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Competition Risks Across the Pharmaceutical Value Chain

Competition dynamics in the pharmaceutical sector are shaped by a complex, fast changing and increasingly global value chain. Given the sector's vital role in safeguarding public health and ensuring timely, affordable access to medicines, understanding where and how competition may be distorted across the chain is vital to help competition authorities respond effectively.

This paper, prepared for the Global Forum on Competition as part of the discussions on competition in the healthcare sector, examines how the structure of the pharmaceutical value chain gives rise to distinct competition risks and focuses on three key drivers of concern: intellectual property and pricing strategies, and increasing vertical integration.

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1. Competition across the pharmaceutical value chain drives pharmaceutical companies to deliver better products and services at lower prices. It is critical to maintain affordability and access to medicines. More specifically, competition encourages manufacturers to innovate creating new and improved medicines, while also motivating generic firms to supply more affordable alternatives. This dynamic helps balance innovation incentives with consumer access and cost containment[1] (UNCTAD, 2015[1]), which is vital given that pharmaceutical spending represents a significant share of government spending in healthcare worldwide (OECD, 2023[2]).

2. Understanding competition risks across the value chain - from research and development through manufacturing, distribution, and final sales - and the roles of key stakeholders, as well as the regulatory barriers influencing competition is essential to strengthen competition enforcement in the sector (WHO, 2020[3]). This note focuses on three drivers of competition risk that have been selected due to their significant impact across the value-chain and its presence in an increasing number of jurisdictions: intellectual property (IP), pricing, and vertical integration risks. IP strategies involve the use of patents and exclusivities to abuse companies' dominant position in the market, delaying generic competition, and creating legal uncertainties that can restrict market entry (UNCTAD, 2015[1]) (European Commission, 2024[4]). Pricing-related risks include practices that may result in excessive, discriminatory, or exclusionary prices, creating barriers to market entry or limiting consumer access and affordability (OECD, 2018[5]). Vertical integration can facilitate foreclosure by enabling firms to control multiple value chain stages, restricting rivals' access to key inputs or distribution channels, and distorting competition especially in concentrated markets (OECD, 2024[6]).

3. This note, prepared for the Global Forum on Competition and related to Competition in the Healthcare Sector, is structured in two sections. The first provides a detailed mapping of the pharmaceutical value chain and key stakeholders, alongside a concise overview of regulatory frameworks that shape market competition. The second section introduces three core drivers of competition risks through the value chain selected for further analysis: the strategic use of intellectual property rights, pricing-related strategies, and vertical integration. These drivers reflect both the unique features of the pharmaceutical industry and common enforcement priorities observed globally.

2. Pharmaceutical Value Chain Mapping and Key Stakeholders

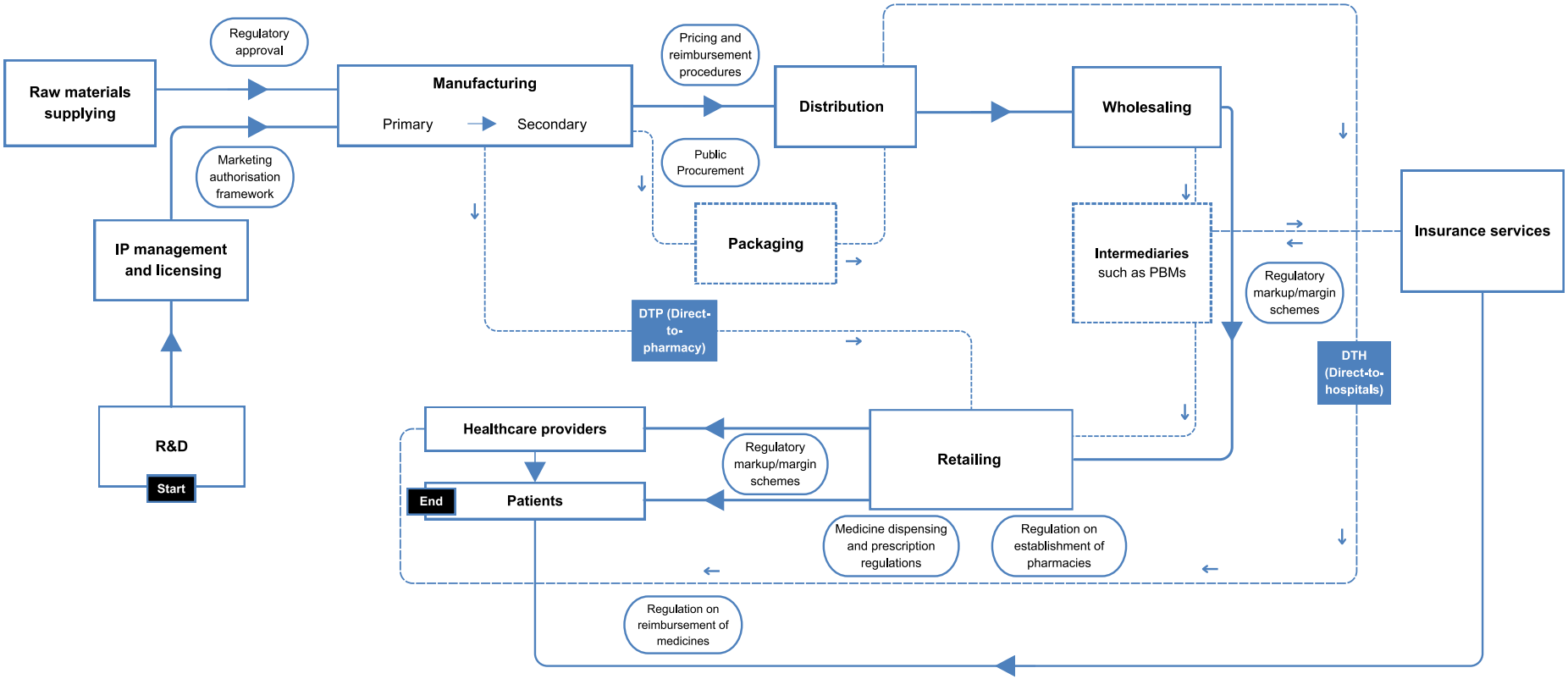
4. The pharmaceutical value chain[2] is complex, dynamic, and increasingly international, often spreading across multiple locations in different countries. While there are similarities across medical value chains, each product chain is unique (OECD, 2024[6]), and components of the value chain can and do differ both between and within markets depending on the type of medicine (and life cycle stage of the medicine), channel of distribution, reimbursement regulation, or geographic region (Aitken, 2016[7]).

