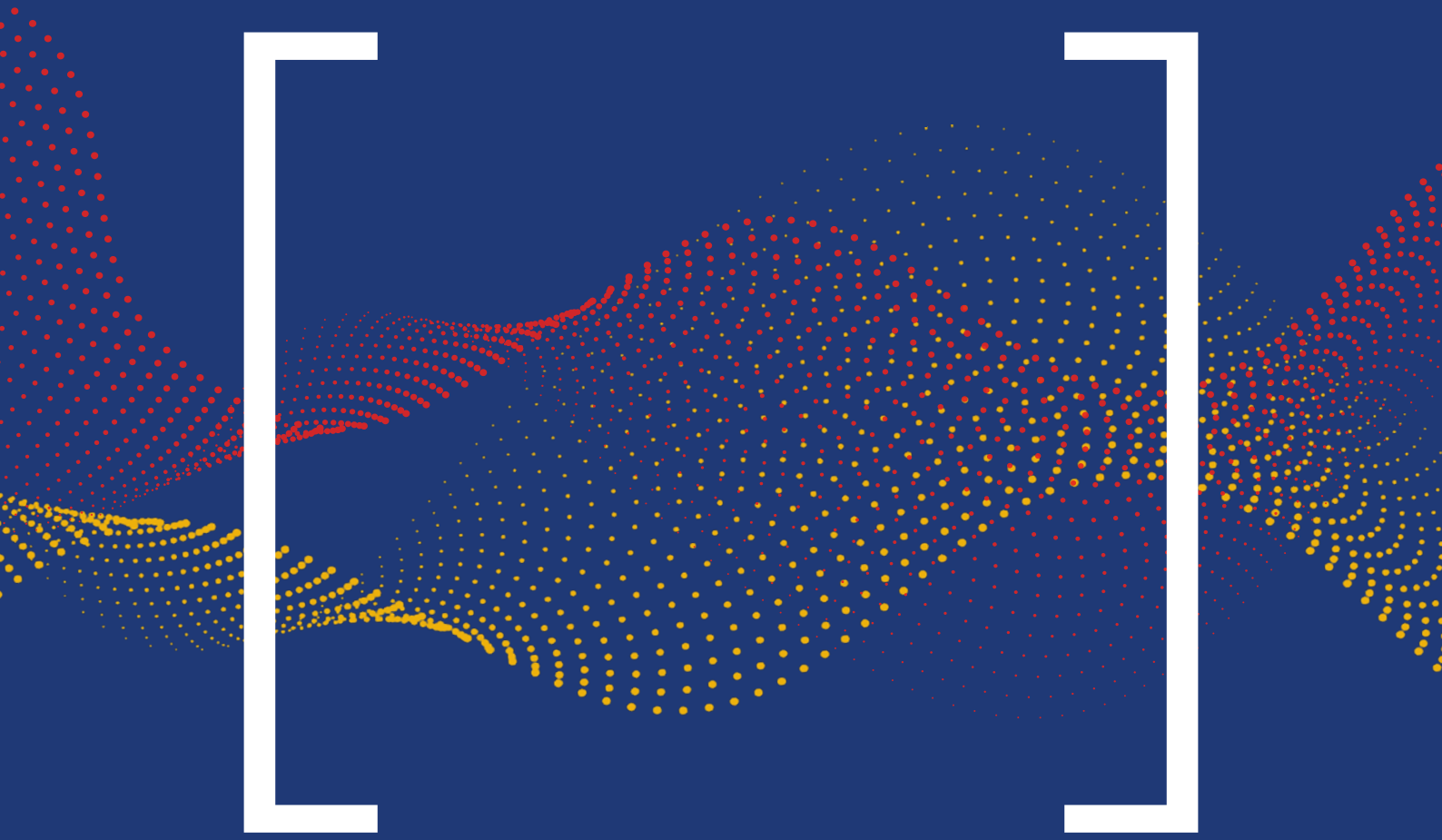
COMPETITION POLICY IN EASTERN EUROPE AND CENTRAL ASIA

Competition Issues in the Pharmaceutical Industry



OECD-GVH Regional Centre
for Competition in Budapest (Hungary)
Review No. 28, July 2026

