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Competition in the Healthcare Sector – Contribution from the European Union

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This contribution is submitted by the European Union under Session II of the Global Forum on Competition to be held to be held on 1-2 December 2025.

More documentation related to this discussion can be found at: oe.cd/chthc.

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1. The healthcare sector in Europe: defining features and challenges

1. Being healthy matters a lot not only to people at individual level, but also to our societies. Access to innovative, safe, efficacious and affordable medicines and health care thus plays a crucial role at Member States' and Union levels.[1] The societal and economic importance of the pharmaceutical sector and the healthcare sector in general became even more apparent during the Covid-19 crisis. The European healthcare sector is marked by several defining challenges and characteristics that shape its current landscape and future priorities.

2. **Chief among these is the continent's aging population, which continues to place mounting pressure on national healthcare systems.** As life expectancy increases, so too does the prevalence of chronic conditions and long-term care needs. Recent OECD data from the Patient-Reported Indicator Surveys (*PaRIS*) show that over 80% of people in OECD countries aged 45 and older who had a primary care consultation in the previous six months have at least one chronic condition, more than 50% have two or more, and more than 25% have three or more.[2] At the same time, Europe's population is ageing: life expectancy in the EU is above 81 years and the proportion of people over age 65 in the EU projected to rise from 21% in 2023 to 29% by 2050, due to rising life expectancy and declining fertility rates. Life expectancy at age 65 now exceeds 20 years, but more than half of these years are impaired by chronic illnesses and disabilities.[3] These demographic shifts are contributing to rising healthcare expenditure. General government expenditure in the EU on health amounted to €1,251 billion or 7.3% of GDP in 2023, increasing from 5.9% in 1995.[4] Government expenditure on medical products, appliances and equipment together amounted to 1.1% of EU GDP in 2023.[5]

3. Despite remarkable scientific progress, significant unmet medical needs remain, particularly in the field of rare diseases and conditions for which no effective treatment currently exists. Despite widespread recognition of the importance of addressing rare diseases, significant challenges persist in their diagnosis, care, and treatment. Diagnostic difficulties are compounded by ongoing gaps in research and knowledge, as well as by the

[1] The terms "Union" and "European Union" (or "EU") are synonymous. The term "Member State(s)" refers to one or more of the 27 member states of the European Union.

[2] OECD (2025), Does Healthcare Deliver?: Results from the Patient-Reported Indicator Surveys (PaRIS), OECD Publishing, Paris, available at https://doi.org/10.1787/c8af05a5-en (last accessed on 27 October 2025).

[3] OECD/European Commission (2024), Health at a Glance: Europe 2024: State of Health in the EU Cycle, OECD Publishing, Paris, available at https://www.oecd.org/en/publications/health-at-a-glance-europe-2024_b3704e14-en.html (last accessed on 27 October 2025).

[4] Eurostat (2025), Government expenditure on health, 21 March 2025, available at https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Government_expenditure_on_health (last access on 27 October 2025).

[5] Idem.

challenges associated with the codification and classification of rare diseases. Even when a diagnosis is achieved, access to appropriate care and treatment continues to vary considerably across EU Member States. The development of effective therapies for rare diseases is hindered by market failures that require targeted intervention and incentives. Substantial obstacles remain in the clinical development process, including evidence generation and the demonstration of efficacy and effectiveness, even when research and development ("R&D") activities are supported. Moreover, when treatments for rare diseases – so-called 'orphan medicines' – successfully progress from R&D to market authorisation, they are often characterised by high prices and limited competition, which further restricts patient access. This situation is largely driven by the small size of patient populations, which reduces the commercial attractiveness of developing treatments for these conditions. The pharmaceutical industry often perceives an unfavourable balance between the high costs of R&D and the limited potential for revenue generation due to low case numbers. From the perspective of health systems, providing access to orphan medicines poses a significant challenge.[6] This paradox underscores the complexity of modern healthcare in Europe: scientific capability has never been higher, yet equitable access to affordable and effective care is increasingly at risk.

4. The Covid-19 pandemic was a global tragedy, with close to 6.8 million deaths reported as of January 2023. **The pandemic has also exposed the tragic failure of the global supply chain in the healthcare sector: health systems were underprepared, understaffed and underinvested**. Building the resilience of health systems has never been more urgent, as new crises beyond a further pandemic could severely test the global community: antimicrobial resistance; armed conflict; climate change; financial crisis; biological, chemical, cyber, and nuclear threats; environmental disasters; and social unrest.[7]

5. **Economically, healthcare represents one of the largest and most vital sectors in Europe**. It contributes significantly to the EU's GDP (10.4% of the GDP in the EU in 2022[8]) and employment, with millions of jobs tied directly or indirectly to pharmaceutical companies, medical devices, biotech firms, and health services. The sector is a key driver of innovation, accounting for a substantial share of R&D investment (the pharmaceutical industry alone invested €55 billion in R&D in Europe in 2024[9]).

6. **Broader macroeconomic and technological trends may have an impact on healthcare markets**. Digitalisation, including the rapid adoption of artificial intelligence (AI), is reshaping how care is delivered, managed, and monitored. From AI-assisted

[6] European Parliament (2024), Tackling rare diseases – Challenges, opportunities and gaps for action on rare diseases in the European Union, Study/In-depth analysis requested by the SANT Subcommittee and provided by the Policy Department for Economic, Scientific and Quality of Life Policies Directorate-General for Internal Policies, June 2024, available at https://www.europarl.europa.eu/RegData/etudes/STUD/2024/754210/IPOL_STU(2024)754210_EN.pdf (last accessed on 27 October 2025).

7 OECD (2023), Ready for the Next Crisis? Investing in Health system Resilience, OECD Health Policy Studies, OECD Publishing, Paris, 2023, available at https://doi.org/10.1787/1e53cf80-en (last accessed on 27 October 2025).

[8] OECD/European Commission (2024), Health at a Glance: Europe 2024: State of Health in the EU Cycle, OECD Publishing, Paris, available at https://doi.org/10.1787/b3704e14-en (last accessed on 27 October 2025), Figure 5.3.

[9] EPFIA (2025), The Pharmaceutical Industry in Figures, Key Data 2025, 3 July 2025, available at https://www.efpia.eu/media/uj0popel/the-pharmaceutical-industry-in-figures-2025.pdf (last accessed on 27 October 2025).

diagnostics to wearable technologies – such as those developed following the Google-Fitbit merger – data-driven approaches are becoming increasingly central to both preventive and personalised healthcare.[10] Healthcare systems also increasingly become targets of cyber and ransomware attacks.[11] At the same time, signs of structural changes in the market have been emerging, with growing consolidation across certain segments of the healthcare sector.

7. **Recent geopolitical developments also demonstrate the strategic importance of supporting European industrial competitiveness, particularly in biotechnology and advanced therapies, as highlighted in the 2024 Draghi Report on European competitiveness**.[12] The report underlines, in particular, the strategic importance of the pharmaceutical sector for the EU, noting its strong scientific base and manufacturing capacity in the on-patent space, but also its underperformance in high-growth areas such as biologics, orphan medicines, and advanced therapies. To close this gap, the EC presented in January 2025 the 'Competitiveness Compass', a new roadmap to restore Europe's dynamism and boost economic growth. For example, in order to close the innovation gap, the compass proposes supporting the development of new technologies, with action plans for a European Biotech Act, Bioeconomy Strategy and Life Sciences Strategy.[13]

8. **The institutional and regulatory landscape of European healthcare creates a layer of complexity.** Healthcare policy remains largely a national competence under EU law, resulting in a patchwork of regulatory regimes, pricing systems, reimbursement frameworks, and access conditions across Member States. This fragmentation creates challenges for cross-border cooperation and consistent market access but also offers opportunities for tailored national approaches to healthcare delivery. At the EU level, institutions such as the European Medicines Agency ("**EMA**") play a crucial role in ensuring harmonised standards for the approval of new medicines, even as national authorities retain control over pricing and reimbursement decisions.

[10] For further information on the topic of digital health, please see the OECD's work on https://www.oecd.org/en/topics/digital-health.html#key-messages (last accessed on 27 October 2025). Not only is the private sector subject to digital transformation, but EU Member States are also taking steps to digitise their healthcare systems.

[11] In January 2025, the EC launched a comprehensive action plan to improve the cybersecurity of hospitals and healthcare providers across the EU. For more information, see https://health.ec.europa.eu/ehealth-digital-health-and-care/digital-health-and-care/european-action-plan-cybersecurity-hospitals-and-healthcare-providers_en (last accessed on 27 October 2025).

[12] Mario Draghi (2024), *The Future of European Competitiveness*, September 2024, available at https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en (last accessed on 27 October 2025).

[13] European Commission (2025), *Competitiveness compass*, available at https://commission.europa.eu/topics/eu-competitiveness/competitiveness-compass_en (last accessed on 27 October 2025). See also European Commission (2025), *Commission work programme 2026*, available at https://commission.europa.eu/strategy-and-policy/strategy-documents/commission-work-programme/ commission-work-programme-2026_en (last accessed on 27 October 2025).

9. As outlined in this submission, EU competition enforcement serves as a key instrument in advancing the European healthcare sector to be affordable, innovative, secure, and globally competitive.

2. Recent initiatives and well-established recipes to address healthcare challenges relating to affordability, innovation and supply

2.1. Some recent regulatory initiatives by the EC

10. In the EU, a number of regulatory initiatives have been taken by the EC to address some of the challenges that the European healthcare sector is facing.

11. On 26 April 2023, the European Commission ("**EC**") adopted a pharmaceutical package proposing to the Council of the European Union and the European Parliament to revise the EU's pharmaceutical legislation, based on preparatory work in the period since the adoption of the Pharmaceutical Strategy for Europe in 2020.[14] This proposed revision of the pharmaceutical legislation aims at making medicines more accessible (in all Member States), available (to address risks of shortages), and affordable (to national health systems and patients), while supporting competitiveness of the EU pharmaceutical industry, combatting antimicrobial resistance, and ensuring higher environmental standards of medicines.

12. Recent geopolitical developments have also sharpened Europe's focus on healthcare security and resilience. As mentioned, the Covid-19 pandemic exposed vulnerabilities in Europe's ability to supply critical medicines and medical equipment, and more recent data from the European Court of Auditors shows that between January 2022 and October 2024 there were 136 critical medicine shortages reported to the EMA.[15] In March 2025 alone, 34 medicines were reported in shortage, including 16 from the EU's list of essential medicines.[16]

13. To address this, the EC proposed in March 2025 the adoption of a Critical Medicines Act ("**CMA**"). The general objective of CMA is to strengthen the security of supply and the availability of critical medicines within the EU, thereby ensuring a high level of public health protection and supporting the security of the European Union, and to improve the availability and accessibility of other specific medicines, where the functioning of the market does not otherwise sufficiently ensure their availability and accessibility to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.[17] These policy priorities underscore that healthcare initiatives in

[14] European Commission, *A pharmaceutical strategy for Europe*, 2023, available at https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en (last accessed on 27 October 2025).