5. Focusing on common core stages, the pharmaceutical value chain typically includes R&D, which involves the discovery of new drug compounds and pre-clinical and clinical testing until obtaining marketing approval, and IP management and licensing to protect innovative compounds. The next phase, manufacturing, consists of producing first active pharmaceutical ingredients (APIs) and then at a secondary stage, completing the final assembly and mixing steps to produce the final products. Subsequently, products are packaged, stored and distributed. Wholesaling facilitates bulk transfer to healthcare providers and pharmacies, while retail and dispensing ensure medicines reach healthcare providers and patients (OECD, 2024[6]) (Gill, 2025[8]).

6. Multiple stages of the value chain are governed by complex regulatory frameworks that encompass a diversity of procedures conducted by different authorities. These also vary across jurisdictions and the type of medicine (generics, hybrids and biosimilars). For instance, in some countries, raw material and API sourcing is subject to regulatory approvals and controls (Khan, 2024[9]) in addition to those in place for international imports and exports. Marketing authorisation, present in most jurisdictions and generally the most burdensome stage for companies, involves rigorous clinical and safety evaluations carried out by independent government bodies, including post-approval safety monitoring and validation requirements (Rajpuriya, 2025[10]).Pricing and reimbursement regulatory procedures often administered by payer institutions[3], are composed of multiple pathways and coverage mechanisms, each governed by specific national eligibility criteria. Additional regulatory requirements cover pharmacy establishments and distribution channels to ensure supply chain integrity and controlled access. Many of these processes run in parallel to IP regulation and public procurement regulation, which also play an important role in market dynamics.

7. Across the pharmaceutical value chain, stakeholders' role and influence also vary by jurisdiction. Key stakeholders encompass researchers, raw materials providers, manufacturers, originator, generic and biosimilar producers, packaging companies (where applicable) wholesalers, pharmacies, intermediaries such as pharmacy benefit managers (PBMs, where applicable), regulators, payer institutions (public and private), healthcare providers and professionals, patients (and organisations representing patients) and insurance providers (public and private) (European Commission, 2021[11]) (Gill, 2025[8]).

Infographic 2.1. Pharmaceutical Value Chain



Note 1: Solid arrows and lines represent the normal flow of goods. Dotted lines represent the possibility of an alternative chain, normally skipping some steps from the value chain. The mapping does not represent international value chain flows.
Note 2: Intermediaries are third-party stakeholders present in some jurisdictions between wholesalers, retail pharmacies, and health care providers.
Source: Adapted from OECD (2024), *Securing Medical Supply Chains in a Post-Pandemic World, OECD Health Policy Studies*, https://doi.org/10.1787/119c59d9-en.

