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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR (2009-2017)

European competition authorities working together for affordable and innovative medicines

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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR (2009-2017)

European competition authorities working together for affordable and innovative medicines

EXECUTIVE SUMMARY

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

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

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

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

Access to cheaper medicines

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

Effective competition from generics and, more recently, biosimilars typically represents a vital source of price competition on pharmaceutical markets and significantly drives down prices (for generics, by 50 % on average). This not only makes older treatments

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much more accessible, but also allows some of the related savings to be redirected to newer, innovative medicines. To mitigate the impact of generic entry, which greatly reduces revenues from commercially successful medicines, originator companies often implement strategies to extend the commercial life of their older medicines. Some of these strategies and other practices that can impact price competition have attracted competition law scrutiny.

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

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

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

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

Access to innovative medicines

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

In merger control, the Commission has prevented transactions that could compromise R&D efforts to launch new medicines or to extend the therapeutic use of existing medicines. The Commission intervened to protect innovation competition in a number of cases which, for example, threatened to thwart advanced R&D projects for life-saving cancer drugs (*Novartis/GlaxoSmithKline Oncology*) or for pipeline insomnia medicines at an early stage of development (*Johnson & Johnson/Actelion*). In the *Pfizer/Hospira* case,

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the Commission was concerned that the merger would do away with one of the two parallel projects to develop competing biosimilars. The Commission cleared all these transactions but only after the companies offered remedies to ensure that pipeline projects were not dropped and found a new operator to drive them forward.

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

Scope for further enforcement action

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

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

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1. INTRODUCTION

The Council asked the Commission to prepare a '*report on recent competition cases following the pharma sector inquiry of 2008/2009*'[1]. It expressed concerns that patients' access to affordable and innovative essential medicines may be endangered by a combination of (i) very high and unsustainable price levels; (ii) market withdrawals, or other business strategies by pharmaceutical companies; and (iii) the limited bargaining power of national governments against those pharmaceutical companies. The European Parliament expressed similar concerns in its resolution on EU options for improving access to medicines[2]. This report is therefore addressed to the Council and the European Parliament.

The pharmaceutical sector and the healthcare sector in general are of particular societal and economic importance. Being healthy and having access to affordable and innovative medicines matters a lot to people. The economic crisis of 2008 and its fallout, the demographic evolution and changes in the types of diseases affecting Europeans have put significant constraints on public healthcare budgets. In recent decades, public spending on healthcare in general has increased to between 5.7 % and 11.3 % of GDP in EU countries[3], and is expected to grow further. Spending on pharmaceuticals constitutes a significant share of government spending on healthcare[4]. In this context, the high prices of medicines can pose a high burden on the national healthcare systems.

Moreover, continued efforts to innovate and invest into 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,[5] can help to safeguard EU patients' access to both affordable and innovative medicines. It has been drawn up in close cooperation with the national competition authorities ('NCAs') of the 28 EU Member States (the Commission and NCAs are jointly referred to as the 'European competition authorities').

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1 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, 17 June 2016, paragraph 48.

2 European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)), 2 March 2017, available at: *http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2017-0061+0+DOC+XML+V0//EN*.

3 5.7 % in Latvia and 11.3 % in Germany in 2016. *Source:* OECD (2017), *Health at a Glance 2017: OECD Indicators*, OECD Publishing, Paris, pp. 134-135 (*http://dx.doi.org/10.1787/health_glance-2017-en)*.

4 Pharmaceuticals sold in retail represented 16 % of healthcare expenditure on average across OECD countries in 2015 (or the nearest year); this figure does not include expenditure on pharmaceuticals in hospitals. *Source:* OECD (footnote 3), pp. 186-187.

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

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The European competition authorities closely cooperate to enforce competition law as well as 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 in the sector. Scrutinising mergers of pharmaceutical companies for their possible negative impact on competition equally serves these two objectives; and 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. The report 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 conduct. '*Vigilant competition law scrutiny*'[6] therefore 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 groundbreaking precedents which clarified the application of EU competition law in 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.

This report covers the period 2009-2017. It provides

- a general overview of competition law enforcement by the Commission and the NCAs in the pharmaceutical sector (Chapter 2);
- a description of the main characteristics of the pharmaceutical sector that shape the competition assessment (Chapter 3); and
- an illustration of how competition law enforcement contributes to affordable medicines (Chapter 4) and to innovation and choice in medicines and treatments (Chapter 5).

6 European Parliament Resolution, Recital H (see footnote 2).

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2. OVERVIEW OF COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR

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 use also advocacy to propose to decision-makers in the public or private sphere pro-competitive solutions to systemic market malfunctioning.

This chapter 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 by pharmaceutical companies. 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[7] empowers both the Commission and the NCAs to apply the prohibitions 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.[8]

2.1.2. Who enforces antitrust rules?

The Commission and the 28 NCAs share enforcement work. The NCAs are fully empowered to apply Articles 101 and 102 TFEU. The Commission and NCAs co-operate

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[7] 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).

[8] By way of example: Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements (OJ C 11, 14.1.2011). An overview of the applicable rules is available at: http://ec.europa.eu/competition/antitrust/legislation/legislation.html.

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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 courts of the Member States are also fully empowered and called upon to apply Articles 101 and 102 TFEU. They do this both in appeals against decisions of NCAs and in litigation between private parties. National courts and competition authorities (NCAs and the Commission) 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 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 most NCAs[9] 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.

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 1: 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 breaking a Commission inspection seal, 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.).[10]

In their proceedings, the European competition authorities safeguard the rights of defence of the investigated parties. For example, during the Commission's administrative proceedings, in the event that the Commission wants to raise objections against the parties' conduct, the investigated parties receive a comprehensive statement of objections and access to the Commission's entire case file. They can then reply to the objections in writing and in an oral hearing before the Commission issues a final decision.

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[9] 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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.011.01.0003.01.ENG&toc=OJ:L:2019:011:TOC).

[10] See footnote 9.

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 several years before a final decision is adopted. To ensure efficient use of resources, the competition authorities 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.

Box 2: 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[11]. Enforcement by competition authorities can therefore be complemented by damages claims before national courts by those harmed by anti-competitive behaviour. For example, in 2010 the United Kingdom NCA fined Reckitt Benckiser GBP 10.2 million for abuse of a dominant position caused by delaying generic competition for its off-patent heartburn medicine Gaviscon Original Liquid. Following this decision, healthcare authorities in England, Wales, Scotland and Northern Ireland filed civil claims for damages against the companies. The authorities claimed that they should be compensated for overpaying for the medicine due to the company's unlawful conduct. By 2014, the claims had been settled for an undisclosed sum.[12]

Similarly, the health authorities in the United Kingdom have sued *Les Laboratoires Servier* for damages resulting (partly) from infringements delaying generic entry as established in the Commission's decision in the *Servier* case.[13] These claims for sums exceeding GBP 200 million are still pending before the United Kingdom courts.[14]

2.1.4. Overview of antitrust enforcement actions in the pharmaceutical sector

In 2009-2017, 13 NCAs and the Commission adopted 29 decisions finding an infringement or accepting binding commitments in antitrust investigations related to pharmaceuticals for human use. The complete list of the 29 cases is available on DG Competition's website[15].

[11] 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).

[12] OECD document 'Generic Pharmaceuticals, – Note by the United Kingdom', 18-19 June 2014, DAF/COMP/WD(2014)67, paragraph 11. Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WD(2014)67&docLanguage=En

[13] Commission Decision of 9 July 2014 in case No COMP/AT.39612 – Servier. For more details see Section 4.1.1.

[14] [2015] EWHC 647 (Ch) – Secretary of State for Health and Others v Servier Laboratories Limited et al.

[15] In this report, the 29 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: http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html. This list also includes links to public information (e.g. press release, text of the decision, Court judgment).

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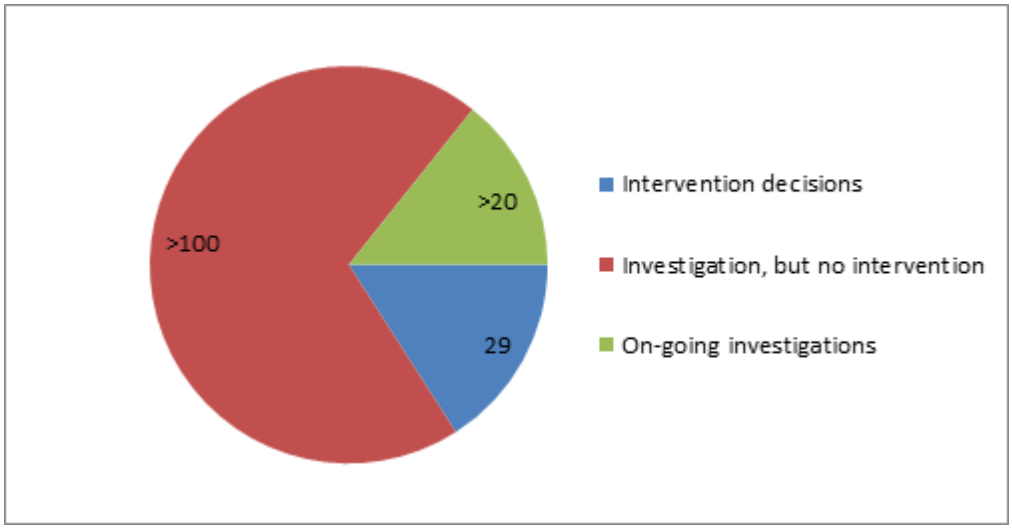
In addition, the European competition authorities also carried out substantial investigation work on competition concerns in more than 100 cases (which did not lead to an intervention decision), and they are currently investigating over 20 cases involving pharmaceuticals. They have also adopted 17 infringement or commitment decisions in cases concerning medical devices and 23 in cases related to other healthcare matters.