[15] European Court of Auditors (2025), *Special report 19/2025: Critical shortages of medicines – EU measures were of added value, but structural problems remain*, 19 September 2025, available at https://www.eca.europa.eu/en/publications/SR-2025-19 (last accessed on 27 October 2025).

[16] Euronews (2025), *EU medicine shortages at record levels, auditors report*, 17 September 2025, available at https://www.euronews.com/health/2025/09/17/eu-medicine-shortages-at-record-levels-auditors-report (last accessed on 27 October 2025).

[17] Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795, COM(2025) 102 final, 11 March 2025, available at

Europe are not only about innovation and affordability but also about stable and resilient supply.

2.2. Competition enforcement as a well-established and proven recipe

14. In addition to the EC's recent regulatory initiatives to confront some of the healthcare challenges faced, competition law continues to serve as a longstanding tool for addressing the market conduct of undertakings. While competition law enforcement has never been absent from the healthcare agenda, the recent challenges facing Europe have underscored its importance in the sector. The enforcement of competition law rules by the EC and the national competition authorities ("**NCAs**") has played a pivotal role in the healthcare sector, in particular with regards to pharmaceuticals, for more than two decades by contributing to the affordability and accessibility of medicines, while fostering innovation. Rather than replacing or interfering 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 fulfils a complementary function to the various regulatory systems.

15. Competition between firms refers to the "*process of rivalry in which firms strive to win customers by making offers intended to be more attractive than those of their competitors. If this process of interaction between firms is effective, it obliges firms to lower their prices, improve the quality and variety of their products, lower their costs, to become more productive, and come up with more innovative products. Over time, effective competition will also (i) reward better performing firms with higher market or industry shares (until they are replaced by even better performing firms) and (ii) force inefficient firms to shrink or even exit the market. The latter two effects are often referred to as the 'reallocation' or 'selection' effect of competition. If the competitive process works well across an entire economy, it is a fundamental driver of overall investments, innovation, productivity growth, business dynamism and employment. Competition is therefore not just beneficial to customers, but one of the essential drivers of long-term growth and the improvement of living-standards of citizens*".[18]

16. Hence, competition law enforcement ensures effective competition on the market, which spurs innovation, increases the quality and choice of products, ensures an efficient allocation of resources, reduces the costs of production, and thereby contributes to consumer welfare.[19] Competition law and policy enforcement aim at preserving these benefits of competition including in the healthcare and pharmaceutical sectors.

17. Indeed, both antitrust and merger (or concentration) control rules have been enforced to ensure that undertakings active in the sector do not resort to practices that undermine the proper functioning of competition and the benefits it delivers to patients and

https://health.ec.europa.eu/ publications/proposal-critical-medicines-act_en (last accessed on 27 October 2025).

[18] European Commission (2024), *Protecting competition in a changing world – Evidence on the evolution of competition in the EU during the past 25 years*, 2024, available at https://competition-policy.ec.europa.eu/system/files/2024-06/KD0924494enn_Protecting_competition_in_a_changing_ world_staff_report_2024.pdf (last accessed on 27 October 2025).

[19] See for instance European Commission (2023), *Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements*, OJ 21.7.2013 C259/1-125, paragraph 518. These guidelines are hereafter referred to as the "**EC horizontal cooperation guidelines**".

consumers, such as fair pricing, higher quality, reliable supply, and continued innovation. In parallel, EU state aid rules provide an important safeguard by ensuring that public subsidies or support to healthcare providers or pharmaceutical companies do not unnecessarily distort competition, unless such measures are justified by overriding public interest objectives.

18. Specifically with regard to antitrust enforcement in the healthcare sector, notable reference is to be made to the findings of the 2009 sector inquiry ("**2009 Sector Inquiry**") which contributed significantly to the debate on EU competition policy for pharmaceuticals, in particular for generic medicines.[20] The report was instrumental in raising awareness of the possible anti-competitive tactics used by companies, and may also have contributed to a more energised enforcement by the NCAs. The enquiry concluded in essence that innovator companies frequently employ a range of strategies aimed at protecting their successful products, by prolonging their market exclusivity and/or by deterring innovation by competitors. Where such practices distort the competitive process by resorting to improper protection of incumbent revenues and price levels, they can impose significant costs on national healthcare budgets and hinder patient access to safe, innovative, and affordable medicines across Europe.

19. A central finding of the 2009 Sector Inquiry was the reliance of originator companies on revenues generated by their best-selling products, which they seek to preserve for as long as possible. To achieve this, companies deploy a 'toolbox of strategies', often in combination, designed to discourage, delay, or even prevent generic entry into the market. These strategies include: (i) strategic patenting; (ii) patent litigation; (iii) patent settlements, including reverse-payment agreements; (iv) interventions in national authorities' decisions on marketing authorisation, pricing, and reimbursement; (v) life-cycle management strategies for follow-on products, such as secondary patents and divisional applications; and (vi) negative information campaigns aimed at dissuading patients and healthcare providers from using generic medicines. In the context of originator-to-originator competition, the report identified additional tactics, notably: (i) defensive patenting strategies primarily intended to exclude competitors without advancing genuine innovation; and (ii) patent litigation and settlement agreements that restrict market entry of rival products.

20. Unlike what is typically the case when scrutinising a merger, antitrust investigations are generally complex, require considerable resources, and are very evidence-intensive. European competition authorities (both the EC and the NCAs) therefore concentrate on the most significant cases – those with the potential to shape industry practices and deter similar anti-competitive conduct in the future. This strategic focus ensures that enforcement delivers impact beyond the individual cases investigated, fostering greater compliance and improving competition across pharmaceutical markets as a whole. In recent years, several landmark decisions by the EC and the NCAs have established important precedents, clarifying how EU competition law applies to novel issues in the sector. These cases, often based on comprehensive market inquiries, have

[20] European Commission (2009), *Pharmaceutical Sector Inquiry Report*, 8 July 2009, available on https://competition-policy.ec.europa.eu/sectors/pharmaceuticals-health-services/pharmaceutical-sector-inquiry_en (last accessed on 27 October 2025).

provided both corrective outcomes and valuable guidance for market participants on lawful and unlawful conduct.

21. As final remark, it should be also emphasised that sensible competition enforcement in the healthcare sector must always duly take account for the sector's inherent interdependence between the regulatory framework – governing the authorisation of healthcare products and granting related exclusivities to marketing authorisation holders – and intellectual property ("**IP**") rights enjoyed by originator companies for their inventions. This interaction means that originator companies may benefit from both (i) patent protection,[21] and (ii) regulatory exclusivities,[22] which, depending on their respective durations, timing, and scope, may provide overlapping or sequential protection against copycatting, including from generic manufacturers.

22. Section C below explains how competition enforcement by the EC has helped maintain the affordability of healthcare products and services by safeguarding price competition. Section D, in turn, provides an overview of how the EC has used competition enforcement as a tool to preserve and stimulate innovation by addressing practices – including consolidation efforts – that (strategically) hinder or suppress innovation, for instance in order to allow blockbusters to continue generating monopoly rents. Section E, finally, provides a brief overview of how competition policy has recently been used at EU level to ensure security of supply and access.

3. The role of the EC's competition enforcement in shaping affordable healthcare

3.1. Competition enforcement as a tool to sustain the affordability of healthcare

23. A fundamental indicator of effective competition is the extent to which market prices reflect underlying costs and competitive dynamics. Price competition is essentially based on choice between different closely interchangeable treatments of requisite quality. In the healthcare sector, prices play a particularly pivotal role due to the essential nature of healthcare products and services and their direct influence on individuals' quality of life and involvement of national reimbursement schemes and health insurance bodies that can influence demand through price-control mechanisms. Consequently, healthcare undertakings may be attracted by the prospect of generating supra-competitive returns that

[21] As an IP right, a patent confers on its holder the exclusive right to exploit the protected invention and a right to prevent third parties from using it, as well as from manufacturing, selling, importing, distributing or stocking the products embodying the invention without the patent holder's consent. In the EU, the full patent term is twenty years from the date of filing a patent application, if the patent is ultimately granted. To account for lengthy testing and trialling of medicinal products before they effectively reach the market and to preserve the incentives to innovate, the patent term of a specific medicinal product in the EU can be extended by a maximum of five years with a supplementary protection certificate ("**SPC**") which in turn can be the subject of a further paediatric extension.

[22] For instance, under the EU regulatory framework applicable to the marketing authorisation ("**MA**") of pharmaceuticals, MA holders can enjoy 8 years of data exclusivity and additional 2 or 3 years of marketing protection. Data exclusivity (or data protection) refers to the period of time during which another applicant cannot rely on the data in support of another marketing authorisation for the purposes of submitting an application, obtaining marketing authorisation or placing the product on the market, i.e. generics, hybrids, biosimilars cannot be validated by EMA. Market protection refers to the period of time during which a generic, hybrid or biosimilar cannot be placed on the market, even if the medicinal product has already received a marketing authorisation.

are not justified by efficiency or innovation considerations, and resort to pricing distortions to that end. Competition enforcement seeks to curb these incentives by scrutinising the situations that create those incentives: different forms of unilateral or cooperative (monopolistic) behaviour (through antitrust enforcement), and consolidation efforts (via merger control scrutiny).

24. Antitrust enforcement has played a significant role in supporting the broader objective of ensuring the affordability of medicines for EU patients and healthcare systems. This has taken shape in the form of targeting practices that hinder or delay the market entry or uptake of medicines – particularly generics and biosimilars – which are essential for stimulating price competition and reducing treatment costs. Antitrust enforcement has also been used in a more straightforward fashion to tackle excessively high prices of healthcare products and services, whether such pricing results from unilateral conduct amounting to abuse of a dominant position (targeted by Article 102 of the Treaty on the Functioning of the European Union ("**TFEU**")) or from coordinated behaviour through anti-competitive agreements between market participants (covered by Article 101 TFEU).[23] A selection of notable EC antitrust enforcement actions is set out in section C.2 below.

25. Similarly, the EC's scrutiny of important, often large transactions has also played an important role in preserving affordability and safeguarding competition across the healthcare sector. The EC's merger control scrutiny in the healthcare sector has focused not only on facilitating and protecting the market entry of generic and biosimilar medicines – often through the imposition of remedies, but also on safeguarding competition more broadly across other healthcare products and services (including medical devices, diagnostics, and digital health solutions) where excessive consolidation poses similar risks of driving up costs for patients and healthcare systems. Broadly speaking, the EC has been looking not only into transactions between originators, but also between originators and generic suppliers, as well as among generics suppliers. It has also closely analysed the markets for the manufacturing of pharmaceutical products notably in the context of acquisitions of contract and development manufacturing organisations (so-called "**CDMOs**").