8. Understanding the distinctive features of the pharmaceutical value chain (including its innovation-driven nature), the intricate pharmaceutical regulatory framework surrounding it, and the map of actors taking part in it, is essential to assess the competition risks that pharmaceutical markets face. These elements shape market dynamics and explain barriers to entry and competition. These barriers include, among others, patent protections that grant temporary market exclusivity to originators (Barrenho et al., 2023[12]); complex and costly regulatory approval processes, which vary across States, that delay generic and biosimilar entry (Jones, 2016[13]) (Jarab AS, 2024[14]); and the intricate relationships between manufacturers, distributors, payers, and regulators which can both hinder or facilitate anti-competitive practices (European Commission, 2024[4]).

3. Competition Risks in the Value Chain

9. Competition risks manifest in various forms along the pharmaceutical value chain. These risks can directly affect patient access to medicines, their affordability, and the incentives for innovation, making them critical areas for competition enforcement and policy focus. This section focuses on three main competition risks, which have been selected for detailed analysis due to their significant and recurring impact across jurisdictions, observed in both upstream and downstream markets: the strategic use of intellectual property rights, which plays a critical role in the early stages of the pharmaceutical value chain (R&D and regulatory approval); pricing-related strategies which are most pronounced during the manufacturing distribution, and retail stages of the value chain; and vertical integration which by nature spans across multiple stages of the value chain but mainly from manufacturing, distribution and retailing.[4] These risks are closely influenced by the structural features of the pharmaceutical value chain, the roles of different market participants, and the complex regulatory environment that governs their interactions, as explained in the preceding section.

3.1. Strategic use of intellectual property (IP)

10. Due to the specific characteristics of the pharmaceutical value chain and the central role of R&D, originator companies, in order to recover investments in pharmaceutical innovation, are granted exclusivity rights under IP law, for limited periods of time. Generic and biosimilar manufacturers typically enter the market only upon patent expiry, introducing competitive pricing. However, patent holders may engage in anticompetitive practices which unlawfully delay or impede generic and biosimilar market entry. These strategies restrict competition, sustain elevated prices, and exert significant pressure on healthcare budgets globally. Some of the main IP-related anticompetitive practices include pay-for-delay agreements, product hopping, and patent thickets, which are covered below (Barrenho et al., 2023[12]) (OECD, 2023[15]) (OECD, 2019[16]).

3.1.1. Pay-for-delay agreements

11. Pay-for-delay agreements are arrangements between originator pharmaceutical companies and generic drug manufacturers, where the generic company agrees to delay or restrict its independent market entry in exchange for compensation from the originator. These agreements are generally seen as detrimental because they artificially prolong the originator's market exclusivity, preventing cheaper generic drugs from entering the market in a timely manner. This harms healthcare systems and taxpayers by sustaining higher drug prices and reduces incentives for pharmaceutical innovation, as competition from generics typically drives originators to develop new medicines rather than relying on older products protected by extended market exclusivity (European Commission, 2024[4]) (FTC, 2025[17]). Key enforcement cases against Teva in the United States and the EU show growing efforts to sanction these practices.

Box 3.1. The US and EU Teva cases

In 2019, the FTC reached a settlement with Teva, which had been accused of engaging in reverse-payment patent settlements that delayed generic competition for drugs including modafinil (used to treat sleep disorders) and Lidoderm (used to treat pain). In 2020, in a similar case, the European Commission fined Teva and Cephalon EUR 60.5 million for delaying entry of cheaper generic medicine of modafinil. The decision concerned a patent settlement agreement whereby Cephalon induced Teva not to enter the market with a cheaper version of modafinil, in exchange for a package of commercial side-deals that were beneficial to Teva and some cash payments.

More recently, in 2024, the European Commission fined Teva EUR 462.6 million for delaying competition for Copaxone, a blockbuster multiple sclerosis drug. The Commission found that Teva artificially prolonged Copaxone's patent protection through strategic filing and withdrawal of divisional patents, creating legal uncertainty and repeatedly forcing competitors into lengthy litigation. Additionally, Teva conducted a systematic disparagement campaign against a competing generic product, spreading misleading information about its safety and efficacy to delay its market entry.

Source: FTC press release of 19 February 2019, FTC Enters Global Settlement to Resolve Reverse-Payment Charges against Teva; European Commission press release of 26 November 2020, Antitrust: Commission fines Teva and Cephalon €60.5 million for delaying entry of cheaper generic medicine; European Commission, Decision of 31 October 2024, AT.40588 Teva Copaxone case.

12. A significant enforcement challenge in pay-for-delay cases is assessing whether value transfers from originator pharmaceutical companies to generics have any plausible commercial justification beyond suppressing competition. This task is complex when the payments or benefits are non-monetary or disguised through licensing, marketing agreements, or other commercial arrangements, making it difficult for authorities to uncover the true nature of the settlement (Bayrak, 2025[18]).