Figure 1: Antitrust investigations in the pharmaceutical sector by European competition authorities (2009-2017)



Competition authorities intervene and impose sanctions

In 24 of the 29 intervention cases involving pharmaceuticals, the case was closed with a prohibition decision finding an infringement of EU competition law. Fines were imposed in 21 cases (and in 87 % of all infringement decisions) for more than EUR 1 billion in total for the relevant period (see Figure 2 below)[16]. In 5 cases, the investigation could be closed without finding an infringement or imposing fines because competition concerns were sufficiently addressed by the commitments of the investigated companies. These were made binding by a decision of the competition authority.

[16] The reported fines are not final as appeals are ongoing in a number of cases. In three infringement decisions, the NCA did not impose a fine.

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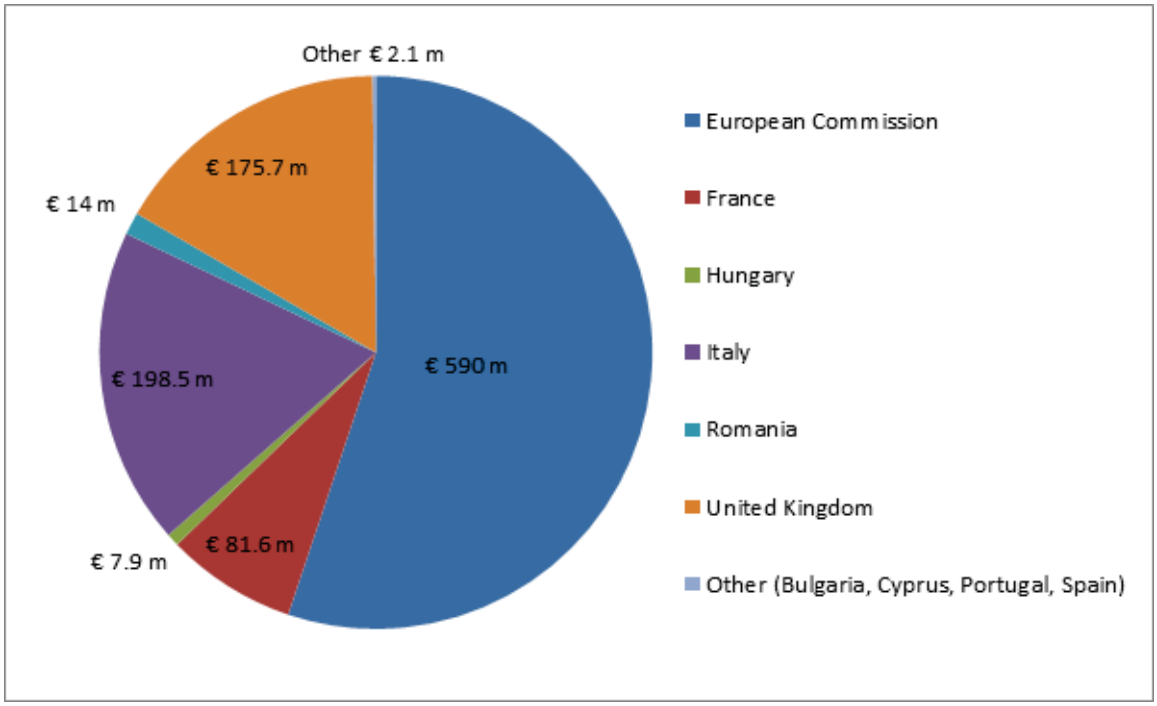
Figure 2: Fines totalling EUR 1.07 billion imposed by European competition authorities in cases involving pharmaceuticals (2009-2017)



To collect evidence, unannounced inspections were carried out in around 62 % of the investigations which lead to an intervention decision. In almost all cases (90 %), requests for information were used. Interviews were conducted in 45 % of the cases.

Most (17) of the investigations that lead to an intervention decision were triggered by complaints, 8 were initiated *ex officio*, and 4 were started 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 (5 cases) and retail distributors (2 cases), and a number of cases related do practices involving both manufacturers and distributors. The investigations involved a wide range of medicines, for example cancer drugs for chemotherapy, antidepressants, strong painkillers, medicines to prevent heart failure or vaccines.

As shown in Figure 3, the most widespread type of competition concerns leading to intervention decisions are abuses of dominance (45 % 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 (31 %); (ii) outright cartels (such as bid rigging); and (iii) vertical agreements (such as clauses prohibiting distributors from promoting and selling products of competing manufacturers), accounted for in 17 % of the cases each[17].

[17] Decisions may establish more than one infringement; therefore the combined percentages exceed 100 %.

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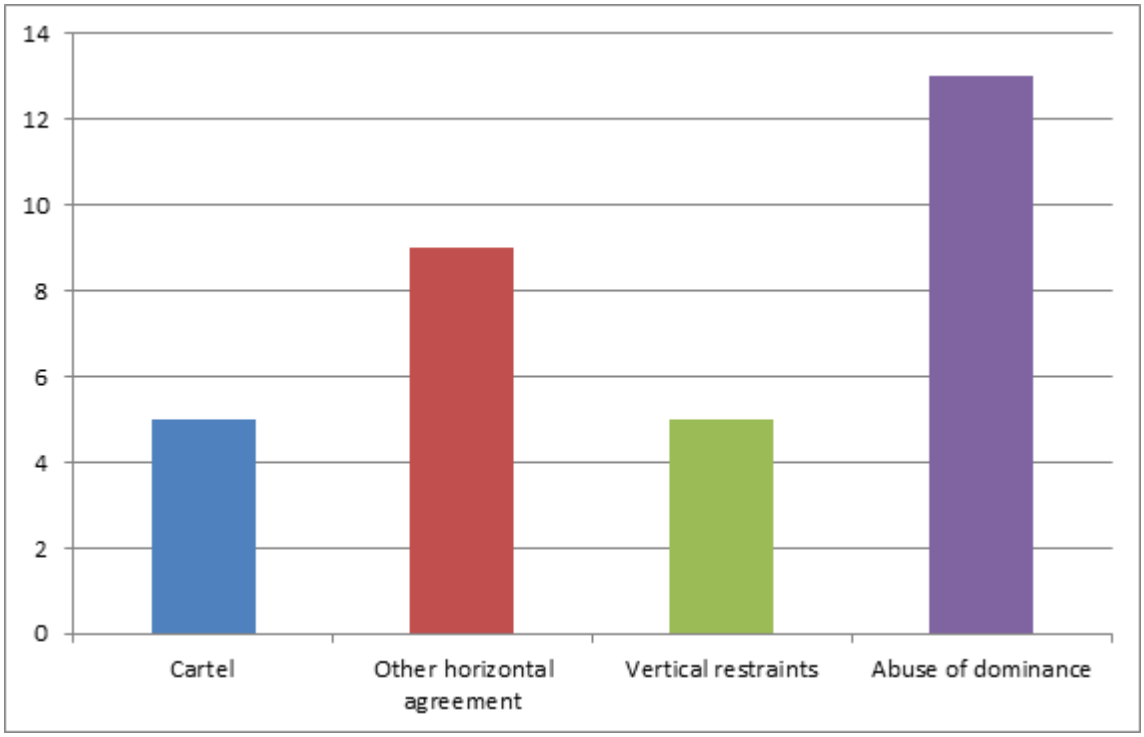
Figure 3: Type of competition concerns where European competition authorities intervened



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 100 cases that were closed for various reasons (in particular 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. In about one third of these cases, the competition issues investigated related to alleged collusion between companies, another third related to alleged refusal or restriction of the supply of medicines, while some 13 % related to alleged barriers to generic or biosimilar entry and some 9 % to alleged parallel trade restrictions.

The European competition authorities are currently investigating more than 20 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. The

Commission's merger control seeks to ensure that consolidation does not significantly impede effective competition in the pharmaceutical sector.

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[18]. If these thresholds are not met, a merger can be caught by national jurisdictions and reviewed by one or several NCAs. The 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[19]. 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[20]. 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[21].

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. The merger must not be implemented until the Commission has given its authorisation.

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.

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[18] 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 results of which are under assessment.

[19] 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.

[20] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC 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).

[21] An overview of the applicable rules is available at: http://ec.europa.eu/competition/mergers/legislation/legislation.html.

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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.

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 problematic molecules 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.

2.2.3. Commission merger control in the pharmaceutical sector in numbers

During 2009-2017, the Commission analysed more than 80 mergers in the pharmaceutical sector. Out of these, 19 were problematic from a competition standpoint. 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 all of the mergers that raised these targeted concerns, allowing the merger to go ahead and protecting competition and consumers in Europe.

As a result, the intervention rate in the pharmaceutical sector was around 22 %[22]. In comparison, the total intervention rate across all sectors during the period was 6 %.

2.3. Market monitoring and advocacy regarding pharmaceuticals and healthcare

In addition to their direct enforcement activities – decisions and investigations on (potential) anti-competitive practices in the pharmaceutical and healthcare sectors – in 2009-2017, the competition authorities took also more than 100 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 in this area (see Chapter 3).

[22] The intervention rate is calculated comparing the number of merger prohibitions, merger approvals subject to remedies and withdrawals of a merger notification in Phase II to the overall number of cases notified to the Commission.

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Competition authorities may conduct market monitoring investigations where, for example, 'the rigidity of prices or other circumstances suggest that competition may be restricted or distorted'[23]. Generally, sector inquiries and other monitoring 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 other regulatory measures that may have an impact on competition conditions in a specific sector.

Of the 30 sector inquiries or market studies undertaken, around a third focused on retail distribution of medicines and competition between pharmacies. Another main focus was the wholesale distribution of medicines, including specific competition issues related to parallel trade or pricing issues. A third main focus of the monitoring activities related to the penetration of generic medicines. This was the focus in particular of the Commission's inquiry into the pharmaceutical sector, for which the final report was adopted in 2009, followed by 8 annual monitoring reports.

More than 70 advocacy activities mostly involved opinions on draft legislative proposals or recommendations to avoid distortion of competition in the pharmaceutical and healthcare sectors. The range of issues covered by such advocacy reports is broad, and includes (i) the removal of barriers to entry for innovative medicines; (ii) the deregulation of pharmacies and online sales of medicines; (iii) better access to medical services and competition issues in relation to medical devices; and (iv) the removal of barriers to competition among manufacturers of originator medicines ('originators') and biosimilars. Many of these advocacy activities helped creating or restoring conditions more conducive to effective and fair competition, and to better access to medicines or medical care for patients.

