does not lead to a situation where an important supplier harms its customers in order to benefit the part of its own business that competes with those customers. This was the reason why the Commission investigated the *Illumina/GRAIL* case and ultimately decided to block the proposed deal. While this case is not a pharmaceutical case, rather involving novel diagnostic tests for cancer, it illustrates the importance of the Commission's actions to protect innovation so that patients and healthcare systems ultimately have access to a range of cutting-edge tools in the fight against cancer.

**Box 16: The *Illumina/GRAIL* case (September 2022)**

This case was the first instance in which the Commission applied its revised approach to case referrals, inviting NCAs to refer the case to it even though the transaction did not meet either national or EU-wide notification thresholds. This was appropriate, as the target had virtually no revenue but was developing a highly promising product and had very significant competitive potential.

The case involved the development of early cancer detection tests, which may revolutionise the ways in which cancer can be spotted in currently asymptomatic patients. Illumina supplies next generation sequencing (“NGS”) systems, which are diagnostic instruments used for a broad range of applications. One of the most prominent applications under development is to use Illumina's sequencing systems to develop and sell tests to detect cancer. GRAIL is a biotech company relying on Illumina's NGS systems to develop a test which it claims could detect around 50 cancers at an early stage in patients without symptoms from a blood sample. Illumina proposed to acquire GRAIL for approximately USD 8 billion, though GRAIL had almost no turnover at the time as it was primarily a development company.

The Commission investigated the deal and found that there was a vibrant and active race to develop cancer detection tests and bring to market tests capable of detecting cancers at an early stage. A number of developers were investing significant capital and efforts to develop cancer detection tests with a view to commercialising them worldwide, including in Europe and in the Member States whose NCAs had referred the case to the Commission. Illumina's NGS systems are at the core of this process, as there is no credible alternative to its systems, which are necessary to develop these tests and to offer them to patients. As a result, if it were allowed to buy GRAIL, Illumina would find it profitable to stop or slow down GRAIL's rivals developing these tests, for instance by stopping supplies to rivals, delaying or reducing the quality of technical support or development collaboration, or increasing prices to raise rivals' costs, so that GRAIL's test is the first and most attractive on the market. This would give GRAIL a head-start over its rivals and reduce the competition it faces (including on prices), meaning that consumers and health systems would have less choice and would need to pay more to access these life-saving tests. As the owner of GRAIL, Illumina would be able to gain a large share of a very profitable market expected to be worth more than EUR 40 billion annually by 2035.

Although Illumina tried to offer remedies to resolve this concern, the Commission found them to be insufficient to avoid significant harm to rival test developers and, ultimately, to consumers. Therefore, the Commission prohibited the transaction, making sure that innovative efforts to develop cancer detection tests, a vital tool in the fight against cancer, can continue on a level playing field. To give effect to this prohibition decision, the Commission has ordered Illumina to divest GRAIL (and fined the parties for unlawfully closing the deal pending the investigation) – this divestment process is ongoing at the time of writing. <sup>(145)</sup>

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<sup>(145)</sup> Case M.10939 – *Illumina/GRAIL* (Restorative Measures under Article 8(4)(a)).

## 7. CONCLUSION

The above overview and examples of competition cases investigated and decided upon by European competition authorities between 2018 and 2022 clearly show that enforcing antitrust and merger control rules helps to ensure that patients and healthcare systems have better access to affordable and innovative medicines and treatments.

Compared to the period 2009-2017 (9 years) covered in the previous report, the average number of pharma antitrust decisions adopted per year in the period 2018-2022 (5 years) increased from around 3 to 5. There is a constant if not increasing inflow of antitrust and merger cases in the pharmaceutical sector. Also, in light of the Covid-19 pandemic, this sector and healthcare in general have been a high priority across the EU.

The report presents a broad variety of anti-competitive practices, some of which investigated for the first time. European competition authorities have tackled these and have set a number of ground-breaking precedents which clarified the application of EU competition law in pharmaceutical markets. 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.

While it significantly contributes to improve competition in pricing and innovation by guidance and deterrence through precedents, competition law enforcement remains complementary to legislative and regulatory action, such as the reform of the EU pharmaceutical legislation and the Pharmaceutical Strategy.