3.1.2. Product hopping

13. Product hopping is a strategy where a brand-name pharmaceutical company seeks to shift demand from a brand-name drug that faces or will soon face generic competition because its regulatory exclusivity is about to expire, to newly patented and or exclusivity protected drugs that do not face generic competition. This often involves introducing slight modifications which add modest changes to an existing product with little or no additional clinical value (e.g., changes in dosage form or formulation) and encouraging patients and doctors to switch before generics enter the market. By withdrawing or de-emphasizing the older drug, companies prevent generics from gaining market share through automatic substitution, thereby maintaining monopoly pricing (FTC, 2022[19]) (Feldman, 2025[20]). Two recent US cases highlight increased enforcement interest on these market strategies.

Box 3.2. The US Actavis and Reckitt Benckiser cases

In 2015, the New York Second Circuit Court of Appeals issued a preliminary injunction against Actavis for attempting to replace Namenda, one of only a few FDA approved immediate-release drugs to treat Alzheimer's disease, with an extended-release version, to prevent generic entry rather than deliver meaningful innovation.

More recently, in 2019, the FTC challenged Reckitt Benckiser for attempting to shift prescriptions from its opioid addiction treatment "suboxone tablets" - whose regulatory exclusivity was about to expire - to a new, patent-protected film formulation, thereby preventing lower-cost generic competition from entering the market. The company settled the case with the FTC, agreeing to refrain from similar reformulation practices and paying a $50 million fine.

Source: Judgment of the United States Court of Appeals for the Second Circuit of 22 May 2015, State of New York v. Actavis; FTC press release of 11 July 2019, Reckitt Benckiser Group plc to Pay $50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone.

14. Most enforcement actions and publicized cases remain concentrated in the United States, with limited precedents outside this jurisdiction, mainly in the EU[5]. In the United States the one key enforcement difficulty lies in proving that reformulations are intended to block generic competition rather than provide genuine therapeutic improvements (FTC, 2022[19]) (Feldman, 2025[20]).

3.1.3. Patent thickets

15. Patent thickets in the pharmaceutical sector involve the strategic filing of numerous patents covering various peripheral or incremental features of a drug, beyond the core active ingredient. This dense overlapping of patent rights creates a "thicket" that effectively extends monopoly control beyond the primary patent term. The effect on the market is a significant barrier to generic or biosimilar entry, resulting in prolonged exclusivity, delayed competition, and sustained high drug prices. The cumulative effect of multiple weak or secondary patents can deter competitors from attempting to enter the market due to anticipated costly, prolonged, and uncertain litigation over many patent claims, rather than the validity of any single patent alone (Feldman, 2025[20]) (Gurgula, 2017[21]). Such practices have attracted attention in a number of jurisdictions.

Box 3.3. India's Novartis and US' AbbVie's cases

A landmark example on prevention of patent tickets is the 2013 Supreme Court of India judgment, in Novartis v. Union of India, which upheld the rejection of a Novartis patent application for the anticancer drug Glivec in a beta crystalline form, which was a new form of the already known molecule imatinib mesylate. The patent was rejected on the grounds that the applicant failed to demonstrate "significantly enhanced efficacy" compared to the existing form as required by Indian patent law, which effectively prevented the creation of patent thickets.

A more recent example, with a very different outcome, is the 2019 AbbVie case in the United States. AbbVie's extensive patent portfolio (comprising more than 165 granted US patents) delayed biosimilar competition for its drug Humira by five years. In 2020, the US District Court for the Northern District of Illinois dismissed a class-action antitrust lawsuit brought by indirect purchasers, ruling that AbbVie's

actions, securing valid patents from the USPTO and enforcing them through litigation and settlements, constituted permissible activities protected under US patent law.

Source: Judgment from the Supreme Court of India of 1 April 2013, Novartis AG v. Union of India & Others; Judgment of 8 June 2020 of the United States District Court of the Northern District of Illinois (Eastern Division).

16. As the previous examples show, the divergence in patent laws across jurisdictions means that some countries provide a more permissive environment for companies to secure numerous secondary patents than others. This disparity complicates global competition enforcement and facilitates the strategic creation of patent thickets. Furthermore, proving claims such as "enhanced efficacy" can be challenging due to subjective legal standards and the lack of a universally accepted test for determining when patent clusters amount to an abuse of dominance. Additionally, effectively identifying and addressing these practices often requires close cooperation between competition authorities and intellectual property agencies, which can be difficult given differing institutional mandates and priorities (Paunov, Borowiecki and El-Mallakh, 2019[22]) (Gurgula, 2017[21]).