OECD RCC OECD-GVH HUNGARIAN COMPETITION AUTHORITY

Inside a competition authority: **REPUBLIC OF KYRGYZSTAN**

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I. FOREWORD

María Pilar Canedo
Academic Director of the OECD-GVH Regional Centre for Competition, OECD

Foreword by the Director

It is a pleasure to introduce this new issue of the RCC Newsletter dedicated to the intersection of competition law and the pharmaceutical sector – an area that continues to attract increasing attention from enforcement authorities, policymakers, and academia alike. The growing importance of healthcare systems, the strategic role of innovation, and the particular sensitivities surrounding access to medicines make this field especially significant for competition law. Ensuring that pharmaceutical markets remain competitive is not only a matter of economic efficiency but also of broader societal concern, closely linked to public health, innovation incentives, and consumer welfare.

Against this background, the topic chosen for this edition reflects both its timeliness and its complexity. The pharmaceutical sector presents unique challenges for competition enforcement, from pricing practices and patent strategies to market entry barriers and regulatory interactions. These issues require a nuanced and well-informed approach, combining legal analysis with economic and sector-specific expertise. The discussions held during the seminar organised in preparation for this publication have demonstrated the richness of perspectives on these matters, as well as the depth of engagement across the RCC network and its partners. The contributions gathered in this issue build upon those exchanges and offer valuable insights into recent developments, enforcement priorities, and analytical approaches in this evolving field.

This edition would not have been possible without the dedication and expertise of its contributors. I would like to extend my sincere thanks to all the authors, both from within the RCC community and from external institutions, who have generously shared their knowledge and experience. Their contributions reflect a wide range of perspectives and provide a comprehensive overview of key issues currently shaping competition law enforcement in the pharmaceutical sector. The diversity and quality of these contributions are a testament to the strength of collaboration within the RCC framework, and to the shared commitment to advancing competition policy through dialogue and exchange.