A complete list of the monitoring and advocacy activities undertaken by the European competition authorities in 2009-2017 is available on DG Competition's website[24].

[23] Article 17 of Council Regulation (EC) No 1/2003, with respect to the Commission's power to conduct a sector inquiry.

[24] http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html. The list includes links to public information and/or the reports itself.

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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 has to take due account of the structure of supply and of demand. A variety of stakeholders pursue different interests in the pharmaceutical markets. The demand side is characterised by consumers (patients), prescribers, pharmacies and health insurance schemes:

– 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, usually 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, for example when there are incentives for pharmacists 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.

– Private and public health insurance schemes are financed by their members (and/or the State) and cover patients' medical costs on their behalf. The reimbursement regime for medicines in a country impacts demand and influences prescribers' and pharmacists' behaviour.

On the supply side, there are manufacturers with distinct business models (supplying originator medicines, generic medicines or, increasingly, both 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 they may compete also 'in the market' when different drugs are relatively substitutable for similar indications.

– Manufacturers of generic products supply non-innovative generic versions of the originator medicine after the originators lose exclusivity, and they do so normally at significantly lower prices. A generic product has the same qualitative and quantitative

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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 needs to be demonstrated by studies. Generic products are usually used to treat the same disease as the reference medicine. Generic companies thus compete to win markets from originators (or from other generics already on the market).

– Some manufacturers supply both originator and generic products. These companies develop distinct business strategies for each type of product.

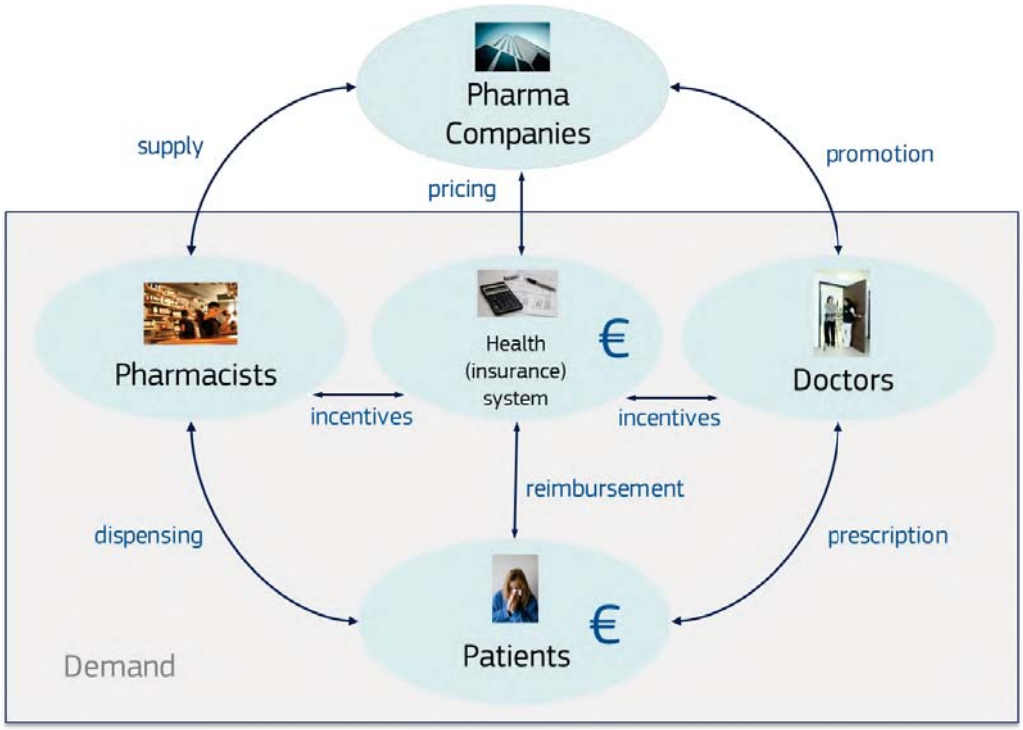
– Wholesalers organise the distribution of pharmaceuticals by purchasing pharmaceutical products from manufacturers and selling them to pharmacies and hospitals.

– The different types of pharmacies fulfil the dual role of advising patients and dispensing them the required medicines.

Finally, Member States also play a significant role in this highly regulated sector – various agencies administer the marketing, pricing, procurement and reimbursement of pharmaceuticals. By using regulations, governments aim to achieve several goals such as (i) maintaining a high quality of pharmaceuticals, safety, efficiency and efficacy; (ii) making pharmaceuticals affordable to everyone by negotiating prices and setting up public health insurance schemes; (iii) promoting innovation and medical research etc.

As shown in Figure 4 below, the demand side in pharmaceutical markets is therefore not driven by a single market operator, but is shaped by the multiplicity of stakeholders whose interests are not necessarily aligned: the patient and his/her medical needs, the physician who is responsible for the effective treatment of the patient but not for the cost, and the reimbursement body and insurers, whose role is to ensure that medicine expenditure is sustainable for the collective benefit of the beneficiaries of health insurance schemes.

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[25], 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 3: Definition of relevant markets for pharmaceuticals

The definition of the relevant market[26] 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 significant competitive pressure on the investigated product) and the geographic dimension (sufficiently homogeneous area from which significant competitive pressure is exerted). To understand which medicines belong to the same market, the authorities need to assess both demand side substitution (e.g. whether prescribers and patients would readily switch from one product to another) and supply side substitution (the existence, or not, of suppliers that could also start producing a specific medicine).

[25] Pharmaceutical innovation, in particular in biologicals, is shifting from big pharma companies to smaller players. While big companies continue to invest heavily in clinical trials and bringing innovation to the market, today core innovation is increasingly generated by small and medium sized companies (SMEs). Innovative SMEs in Europe face a funding challenge, partly due to the fragmented European public markets.

European Investment Bank publication: *Financing the next wave of medical breakthroughs - What works and what needs fixing?* March, 2018
http://www.eib.org/attachments/pj/access_to_finance_conditions_for_life_sciences_r_d_en.pdf

[26] Commission notice on the definition of the relevant market OJ C 372, 9.12.1997, p. 5-13.

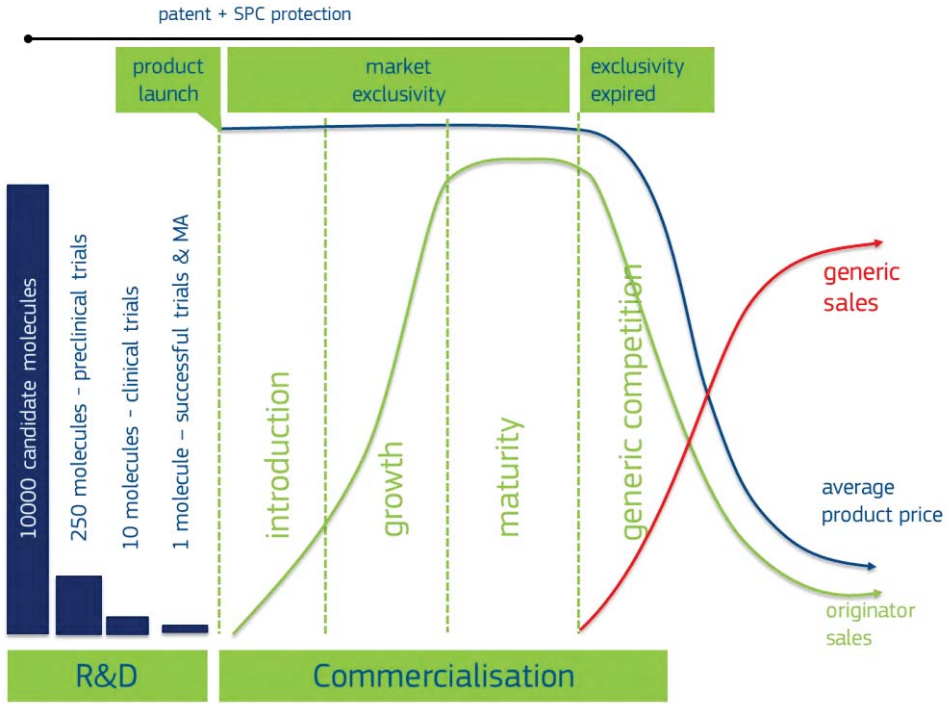
The market definition, i.e. identifying the sources of competitive pressure, helps competition authorities to assess whether the investigated company enjoys market power, or dominance, and whether the conduct being investigated would be likely to harm competition rather than being offset by offers from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

With regard to the relevant product market, understanding which other products are therapeutically substitutable is a necessary first step in identifying relevant competing drugs. However, the determining factor is whether the relevant drugs can effectively be substituted also in economic terms. Only medicines that are actually able to substitute the investigated product in response to changes in market conditions can be considered as belonging to the same product market. For example, if the positioning of a medicine (price, quality, innovative activity, promotional activity) is geared against losing prescriptions to another medicine with a different molecule, this suggests that the products based on two different molecules are likely to be in the same market. However, if the main competitive threat comes from generic versions, 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 can change over time and not only depends on the availability of substitutable medicines, but is to a large extent affected by pricing and reimbursement regulation[27].

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.

Figure 5: Pharmaceutical product life-cycle



The life-cycle of a new drug begins with a new chemical compound, which is usually discovered through basic research conducted by originator manufacturers or independent research facilities (universities, specialised laboratories), often supported by public

[27] See section 3.2.2.

funding. Originator manufacturers then test whether a pharmaceutical product containing the chemical 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.

The development cycles for innovative drugs are usually risky and lengthy, and entail high development costs[28]. 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 development. Once on the market, new medicines strive to secure prescriptions by either diverting demand from other medicines or by growing the market demand itself. 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 versions of the same medicine starts to build up. Upon generic entry, the originator may typically lose significant sales volumes and average market prices 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[29]. 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.[30] 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

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[28] Recent 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 (converted from USD). 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.