26. In this context and pursuant to its framework, the EC looks at the interactions between the acquirer and the target at horizontal level (as direct competitors active at the same level of the supply chain) but can also consider vertical relationships as potentially requiring in-depth assessments. The latter would be appropriate, for example, in the case of a pharmaceutical company purchasing development and/or manufacturing capabilities. A selection of notable EC merger enforcement actions is set out in section C.3 below.

3.2. EC antitrust enforcement

27. Over the past two decades, the EC's antitrust enforcement activity has tackled a whole gamut of strategies deployed by undertakings to suppress the impact of genuine price competition that are liable to undermine the affordability of healthcare products and services.

[23] Competition policy provides a framework to address a wider range of anti-competitive practices that can undermine effective price competition. These include refusal to supply, resale price maintenance, bid rigging, market sharing, and the exchange of commercially sensitive information. Each of these practices, whether directly or indirectly, can lead to inflated medicine prices, undermining access to affordable treatments and imposing unnecessary costs on healthcare systems and patients alike.

28. Antitrust enforcement in the healthcare sector has been particularly focussed on practices capable of hindering the entry and expansion of generic rivals. This has been evidenced by the string of 'pay-for-delay' cases (see *Lundbeck, Fentanyl, Servier and Cephalon*) in which pharmaceutical companies were found to have entered into commercial and (IP) settlement agreements that delayed the market entry of cheaper generic medicines. Drawing inspiration from its landmark *AstraZeneca* decision,[24] the EC has also progressively broadened its antitrust scrutiny to include novel theories of harm, such as the dissemination of misleading information to undermine competitors (see *Teva Copaxone*) and the manipulation of regulatory and intellectual property frameworks (a practice often referred to as 'gaming the system') (see *Teva Copaxone*). That said, classical price-fixing cartels (see the *SNBB* cartel) and excessive pricing (see *Aspen*) have never left the EC's radar. This expansive enforcement agenda underscores the EC's commitment to preserving effective competition in a sector characterised by high innovation, regulatory complexity, and significant consumer dependence.

29. Over the last decade and a half, the EC' antitrust enforcement actions have built a fine track record of targeting so-called 'pay-for-delay' agreements. These encompass a variety of arrangements (not necessarily related to IP rights) between originator and generic companies, whereby the generic company agrees to restrict or delay its independent entry onto the market in exchange for significant benefits transferred from the originator. The originator company pays its competitor, the generic company, to stay out of the market for a period of time that may be shorter or longer – whereby even short delays may come at a high cost to the society at large.[25]

[24] A seminal case of competition enforcement in the pharmaceutical sector is the EC's *AstraZeneca* decision of 2005 (EC Decision of 15 June 2005, COMP/A.37.507/F3 – *AstraZeneca*) in which the EC, *inter alia*, found that AstraZeneca had been gaming the regulatory framework (as opposed to *Teva Copaxone* where the findings related only to gaming the patent framework). On 15 June 2005, the EC fined AstraZeneca €60 million for, *inter alia*, misusing regulatory procedures for marketing pharmaceuticals in order to delay market entry of generic drugs bound to compete with its blockbuster Losec (omeprazole), which pioneered a new generation of medicines to treat stomach ulcers and other acid-related diseases. Losec initially received patent protection in Europe in 1979. From 1993 to 2000 AstraZeneca infringed article 102 TFEU by blocking or delaying market access for generic versions of Losec and preventing parallel imports of Losec. AstraZeneca did so, *inter alia*, by submitting requests for deregistration of the MAs for Losec capsules in Denmark, Sweden and Norway, combined with the withdrawal of Losec capsules from the market and the launch of Losec MUPS tablets ('Multiple Unit Pellet System'; a system of tablets with multiple microgranules) in those three countries. According to the EC's decision, those steps were taken in order to ensure that certain regulatory registration routes would not be available to producers of generic omeprazole and they also had the consequence that parallel importers were likely to lose their parallel import licences. The EC took issue with the strategic implementation of the regulatory framework in order to artificially protect from competition products that were no longer protected by a patent and for which the period of data exclusivity had expired. At the time, generic products could only be marketed and parallel importers only obtain import licenses if there was an existing reference market authorisation for the original corresponding product (Losec). The purpose of a market authorisation is the right to sell a medicine and not to exclude competitors. Unlike patents, SPCs and data exclusivity, market authorisations are not intended to reward innovation and the finding of an abuse cannot therefore affect incentives to innovate. Subsequent changes in the applicable EU legislation have made it impossible to repeat this specific conduct. The decision was ultimately upheld by the EU courts (except with regard to Denmark and Norway) – see judgments of 1 July 2010, *AstraZeneca v Commission*, T-321/05, EU:T:2010:266; and of 6 December 2012, *AstraZeneca v Commission*, C-457/10 P, ECU:C:2012:770.

[25] See also European Commission (2024), *Report from the Commission to the Council and the European Parliament – Update on Competition Enforcement in the Pharmaceutical Sector (2018-*

30. ***Lundbeck – pay-for-delay agreements under Article 101 TFEU***. On 19 June 2013, the EC fined the Danish company Lundbeck (€93.8 million) and a number of pharmaceutical companies (€52.2 million) for having operated anti-competitive IP settlement agreements in violation of Article 101 TFEU between 2002 and 2003 where they essentially agreed to delay the market entry of generic versions of Lundbeck's citalopram, an antidepressant.[26] Citalopram's Active Pharmaceuticals Ingredient ("**API**") and production processes were protected under Lundbeck's original patents, valid in several European countries until 2003. Lundbeck subsequently developed and patented new production processes for citalopram. In 2002, Lundbeck concluded settlement agreements with several generic manufacturers – Generics UK (Merck KGaA), Alpharma, Arrow, and Ranbaxy – to resolve potential patent disputes regarding the launch of generic citalopram. Under these agreements, Lundbeck provided substantial payments and other benefits (such as purchasing generic stock for destruction or guaranteeing distribution profits) in exchange for the generics' commitment not to market citalopram within the European Economic Area ("**EEA**") or certain Member States. The EC held that Lundbeck and its generic counterparts were (at the very least) potential competitors and concluded that these agreements constituted restrictions of competition 'by object' within the meaning of Article 101(1) TFEU.[27]

31. On appeal against the General Court of the European Union's ("**GC**") dismissals of the annulment actions against the EC's decision,[28] the Court of Justice of the European Union ("**ECJ**") confirmed the EC's approach towards potential competition and restriction by object.[29]

32. ***Fentanyl – pay-for-delay agreement under Article 101 TFEU***. On 10 December 2013, the EC fined pharmaceutical companies Johnson & Johnson and Novartis (Sandoz) €16 million for operating between 2005 and 2006 a 'co-promotion' agreement, providing for monthly payments from Johnson & Johnson for as long as its close and (at least) potential competitor Novartis abstained from entering the market in the Netherlands with its generic version of Johnson & Johnson's product fentanyl, a strong painkiller.[30] These

2022), 26 January 2024, available at https://op.europa.eu/en/publication-detail/-/publication/8aeb6cf3-bc34-11ee-b164-01aa75ed71a1 (last accessed on 27 October 2025), p. 23 to 25.

[26] EC Decision of 19 June 2013, AT.39226 – *Lundbeck*.

[27] Article 101 TFEU prohibits agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between EU Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market. For an overview of the distinction between restrictions '*by object*' and '*by effect*', please refer to the EC horizontal cooperation guidelines (2023/C 259/01), paragraphs 22 to 33, for an antitrust analysis of horizontal agreements, and to European Commission (2022), Guidelines on vertical restraints (2022/C/ 248/01), for an antitrust analysis of vertical agreements.

[28] Judgments of 8 September 2016, *Lundbeck v Commission*, T-472/13, EU:T:2016:449; *Merck v Commission*, T-470/13, EU:T:2016:452; *Xellia Pharmaceuticals and Alpharma v Commission*, T-471/13, EU:T:2016:460; *Arrow Group and Arrow Generics v Commission*, T-467/13, EU:T:2016:450; *Generics (UK) v Commission*, T-469/13, EU:T:2016:454; *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*, T-460/13, EU:T:2016:453.

[29] Judgments of 25 March 2021, *Lundbeck v Commission*, C-591/16 P, EU:C:2021:243; *Merck v Commission*, C-614/16 P, EU:C:2021:246; *Xellia Pharmaceuticals and Alpharma v Commission*, C-611/16 P, EU:C:2021:245; *Arrow Group and Arrow Generics v Commission*, C-601/16 P, EU:C:2021:244; *Generics (UK) v Commission*, C-588/16 P, EU:C:2021:242; and *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*, C-586/16 P, EU:C:2021:241.

[30] EC Decision of 10 December 2013, AT.39685 – *Fentanyl*. This decision was not appealed.

monthly payments exceeded the profits that Novartis (Sandoz) expected to obtain from selling its generic product, for as long as there was no generic entry in the Netherlands. Consequently, Novartis (Sandoz) did not offer its product on the market. The agreement was stopped in December 2006 when a third party was about to launch a generic fentanyl patch.[31] The agreement therefore 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 taxpayers who finance the Dutch health system. According to internal documents, Novartis (Sandoz) would abstain from entering the market in exchange for "*a part of* [the] *cake*". Instead of competing, Johnson & Johnson and Novartis agreed on cooperation so as "*not to have a depot generic on the market and in that way to keep the high current price*".

33. ***Servier – pay-for-delay and killer acquisition under Articles 101 and 102 TFEU***. On 9 July 2014, the EC fined the French company Servier approx. €330 million, and five producers of generic medicines – namely, Niche/Unichem, Matrix (Mylan), Teva, Krka and Lupin – approx. €97 million, for concluding a series of deals all aimed at protecting Servier's bestselling blood pressure medicine, perindopril, from price competition by generics in the EU.[32] Servier implemented a strategy to exclude competitors and delay the entry of cheaper generic medicines to the detriment of public budgets and patients in breach of EU antitrust rules. This strategy combined a technology acquisition (2004)[33] to remove the most advanced source of alternative technology not covered by Servier's remaining patents (therefore 'killing' the competitive potential of that technology), and a series of patent settlements (2005-2007) with generic rivals who were challenging Servier's patent potentially covering their products.[34] The EC found that Servier's conduct breached both Articles 101 and 102 of TFEU, the latter based on a finding of a narrow relevant market consisting of only perindopril (branded and generic) in four nation-wide geographic markets (UK, France, Poland and Netherlands) where Servier was found to be dominant. Servier was also found to be dominant in the upstream EU market for perindopril API technology.