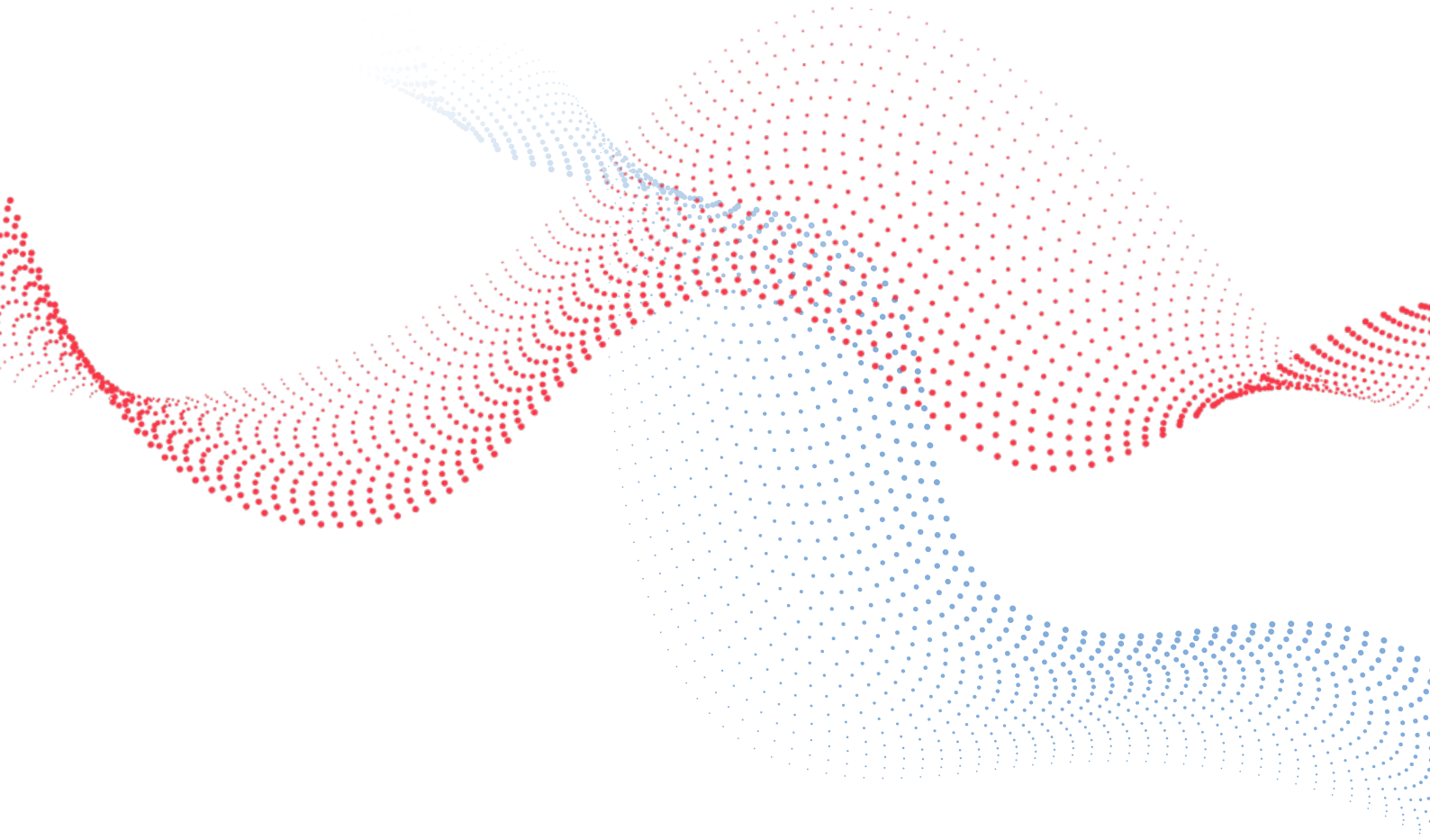
In particular, this issue highlights several important cases and enforcement trends that illustrate the relevance of competition law in addressing challenges within the pharmaceutical industry. By examining these cases in detail, the publication not only documents recent developments but also provides a source of reflection and inspiration for future enforcement actions. It is our hope that the analysis presented here will contribute to a deeper understanding of the tools available to competition authorities and will support continued efforts to promote effective and coherent enforcement across jurisdictions.

We are also especially pleased to include in this issue an "Inside the Competition Agency" contribution from our colleagues in Kyrgyzstan. Their comprehensive and insightful presentation of recent developments within their authority offers a valuable perspective on competition law enforcement in their jurisdiction. We are grateful for their willingness to share this work with the RCC community. Their contribution exemplifies the spirit of openness and cooperation that underpins the network and provides an opportunity for all beneficiary agencies to learn from their experience. Such exchanges are essential in strengthening mutual understanding and enhancing cooperation, particularly in a context where cross-border issues and shared challenges increasingly define competition enforcement.

Finally, this issue reaffirms the importance of continued dialogue and collaboration within the RCC. The challenges posed by the pharmaceutical sector – and more broadly by rapidly evolving markets – require not only strong legal frameworks but also constant engagement, knowledge-sharing, and mutual support among competition authorities. By bringing together diverse perspectives and fostering exchange, the RCC contributes meaningfully to this objective.

As readers will discover throughout this issue, this year's RCC Outside Seminar took place last semester in Yerevan. It was an outstanding event that will remain a cherished memory for all of us, thanks to the warm hospitality and exceptional organisation provided by our colleagues at the **Competition and Consumer Protection Commission of the Republic of Armenia**. We would like to express our sincere gratitude for their generosity, professionalism, and dedication, all of which contributed to making the seminar such a remarkable success.

I hope that this publication will prove both informative and inspiring, and that it will support ongoing efforts to ensure that competition policy continues to serve its fundamental purpose: promoting fair, innovative, and efficient markets for the benefit of society as a whole. Looking ahead to our January edition, we will focus on the **topic of digital markets, local operators,** and **competition**. We encourage all members to share their expertise, insights, and experiences, and we look forward to receiving a diverse range of contributions that will enrich the discussion on this important and timely subject.