[29] 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, table S2).

[30] On exclusivities see Box 4 and the following Section.

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. Patent protection can be extended by supplementary protection certificates (SPCs) which have been created to compensate for the period of exclusivity lost by the manufacturer due to the long periods needed to obtain MA for the patented medicine. There can also be other protection instruments granting exclusivity (see Box 4 below).

While the medicine is on the market, manufacturers usually continue to improve its manufacturing process, pharmaceutical form, and/or composition (different salts, esters, crystalline forms etc). These improvements may result from patentable innovations. Such patents, often called 'secondary patents', may make it more difficult for generics to quickly enter the market even if the active ingredient is no longer patented and can be used to produce their generic medicines.

Box 4: Patents and other exclusivities provide a period of protection against generic products

Patents provide the innovator (originator) with an exclusive civil right to the commercial exploitation of the invention for up to 20 years from the patent application. A manufacturer usually applies for the patent very early in the development process to prevent another researcher applying for a patent for the same invention or publishing it. This means that the 20 year patent protection period starts long before the drug enters the market. SPCs can then extend the period of patent protection by up to 5 years.

Originator medicines can benefit from other exclusivities, notably market and data exclusivity. The originator medicine enjoys 8 years of exclusivity over the data on pre-clinical and clinical studies submitted to obtain the MA. During this data exclusivity period, companies – typically generic producers – cannot apply for an MA for the same medicine by way of an abridged MA procedure, which relies in part on the data submitted for the originator medicine.

Market exclusivity means that generic medicines cannot enter the market and compete with the originator medicine until 10 years have passed from the date of the MA to the originator medicine. Orphan medicines (i.e. medicines developed for rare diseases) also benefit from a period of 10 years of market exclusivity in which no similar medicine to treat the same disease (whether generic or originator) can be marketed. When medicines used by adults are adapted to meet the medical needs of children, this may also be rewarded by an additional period of exclusivity (SPC, data or market exclusivity).

Loss of protection and generic 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 competition with increased access to cheaper medicines after loss of exclusivity. Competitive pressure from generics may be significantly different and stronger than pressure from other originator medicines. 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. Most Member States have regulatory mechanisms to encourage the prescription and/or dispensing of generic medicines instead of the more expensive originator medicine.

Once a generic medicine enters the market, these mechanisms lead to stronger price competition from generics and to important shifts in volumes of product sold from the originator to the generic, potentially even threatening the entire patient population of the originator. As a result, the entry of cheaper generics 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.

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.

Box 5: Biological medicines and biosimilars

Biological medicines contain active substances from a biological source such as living cells or organisms (human, animals and microorganisms such as bacteria or yeast). Cutting-edge technology is often used to produce them. Compared to chemically synthesised medicines, biological medicines are usually much more difficult to produce.

Most biological medicines in current clinical use contain active substances made of proteins. These can differ in size and structural complexity, from simple proteins like insulin or growth hormone to more complex ones such as coagulation factors or monoclonal antibodies. Biological medicines offer treatment options for patients with chronic and often disabling conditions such as diabetes, autoimmune diseases and cancers.

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the reference medicine). Unlike the molecules of classical medicines, which are smaller and chemically synthesised, the much more complex biosimilars are extracted or synthesised from biological sources in conditions that do not allow the reference product to be fully replicated (due to different cell cultures, secret process know-how etc.). Biosimilars are therefore not exact copies of reference medicines and do not meet the conditions to qualify as generic medicines.

Biological drugs are among the most expensive therapies, and their uptake is steadily increasing. 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[31].

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 also leads to higher barriers to entry for biosimilars compared to classical generics.

In addition to stimulating price competition, generic and biosimilar entry also helps to foster innovation. First, after protection expires, the knowledge behind the innovation (and disclosed in patent applications and MA files) can be freely used by other innovators to develop similar or unrelated 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 its future revenue streams. Generic/biosimilar competition therefore not only results in lower

[31] European Commission Directorate-General for Economic and Financial Affairs and Economic Policy Committee (Ageing Working Group), *Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability*, Volume 1, Institutional Papers 37. October 2016. Brussels, page. 139, available at: https://ec.europa.eu/info/sites/info/files/file_import/ip037_vol1_en_2.pdf.

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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 protection time. In addition to judicial and regulatory control, competition authorities are called upon to ensure that incentives to innovate are not distorted and that healthcare systems are not worse off as a result of companies unduly extending their market exclusivity. Finally, transparency concerning patents and other exclusivities protecting a medicine can play an important role in facilitating competitive and viable entry by generics or biosimilars.

The Commission is currently carrying out an evaluation of the incentives systems for pharmaceuticals in the EU and has in this context also commissioned an external study analysing the impact of pharmaceutical incentives on innovation, availability and accessibility of medicinal products, which is now concluded and published.[32]. This follows, amongst others, the already mentioned Council's Conclusions[33]. The objective of the evaluation is to assess whether the existing systems strike the right balance between the incentives provided to originators, the interest in continued investment in R&D and the interest to render medicines more available and accessible.

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 and generic 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' ('HTA'); 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

[32] Study by Copenhagen Economics, available at: https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf.

[33] See footnote 1.

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used to treat the same condition), and spark a higher degree of economic substitution. Such measures may profoundly transform the nature and intensity of competition for alternative medicines, as suppliers are no longer protected from price-driven competition.

4. 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, activities against practices that hinder or delay the entry of generic medicines and the resulting price competition (Section 4.1), and against excessively high prices of medicines when they amount to an abuse of dominant position by a pharmaceutical company ('unfair' prices) (Section 4.2). In addition, the European competition authorities have also addressed a number of other anti-competitive practices (e.g. bid rigging in hospital tenders, market sharing between pharmacies, restrictions of parallel trade, etc.) that either directly or indirectly lead to higher prices of medicines (Section 4.3). 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 4.4).

4.1. Antitrust enforcement supports swift market entry of cheaper generic medicines

Effective generic competition typically represents one, if not the main, source of price competition on pharmaceutical markets and drives prices down significantly. For example, a recent study prepared for the Commission[34] found that prices of innovator medicinal products drop by 40 % on average in the period after the 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.

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.[35] Availability of cheaper generic medicines directly translates into significant savings for patients and national healthcare systems.

Therefore, on the one hand generic entry brings benefits to patients and national healthcare systems while on the other it significantly reduces the originator companies' profits from their no longer patent protected product. To mitigate the impact of generic entry, originator companies often devise and implement a variety of strategies to extend the commercial life of their innovative medicines (e.g. patent filing strategies, patent disputes and oppositions, settlement agreements, interventions before competent authorities and life cycle strategies for follow-on products). While these practices are not as such illegitimate, in specific cases they attract the scrutiny of competition authorities[36].

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[34] Copenhagen Economics, study quoted in footnote 28.

[35] Commission Decision of 19 June 2013 in case COMP/AT.39226 – *Lundbeck*, paragraph 726.

[36] European Commission's Report on the pharmaceutical sector inquiry of 8 July 2009, pages 195-196.

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4.1.1. 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 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 shorter or longer period of time.

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

These two players (originator and generic would-be entrant) benefit at the expense of healthcare systems and tax payers. 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 extra profit for the originator and generic companies. Taking into account the scale of price reductions brought about by generic entry, even short delays can have a significantly negative impact on competition.

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 patent disputes between originator and generic companies[37]. However, they can also take the form of any other commercial arrangement. An example for this is the *Fentanyl* case where Johnson & Johnson and Novartis (through their Dutch subsidiaries) agreed on delaying – against payment – market entry of the generic pain-killer fentanyl by entering into a co-promotion agreement[38].

Box 6: The *Fentanyl* case

Johnson & Johnson developed fentanyl, a potent painkiller used especially for cancer patients, and have commercialised it in different formats including a patch. In 2005, Johnson & Johnson's patents on the fentanyl patch expired in the Netherlands and Novartis' subsidiary Sandoz was on the verge of launching its generic fentanyl patch.

However, in July 2005, instead of launching its generic product, Sandoz concluded a 'co-promotion agreement' with a subsidiary of Johnson & Johnson. The agreement provided that Sandoz would not be allowed to enter the Dutch market in return for monthly payments calculated to exceed the profits that Sandoz expected to obtain from selling its generic product. The agreement was terminated in December 2006 when another generic entered the market.

[37] The Commission's annual monitoring exercises of patent settlements in the pharmaceutical sector have shown that most of the settlements (around 90 %) fall into categories that at first view do not raise the need for competition law scrutiny. Companies, in most cases, are able to settle their disputes in a manner that is typically considered unproblematic from a competition law perspective (see also Section 2.3).

[38] Commission Decision of 10 December 2013 in case COMP/AT.39685 – *Fentanyl*.

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Contemporaneous internal documents found by the Commission showed that Sandoz decided to abstain from entering the market in exchange for '*a part of [the] cake*', that is for a part of the originator's exclusivity profits shielded from generic competition. Instead of competing, the two rivals agreed to cooperate aiming '*not to have a depot generic on the market and in that way to keep the high current price*'.

The agreement delayed the entry of a cheaper generic medicine for seventeen months and kept prices for fentanyl in the Netherlands artificially high – to the detriment of patients and the Dutch healthcare system. The Commission concluded that the object of this agreement was to restrict competition contrary to Article 101 TFEU and imposed fines of EUR 10.8 million on Johnson & Johnson and EUR 5.5 million on Novartis. The parties did not appeal the Commission's decision.