3.2. Pricing-related strategies risks

17. Pharmaceutical products account for a considerable share of public healthcare spending and thus their pricing is increasingly subject to regulatory attention, particularly where producers hold market power that may allow them to distort prices.[6] Pricing across the pharmaceutical value chain is complex, and in many cases, the manufacturer's selling price represents only a fraction of the retail price of a drug (Aitken, 2016[7]).

18. In markets where prices are not subject to regulatory control, pricing power arises from patent protection, limited supplier numbers, and regulatory barriers, affecting both upstream suppliers (*e.g.*, API producers) and downstream manufacturers and distributors (Falcão, 2025[23]). In some cases, this power has been used to trump "*patient's access to affordable and innovative medicines [charging] very high and unsustainable price level[s]*[7] (European Commission, 2024[4]), which can in turn "*restrict [market] entry and distort procurement outcomes*" (OECD, 2018[5]).[8] In other cases, the power has been used to lower prices during a period of time to exclude competitors from the market (Germain Gaudin, 2016[24]). These anticompetitive practices are most noticeable during the manufacturing distribution, and retail stages of the value chain. Some of the main pricing-related anticompetitive practices include excessive pricing, predatory pricing and abusive rebates, which are covered below.

3.2.1. Excessive pricing

19. Dominant pharmaceutical companies can charge excessive prices to distributors, wholesalers, and retailers (which ultimately are passed on to the health providers and patients), on essential patented[9] or orphan drugs particularly in the absence of alternatives or where suppliers hold *de facto* monopolies, which can severely impact affordability and access (OECD, 2018[5]) (European Commission, 2024[4]). Enforcement concerning the pricing of off-patent medicines in the EU and United Kingdom have increased since 2018 (Zacharodimos, 2024[25]), but remains rare outside of Europe, with only a few exceptions in South Africa and Israel. This could be due to alternative regulatory interventions to address high drug prices in some countries[10], lack of tools under the competition framework to persecute excessive prices in some jurisdictions, or reluctance of competition authorities to intervene in these markets where regulation already plays a big role.

Box 3.4. The Leadiant and Aspen cases

The Leadiant cases in Netherlands, Italy, Spain and Israel serve as example of effective enforcement actions against excessive pricing. Leadiant was fined for abuse of dominance in relation to a number of Leadiant' s drugs (such as CDCA which treats a rare disease that if untreated, can lead to dementia and death). Leadiant, through different market strategies, including relaunching drugs under new names and obtaining new orphan designations, imposed huge price increases in these jurisdictions which constituted an abuse of a dominant position.

The Aspen cases in Italy and the EU constitutes another key example. Both competition authorities investigated excessive pricing on a number of Aspen cancer drugs. The EU case ended with Aspen committing to price reductions and ongoing supply guarantees under EU competition oversight, while the Italian Competition Authority imposed a EUR 5.2 million fine.

Source: Decision of the Autoriteit Consument en Markt of 1 July 2021, decision of the Autorità Garante della Concorrenza e del Mercato of 31 May 2022, and decision of the Comisión Nacional de los Mercados y la Competencia of 10 November 2022, Decision of Israeli Competition Authority of 21 June 2023; Decision of the Autorità Garante della Concorrenza e del Mercato of 29 September 2016; Commission Decision of 10 February 2021.

20. Competition authorities have encountered some common enforcement challenges when addressing excessive pricing. One long-term difficulty in these cases has been establishing dominance, which often depends on a company's exclusive rights or unique supply arrangements (Provost, 2018[26]); another significant challenge has been benchmarking "fair pricing", namely, because of the different levels of the pharma value chain, the high R&D costs especially for orphan drugs, and the lack of transparency in pharmaceutical costs (European Commission, 2024[4]) (OECD, 2018[5]). Furthermore, competition authorities are still struggling to balance enforcement with product availability when there are supply constraints and lack of alternatives in the market (Vreese, 2024[27]).

3.2.2. Predatory pricing

21. Predatory pricing in the pharmaceutical sector involves dominant companies deliberately setting prices below cost to eliminate or exclude competitors, particularly generic or biosimilar entrants. This practice distorts market dynamics by temporarily lowering prices to drive rivals out, after which prices are often sharply increased to recoup losses (FTC, 2024[28]) (Germain Gaudin, 2016[24]).

Box 3.5. Austria's Temozolomide case

Austria's 2021 Temozolomide serves as good example of enforcement action against this type of anti-competitive conduct. Merck Sharp & Dohme (MSD) reached a commitment with the Austrian Federal Competition Authority (FCA) to end suspected predatory pricing targeting biosimilar entry. MSD allegedly sold Temodal, a chemotherapy drug used to treat brain cancer, to hospitals below cost to block generic competitors, using below-cost pricing and free samples to secure hospital loyalty and patient lock-in illegal rebates (see below).