34. Unlike other pay-for-delay cases (e.g. *Lundbeck* or *Cephalon*) that focused exclusively on applying Article 101 TFEU to agreements between suppliers of a branded pharmaceutical product and prospective generic entrants, the EC's decision in this case also found Servier to have engaged in unilateral conduct falling outside the scope of competition

[31] The agreement included a non-entry mechanism whereby Johnson & Johnson's monthly payments would have ceased if Novartis (Sandoz) or any third party entered the market. Johnson & Johnson did not consider any other existing potential partners for the co-promotion agreement but just focused on its close competitor Novartis (Sandoz). The latter engaged in very limited or no actual co-promotion activities.

[32] EC Decision of 9 July 2014, AT.39612 – *Perindopril (Servier)*.

[33] The acquired API company developed a non-infringing form of perindopril API and was co-developing perindopril with several generics. By virtue of this acquisition, Servier internalised this non-infringing technology. The acquired technology was never put to use by Servier. Evidence showed that it was a part of Servier's 'defence mechanism'. Servier's acquisition foreclosed an important and very scarce source of potential competition. Competition was not removed on the merits of Servier's technology, but by an acquisition eliminating this independent source.

[34] Before settlement, Servier and generic entrants were litigating on the validity and infringement of a Servier patent protecting a crystalline form of perindopril. 5 out of 6 generics companies settled with Servier.

on the merits, and therefore in violation of Article 102 TFEU.[35] The EC's decision was appealed by Servier and the other companies involved to the GC, who dismissed in part the actions brought. While confirming that the agreements concluded by Servier with Niche/Unichem, Matrix (Mylan), Teva and Lupin constituted infringements, the GC annulled the EC's decision as regards, first, abuse of a dominant position by Servier and, second, the agreements concluded by Servier with Krka.[36]

35. On 27 June 2024, the ECJ delivered its judgment in the nine appeals against the judgments of the GC.[37] The ECJ sided almost fully with the original EC decision dismissing the parties' appeals against the parts of the GC judgments upholding the original EC decision with respect to Article 101 TFEU and setting aside the parts of the GC's judgments that found errors in the EC's original decision.[38] The GC now has to rule on Servier's pleas alleging (i) methodological errors in the econometric analysis of the EC in determining the relevant product market (relevant for the application of Article 102 TFEU), and (ii) that the EC decision erred in finding that an agreement whereby Servier also acquired Krka's patented technology was also a part of the by object and by effect restriction of competition.[39]

36. ***Cephalon – pay-for-delay under Article 101 TFEU***. On 26 November 2020, the EC fined Teva and Cephalon €30 million and €30.5 million respectively for agreeing to delay for several years the market entry of a cheaper generic version of Cephalon's drug for sleep disorders, modafinil, after Cephalon's main patents had expired.[40] The infringement lasted, for almost all EU Member States and EEA countries, from December 2005 to October 2011, when Teva acquired Cephalon and they became part of the same group. Modafinil is used to treat excessive daytime sleepiness associated with narcolepsy.

37. Teva held its own patents relating to modafinil's production process, was ready to enter the modafinil market with its own generic version, and it had even

[35] The analysis under Article 101 TFEU was similar to the one developed by the EC in *Lundbeck* (see above).

[36] Judgments of 12 December 2018, *Biogaran v Commission*, T-677/14, EU:T:2018:910; *Servier and Others v Commission*, T-691/14, EU:T:2018:922; *Teva UK and Others v Commission*, T-679/14, EU:T:2018:919; *Mylan Laboratories and Mylan v Commission*, T-682/14, EU:T:2018:907; *Unichem Laboratories v Commission*, T-705/14, EU:T:2018:915; *Niche Generics v Commission*, T-701/14, EU:T:2018:921; *Krka v Commission*, T-684/14, EU:T:2018:918; and *Lupin v Commission*, T-680/14, EU:T:2018:908.

[37] Judgments of 27 June 2024, *Biogaran v Commission*, C-207/19 P, EU:C:2024:553; *Servier and Others v Commission*, C-201/19 P, EU:C:2024:552; *Teva UK and Others*, C-198/19 P, EU:C:2024:551; *Mylan Laboratories and Mylan v Commission*, C-197/19 P, EU:C:2024:550; *Commission v Servier and Others*, C-176/19 P, EU:C:2024:549; *Unichem Laboratories v Commission*, C-166/19 P, EU:C/2024:548; *Niche Generics v Commission*, C-164/19 P, EU:C:2024:547; *Commission v Krka*, C-151/19 P, EU:C:2024:546; and *Lupin v Commission*, C-144/19 P, EU:C:2024:545.

[38] In relation specifically to the infringement relating to the agreement with Lupin, the ECJ found that the GC erred when it confirmed the period to be taken into account for determining the amount of the fine, and thus reduced the fine accordingly.

[39] See cases *Servier and Others v Commission*, T-691/14 RENV; and *Krka v Commission*, T-684/14 RENV.

[40] EC Decision of 26 November 2020, AT.39686 – *Cephalon*.

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

38. On 18 October 2023, the GC fully upheld the decision, accepting the EC's reasoning that the side deals would not have been carried out at all or under the same conditions favourable to Teva had Teva not agreed to the non-compete and no-challenge clauses in the settlement agreement.[41] The GC's judgment was fully upheld on appeal by the ECJ.[42]

39. ***Teva Copaxone – patent gaming and disparagement***. In October 2024, the EC imposed a €462.6 million fine on Teva for having engaged in a single and continuous infringement of Article 102 TFEU consisting of, on the one hand, misuse of the patent system and disparagement of a competitor vis-à-vis healthcare professionals ("**HCPs**"), on the other hand.[43] A leading global producer of generic medicines, Teva long relied on its originator multiple sclerosis drug Copaxone (with glatiramer acetate ("**GA**") as API) for a large share of its profits. As Copaxone's patent exclusivity neared expiry in 2015, Teva in the preceding years had already started seeking ways to preserve its revenues through the Copaxone Continuation Project (CCP), a strategy designed to extend the drug's commercial success beyond patent expiry by hindering the market entry and uptake of GA

[41] Judgment of 18 October 2023, *Teva Pharmaceutical Industries and Cephalon v Commission*, T-74/21, EU:T:2023:651.

[42] Judgment of 23 October 2025, *Teva Pharmaceutical Industries and Cephalon v Commission*, C-2/24 P, EU:C:2025:825.

[43] EC Decision of 31 October 2024, AT.40588 – *Teva Copaxone*. For a more elaborate summary of the case, see CPI Antitrust Chronicle (2025), *Patent Gaming and Disparagement: Commission fines Teva for improperly protecting its blockbuster medicine*, 14 May 2025, https://www.pymnts.com/cpi-posts/patent-gaming-and-disparagement-commission-fines-teva-for-improperly-protecting-its-blockbuster-medicine/ (last accessed on 27 October 2025).

medicines competing with Copaxone in a number of Member States.[44] The decision is currently being challenged before the GC.[45]

40. The first abuse consisted in Teva misusing the European Patent Office's ("**EPO**") patent rules and procedures by engaging in a scheme sometimes referred to as 'divisionals game'. This strategy implies filing so-called 'divisional patents' which are patents derived from an earlier 'parent' patent application and whose subject matter is essentially already contained in the earlier patent.[46] Divisional patent applications were historically tailored to protect distinct inventions within the same disclosure as a means for an applicant to respond to the objections for lack of unity of invention. Teva repeatedly and in a staggered manner filed for such divisional patents and then strategically withdrew the challenged patents before the competent appeal instances could adopt a decision. The EC considered Teva's divisional applications to have no substantive technical justification. Rather, the EC found that Teva had obstructed effectiveness of patent validity challenges which are an important expression of competition between originator and generic companies and thus artificially prolonged the legal uncertainty concerning the validity of its remaining patents, in various EPO proceedings allowing Teva to continue relying on these patents to obtain injunctions before national courts.

41. The second abuse consisted in the systematic disparagement campaign implemented by Teva, which targeted HCPs and casted doubts about the safety and efficacy of a competing GA generic and its therapeutic equivalence with Copaxone. To assess the abusive nature of Teva's communications, the EC considered whether Teva's messages were both objectively misleading (in other words, whether the messages were inaccurate or incomplete and capable of confusing their addressees, including by being capable of inducing them in error) and capable of discrediting the competing product (*i.e.* whether such a statement was capable of creating or spreading a negative perception of that product). The EC found that, even if Teva

[44] Patents covering new API, the biologically active component of a medicinal product, provide the broadest protection. These API patents, referred to also as 'primary', 'basic' or 'compound' patents, apply to any product, which includes the protected active substance, irrespective of its formulation, dosage or application. In addition to API patents, pharmaceutical companies typically apply for patents covering a specific aspect of a medicinal product. These so-called 'secondary' patents may cover, amongst others, production processes, new therapeutic indications, novel forms of the compound (salt forms, enantiomers), dosing regimens, final formulations (tablets, intravenous etc.) combining the API with other ingredients, or providing for different ways of delivering the API (injectable drug, gel or a tablet).

[45] Case *Teva Pharmaceutical Industries and Teva Pharmaceuticals Europe v Commission*, T-19/25.

[46] Although a divisional patent application is filed later than the parent application, it retains the filing date of the original parent application and benefits from the same priority date. Similarly, each divisional application within the patent family will have the filing date of the original parent application and, if granted, will have a term of validity lasting twenty years from the date of the filing of the original parent application. An applicant may file divisional applications not only in relation to a pending parent patent application, but also in relation to another pending divisional patent application. Divisional applications are procedurally independent from their parent application. The procedural independence of divisional grant proceedings also determines that a refusal of the parent application will not have an effect on the content of a divisional application. That said, the procedural independence of divisionals must be distinguished from the interdependence between the validity of the parent patents and their divisionals due to the precedent effect of EPO decisions.

possessed evidence or harboured genuine doubts regarding the safety, efficacy, or therapeutic equivalence of Synthon's GA compared to Copaxone – distinct from those concerns already raised, assessed, and dismissed during the marketing authorisation procedure – it should have pursued the appropriate regulatory channels and contacted the competent authorities, rather than engaging with payers and HPCs.

42. ***SNBB price cartel***. In October 2023, the EC fined a group of pharma companies, that were prepared to admit guilt in a settlement, a total of €13.4 million for participating in a worldwide cartel concerning an important pharmaceutical ingredient, N-Butylbromide Scopolamine/Hyoscine ("**SNBB**").[47] In July 2025, the EC adopted a separate infringement decision and fine (€489,000) against Alchem for participation in the same cartel.[48] It is the first cartel case in the pharmaceuticals market and, in specific, in the API market, including both producers and distributors. It was also a case of diverse parties from a large, European multi-national, represented by three law firms to a small, unrepresented, family-owned company in India.

43. SNBB is an important input material for the production of the drug Buscopan and its generic versions. The conduct of the parties consisted of bilateral and multilateral contacts regarding sales prices and the allocation of quotas on the worldwide merchant market for SNBB. The objective was to coordinate and agree on the level of the minimum sales price of SNBB for customers (*i.e.* distributors and generic drug manufacturers) worldwide and on the allocation of quotas between SNBB producers and exchange of commercially sensitive information. The participants engaged in those types of conduct with the common aim of stabilising the world market price and preventing it from falling. The addressees met physically at so-called 'Club' meetings once or twice per year. Additional exchanges about those topics took place via telephone and emails too.