Pay-for-delay agreements were found to be anti-competitive in various other circumstances. In the *Lundbeck* decision of 2013 the Commission imposed a fine of EUR 93.8 million on Danish pharmaceutical company Lundbeck, as well as fines totalling EUR 52.2 million on four producers of generic medicines, for entering into agreements that delayed the market entry of generic citalopram. This blockbuster antidepressant medicine was Lundbeck's bestselling product at the time. Under these agreements the generic companies committed not to compete with Lundbeck, who paid significant sums of money to generic companies, purchased generics' stock of generic medicine solely to destroy it, and offered guaranteed profits in a distribution agreement. Internal documents refer to a '*club*' being formed and '*a pile of $$$*' to be shared among the participants. In the judgment upholding the Commission's decision, the General Court confirmed that pay-for-delay agreements are akin to market sharing, which constitutes a serious infringement of Article 101 (restriction by object)[39]. The judgment of the General Court is on appeal to the Court of Justice.

In addition to infringing Article 101 TFEU, pay-for-delay agreements can also infringe Article 102 TFEU. This may be the case when the originator holds a dominant position and the agreements are part of a strategy to delay generic entry. In 2014, the Commission imposed fines totalling EUR 427.7 million on the French pharmaceutical company Servier and five producers of generic medicines (Niche/Unichem, Matrix/Mylan, Teva, Krka and Lupin) for concluding a series of deals aimed to protect Servier's bestselling blood pressure medicine, perindopril, from price competition by generics in the EU[40]. Servier paid several tens of millions of euros to the generics amounting to '*buy [them] out*' from the perindopril market. Servier's strategy of delaying generic entry included acquiring a competing technology and consecutively concluding the patent settlement agreements. On 12 December 2018, the General Court confirmed the Commission's findings under Article 101 (with the exception of the Krka agreement) but rejected the Commission's market definition and consequently annulled the conclusion that Servier's conduct also infringed Article 102 TFEU.[41] As a consequence, the Court reduced the total fines to EUR 315 million. The judgments can be appealed by the parties and the Commission.

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[39] Judgment of the General Court of 8 September 2016, *H. Lundbeck A/S and Lundbeck Ltd v European Commission*, T-472/13, paragraph 401.

[40] Commission Decision of 9 July 2014 in case COMP/AT.39612 – *Servier*.

[41] Judgment of the General Court of 12 December 2018, *Servier SAS, Servier Laboratories Limited* and *Les Laboratoires Servier* v *European Commission*, T-691/14.

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Similarly, in the *Paroxetine* decision of February 2016[42], the United Kingdom NCA found, among other things, that GlaxoSmithKline abused its dominant position by entering into pay-for-delay agreements with generic competitors. The NCA found that GlaxoSmithKline, through payments and other benefits, induced three potential competitors (IVAX, Generics (UK) and Alpharma) to delay their potential independent entry into the paroxetine market in the United Kingdom. GSK's agreement with Generics (UK) was also found to infringe Article 101 TFEU, with the Alpharma agreement found to infringe the UK equivalent of Article 101 TFEU. The NCA imposed fines totalling GBP 44.99 million (approximately EUR 56.3 million)[43] on the companies involved in these infringements. All of these findings are on appeal before the Competition Appeal Tribunal, which has referred questions for a preliminary ruling to the Court of Justice[44].

4.1.2. Other practices hindering market entry of generic medicines

In addition to the pay-for-delay 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 entry. All of these practices prevented price reductions from generic entry and therefore directly harmed patients and healthcare systems.

Misuse of the regulatory framework

The seminal judgments of the General Court (in 2010) and the Court of Justice (in 2012) in *AstraZeneca*[45] established that misleading public authorities and misusing the regulatory procedures as a part of a commercial strategy to launch a follow-on product, can in certain circumstances constitute an abuse of a dominant position.

These judgments largely upheld the Commission's finding that AstraZeneca had abused its dominant market position by blocking or delaying market access for generic versions of Losec, a medicine used to treat gastrointestinal conditions[46]. The Commission found that AstraZeneca made misleading representations to the patent offices to extend the period of patent protection for Losec. In addition, AstraZeneca misused rules and procedures applied by the national medicines agencies by selectively deregistering the MAs for Losec capsules. At the time, generic and parallel imported products could only be marketed in a given Member State if the MA for the originator product was still in force. The strategic deregistration by AstraZeneca of its MA for Losec therefore made it impossible for generic competitors and parallel importers to compete with AstraZeneca. The Commission fined AstraZeneca EUR 60 million (the General Court annulled part of the Commission's decision in respect of the second abuse, resulting in a lowering of the fine from EUR 60 million to EUR 52.5 million).

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42 Decision of the Competition and Markets Authority of 12 February 2016.

43 All EUR counter values in this report are calculated against the European Central Bank average exchange rate in the year of the NCA's decision.

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

45 Judgment of the General Court of 1 July 2010, *AstraZeneca AB and AstraZeneca plc v Commission*, T-321/05. Judgment of the Court of Justice of 6 December 2012, *AstraZeneca AB and AstraZeneca plc v European Commission*, C‑457/10 P.

46 Commission Decision of 15 June 2005 in case COMP/AT.37507 – *Generics/AstraZeneca*.

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Similarly, in April 2011 the United Kingdom NCA found that Reckitt Benckiser had abused its dominant position by withdrawing and delisting National Health Service (NHS) presentation packs of Gaviscon Original Liquid[47].

Box 7: The *Gaviscon* case

Gaviscon products are alginate-based compounds that are used to treat acid reflux (heartburn), gastro-oesophageal reflux disease (GORD) and dyspepsia.

The United Kingdom NCA found that Reckitt Benckiser withdrew Gaviscon Original Liquid to limit pharmacy choice and hinder competition from suppliers of generic medicines. The withdrawal was made after the patent for Gaviscon Original Liquid expired but before the generic name for the product was published. Without a generic name, the prescribing doctors could not prescribe the same medicine by using its generic name and the pharmacies were not able to substitute the original product with its cheaper generic versions.

In internal documents Reckitt Benckiser identified that their '*objective [was] … to delay for as long as possible, the introduction of a generic name*'. Following the withdrawal, most prescriptions were issued for Gaviscon Advance Liquid which was another version of the product still patent protected, and therefore without generic substitutes.

The NCA found that the withdrawal was likely to restrict the development of full generic competition and fined the company GBP 10.2 million (approximately EUR 11.8 million). The fine was the subject of an earlier agreement under which the company admitted its conduct infringed the United Kingdom and EU competition law and agreed to cooperate with the NCA.

In addition, in January 2011 the Italian NCA fined Pfizer EUR 10.7 million for adopting a complex legal strategy of filing for and obtaining intellectual property rights (divisional patents, SPCs and paediatric extension). The NCA found that this strategy aimed to delay entry of generic medicines[48]. Pfizer challenged the NCA's decision and the appellate proceedings were ultimately closed with the final judgment of the Italian State Council[49], which upheld the NCA's decision.

Disparagement and other practices curbing demand for generics

Another type of practice affecting generic competition is the strategy used by some dominant companies to disparage (denigrate) the generic entrant to hinder the uptake of cheaper generics.

The Court of Justice recently provided guidance on which type of dissemination of information to the authorities, healthcare professionals and the general public raises concerns under the EU competition rules. The Court clarified that companies must not 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[50].

47 Decision of the Office of Fair Trading of 12 April 2011.

48 Decision of the Autorità Garante della Concorrenza e del Mercato of 11 January 2011.

49 Judgment of the Consiglio di Stato of 12 February 2014.

50 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. For more details on the *F. Hoffmann-La Roche* case of the Italian NCA, see Section 4.3.1.

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The French NCA adopted a series of decisions against companies engaged in disparagement practices, i.e. producing and disseminating incomplete and misleading information (vis-à-vis doctors, authorities and the general public) which could prevent competing products from entering or expanding.

In the *Plavix* decision[51] from May 2013, the French NCA considered that Sanofi-Aventis had abused its dominant position on the French market for clopidogrel (the active ingredient of its leading drug Plavix, used to prevent cardiac diseases). Sanofi-Aventis had a comprehensive communication strategy aimed at misleading physicians and pharmacists into stopping the mechanisms of generic substitution. The company's disparagement strategy promoted its products (both Plavix as the originator medicine and Clopidogrel Winthrop – Sanofi's own generic version of Plavix) and limited the market entry of competing generic medicines. In particular, the NCA found that Sanofi's sales representatives misled doctors and pharmacists about the quality and safety of competing generics, and tried to dissuade them from substituting generic versions of Plavix except with Sanofi's own generic – Clopidogrel Winthrop. The French NCA imposed a fine of EUR 40.6 million on Sanofi. The NCA's decision was confirmed by the Paris Court of Appeal[52] and the Supreme Court[53].

Much like pay-for-delay agreements, disparagement practices are often only a part of a broader strategy aimed at hindering generic competition. In December 2013 the French NCA fined the company Schering-Plough EUR 15.3 million for having abusively hindered the entry of generic versions of buprenorphine (an opioid used for treating addiction and sold by Schering-Plough as Subutex)[54]. This consisted of (i) awarding dispensing chemists commercial advantages (particularly discounts) inducing brand loyalty, and (ii) disparaging the generic competitors. For example, Schering-Plough organised seminars and telephone meetings and briefed its sales teams and pharmaceutical representatives so that they could spread alarmist messages among doctors and pharmacists on the risks of prescribing or issuing Arrow Generique's generic product. This was despite Schering-Plough not having any specific medical studies at its disposal which could have justified its arguments. The NCA also imposed a fine on Schering-Plough's parent company, Merck & Co (EUR 414,000), for entering into an agreement aimed at implementing the abusive strategy with its supplier Reckitt Benckiser, which in turn was fined EUR 318,000). The French NCA's decision was confirmed by the Paris Court of Appeal[55] and the Supreme Court[56].

Another example of enforcement against disparagement practices is the *Durogesic* case which was also decided upon by the French NCA.[57]

Box 8: The French *Durogesic* Case

Following a complaint by the company Ratiopharm France (Teva Santé), the French NCA adopted a decision imposing a fine of EUR 25 million on Janssen-Cilag and its parent company

[51] Decision of the Autorité de la concurrence of 14 May 2013.

[52] Judgment of the Cour d'appel de Paris of 18 December 2014.

[53] Judgment of the Cour de cassation of 18 October 2016.