Source: FCA, commitment decision of 6 April 2021, Austrian temozolomide case, https://www.bwb.gv.at/en/news/detail/merck-sharp-dohme-gmbh-and-afca-reach-agreement-before-the-cartel-court-on-commitments-to-end-proc;

22. In predatory pricing cases authorities must distinguish between legitimate competitive pricing and exclusionary below-cost pricing combined with a likelihood of recouping losses, which is not always an easy task due to regulatory price controls, patent rights, and high fixed costs intrinsic to the sector (European Commission, 2024[4]). This also makes economic analysis especially burdensome for competition authorities, as the assessment is complex and data-intensive (FTC, 2024[28]).

3.2.3. Illegal rebate schemes

23. While rebates can be legitimate commercial tools used by pharmaceutical companies to secure formulary placement and volume discounts, they have increasingly drawn scrutiny for their potential to distort competition. As explained above, the pharmaceutical value chain involves multiple actors, including intermediaries such as pharmacy benefit managers (PBMs), which negotiate rebates and control formulary access. Other key players in the value chain — like wholesalers, pharmacies, and hospitals — also play crucial roles in distribution and rebate negotiations. For instance, some originator companies use rebates strategically to secure preferential access for their products or even exclusivity, effectively locking out lower-priced generics or biosimilars. These abusive practices create financial disincentives for payers to include generics on their formularies, thereby impeding market entry by generics and reducing the likelihood of price reductions that benefit healthcare systems and patients, inflating overall drug spending (Nitzan Arad, 2022[29]) (ICN, 2009[30]). There have been a number of important investigations and enforcement actions specifically targeting abusive rebate schemes.[11]

Box 3.6. Dutch AbbVie case and US United Health Lawsuit

In 2021, the Dutch Authority for Consumers and Markets (ACM) fined AbbVie for anticompetitive rebates offered to secure exclusivity and block competition in the biosimilar market, demonstrating direct intervention against exclusionary rebate practices. Similarly, in September 2024, the Federal FTC sued major PBMs Optum Rx, Caremark, and Express Scripts, along with their group purchasing organizations, alleging they used rebates and fees to artificially foreclose competition from lower-cost medicines inflating insulin prices, withholding cheaper alternatives from formularies and distorting competition. These cases exemplify enforcement bodies' increasing focus on rebate schemes that distort pharmaceutical supply chains and market access.

Source: ACM, Decision of 19 July 2021, Dutch AbbVie case; FTC, 20 September 2024, Lawsuit against PBMs Optum Rx, Caremark, and Express Script, and their respective group purchasing organizations (GPOs).

24. Enforcement against illegal rebates presents some challenges. The opacity of rebate agreements, confidentiality clauses, and complex multi-tiered supply chains complicate detection and compiling sufficient evidence to meet the burden proof. Furthermore, the interplay of regulatory price controls, patent protections, and reimbursement mechanisms in pharmaceuticals creates ambiguity on cost, pricing, and further complicates market power assessment.

3.3. Vertical integration risks

25. In recent years, the pharmaceutical market has experienced a significant wave of vertical integration across different parts of the healthcare value chain. For example, in the US, many major PBMs have merged with large health insurers (Gray, 2023[31]). The consolidation of manufacturers, wholesalers, retailers/pharmacies, and insurers within a single corporate structure can significantly enhance the market power of the combined entity. Such vertical integration can create incentives for exclusionary tactics, including preferential contracting and bundling of products, which may disadvantage competitors. As the merged firm's market power grows, there is an increased risk of elevated prices, not only for its own products but potentially across the broader market. This can manifest directly through higher list prices, reduced rebates or discounts, or indirect strategies such as delaying the introduction of more affordable generic alternatives. Margin squeeze, covered below, is one of the most harmful ways in which a vertically integrated company in the pharmaceutical sector may try to restrict competition through pricing.

26. Furthermore, vertical integration can raise barriers to entry for competitors both upstream, such as API suppliers, and downstream, including other distributors and pharmacies, thereby restricting overall market access (European Commission, 2024[4]). It may also facilitate exclusionary conduct, through input and customer foreclosure. The consolidated entity may leverage its position to fully or partially restrict access to critical upstream or downstream markets, such as active pharmaceutical ingredients, logistics, or data services, for rivals (Gray, 2023[31]), often by means of exclusivity agreements or deteriorating supply terms.