44. ***Aspen – excessive pricing.*** In 2021, the EC concluded its 2017 excessive pricing investigation in the pharmaceutical sector, by adopting a commitments decision against Aspen, a South African pharmaceutical company, that since 2012 had been progressively increasing the price (often by several hundred percent) of six critical off-patent cancer medicines mainly used in the treatment of leukaemia and other haematological cancers across several Member States where it sold the medicines.[49]

45. Following the framework of analysis set out by the ECJ in the *United Brands* judgement,[50] the EC notably found that Aspen consistently earned very high profits from the sales of these medicines in Europe, when compared to the profit levels of similar companies in the industry, without any justifications (such as reward for significant innovation or commercial risk-taking). The investigation did not reveal

[47] EC Decision of 19 October 2023, AT.40636 – *SNBB*.

[48] EC Decision of 4 July 2025, AT.40636 – *SNBB*, not yet available. A press release can be found on https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1721 (last accessed on 27 October 2025).

[49] EC Decision of 10 February 2021, AT.40394 – *Aspen*.

[50] Judgment of 14 February 1978, *United Brands v Commission*, C-27/76, EU:C:1978:22.

any legitimate reasons for Aspen's very high profit levels. In particular, Aspen's medicines have been off-patent for 50 years, which means that any R&D investment on the medicines has long been recouped. Aspen could achieve these price increases, because patients and doctors had mostly no alternatives to using these particular cancer medicines. When national authorities tried to resist Aspen's requests for price increases, Aspen went as far as threatening to withdraw the medicines from the national list of reimbursable medicines and in some cases was ready to even withdraw from normal supply in the market. Aspen's commitments ensured that: (i) Aspen reduced its prices across Europe for all six cancer medicines by, on average, approximately 73 %; (ii) these new prices are the maximum that Aspen can charge for the coming ten years; and (iii) Aspen guaranteed the supply of these medicines for the next five years, and, for an additional five-year period, would either continue to supply itself or make its marketing authorisation available to other suppliers.

4. EC merger enforcement

46. Mergers between companies can create or increase the market power of the merged entity by eliminating competitive pressure between the merging parties and in turn 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. On the other hand, acquisitions of smaller pharmaceutical companies with limited funds and production capabilities, or vertical integration of a pharmaceutical company with a drug developer or manufacturer (for example CDMOs or CROs) can increase the number of available products on the market, their reach, and roll-out speed. Complementary mergers can also benefit competition as they can create R&D synergies between the portfolio of the acquirer and the target.

47. EU merger control rules mandate the EC to intervene, often via remedies (so-called merger 'commitments'), where the merger is likely to adversely affect competition, and thereby lead, *inter alia*, to higher prices. In recent years, the EC has tackled the risk of elevated pricing deriving from market consolidation in a broad range of healthcare markets.

48. For example, in ***Mylan/Upjohn* (2020)**,[51] the EC investigated horizontal overlaps between two generics manufacturers[52] ultimately raising competition concerns for 12 different molecules aimed at treating a broad range of diseases such as those affecting the nervous system (e.g. anxiety), the urinary tract and the cardiovascular system. Indeed, prior to the merger, Upjohn was in most cases already the leading supplier, and the deal would strengthen its market power, in some cases leading to a near-monopoly with few credible alternatives to put pressure on prices. While the EC's investigation found that no competition concerns arose for the majority of the products supplied by both Mylan and Upjohn, in some countries and for some molecules, the EC found the transaction would raise competition concerns because of the strong position of the two companies and the limited number of significant competitors on the market. To address these concerns, Mylan and Upjohn offered to divest to one or more suitable purchasers, Mylan's business in the

[51] EC Decision of 22 April 2020, M.9517 – *Mylan/Upjohn*.

[52] Mylan is one of the largest suppliers of generic medicines in the EEA and Upjohn was a subsidiary of Pfizer which marketed Pfizer's off-patent branded and generic medicines.

relevant markets, including the applicable marketing authorisations, contracts and brands, as well as transitory manufacturing and supply arrangements.

49. More recently, in ***Cooper/Viatris*** **(2024)**,[53] the EC found that the transaction between two generics suppliers would raise serious doubts as to its compatibility with the internal market with regards to two specific markets, namely the markets for: (i) laxative enemas for infants in Portugal; and (ii) earwax removal products in Germany. In these markets, the merged entity would have held very high market shares, only faced competition from a very limited number of alternative players which was unlikely to increase. The EC also found that post-merger there would not be sufficient potential competitors to exert sufficient competitive pressure on the merged entity. As a result, the transaction would have led to reduced choice for consumers and potentially higher prices. To address the EC's competition concerns, the parties proposed to divest (i) Cooper's rights, title and interests in its infant laxative medicine Bebegel (this includes the right to develop and manufacture Bebegel to sell or/and market it in any form in Portugal and, at the option of the purchaser, in France); and (ii) Cooper's rights, title and interests in its earwax removal product Otowaxol (this included the right to develop and manufacture Otowaxol to sell or/and market it in any form in Germany and, at the option of the purchaser, in Ireland).

5. Beyond price in healthcare markets – fostering innovation and quality

5.1. Competition enforcement as a tool to sustain foster innovation and quality

(1) Innovation covers both innovation in terms of new medicines but also choice between different treatments as well as improvements of other parameters, e.g. quality in terms of efficacy, safety or an improved production process. 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 and healthcare. However, incentives to innovate can be curbed by both anti-competitive practices and mergers. Preservation and stimulation of innovation therefore amounts to a key factor in the EC's enforcement of antitrust and merger rules. A selection of both strands of competition enforcement are provided in Sections D.2 (antitrust) and D.3 (mergers) below.

5.2. EC antitrust enforcement

50. Antitrust enforcement occupies a pivotal position in fostering and safeguarding innovation within healthcare markets. From this perspective, key dimensions of effective antitrust oversight include: (i) preserving a level playing field and preventing the exclusion of innovative drugs and medical devices from market access, and (ii) addressing strategic conduct that may distort innovation pipelines or impede progress in critical therapeutic areas.[54]

51. Innovation-related concerns may arise when originator companies engage in practices that impede the entry or expansion of other (potentially) competing originator products (see *Boehringer Ingelheim* and *Vifor*). Similar concerns can also emerge indirectly

[53] EC Decision of 26 June 2024, M.11383 – *Cooper/Viatris (European OTC Business)*.

[54] Pipeline products or pipelines are in essence products likely to be brought to market in the short or medium term. They also cover services. Pipeline products at early stages of clinical development face higher uncertainty as to their future clinical use than pipeline products at advanced stages of development.

when originator companies employ exclusionary tactics – such as pay-for-delay agreements or patent gaming – to obstruct generic competition, making antitrust intervention worthwhile to preserve innovation incentives in these cases as well.

52. Antitrust scrutiny of practices such as the anticompetitive extension of IP rights protection (for instance patents and SPCs[55]) serves to maintain the delicate balance between the incentive to innovate and the imperative of market contestability by innovative healthcare products and services. In doing so, antitrust enforcement not only prevents the entrenchment of monopoly power but also reinforces the dynamic objectives of the patent system by ensuring that exclusivity remains a reward for genuine innovation rather than a mechanism for its obstruction.

53. ***Boehringer Ingelheim investigation into misuse of patent system***. On 6 July 2011, the EC closed its antitrust investigation into allegations by Spanish pharmaceutical company Almirall that the German pharmaceutical company Boehringer Ingelheim had filed for unmeritous patents regarding new treatments of chronic obstructive pulmonary disease ("**COPD**").[56] Boehringer at the time was the market leader in the treatment of COPD, with its blockbuster drug Spiriva. In 2003, Boehringer filed patent applications for new treatments of CODP. These applications related to combinations of three broad categories of active substances treating COPD with a new active substance that had been discovered by Almirall. Almirall objected to these filings, alleging that the patents were unmeritous, but once granted could nonetheless block or considerably delay the market entry of its own innovative combination medicines. The patent applications allegedly also had a negative impact on Almirall's efforts to bring to market the product based on the active substance discovered by Almirall (so called mono-product).

54. The EC's investigation focussed on whether Boehringer had misused 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 Almirall. In autumn 2010 the EC suggested to Boehringer and Almirall to find a mutually acceptable solution to their patent dispute, within the limits of EU antitrust rules. As Boehringer agreed to remove the alleged blocking positions, all obstacles to the launch of Almirall's products were lifted and the EC no longer needed to pursue the case.

55. ***Vifor possible disparagement of rival innovator***. On 22 July 2024, the EC made commitments offered by Vifor, a leading manufacturer of intravenous iron

[55] In the same decision as referred to in footnote 24 above, the EC found that from 1993 to 2000 AstraZeneca infringed Article 102 TFEU, *inter alia*, by giving misleading information to several national patent offices in the EEA resulting in AstraZeneca gaining extended patent protection for Losec through SPCs (to which it was not entitled or only for a shorter duration). In this specific case, the patent offices essentially relied on information supplied by AstraZeneca and they were not obliged – as in normal patent assessments – to consider whether the products were innovative. AZ's misleading conduct amounted to an abuse in Belgium, Denmark, Germany, the Netherlands, Norway and the United Kingdom.

[56] EC Decision (initiation of proceedings) of 29 March 2007, AT.39246 – *Boehringer*; and EC Decision (closure of proceedings) of 6 July 2011, AT.39246 – *Boehringer*. See also European Commission (2011), *Press release*, 6 July 2011, available at https://ec.europa.eu/commission/presscorner/detail/en_/ip_11_842 (last accessed on 27 October 2025).

treatments, legally binding under EU antitrust rules.[57] The EC was concerned that for many years (since 2010 and ongoing at least until 2022), Vifor may have restricted competition in the market for intravenous iron treatment by disseminating potentially misleading information about the safety of Monofer, an iron deficiency treatment marketed by Pharmacosmos, Vifor's closest competitor in Europe. Iron deficiency is quite common, especially among women and persons suffering from chronic diseases, cancers and blood losses.