II. 2026 PROGRAMME

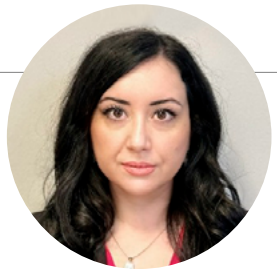
Programme of Work for 2026

I. WORKSHOPS AND CONFERENCES			
	Date	**Topic of the Workshop**	**Audience**
1.	25-27 February **Budapest**	**Pharma markets with special focus on Bid rigging practices.** From Regulation and advocacy to enforcement, the seminar will focus on the main competition problems in these markets in small economies.	Staff of the agencies dealing with public procurement infringements and pharma markets
2.	18-20 March **Yerevan**	**Competition Agency Tools for Promoting Growth and Welfare** Competition agencies utilize a broad set of instruments — including antitrust enforcement, market analysis, and advocacy for pro-competitive policies — to stimulate innovation, improve market efficiency, and ultimately advance economic growth and consumer welfare. They will be the focus this seminar.	Competition officials with experience in related matters both in enforcement and advocacy
3.	14-15 May **Budapest**	**Judge's trainings. Abuses of dominance:** This seminar will allow the judges of the member states of the European Union together with those of Montenegro, Kosovo and North Macedonia to have a better understanding of the grounds of the evolution of case law at national and EU level.	Judges of EU or beneficiary countries
4.	15-18 September **Malaga**	**New Staff training:** This seminar will focus on the main concepts of competition enforcement and advocacy. Analysis of agreements, abuse of dominance, merger control and advocacy will be covered in this seminar	Staff of the agencies with less than 2 years' experience in their field of work in the agency
5.	20-21 October **Budapest**	**GVH staff training:** A group of international experts will discuss with GVH staff their views of the challenges that competition agencies face in this moment. This year we will cover the main ECJ cases on cartels and abuse of dominance.	Board members, Directors, and staff of the GVH
6.	9-11 November **Vienna**	**Digital tools and market fairness: The Evolving Role of National Competition Agencies:** The seminar explores how national competition agencies are leveraging advanced digital tools to monitor, analyse, and regulate the influence of domestic digital platforms on market competition. It also examines best practices and technological innovations that enhance agencies' ability to detect anti-competitive behaviours and ensure fair digital market environments.	Competition officials with experience in related matters both in enforcement and advocacy
7.	19-20 November **Budapest**	**Judge's trainings. Deterrence and competition:** This seminar will allow the judges of the member states of the European Union together with those of Montenegro, Kosovo, and North Macedonia to have a better understanding of the grounds of the evolution of case law at national and EU level.	Judges of EU or beneficiary countries
II. Publications:			
The GVH-OECD Regional Center for Competition will publish (both in English and Russian):			
- 2 numbers of the Newsletter *"Competition Policy in Eastern and Europe and Central Asia"* - The Annual Report with the summary of its activities			
III. Videos:			
Two videos in the section *"Key Competition Topics explained in a few minutes"* on the topics:			
- AI, energy and competition - Prioritisation			
V. RFI:			
The RCC will continue to create a Hub of exchange of information on cases for the Agencies in the Region.			

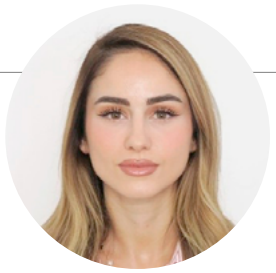
III. ARTICLES ON COMPETITION ISSUES IN THE PHARMACEUTICAL INDUSTRY

1. RCC Country Contributions

Competition and Compliance in Pharmaceutical Markets in Albania



Mimoza Kodhelaj
Director,
Albanian Competition Authority



Anisa Buxheli
Director,
Albanian Competition Authority

4. Introduction

The pharmaceutical market in Albania occupies a unique position within the national economy due to its relevance for public health, pricing, distribution, and the regulatory controls associated with medicinal products. It operates under a dual legal regime: pharmaceutical regulations that govern authorization, safety, storage, and traceability of medicinal products, and competition legislation that ensures markets remain open, dynamic, and free from distortive practices. This dual framework creates an environment in which compliance is not merely a matter of formalities but a fundamental business requirement. Undertakings active in the production, import, distribution, and retail of medicinal products must understand and internalize the principles governing lawful cooperation, market behavior, and vertical restrains.