[54] Decision of the Autorité de la concurrence of 18 December 2013.

[55] Judgment of the Cour d'Appel de Paris of 26 March 2015.

[56] Judgment of the Cour de Cassation of 11 January 2017.

[57] Decision of the Autorité de la concurrence of 20 December 2017.

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Johnson & Johnson for delaying the arrival to the market of a generic version of Durogesic and then blocking the market growth of this generic medicinal product. Durogesic is a powerful opioid analgesic, with the active ingredient fentanyl[58]. Janssen-Cilag was deemed to have been involved in two anti-competitive practices:

– Repeated unjustified approaches to the French agency for medical safety of health products, aiming to convince the authority to refuse to grant, at national level, generic status to competing medicinal products, even if this status was already obtained at EU level, and

– A major campaign disparaging the generic versions of Durogesic among office- and hospital-based healthcare professionals (doctors, pharmacists). Janssen-Cilag used misleading language to create doubts concerning the effectiveness and safety of these generic medicinal products. This involved sending out numerous newsletters to medical practitioners, making statements in the press as well as Janssen-Cilag training a specialist team of 300 sales representatives called '*commandos*'. They were told to emphasise that generic alternatives have neither the same composition, nor the same quantity of the active ingredient fentanyl as its Durogesic patch, and could entail risks of adverse effects or recurrence of pain for certain patients.

These practices delayed the market entry of generic medicines by several months and discredited the generic versions of Durogesic. The strategy implemented by Janssen-Cilag had large-scale effects targeting all the healthcare professionals likely to prescribe or dispense Durogesic. The NCA's decision is currently under review by the Paris Court of Appeal.

Finally, the demand for generic products can also be unduly restricted by other market participants fighting to preserve their particular interests. In March 2009 the Spanish NCA intervened against several associations of pharmacists over their recommendations against Laboratorios Davur's generic products[59]. Following the introduction and marketing of cheaper generic products by Laboratorios Davur, the associations instituted a collective boycott of its products by the pharmacists. One pharmacist even openly explained to Laboratorios Davur that '*[Laboratorios Davur's] commercial strategy of low prices produces or can produce important economic damages to me, given that, as a pharmacist I work with a percentage of the final sale prices*' and that '*in the future no other product of Laboratorios Davur will enter in [the pharmacist's] pharmacy*' (original in Spanish). The decision imposed a total of fines amounting to EUR 1 million on several of the associations. The decision was appealed and upheld by the courts for three of the four associations fined, but the amount of the fines was reduced[60].

4.2. Enforcement against dominant firms charging unfairly high prices (excessive prices)

Unfair pricing conduct concerns in essence the abuse of a dominant position by imposing excessive prices on patients and healthcare systems.

4.2.1. The prohibition of unfair pricing by dominant firms and its limits

Exploitative conduct by way of unfair pricing (sometimes referred to as 'excessive pricing') is prohibited under EU competition rules (Article 102(a) TFEU). The Court of Justice has laid out a set of conditions under which a dominant company' prices can be

[58] For a different case concerning fentanyl, see also Box 6.

[59] Decision of the Comisión Nacional de los Mercados y la Competencia of 24 March 2009.

[60] Decision of the Audiencia Nacional of 18 January 2011.

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found as unfair, and thus in breach of Article 102 TFEU which prohibits abuses of a dominant position[61].

In investigating potentially unfair prices, competition authorities carefully balance the need to reward dynamic efficiency and innovation against the harm such prices inflict on consumers and society. Moreover, they consider whether 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 in the EU show that a heightened degree of vigilance under competition law is merited regarding pricing practices in the pharmaceutical sector.

4.2.2. Examples of cases concerning unfair prices

European competition authorities have been pursuing a number of unfair pricing cases in the pharmaceutical industry concerning off-patent medicines.

Box 9: The Italian Aspen case

In September 2016, the Italian NCA imposed a EUR 5.2 million fine on the pharmaceutical company Aspen for abusing its dominant position by setting unfair prices for important medicines in Italy[62]. These off-patent medicines included Leukeran, Alkeran, Purinethol and Tioguanine, which were used to treat cancer. They had been included in a wider package of pharmaceutical products, for which Aspen purchased the marketing rights from the originator GlaxoSmithKline in 2009. The NCA found that Aspen abused its dominant position in Italy by imposing price increases of between 300 % and 1,500 % and by applying particularly aggressive tactics towards the Italian Medicines Agency in negotiating these prices. Aspen even threatened to '*initiate supply termination*', i.e. withdraw the drugs if the Agency did not accept the requested higher prices. Following the acceptance of price increases, Aspen's consultant concluded: '*I wouldn't [have] expected to conclude the negotiation so favourably, but I remember when you told me in Rome that everywhere at the beginning it seems it was kind of 'mission impossible' and then the prices increase where always authorised …Let's celebrate!*'.

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[63]. An appeal against this judgment is pending before the Italian State Council.

In May 2017, the Commission also opened a formal investigation into concerns that Aspen Pharma may have engaged in unfair pricing concerning cancer medicines mentioned above in the rest of the EEA (except Italy).[64]

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61 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.

62 Decision of the Autorità Garante della Concorrenza e del Mercato of 29 September 2016.

63 Judgment of the Tribunale Amministrativo Regionale per il Lazio of 26 July 2017.

64 See http://europa.eu/rapid/press-release_IP-17-1323_en.htm.

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In December 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[65]. In an internal document, Pfizer explained at the time: *'We need to work out how we can position this as 'no change' with patients & physicians; and at the same time 'change' with DH [UK Department of Health] and payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS [National Health Service] in [a] time of funding crisis.'*

In 2012, Pfizer and Flynn had entered into agreements under which Pfizer transferred its marketing authorisations for phenytoin sodium (sold under the brand name Epanutin) to Flynn, but continued to manufacture and supply the product to Flynn for distribution in the United Kingdom. However, the supply prices to Flynn were between 780% and 1,600 % higher than what Pfizer had previously charged distributors. Following the transfer, Flynn genericised Epanutin (it started selling the medicine under its generic name phenytoin sodium, without the brand name) take advantage of a loophole in the law at the time which did not subject generic medicines to any price limits (contrary to branded medicines). Flynn hiked up prices to distributors by up to 2,600 %, compared to previous price levels when the medicine was sold branded. The NCA fined Pfizer GBP 84.2 million (EUR 103 million) and Flynn GBP 5.16 million (EUR 6.32 million). On 7 June 2018, the United Kingdom Competition Appeal Tribunal issued its judgment, in which it upheld several findings of the CMA (i.e. the narrow market definition and that Pfizer and Flynn each held dominant positions). It, however, found that the CMA conclusions on abuse of dominance were in error ultimately deciding to remit the case back to the NCA for further consideration. The NCA has sought permission to appeal against the Competition Appeal Tribunal's judgment.

By the decision from January 2018[66], 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[67], the Danish Competition Appeal Tribunal upheld the decision made by the Danish NCA.

4.3. Other anti-competitive practices capable of inflating prices

As well as practices delaying generic entry and imposing unfair prices for medicines, European competition authorities intervened against various other anti-competitive practices that inflate prices of medicines, or keep them inflated. Some of these practices are specific to the pharmaceutical sector and driven by its economic and regulatory

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65 Decision of the Competition and Markets Authority of 7 December 2016.

66 Decision of the Konkurrence- og Forbrugerstyrelsen of 31 January 2018.

67 Judgment of the Konkurrenceankenævnet of 29 November 2018.

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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.

4.3.1. Coordination as a means to achieve higher prices

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

In 2014 the Italian NCA found that Hoffmann-La Roche and Novartis had entered into an anti-competitive agreement aiming to discourage and limit off-label use of Hoffmann-La Roche's oncology medicine – Avastin for treatment of the 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 entrusted 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 to treat eye diseases instead of Lucentis because of its significantly lower price.

The NCA established that Novartis and Hoffmann-La Roche had put in place an arrangement designed to artificially differentiate Avastin from Lucentis whereas, according to the NCA, Avastin and Lucentis are equivalent in all respects for the treatment of eye diseases. The arrangement was intended to disseminate information raising concerns about the safety of Avastin used in ophthalmology to shift demand towards the more expensive Lucentis. An internal Novartis presentation explained: *'Leverage safety data and regulator's statements against unlicensed intraocular use of bevacizumab for wet AMD to avoid off-label erosion'*. 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. The fine imposed on Hoffmann-La Roche amounted to EUR 90.6 million and the fine imposed on Novartis amounted to EUR 92 million.[68]

In the second-instance appeal procedure against the NCA's decision, the Italian State Council sent a preliminary reference to the Court of Justice of the European Union on several questions concerning the interpretation of Article 101 TFEU. In its answers the Court of Justice clarified, among other things, that (i) in principle, a medicine used off-label for the same therapeutic indications as another product used on-label can be included in the same product market and that (ii) communication of misleading

[68] Decision of the Autorità Garante della Concorrenza e del Mercato of 27 February 2014.

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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[69].

In another case, the Spanish NCA established that an agreement between an association of pharmacists in Castilla-La Mancha and the region's health service amounted to market sharing, as it introduced a rotation between pharmacies for the supply of medicines to healthcare centres.[70] The Court of Appeal [71] and the Supreme Court[72] upheld the NCA's decision in its entirety.

Other examples of interventions against collusive behaviour include decisions by the Hungarian NCA in 2015 (bid rigging in hospital tenders)[73], the Slovenian NCA in 2013 (bid rigging, price fixing between wholesalers and distributors, market sharing and exchange of information related to prices and sale)[74], the Danish NCA in 2014 (coordination between wholesalers of fees and other trading conditions)[75], and the German NCA in 2017 (exchange of sensitive information between wholesalers via a common IT system)[76]. In 2015 the Italian NCA adopted a commitment decision requiring Novartis and Italfarmaco to adjust their market behaviour and make amendments to their co-marketing agreement[77]. The binding commitments alleviated the NCA's concerns regarding the exchange of sensitive information and cooperation in tendering in regional public procurements.