56. The EC preliminarily found that Vifor may be dominant in several national markets (Austria, Finland, Germany, Ireland, Portugal, Romania, Spain, Sweden and the Netherlands) for the provision of intravenous iron medicines. Vifor's communication campaign – which raised concerns about the safety of Monofer vis-à-vis HCPs, despite approval by health authorities as effective and safe, and EMA's assessment – may have unduly hindered Monofer's uptake in the EEA. The EC took the preliminary view that while a dominant firm can promote the qualities of its own product, it cannot – through that promotion or other means – disparage a rival pharmaceutical product by creating false (or exaggerated) perceptions about its material characteristics, including its safety and efficacy, when such disparagement is capable of restricting competition.[58]

57. To address the EC's preliminary concerns, Vifor committed, for a period of 10 years, to launch a communication campaign to rectify and undo the effects of the potentially misleading messages previously disseminated by Vifor.[59]

5.3. EC merger enforcement

58. Merger control can play a key role in protecting innovation in the health sector. Preventing the acquisition of excessive market power including through the acquisition of rivals ensures that the incentive to innovate remains. The protection of innovation as a key parameter of competition is enshrined in the EU merger control framework.[60] On the one hand it acknowledges that mergers can lead to an increased ability to bring an innovation to the market. This could be the case for acquisitions of small innovators which do not have the capacity to manufacture their innovation at scale absent support from a larger corporation. On the other hand, there are also instances, where incumbent pharmaceutical companies acquire promising pipeline products followed by the discontinuation of competing pipelines (a constellation that is often referred to as 'killer acquisitions'). Also,

[57] EC Decision of 22 July 2024, AT.40577 – *Vifor (IV iron products)*.

[58] The test applied for anti-competitive disparagement is the same as the one applied in *Teva Copaxone* – see paragraph 41 above.

[59] The decision to accept commitments was based on various case-specific considerations, including the need to stop Vifor's alleged disparagement of Monofer and address its potential long-term anticompetitive effects. A settlement agreement concluded between Vifor and Pharmacosmos to bring to an end a number of other proceedings across Europe was taken into consideration in the EC's decision to explore commitments. While the commitments do not include an obligation to compensate national healthcare systems for financial harm, the decision could be used as evidence in stand-alone actions before national courts, potentially leading to damages claims under national liability rules. In 2025, the UK Competition and Markets Authority accepted similar commitments from Vifor, including a voluntary payment of £23 million to the UK National Health Service.

[60] European Commission (2004), Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ C 31, 5 February 2004 ("**Horizontal merger guidelines**"), recital 38.

a merger between two large innovators can lead to the discontinuation of competing pipelines and the overall lowering of R&D efforts.[61]

59. In the process of its merger guidelines review and in line with the updated Market Definition Notice,[62] the EC is also assessing to what extent its merger control framework should take into account the fostering of innovation in the healthcare sector.

5.3.1. EC approach to the assessment of innovation aspects in horizontal mergers

60. For the assessment of a merger's impact on pipeline and innovation competition, the EC has developed a four-layer approach to its competitive assessment framework.[63] This framework corresponds to type of the overlaps between the parties' activities in terms of (i) actual (product and price) competition, assessing the overlaps between the parties' existing (marketed) products, (ii) potential (product and price) competition, (iii) innovation competition in relation to the parties' ongoing pipeline products, and (iv) innovation competition in relation to the capability to innovate in certain innovation spaces.

61. One layer mentioned above considers potential competition assessing the overlaps between: (i) the parties' existing marketed and pipeline products at advanced stages of development ('*pipeline-to-marketed*'); and (ii) the parties' pipeline products at advanced stages of development ('*pipeline-to-pipeline*').[64] This approach has recently been taken by the EC in the cases of ***AbbVie/Allergan*** (2020) and ***J&J/Tachosil*** (2020) concerning medicines for inflammatory bowel disease and haemostatic patches respectively.

62. In ***AbbVie/Allergan*** (2020), the EC assessed a late-stage pipeline-to-pipeline overlap ultimately finding that brazikumab, a treatment for IBD that Allergan was developing was likely to compete closely with a product AbbVie was developing (risankizumab), as both products had the same mode of action and line of treatment and were in the late stages of development.[65] The EC thus found that AbbVie would be likely to discontinue the development of Allergan's pipeline product post-transaction. The EC's investigation revealed that the merger would likely lead to a loss of innovation for the relevant treatments, as both products were part of a promising class of biologics for which only two other competing pipeline products existed. The transaction would likely have had the effect of lessening innovation by preventing a promising drug from reaching the market. To address these concerns, the EC accepted the parties' proposal to divest Allergan's

[61] For a comprehensive overview to the EC's approach in assessing innovation competition in pharmaceutical mergers, see European Commission (2024), *Competition policy brief – Assessing innovation Competition in Pharma Mergers*, 1 April 2024, available at https://competition-policy.ec.europa.eu/document/download/b0042baf-a258-4c31-b31a-6331cb8d54a2_en?filename=kdak24001enn_competition_policy_brief_non-price_merger-control.pdf (last accessed on 27 October 2025).

[62] European Commission (2024), Notice on the definition of the relevant market for the purposes of Union competition law, C/2024/1645, 22.2.2024. Paragraphs 90-93 of that notice introduce specific guidance regarding the definition of innovation spaces.

[63] This structured framework was first introduced in cases involving the agrochemical sector (EC Decision of 27 March 2017, M.7932 – *Dow/Du Pont*; EC Decision of 21 March 2018, M.8084 – *Bayer/Monsanto*), before being applied to the pharmaceutical sector too (*e.g.* in EC Decision of 29 July 2019, M.9294 – *BMS/Celgene*, paragraph 22).

[64] For pharmaceutical products, the EC in principle considers programmes in Phase II and III clinical trials as being at an advanced stage of development

[65] EC Decision of 10 January 2020, M.9461 – *AbbVie/Allergan*.

brazikumab to a suitable purchaser, removing the overlap in its entirety and safeguarding the development of this pipeline.

63. In ***J&J/Tachosil*** (2020), the EC assessed an overlap between Takeda's marketed dual haemostatic patch 'Tachosil' used by surgeons and doctors to manage bleeding during surgery, and J&J's pipeline products in the space.[66] The EC raised serious doubts regarding the compatibility of the transaction with its merger control rules and subsequently opened an in-depth investigation. Indeed, on a preliminary basis, the EC found that J&J would have strong incentive to enter the market absent the transaction and that conversely, no other credible player would have such incentive. In addition, the EC considered that the market was characterised by high barriers to entry and strong brand loyalty which both further hindered competitor's expansion into the space. J&J ultimately abandoned the transaction[67] and went ahead with the development and commercialisation of its own pipeline products,[68] bringing a welcome competitive challenge to Tachosil's leading position on the market, as the EC had anticipated.

64. Another layer consists of an analysis of innovation competition in relation to the parties' ongoing pipeline products, assessing the risk of significant loss of innovation competition resulting from the discontinuation, delay or redirection of the overlapping pipelines (including early-stage pipelines).

65. In ***AstraZeneca/Alexion Pharmaceuticals*** (2021), the EC conducted a comprehensive competitive analysis of horizontal overlaps between the parties' pipeline drugs for the treatment of lupus nephritis, follicular lymphoma, and peripheral T-cell lymphoma, many of which were in Phase I and early Phase II clinical trials.[69] It concluded that no competition concerns were likely to arise because the parties' pipeline products were expected to be sufficiently differentiated such that effective competition would remain in the market post-transaction.

66. Similarly, in ***Pfizer/Seagen*** (2023), the EC carefully assessed pipeline-to-pipeline overlaps in the oncology field including with respect to early-stage pipelines.[70] Further to this assessment, the EC found that the overlapping pipelines were not likely to compete closely if and when they were marketed as they had different modes of action and targets. Consequently, the merger was cleared unconditionally. While in this case the EC undertook a very thorough analysis of the potential competitive constraints of early-stage pipelines, in most cases, potential competitive constraints exerted by drugs in early clinical stages are only exceptionally assessed. This is because at a very early stage the indication and

[66] EC Decision of 30 March 2020, M.9547 – *Johnson & Johnson/Tachosil.*

[67] Withdrawal of notification (on 8 April 2020) of concentration in M.9547 – *Johnson & Johnson/ Tachosil*, 2020/C, 124/01, 17 April 2020.

[68] See Johnson & Johnson (2023), *Ethicon Introduces ETHIZIATM Hemostatic Sealing Patch, Clinically Proven to Stop Disruptive Bleeding*, 15 November 2023, available at https://www.jnj.com/media-center/press-releases/ethicon-introduces-ethiziatm-hemostatic-sealing-patch-clinically-proven-to-stop-disruptive-bleeding (last accessed on 27 October 2025).

[69] EC Decision of 5 July 2021, M.10165 – *AstraZeneca/Alexion Pharmaceuticals*.

[70] EC Decision of 19 October 2023, M.11177 – *Pfizer/Seagen*.

therapeutic use of the pipeline may still be undetermined, and it may be difficult to predict the competitive interaction between the various drugs.

67. The decisions in ***AstraZeneca/Alexion Pharmaceuticals*** (2021) and ***Pfizer/Seagen*** (2023) nonetheless affirm the importance of analysing innovation competition and simultaneously reveal the underlying difficulties of evaluating early-stage pipelines, as often the exact profiles and prospects of these drugs remain speculative due to their early stage of development and the limited availability of data.

68. The fourth and final layer of the EC's innovation competition assessment takes into account the capability to innovate in certain innovation spaces, assessing the risk of a significant loss of innovation competition resulting from a structural reduction in the overall level of innovation. This framework of assessment has been applied in animal healthcare and pharmaceuticals cases.

69. In ***Elanco Animal Health/Bayer Animal Health Division*** (2020), which concerned pharmaceutical products for pets and livestock, the EC considered whether the transaction could lead to a reduction in competition in certain innovation spaces.[71] The EC found that the transaction would not result in a significant reduction in innovation competition, as the parties were not considered to be particularly strong innovators in the animal health space, especially in comparison to their competitors.

70. In ***AstraZeneca/Alexion Pharmaceuticals*** (2021), the EC considered that the transaction was unlikely to raise competition concerns in this respect because the parties were not active in the same R&D spaces, as Alexion's R&D mainly focused on rare diseases, which were outside the scope of the main drug portfolio of AstraZeneca. In ***Pfizer/Seagen*** (2023), the EC found that the transaction would not lead to a loss of innovation in the field of oncology in general and in antibody drug conjugates (ADCs) in particular, given that a significant number of players engaged in R&D activities would remain in the market.

5.3.2. EC approach to the assessment of innovation aspects in vertical mergers

71. Non-horizontal pharmaceutical mergers may raise competitive concerns from the viewpoint of innovation by creating the ability and incentive for the merged entity to engage in foreclosure strategies that hinder innovation post-transaction. For instance, the vertical link could enable the acquirer to profitably foreclose competitors' access to an important input, thereby reducing their ability to develop a new downstream product.