27. **Input foreclosure** occurs when the integrated entity limits or degrades the quality of those supplies to rivals, raising their costs and potentially forcing them to exit the market. For instance, in the 2016 *Teva/Allergan Generics* merger, the European Commission identified risks that the combined entity would be able to restrict supply or worsen commercial terms for generic pharmaceutical products, which rival manufacturers depended on for critical inputs. To address these concerns, Teva agreed to divest specific portfolios of generic medicines and provide legally binding commitments guaranteeing continued supply to competitors. These remedies aimed to safeguard rival access to essential generic

pharmaceutical inputs, prevent a rise in market concentration, and ultimately protect competition and consumers from price increases or reduced availability of generics.[12]

28. **Customer foreclosure**, on the other hand, arises where the downstream integrated firm ceases to purchase products from upstream competitors. This reduction in the number of available customers can reduce rivals' commercial opportunities, drive market exit, and further increase concentration and market power in the sector (Barlas, 2018[32]). Amgen's 2023 acquisition of Horizon in the US illustrates recent antitrust enforcement addressing vertical customer foreclosure risks in pharmaceutical mergers. The FTC was concerned that the merger would allow Amgen to leverage its broad portfolio of blockbuster drugs to pressure insurers and PBMs into favouring Horizon's monopoly products Tepezza and Krystexxa or disadvantaging their rivals. The case was settled in 2024 with Amgen agreeing to behavioural commitments prohibiting bundling, conditional rebates, and requiring contract oversight by an independent monitor to prevent foreclosure and preserve market competition.[13]

3.3.1. Margin squeeze

29. Margin squeeze in this sector takes place when vertically integrated pharmaceutical companies' dominant in an upstream market set prices for their products or services in a related downstream market at levels that prevent rivals from earning viable margins. This conduct effectively forecloses competitors, impairing biosimilar entry, generic substitution, or alternative service provision (OECD, 2010[33]). Margin squeeze cases are notable in pharmaceutical markets globally due to the sector's complex value chain structure and regulatory environment

Box 3.7. Romania's Roche case and UK Healthcare at Home / Genzyme case

Romania's 2019 Roche case illustrates the risks of margin squeeze across the value chain. In this case, Roche was fined EUR 12.8 million for margin squeeze practices in supplying oncology medicines (rituximab, trastuzumab, bevacizumab). Romanian law requires manufacturers to supply medicines to at least three distributors to avoid monopolizing the distribution market. Roche participated in a Romanian centralised public procurement procedure within the Romanian National Oncology Program and in several hospital tenders. At the same time, Roche supplied its medicines to competing distributors to the tenders at prices higher than its own bids in the tenders. By charging the distributors higher prices than those at which Roche bid, Roche squeezed the distributors' profit margins, making it difficult for them to compete effectively by bidding on or promoting biosimilar alternatives.

Another landmark example is the 2003 Healthcare at Home / Genzyme margin squeeze case in the United Kingdom, where dominant Genzyme bundled drug treatment with homecare services at a single price, squeezing out competitors from providing the downstream service, making it difficult for competitors like Healthcare at Home to offer competing homecare services.

Source: Decision 92 of the Consiliul Concurentei of 16 December 2019; Decision no. CA 98/3/93 of 27 March 2003.

30. A key challenge in persecuting margin squeeze abuses in the pharmaceutical sector stems from regulatory price controls, patent protections, and reimbursement schemes. These factors complicate the task of determining the correct cost and appropriate levels of profits to benchmark against in order to judge margin squeeze conduct. Authorities often debate whether to use average variable cost, long-run average incremental cost, or the as-efficient competitor standard (Yannelis, 2015[34]) (Townsend, 2021[35]).

4. Conclusion and issues for discussion

31. The pharmaceutical value chain is complex, dynamic, and increasingly international, encompassing multiple stages. This complexity is intensified by diverse regulatory frameworks, intellectual property protections, and the active involvement of multiple stakeholders, each playing distinct roles that vary across jurisdictions. These unique characteristics create interrelated competition risks that can significantly affect medicine affordability, access, and innovation incentives.

32. Competition risks arise notably from pricing-related strategies, strategic use of intellectual property rights, and vertical integration along the value chain. Practices such as excessive or predatory pricing, patent thickets, pay-for-delay agreements, product hopping, and vertical foreclosure not only distort market dynamics but also delay generic and biosimilar entry. This, in turn, sustains high prices and limits access to essential medicines for patients worldwide, placing considerable pressure on healthcare systems.

33. Given the cross-border nature of pharmaceutical markets, these competition concerns transcend national boundaries and require coordinated action. Effective enforcement must be supported by international cooperation among competition authorities, regulators, and policymakers. Sharing enforcement experiences, and jointly addressing anti-competitive conduct can enhance market transparency and competitive outcomes globally.

34. Furthermore, understanding the pharmaceutical value chain's intricacies and the evolving competitive strategies within it is essential for crafting effective policy responses. A comprehensive competition policy and health regulation approach, adopting innovative methodologies will be critical to adapting to market developments, including advances in technologies and AI-driven pricing strategies.