In a commitment decision in 2011, the Lithuanian NCA addressed possible vertical price coordination in agreements between manufacturers and wholesalers[78]. These agreements included a provision requiring that the wholesalers and manufacturers coordinate retail prices of medicines, thus possibly resulting in prices of medicines being raised for the patients. The accepted commitments provided for such provisions to be deleted.

4.3.2. Making it more difficult for rivals to compete

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.

For example, in 2013, the Cypriot NCA found that the distributor Phadisco and Wyeth Hellas (subsequently acquired by Pfizer Hellas) abused their dominant position on the

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69 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.

70 Decision of the Comisión Nacional de los Mercados y la Competencia of 14 April 2009.

71 Decision of the Audiencia Nacional of 6 June 2012.

72 Decision of the Tribunal Supremo of 9 March 2015.

73 Decision of the Gazdasági Versenyhivatal of 14 September 2015.

74 Decision of the Javna agencija Republike Slovenije za varstvo konkurence of 14 October 2013.

75 Decision of the Konkurrence- og Forbrugerstyrelsen of 24 November 2014.

76 Decision of the Bundeskartellamt of 27 April 2017.

77 Decision of the Autorità Garante della Concorrenza e del Mercato of 4 June 2015.

78 Decision of the Konkurencijos tarybą of 21 July 2011.

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market for pneumococcal vaccine by offering discounts to doctors and pharmacists, which hindered competition by their rivals[79].

In 2015, the Italian NCA accepted commitments from ICE – Industria Chimica Emiliana related to the supply of cholic acid (used to produce a drug for liver diseases)[80]. The NCA suspected that ICE was abusing its dominant position by using exclusionary practices including creating obstructions in the supply of bovine bile (the raw substance necessary to produce cholic acid), thus preventing competitors from effectively competing for the benefit of patients and the Italian healthcare system. In order to eliminate these concerns, ICE committed to supplying the market with certain quantities of bovine bile, at prices that allowed other manufacturers to compete.

In 2011, the Romanian NCA adopted three decisions against a number of companies found to be restricting parallel trade in medicines, thus making it more difficult for the distributors from one country (Romania) to compete on the markets in other countries[81]. The mechanisms used by the investigated companies included contract clauses (i) prohibiting or limiting export of medicines, (ii) enabling distributors' compliance with the export prohibition to be monitored and (iii) penalising violations of the prohibition. The aggregate fines imposed by the Romanian NCA in the three cases amounted to RON 59.4 million (approximately EUR 12.75 million). Several other NCAs (e.g. the Spanish and the Greek) have also tackled various issues related to restrictions of parallel trade.

4.4. 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.

4.4.1. 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

[79] Decision of the Επιτροπή Προστασίας Τού Ανταγωνισμού of 12 April 2013.

[80] Decision of the Autorità Garante della Concorrenza e del Mercato of 15 July 2015.

[81] Decisions of the Consiliul Concurentei of 28 October 2011 and Decision of the Consiliul Concurentei of 27 December 2011.

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cheaper generic versions. Generics are normally full substitutes of the originator product and competition takes place mostly on price[82].

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[83].

4.4.2. 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 *Teva/Allergan* case, where the acquisition of Allergan by Teva, the global number one generic company, threatened to largely eliminate competition from its closest rival, in a number of markets.

Box 10: The *Teva/Allergan* case

In March 2016 the Commission found that the merger would soften price competition in a number of markets and cleared the acquisition of the generic business of Allergan Generics by Teva Pharmaceutical Industries only after Teva committed to divest relevant parts of the acquired business to independent buyers.

Before the transaction, Teva was already the largest global generic manufacturer and Allergan was the fourth largest generics manufacturer worldwide. The transaction concerned hundreds of generic medicines marketed and in development, and was unprecedented in the pharmaceutical sector both in its size and the number of markets where the companies' generic products competed.

The Commission's market investigation 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) and that for a number of products, competition would have been curbed by the merger. Therefore, the Commission identified potential competition concerns for a large number of medicines all over the EU.

Also, looking at the overall market position of the parties that supply generic medicines at national level, the Commission concluded that in some Member States, the parties were among the largest generic players as well as each other's closest competitors. Therefore, the Commission assessed the possible impact of the merger on prices not only for specific products but also at the level of the parties' whole portfolio of generic medicines.

For example, in the United Kingdom, where prices of generics are set freely, Teva and Allergan were the only generic players capable of selling their portfolio of medicines directly (without intermediaries) to pharmacies through loyalty schemes. All the other players had to go through wholesalers. Because of this specific market feature, the Commission concluded that Teva and Allergan exerted a unique pricing competitive pressure on each other in their relationships with pharmacies. This competitive pressure would have been eliminated by the merger and the elimination of pricing competition would have had a knock-on effect on prices to consumers.

To address the Commission's concerns, including the risk of price increases, the companies offered remedies. Specifically, they committed to selling the bulk of Allergan Generics' generics business in Ireland and the United Kingdom including a manufacturing plant and the full sales organisation, to a suitable independent buyer.

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82 The Commission refers to the homogeneous nature of generic in a number of decisions, for example in M.6613 - WATSON/ACTAVIS.

83 These are the so-called 'non-coordinated or unilateral effects' on price.

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The Commission's role in a merger approved with commitments (conditional clearance) 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.).

Although one of the largest mergers on record in the pharmaceutical sector, the Teva/Allergan is only one of several transactions where, thanks to the Commission's investigation, concerns over possible price increases were identified and addressed through proposed divestitures to prevent concentration that could lead to adverse price effects. The Commission intervened in mergers between originator and generic companies (e.g. Sanofi/Zentiva, Teva/Cephalon), between generic companies (Teva/Ratiopharm, Teva/Barr, Mylan/Abbott EPD-DM), and between originators (GSK/Novartis regarding human vaccines).

4.4.3. Merger control also helps to preserve price pressure from biosimilars

Preserving price competition is not only the focal point in the Commission's review of mergers involving synthetic medicines but also in review of mergers involving biological medicines[84]. Biological medicines are among the most expensive therapies and their uptake is steadily increasing, with global annual sales worth billions of euros. With every additional biosimilar entry price competition is strengthened and prices are further reduced. Therefore, competition from biosimilars can generate large savings in our healthcare systems, while enabling more patients to benefit from cheaper biological therapies. The Commission's intervention in Pfizer's acquisition of Hospira clearly highlights this point.

Box 11: The *Pfizer/Hospira* case

In 2015, the Commission cleared Pfizer's acquisition of Hospira subject to receiving remedies which ensured that price competition between biosimilars was not compromised, as the proposed merger would have brought two competing *infliximab* biosimilars under Pfizer's ownership (Hospira's *Inflectra* and Pfizer's pipeline biosimilar)[85].

Infliximab is an anti-tumour necrosis factor agent used to treat autoimmune diseases (such as rheumatoid arthritis). Its original version, Remicade, was developed by Johnson & Johnson and marketed by Merck Sharp & Dohme in Europe. Before the merger, only one infliximab biosimilar had been launched and was co-marketed independently by Celltrion (which developed the biosimilar and marketed it as 'Remsima') and by Hospira (brand name 'Inflectra').

Hospira's Inflectra and Celltrion's Remsima were the same medicine and, as a result, were known to doctors and purchasers to be perfectly interchangeable. Consequently, they competed on price only. However, due to the resistance to switching stable patients that receive Remicade treatment to the biosimilar copies, infliximab biosimilars were only a limited source of competitive pressure to the original medicine Remicade.

84 See Box 5.

85 Commission Decision in case M.7559 Pfizer/Hospira.

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The transaction would have brought Hospira's Inflectra into Pfizer's product portfolio in addition to Pfizer's own pipeline *infliximab*, yet to be put on the market. This was likely to reduce incentives for Pfizer's to compete under two alternative scenarios. Under the first scenario, Pfizer would delay or discontinue the development of its own biosimilar drug and focus on the acquired Hospira's product. Apart from the impact on innovation[86], this would soften future price competition between biosimilars, as new entrants have to price aggressively to gain market share from established suppliers. Under the second scenario, Pfizer would prioritise the development of its own biosimilar and repatriate Hospira's product to Celltrion, removing existing intense price competition between Hospira' Inflectra and Celltrion's Remsima, which had led to the significant price decrease compared to the original product, Remicade.

To prevent such effects and ensure that a sufficient number of biosimilars would enter the market and exert price pressure on the expensive reference biological product, the companies proposed that Pfizer's *infliximab* pipeline development be divested to a suitable buyer. This was accepted by the Commission. In February 2016, Novartis announced that it had acquired the divestment business.

[86] Effects on innovation are discussed in more detail in Chapter 5.

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5. 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.

5.1. Antitrust enforcement fosters innovation and choice

This Section 5.1 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 5.2 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[87].

5.1.1. 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.

For example, in 2011 the Commission was able to close an antitrust investigation into allegations that the German pharmaceutical company Boehringer Ingelheim had filed for unmeritorious patents regarding new treatments for chronic obstructive pulmonary disease (COPD). The Commission's investigation concerned Boehringer's alleged misuse of the patent system in relation to combinations of three broad categories of active substances treating COPD with a new active substance that had been discovered by the Spanish pharmaceutical company Almirall. Almirall had raised concerns that Boehringer's patent applications would have the potential to block or considerably delay the market entry of Almirall's competing medicines.

[87] 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.

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In 2011 the companies concluded a settlement agreement that addressed the Commission's concerns by removing the alleged blocking positions and, as a result, removed the obstacles to the launch of competing products by Almirall (complainant in the case), so that the Commission no longer had to pursue the case.

Also, as recognised by the General Court in *AstraZeneca,* restrictions of generic entry reduce the incentives for pharmaceutical companies to engage in innovation, since generic entry serves to effectively enforce the end to their market exclusivity. In this context, enforcement activities focused on removing obstacles to generic entry directly contribute to innovation in the pharmaceutical sector.

Where an incumbent company can rely on exclusivity for its legacy product longer than it is entitled to under the applicable legal regime, this can affect its incentives to take risks to innovate.