72. This was the case in ***Illumina/GRAIL*** (2022), in which the EC blocked for innovation-related vertical competition concerns. The EC concluded that the acquisition of GRAIL, a development company that uses Illumina's next generation sequencing ("**NGS**") systems to develop its innovative and promising cancer detection tests, would enable and incentivise Illumina, the unrivalled supplier of NGS systems, to engage in foreclosure strategies against GRAIL's rivals with a consequence of hindering the development and commercialisation of early cancer detection tests to the detriment of competition in the internal market. As Illumina's NGS technology was found to be a "must-have" input on which GRAIL and its rivals depended, the transaction would have allowed

[71] EC Decision of 8 June 2020, M.9554 – *Elanco Animal Health/Bayer Animal Health Division.*

Illumina to cut GRAIL's rivals access to the technology, or to increase prices, degrade quality or delay supplies of its systems. These actions would have allowed GRAIL's product to reach the market first, thereby boosting its competitive position to the detriment of its rivals. Although Illumina would benefit from its anticompetitive behaviour only at a later stage following the commercialisation of GRAIL's cancer detection tests, the EC found that the significant market potential and the ongoing innovation race in the development and commercialisation of early cancer detection tests gave Illumina an incentive to foreclose already at the time of the transaction. In the absence of suitable remedies to ensure that early cancer detection tests with different features and price points would come to the market, the EC prohibited the transaction.[72] The prohibition decision was ultimately withdrawn in light of the ECJ's finding that the EC did not have jurisdiction to investigate the transaction.[73]

73. More recently, the EC conducted a thorough assessment of the acquisition of Catalent by Novo Holdings and Novo Nordisk. In ***Novo Holdings/Novo Nordisk/Catalent*** (2024), the key question was whether the acquisition would limit access to drug manufacturing services, such as those offered by Catalent, of pharmaceutical companies which were competing with NovoNordisk and Novo Holdings notably in the area of metabolic diseases (*e.g.* diabetes, obesity, fatty-liver disease).[74] This would have impacted the access to manufacturing capabilities of small and medium pharmaceutical companies which usually outsource manufacturing of their product both at the clinical and the development stages. Clinical manufacturing restrictions directly affect the development of a pipeline product as they can cause delays in the conduct of clinical trials. Further down the line of product development, commercial manufacturing restrictions can also delay the launch of a product as specific manufacturing capabilities need to be included in submissions to regulatory authorities ahead of commercialisation, and low limited volumes can impact the reach of a commercial launch more generally. Consequently, the takeover was cleared unconditionally.

74. After careful review, however, the EC found that there were a number of credible alternative companies offering drug manufacturing services similar to Catalent. Therefore, while Novo Nordisk and Novo Holding could be found to have the incentive to foreclose their rivals, the effect of such foreclosure would be limited as said rivals would be able to find other manufacturers to develop and manufacture their pipeline.

5.3.3. Ongoing monitoring of transactions and cooperation with Member States

75. In light of the recent challenges[75] to the EC's jurisdiction over transactions where the target revenues do not accurately represent its competitive potential and where said revenues (or lack thereof) fail to meet the relevant thresholds pursuant to the EU Merger

[72] EC Decision of 6 September 2022, M.10188 – *Illumina/GRAIL*.

[73] See EC Decision (withdrawal) of 6 September 2024 – M.10188 – *Illumina / GRAIL* (Article 6(1)(c) decision and prohibition decision under Article 8(3)); M.10483 – *Illumina / GRAIL* (Article 14 procedure); M. 10493 – *Illumina / GRAIL* (interim measures under Article 8(5)(a)); M.10938 – *Illumina / GRAIL* (interim measures under Article 8(5)(c)); M.10939 – *Illumina / GRAIL* (restorative measures under Article 8(4)(a)).

[74] EC Decision of 6 December 2024, M.11486 – *Novo Holdings/Novo Nordisk/Catalent*.

[75] See judgment of 13 July 2022, *Illumina v Commission*, T-227/21, EU:T:2022:447; and judgment of 3 September 2024, *Illumina v Commission*, Joined Cases C-611/22 P and C-625/22 P, EU:C:2024:677.

Regulation,[76] the EC has looked to map out the volume and impact such transactions could have on the internal market. This is notably the case where such transactions in the pharma sector could lead to the discontinuation of overlapping pipeline projects either on the target's side ('killer acquisition') or on the acquirer's side (so-called 'reverse killer-acquisition'). At the request of the EC, an *ex-post* evaluation was conducted and found that around 40% of transactions in the pharma sector which included overlapping R&D projects lead to the discontinuation of one of them.[77]

76. From the perspective of merger control, transactions reviewable pursuant to the EU Merger Regulation must meet the criteria to be considered 'concentrations'.[78] This can include acquisitions of subsidiaries, branches, IP rights, and on some occasions, exclusive licensing agreements.[79] In addition, the concentration must have a sufficient link to the EU, referred to as 'EU dimension' and measured in terms of turnover.[80] It should be noted that in addition, EU Member States can refer to the EC a concentration for which they would have jurisdiction, including through the exercise of ex officio powers. The exercise of these ex officio powers ('call-in rights') can be challenging as the process of identifying a concentration which should be reviewed requires significant monitoring, research, and coordination, sometimes within a short timeframe. This further complicates the EC's efforts to capture concentrations which may have a significant impact on the European healthcare markets but are below the thresholds for notification under the Merger Control Regulation.

77. Transactions falling outside the aforementioned merger control framework can, however, fall within the purview of EU antitrust rules as confirmed by the *Towercast* preliminary ruling of the ECJ. On the basis of this preliminary ruling, under current applicable legislation, Member States could use Article 102 TFEU to investigate and vet (healthcare) mergers not subject to their national merger control regimes.[81]

6. Securing supply through competition enforcement

6.1. Competition policy to contribute to security of supply

78. The structure of supply is a key element of effective competition. Ensuring that supply chains remain robust, diverse and competitive, is essential to safeguarding consumer welfare and market efficiency.

[76] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the "**EU Merger Regulation**"), OJ L 24, 29 January 2004.

[77] European Commission/Lear (2024), *Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector leading to the discontinuation of overlapping drug research and development projects*, Final Report May/November 2024, available at https://op.europa.eu/en/publication-detail/-/publication/6eacab93-b129-11ef-acb1-01aa75ed71a1 (last accessed on 27 October 2025).

[78] Have a market presence to which a market turnover can clearly be attributed. See European Commission (2008), Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings, 2008/C 95/01, 16 April 2008, paragraph 24.

[79] See for example EC decision of 18 December 2015, M.7872 – *Novartis/GSK (Ofatumumab outoimmune indicators)*.

[80] EU Merger Regulation, Articles 1(2) and 1(3).

[81] Judgment of 16 March 2023, *Towercast*, C-449/21, EU:C:2023:207.

79. It is therefore important that initiatives by market participants, whether in the form of cooperation or consolidation, and measures adopted by EU Member States impacting the supply of goods and services do as much as possible refrain from distorting the proper functioning of the market mechanism. However, as demonstrated by the experiences from the Covid-19 pandemic and recent geopolitical circumstances, supply structures are vulnerable to significant strain, triggering the need for companies to collaborate and consolidate in order to maintain their relevance and viability such as to ensure sufficient supply and fair distribution to customers and consumers. Indeed, from March 2020 through to 2022, businesses within the EU faced particular supply-related challenges due to the consequences of the Covid-19 pandemic. Many of these businesses were in a position to play a crucial role in mitigating the effects of the crisis by resorting to actions that would be met with suspicion from a competition perspective.

80. While market and government initiatives impacting supply structures are carefully scrutinised under the competition rules to prevent anti-competitive effects on the market, competition enforcement and policy do not stand in the way of initiatives and cooperation enhancing security of supplies that have pro-competitive effects.

81. In order to mitigate the detrimental effects on supply structures during the Covid-19 pandemic, competition enforcement and policy were applied in a pragmatic and flexible manner, enabling affected companies to development of solutions aimed at addressing the adverse impact of Covid-19, especially within the healthcare sector. But even outside the context of the exceptional circumstances of a global pandemic, EU competition rules on antitrust and mergers duly take pro-competitive elements of cooperation and consolidation into account, as well as any resulting efficiencies (see Section E.2 below).

82. Finally, with the adoption of the CMA proposal early 2025, the EC took a further important regulatory initiative to bolster the security of supply of critical medicines in compliance with the EU state aid rules (see Section E.3 below).

6.2. EC antitrust enforcement and merger control

83. Antitrust enforcement and merger control by the EC play a vital role in sanctioning and preventing practices that could undermine healthy supply structures, such as collusive arrangements, abuses of dominant positions, or excessive market concentration. Less competition risks making an economy ‘brittle’ and thus also less resilient.

84. At the same time, it is essential that competition policy and its enforcement duly take into account pro-competitive initiatives that will benefit customers and consumers in the given circumstances of the project. The EC horizontal cooperation guidelines, for instance, provide ample explanations on how different forms of horizontal cooperation between market participants (for example joint purchasing and stockpiling) can be designed in conformity with EU competition rules and under what circumstances claimed pro-competitive effects can countenance cooperation between market participants which are otherwise required to determine their commercial strategy and efforts independently on the market.[82] Similarly, while mergers may reduce competition at first sight, they can also generate important benefits – so-called ‘efficiencies’ – which can, in turn, lead to cost savings, improved products and enhanced services, and better access to supplies. The EC considers any substantiated efficiency claim in the overall assessment of the merger and may decide that, as a consequence of these efficiencies that the merger brings about, there are no grounds for declaring the merger incompatible with the common market. In order

[82] Referred to in footnote 19 above.

for that to happen, the merging parties need to demonstrate that the claimed efficiencies benefit consumers, are merger-specific and are verifiable.[83]

85. Specific initiatives were implemented throughout Europe to ensure that competition policy and enforcement contributed proactively to addressing and mitigating the economic and social consequences of the crisis.

86. In response to this need, the EC, the NCAs and the EFTA Surveillance Authority issued on 23 March 2020 a joint statement on the application of the EU antitrust rules during the Covid-19 pandemic, explaining how competition authorities could help companies deal with the crisis. The statement clarified that the European Competition Network ("**ECN**") would not actively intervene against necessary and temporary measures put in place in order to avoid a shortage of supply, but that it would, however, not hesitate to take action against companies taking advantage of the crisis situation by cartelising or abusing their dominant position. In this context, the ECN pointed out that the existing rules allowed manufacturers to set maximum prices for their products, which could prove useful to limit unjustified price increases at the distribution level.[84]

87. During the Covid-19 pandemic, the EC also adopted a Temporary Framework Communication (8 April 2020) that set out the criteria that the EC would follow when assessing cooperation projects aimed at addressing a shortage of supply of essential products and services during the coronavirus outbreak.[85] It also introduced the possibility for the EC to provide companies with written comfort (via ad hoc 'comfort letters') on specific and well-defined cooperation projects falling within its scope

88. In this context, the EC issued on 8 April 2020 a 'comfort letter' to Medicines for Europe (an association of pharmaceutical manufacturers) and participating companies, in relation to a voluntary cooperation project to address the risk of shortages of critical hospital medicines for the treatment of coronavirus patients.[86] On 25 March 2021, the EC issued a further comfort letter, addressed to co-organisers of a pan-European matchmaking event, which aims at addressing bottlenecks in the production of Covid-19 vaccines and accelerating the use of additional available capacities across Europe.[87] These measures

[83] See the 'efficiencies' sections in European Commission (2008), Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ C 265, 18 October 2008, recitals 13, 21, 22, 52-57 and 77; and Horizontal merger guidelines, recitals 76-88.