35. To facilitate reflection on these themes, the following list of questions is provided. While not exhaustive, these questions are designed to encourage thoughtful discussion on how competition authorities can effectively identify and address competition risks throughout the value chain:

- What legal, institutional, or methodological tools or reforms do you believe could enhance competition authorities' capacity to enforce competition law more effectively in the pharmaceutical sector?
- Have you co-operated with other government agencies or international organizations to strengthen competition law enforcement in the pharmaceutical sector? What factors have facilitated or hindered such co-operation to date?
- What potential challenges do you encounter when investigating pricing-related concerns, especially those involving emerging technologies such as AI or algorithmic pricing in the pharmaceutical sector? How do these challenges influence your investigative approach? Could you provide examples of enforcement actions you have taken, and the lessons learned from those cases?
- How do you perceive the interplay between a potential competition law infringement and an IP law infringement in the pharmaceutical sector?

- How do you approach cases where IP and regulatory tools are used strategically to maintain high prices of medicines and limit market access to healthcare services? Could you share examples of actions taken and insights gained from these cases?
- What specific challenges arise when investigating vertical arrangements in the pharmaceutical sector that potentially create barriers for upstream or downstream competitors, and how do these challenges shape the strategies and tools you use in enforcement? Could you provide examples of enforcement actions and lessons learnt?

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Endnotes

[1] A substantial share of prescription drug costs is covered either entirely or predominantly by national reimbursement agencies or health insurance systems, which are typically financed through public taxes and insurance contributions (OECD, 2023[2]).

[2] In the context of this background note, the term *value chain* refers to the "full range of activities that firms and workers do to bring a *[pharmaceutical]* product from its conception to its end use and beyond" (De Backer and Miroudot, 2013[46]).

[3] These can be ministries, social health insurance funds and private insurance funds.

[4] The competition risks outlined in this note are not exhaustive, and other risks, such as killer acquisitions in the pharmaceutical sector, should not be overlooked. In recent years, concerns have grown regarding transactions that may harm innovation and competition by discontinuing overlapping drug research and development projects. These so-called "killer acquisitions" have prompted increased regulatory scrutiny and academic research (European Commission, 2024[42]).

[5] For instance, OFT Decision of 13 April 2011, *Reckitt Benckiser;* European Commission Decision of 15 June 2005, *AstraZeneca Losec*; Romanian Competition Authority Decision of 13 January 2025, *Boehringer-Ingelheim*.

[6] The growing use of AI tools in the market has transformed pricing dynamics, enabling more data-driven and adaptive price setting, yet also heightening enforcement challenges where these tools reduce market transparency or facilitate parallel pricing strategies (Feldman, 2024[16]).

[7] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, 17 June 2016, paragraph 48 (OJ C 269, 23.7.2016, p. 31). European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)), 2 March 2017.

[8] In most countries a significant portion of pharmaceutical expenses is paid for through public healthcare systems, sometimes via procurement processes (Gugler, 2023[38]).

[9] While most national competition laws do not prohibit competition authorities from pursuing cases involving excessive pricing of patented medicines, there is a prevailing reluctance among enforcement agencies to intervene in such matters (OECD, 2018[44]) (Mazhuvanchery, 2022[43]). Notable exceptions include the 2003 *Hazel Tau* case, where South Africa's Competition Commission found GSK and Boehringer Ingelheim had abused their position of dominance by charging excessive prices for patented ARVs drug used in HIV/AIDS treatment, leading to a licensing settlement. More recently, the South African Commission's 2022 finding against Roche for excessive prices on patented breast cancer treatment drug trastuzumab marks a significant development, with the case now pending before the Competition Tribunal (Mazhuvanchery, 2022[43]).

[10] See for instance, the US Inflation Reduction Act (IRA) 2022 introduces drug pricing reforms, including Medicare price negotiation for certain drugs, inflation-based rebates, and out-of-pocket caps. These efforts reflect a broader government focus on mitigating the impact of high pharmaceutical costs on patients and healthcare budgets, despite the absence of a formal excessive pricing legal framework in the antitrust context

[11] E.g., Dutch Competition Authority 2022 Investigation into Arthritis Drug (Pfizer) rebates; Korean FTC Decision of October 2023, JW Pharmaceutical; FCA, commitment decision of 6 April 2021, Austrian temozolomide case.

[12] European Commission press release of 10 March 2016, Mergers: Commission approves acquisition of Allergan Generics by Teva, subject to conditions

[13] FTC press release of 1 September 2023, Biopharmaceutical Giant Amgen to Settle FTC and State Challenges to its Horizon Therapeutics Acquisition