In the *Servier* case mentioned above[88], Servier engaged in a strategy to delay generic entry for its blockbuster medicine perindopril (Coversyl), mainly by removing a number of competitors that were close to launching a generic version of perindopril. Generic delay not only allowed Servier extra time to reap large profits from Coversyl (which Servier dubbed as its '*dairy cow product*'), but also to switch its patient base to the follow-on product Bio-Coversyl, which had no clinical advantages over the old product. When a secondary patent, which was the cornerstone of Servier's anti-generic strategy, and which Servier sought to protect with illegal pay-for-delay agreements and a technology acquisition, was ultimately annulled, Servier commented: '*4 years gained – great success*', referring to the time period since the basic, compound patent for perindopril had expired[89].

Antitrust enforcement may also improve patient choice by protecting their access to available treatments. For example, in April 2012 the Portuguese NCA found that Roche Farmacêutica Química ('Roche') was abusing its dominant position by offering multiproduct rebates in hospital tenders and fined the company EUR 900,000[90]. Roche made the discounts conditional on tied purchases of other medicines, thus leveraging its dominant position for some of the tendered products to exclude competitors of the other products. For example, the discount scheme favoured sales of Roche's biological medicine NeoRecormon (epoetin beta used to treat anaemia) to the detriment of the competing product Aranesp(R) marketed by Amgen (complainant in this case). The NCA established that Roche's anti-competitive rebate scheme prevented competitors from successfully participating in hospital tenders and therefore impaired their ability and incentives to enter the market and expand. This was likely to ultimately affect the choice of medicines available to hospital doctors and patients. This decision was not appealed.

The decision of the Italian NCA in the *Hoffmann La Roche* case already mentioned [91] also promoted patient choice as it safeguarded their access to Avastin, (oncological medicine) used to treat a specific eye disease (AMD). As recently clarified by the Court

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88 Commission Decision of 9 July 2014 in case No COMP/AT.39612 – *Servier*. See Section 4.1.1.

89 Commission Decision of 9 July 2014 in case No COMP/AT.39612 – *Servier*, paragraphs 225, 2768, and 2984.

90 Decision of the Autoridade da Concorrência of 12 April 2012.

91 Decision of the Autorità Garante della Concorrenza e del Mercato of 27 February 2014. See also Section 4.3.1.

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of Justice, such off-label use of medicines (i.e. use for treatments different from those for which it received a marketing authorisation under the responsibility of a prescribing doctor) is not in principle contrary to EU law[92].

5.1.2. 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. For example, the EU Block Exemption Regulation on R&D agreements[93] provides a broad safe harbour from competition law enforcement for R&D agreements between competitors (provided that certain conditions related to market shares of the companies are met and the agreement does not contain certain hard-core restrictions of competition). The block exemption regulation is further explained by the accompanying Horizontal Co-operation Guidelines.[94]

5.2. 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.

5.2.1. How can mergers harm innovation in the pharmaceutical sector?

Consolidation in an industry may 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.

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

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92 Judgment of the Court of Justice of the European Union of 23 January 2018.

93 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).

94 Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (OJ C11, 14.1.2011, p. 1).

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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. When the Commission encounters such scenarios, it expresses concerns about the transaction to the merging parties, and if there are no suitable remedies, it can block the transaction.

5.2.2. How can merger control preserve conditions for innovation?

Merger control seeks to ensure that the transaction does not significantly impede competition, including on innovation[95], 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.

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. A good example is the *Novartis/GlaxoSmithKline Oncology* merger where the Commission was concerned that the merger would negatively impact the incentives for the acquiring company to continue R&D of life-saving cancer drugs.

Box 12: The *Novartis/GSK Oncology* case

In 2015, the Commission found that the merger threatened the development of certain pipeline medicines for treating cancer but cleared it in view of the commitment to divest certain businesses and thereby exclude them from the merger.

Through the transaction, Novartis would, among other things, have acquired two oncology products from GSK, marketed for the treatment of skin cancer, and being researched for the treatment of ovarian and other cancers. The two drugs competed directly with Novartis' own pipeline development projects, resulting in duplicate clinical programmes. The Commission was concerned that Novartis would, for each of the two overlapping products, discontinue one of the parallel R&D programmes, as these would have been lengthy and costly. In its assessment, the Commission took into account the expected benefits of these two innovative drugs under

[95] 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.

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development for patients and the healthcare systems in the treatment of several types of cancers for which the drugs were tested.

To restore the conditions needed for continued innovation concerning these pipeline projects, Novartis offered remedies: it would return one of the drugs to its owner and licensor Array BioPharma Inc. (Array) and would divest the other drug to Array. In addition, Novartis committed to finding a suitable partner that could cooperate with Array and step into Novartis' shoes to further develop and commercialise the two drugs in the EEA. The Commission approved Pierre Fabre as a suitable partner of Array.

The Commission continues to monitor the implementation of the commitments, as clinical trials involving the two drugs divested by Novartis are still ongoing. Recent developments in advanced clinical trials have presented encouraging results for each of the two products, which could reach the market in the near future.

Without a remedy, these two drugs would likely have been discontinued. Therefore, it is likely that the remedy has helped to preserve innovation and bring about more competition in the treatment of skin cancer and other tumours. This has resulted in a wider choice of innovative treatments and better care for patients.

In some mergers between originator companies[96], the Commission sought to remove competition concerns related to pharmaceutical pipeline products at an advanced stage of development. In other cases, competition concerns were also identified where the merger would reduce innovation incentives for pipeline products in an earlier development stage, such as in the early phases of clinical trials.

This was for instance the case in the *Novartis/GSK Oncology* decision, where the Commission identified innovation concerns related to pipeline medicines both in early and in advanced development phases. This approach is present also in the *Johnson & Johnson/Actelion* case, where two competing pipeline medicines for insomnia, both of them in the Phase II of clinical trials, raised competition concerns that had to be remedied.

Box 13: The *Johnson & Johnson/Actelion* case

In its decision of June 2017, the Commission considered that one of the two parallel projects to develop new insomnia medicines could be abandoned after the merger, but cleared the acquisition of Actelion by Johnson & Johnson (J&J) thanks to remedies offered by the company.

While the activities of the two companies were largely complementary, they were independently developing innovative medicines to treat insomnia, Actelion on its own and J&J together with its partner Minerva.

Both medicines were based on a novel mechanism of action, called orexin-antagonists, which had already shown the potential for having fewer side effects and a reduced risk of dependency compared to existing insomnia treatments. Since other competing pipeline programmes were scarce, the Commission was concerned that abandoning one of the parallel development projects could harm competition on innovation.

J&J offered remedies to ensure that it would not negatively influence the development of either insomnia research programmes and that the clinical trials for both products would continue. In particular, the remedies consisted of two sets of complementary commitments:

– J&J committed not to influence any of the strategic decisions regarding the development of Actelion's insomnia pipeline. To that end, J&J committed to limiting its investment to a

[96] M.5661 Abbott/Solvay Pharmaceuticals, M.5778 Novartis/Alcon, M.5999 Sanofi-Aventis/Genzyme, etc.

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capped minority shareholding in the company that will be developing this pipeline[97] and further committed not to nominate any board member in this company, and not to receive any information about the insomnia pipeline product.

– Concerning its own pipeline product, J&J granted full control over its global development to its partner Minerva and committed to continuing to finance the project, ensuring that the programme will be developed independently.

The Commission concluded that these remedies were sufficient to eliminate the competition concerns and ensure that patients and the healthcare systems would not be harmed by the transaction through a loss of product variety or from reduced future product competition due to the merger. On this basis, the Commission cleared the transaction.

In the *Pfizer/Hospira* merger case mentioned above[98], the Commission was not only concerned that Pfizer's acquisition of Hospira's competing project involving the development of the biosimilar infliximab would lead to higher prices, but also that eliminating one of the two parallel development projects would be detrimental for innovation and patient choice. While biosimilar drugs have the same therapeutic mechanism and are clinically equivalent to the original biological product, they are not exact copies. Consequently, there is some room for product differentiation and non-price competition between different biosimilars of the same molecule. Thanks to the remedy that involved Pfizer divesting its *infliximab* project to Novartis, the Commission ensured there would be future innovation in biosimilars and that the important development project would not be removed from the competitive landscape.

97 As part of the original merger agreement between J&J and Actelion, Actelion's early stage R&D programmes, including on its insomnia pipeline drug, were to be transferred to a newly created company, in which J&J would have a minority shareholding and to which J&J would provide financing.

98 See Box 11.

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6. CONCLUSION

This overview and the many specific examples of competition cases investigated and decided upon by European competition authorities since 2009, show that enforcing antitrust and merger control rules significantly contributes to ensuring that patients and healthcare systems have access to affordable and innovative medicines and treatments. While the authorities have to prioritise the most important cases, the enforcement cases mentioned clearly demonstrate their readiness to take on investigations.

The Commission's 2009 comprehensive inquiry into obstacles hindering the proper functioning of competition in the pharmaceuticals sector prepared the ground for a series of enforcement actions by European competition authorities. Since then, European competition authorities not only stepped up their enforcement activity in terms of numbers. They also took action, in the interest of patients and healthcare systems, against anti-competitive practices that, until then, had not yet been addressed in competition decisions. These decisions (and subsequent court judgments) provide valuable guidance to market participants and deter future infringements.

European competition authorities are committed to effectively intervening against anti-competitive behaviour by companies and preventing harmful mergers. Despite its significant contributions to improve competition in pricing and innovation by guidance and deterrence through precedents, competition law enforcement remains complementary to legislative and regulatory action.

The past enforcement record provides a solid basis for competition authorities to build on and continue their commitment to rigorously enforce competition law in the pharmaceutical sector in the future. Authorities must remain vigilant and pro-active in investigating potentially anti-competitive situations, including where new practices used by companies or new trends in the industry are concerned, such as the growing relevance of biosimilars. Ensuring that effective competition law enforcement helps patients and healthcare systems to access affordable and innovative medicines is a priority for the Commission.

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