[84] European Competition Network (2020), Antitrust: Joint statement by the European Competition Network (ECN) on application of competition law during the Corona crisis, 23 March 2020, available at https://competition-policy.ec.europa.eu/system/files/2021-03/202003_joint-statement_ecn_corona-crisis.pdf (last accessed on 27 October 2025). A similar statement was issued by the International Competition Network and published on 8 April 2020, available at https://www.international competitionnetwork.org/wp-content/uploads/2020/04/SG-Covid19Statement-April2020.pdf (last accessed on 27 October 2025).

[85] European Commission (2020), Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak, 2020/C 116 I/02, 8 April 2020, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj: JOC_2020_116_I_0002 (last accessed on 27 October 2025).

[86] Available at https://competition-policy.ec.europa.eu/system/files/2021-03/medicines_for_europe_comfort_letter.pdf (last accessed on 27 October 2025).

[87] Available at https://competition-policy.ec.europa.eu/system/files/2022-09/comfort_letter_coronavirus_ matchmaking_event_25032021.pdf (last accessed on 27 October 2025).

illustrated how carefully designed collaboration could be both lawful and pro-competitive, helping to boost output and protect public health during a crisis.

89. With the gradual improvement of the sanitary situation and the lifting of mobility restrictions, the EC withdrew the Temporary Framework in October 2022, noting that the extraordinary conditions that had justified its adoption were no longer present.[88] Nevertheless, it recognised the continuing need to provide businesses with legal certainty in moments of crisis. To this end, the revised Informal Guidance Notice now offers a structured avenue for companies to seek clarification in cases involving novel initiatives by companies.[89] These may include initiatives aimed at addressing security of supply and access.

90. The ongoing review of the merger guidelines also specifically envisages a role for resilience considerations in merger control, as long as they are relevant for competition on the markets concerned.[90] Mergers can for example help companies secure access to inputs from outside the EU internal market they need to compete effectively, which may be considered if it translates to benefits in the market at large. The EC traditionally also assessed to what extent a merger may reduce dependable sources of supply, thereby exposing customers to more dependencies. In markets characterised by imports, the assessment has also considered whether sources of supply located outside the EU internal market may be less dependable and expose businesses located in the EU internal market to shocks and uncertainties, overall reducing their resilience (resulting *e.g.* from currency risks, lead times, just-in-time supply chains, quality considerations, or general geopolitical and trade uncertainty).

91. Taken together, these measures demonstrate that the EC seeks to take a balanced approach: upholding competition to protect long-term market integrity while offering flexibility to enable effective and pro-competitive cooperation.

6.3. Critical Medicines Act and state aid

92. The CMA, proposed by the EC on 11 March 2025, aims to enhance the availability, supply, and production of critical medicines within the EU, addressing ongoing medicine shortages and supply chain vulnerabilities.[91] It essentially seeks to strengthen the security

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88 European Commission (2022), Withdrawal of Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak, 2022/C 381/03, 4 October 2022, available at https://eur-lex.europa.eu/legal-content/EN/ TXT/PDF/?uri=CELEX:52022XC1004(01) (last accessed on 27 October 2025).

89 European Commission (2022), Commission Notice on informal guidance relating to novel or unresolved questions concerning Articles 101 and 102 of the Treaty on the Functioning of the European Union that arise in individual cases (guidance letters), SWD(2022) 326 final, 3 October 2022, available at https://competition-policy.ec.europa.eu/document/download/aa6057d9-c027-4a24-97e2-2120c13e3003_en (last accessed on 27 October 2025).

90 The consultation documents are available on https://competition-policy.ec.europa.eu/mergers/review-merger-guidelines_en (last accessed on 27 October 2025).

91 European Commission (2025), Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795, 2025/102 final, 11 March 2025, available at https://health.ec.europa.eu/document/download/2abe4fc8-059e-47d9-

of supply and availability of the critical medicinal products featuring on the Union list of critical medicines, for which a shortage of supply would result in serious harm to patients because of a lack of alternatives. However, the CMA also targets other medicines of common interest whose supply is subject to market failures.

93. The CMA approaches critical medicines shortages in various ways. Certain industrial projects can be designated as '**strategic projects**' for critical medicines or their ingredients so that they benefit from easier access to funding and fast-tracked permit-granting processes. The CMA introduces lighter requirements and programmes in the sphere of **public procurement** procedures to incentivise the resilience of supply chains of critical medicines or to improve access to other medicines of common interest. In order to address availability and access disparities of critical medicines and other medicines of common interest among Member States, the CMA also offers a framework and tools to leverage the aggregated demand of participating Member States through EC facilitated **collaborative procurement**. Finally, the CMA offers levers to intensify **international partnerships** with likeminded countries/regions to broaden the supply chain and reduce dependencies on single suppliers.

94. Simultaneously with the proposal of the CMA, the EC has also issued state aid guidance explaining in detail how the current state aid framework can be used to support strategic projects for critical medicines.[92] Article 107(1) TFEU stipulates that any aid granted by an EU Member State, or through State resources in any form, which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods must, in so far as it affects trade between EU Member States, be incompatible with the internal market. However, the same Article describes situations where aid measures can be declared compatible by the EC following prior notification by a Member State.[93] Furthermore, the EC has adopted a set of block exemption rules which allow Member States to design measures in a way compatible with the internal market without the need of prior authorisation from the EC.[94] State financing for CMA may therefore be designed in a way that (i) escapes the application of EU State aid control, (ii) is block exempted, or (iii) needs to be explicitly authorised by the EC.

95. In a number of situations, support for strategic projects in the sense of the CMA would not be considered as constituting state aid. For instance, financing through centrally (EU) managed programmes such EU4Health Programme, Horizon Europe and the Digital Europe Programme falls outside the scope of application of state aid rules. Small (*de minimis*) aid amounts (EUR 300 000 for general measures or EUR 750 000 for Services of

a20a-d9e3bfc5dc2c_en?filename_=mp_com2025_102_act_en.pdf (last accessed on 27 October 2025). The CMA is without prejudice to Union competition law, including antitrust, merger and state aid rules.

92 European Commission (2025), Guidance on the application of State aid rules in the context of the Critical Medicines Act, available at https://competition-policy.ec.europa.eu/document/download/a51c37be-2f9f-4d92-bdf5-ae38bfa91908_en (last accessed on 27 October 2025).

93 Article 108(3) TFEU provides that Member States may not implement new state aid measures before they have been approved by the EC (the so-called 'stand still obligation') following a notification of the intended measure to the EC. Any new aid put into effect without the authorisation of the EC is unlawful.

94 These can be consulted on https://competition-policy.ec.europa.eu/state-aid/legislation_en (last accessed on 27 October 2025).

General Economic Interest ("**SGEI**") are also exempted.[95] Member States contemplating providing support to a SGEI for critical medicines designed in line with the four *Altmark* criteria do not need to apply EU state aid rules.[96] More specifically, this covers critical medicines projects that comply with the following cumulative conditions: (i) the recipient undertaking must actually have public service obligations to discharge and those obligations must be clearly defined; (ii) the parameters on the basis of which the compensation is calculated must be established in advance in an objective and transparent manner; (iii) the compensation cannot exceed what is necessary to cover all or part of the costs incurred; and (iv) the compensation has the lowest cost to the community (ensured through a competitive tender or with a reference to a comparable company).

96. The EU rules on SGEIs provide a number of possibilities for Member States to support critical medicines projects, often without the need of EC approval. In addition to SGEI *de minimis* exemptions, the current 'SGEI Decision' offers the possibility to Member States to exempt a number of projects supporting critical medicines from the obligation to notify the support measures to the EC for approval.[97] The EC proposal for the revision of the SGEI Decision makes it clear that compensation not exceeding an annual amount of EUR 20 million for the provision of a SGEI in the area of critical medicines should be exempted from the notification requirement.[98] Certain projects could also fall under the scope of the General Block Exemption Regulation (*e.g.* support for SMEs).[99]

97. Finally, critical medicines projects may also fall under the scope of other state aid rules, such as the SGEI Framework[100], the Regional Aid Guidelines[101] for projects in assisted areas, the Climate, Environmental protection and Energy Guidelines,[102] the R&D&I Framework[103] for research and development projects or the rules on Important

[95] SGEIs are commercial services of general economic interest subject to public service obligations imposed on one or more providers, that would not be supplied by the market without public intervention or would be supplied under different conditions in terms of objective quality, safety, affordability, equal treatment, or universal access.

[96] Judgment of 24 July 2003, *Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH*, C-280/00, EU:C:2003:415.

[97] European Commission (2012), Commission Decision of 20 December 2011 on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380), OJ L 7, 11 January 2012.

[98] The document is up for public consultation between 3 October 2025 and 4 November 2025, and available at https://competition-policy.ec.europa.eu/public-consultations/2025-sgei_en (last accessed on 27 October 2025).

[99] European Commission (2014), Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, OJ L 187, 26 June 2014.

[100] European Commission (2012), Communication from the European Commission on a European Union framework for State aid in the form of public service compensation, 2012/C 8/03, 11 January 2012.

[101] European Commission (2021), Communication from the European Commission on Guidelines on regional State aid, 2021/C 153/01, 29 April 2021.

[102] European Commission (2022), Communication from the European Commission on Guidelines on State aid for climate, environmental protection and energy, 2022/C 80/01, 18 February 2022.

[103] European Commission (2022), Communication from the European Commission on the Framework for State aid for research and development and innovation, 2022/C 414/01, 28 October 2022.

Projects of Common European Interest.[104] Projects complying with all relevant criteria of these instruments would then have to be declared compatible with EU state aid rules by the EC. If none of these frameworks applies, it is still possible that the EC declares the aid compatible directly on the basis of Article 107(3)(c) TFEU, which refers to aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest.

7. Conclusion

98. Effective competition enforcement by the EC (and NCAs) is and remains indispensable to addressing the multifaceted challenges of the European healthcare sector. As the sector grapples with demographic pressures, technological transformation and geopolitical uncertainties, the EC's continued vigilance in applying antitrust, merger control, and state aid rules helps preserve the integrity of healthcare markets. By curbing anti-competitive conduct, preventing harmful consolidation, and promoting fair market access, it safeguards both patients and public budgets while at the same time fostering an environment where rivalry drives efficiency, innovation, and secure supply chains. In doing so, competition enforcement stands as a cornerstone of a healthcare ecosystem that is not only competitive, but also responsive to the needs of European citizens.

[104] European Commission (2021), Communication from the European Commission on the Criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest, 2021/C 8481 final, 25 November 2021.