A strong compliance culture reduces the risk of market distortions, enhances trust among market participants, and supports the sustainability of supply chains that service both hospitals and retail pharmacies. Competition compliance in the pharmaceutical sector requires a coherent structure that integrates regulatory obligations, transparent supply-chain practices, and internal mechanisms designed to prevent anticompetitive conduct.

On this context the Albanian Competition Authority (ACA) besides enforcing the law, has intervened through advocacy events to disseminate the compliance benefits among pharma operators as it will be described latter.

5. Market of Paramedical Materials

When the COVID-19 pandemic struck, demand for essential paramedical materials like masks, alcohol, disinfectant gel, and thermometers rose sharply. Very soon, complaints from citizens and reports in the media revealed that prices for these products were increasing in a coordinated and suspicious way.

The first step was a monitoring procedure carried out by the Secretariat of ACA. This procedure examined the conduct of undertakings across both wholesale and retail levels and uncovered signs of possible anticompetitive conduct. After that, the CC opened a preliminary investigation into the market for paramedical materials, with the aim of determining whether restrictions of competition were indeed present. Besides, in order to protect consumers, the CC imposed temporary measures to undertakings, as they were prohibited to set unfair prices, required to publish cost-based prices, and warned that violations of competition law could lead to fines of up to 10% of their annual turnover. Despite this, several undertakings ignored the measures, prompting the CC to fine them and impose obligations to prevent practices such as price-fixing, market sharing, or discriminatory trading conditions.

As the investigation moved forward, it was assessed that there were restrictions on concerted practices between undertakings in the market, so the CC decided to open the in-depth investigation. A number of undertakings chose to cooperate with the Authority by offering voluntary commitments. These commitments were designed to restore transparency and fair competition, and once assessed, they were deemed clear, sufficient, and enforceable. The CC accepted them and transformed through decision into binding obligations, while stricter conditions were imposed on the rest to ensure compliance.

By 2021, the CC closed the in-depth investigation with a series of decisions that imposed conditions on all undertakings, ensuring they refrained from agreements that restricted competition. There was established also a monitoring period of one year, during which the conduct of all undertakings in the market was closely observed. By 2022, the monitoring confirmed that the undertakings had respected the obligations and commitments. The CC formally closed the monitoring procedures, marking the end

of a case that had begun in the chaos of the pandemic but concluded with restored order in the market.

This case shows how, in a moment of crisis, businesses attempted to exploit consumer vulnerability through coordinated price increases. The ACA acted decisively, first with emergency interim measures, then with fines, obligations, and commitments. Ultimately, the enforcement ensured transparency, fair pricing, and the protection of consumers at a time when access to these materials was critical. It stands as a reminder that even in emergencies, competition law remains a vital safeguard against abuse.

6. Competition Compliance in Pharmaceutical markets

As described previously, the Albanian pharmaceutical market is characterized by several exclusive import rights, strict authorization procedures, dependence on a limited number of distributors, and high product differentiation. These characteristics may create high barriers to entry and increase the risk that vertical contractual relationships may unintentionally hinder market access. Compliance programs must emphasize non-discriminatory supply conditions, transparent criteria for selecting distributors or pharmacies, and objective justifications for any form of exclusivity.

During 2025, the ACA benefited by a technical assistance project with UNCTAD, funded by EBRD and SECO that made possible the preparation and dissemination of Competition Compliance Manuals in the pharma markets.

A well-structured compliance manual guides undertakings in identifying and mitigating risks associated with potentially restrictive agreements. Pharmaceutical companies must be particularly attentive to how they structure exclusivity, selective distribution, discounts, rebate schemes, and incentives. These practices must comply with the general principles of proportionality and necessity, meaning that restrictions should serve legitimate regulatory or efficiency purposes without going beyond what is required to maintain product integrity or safety, and avoid unjustified market foreclosure or restrictions on parallel trade.

Competition compliance also concerns information management; companies must be cautious about sharing sensitive data. Improper exchanges of pricing strategies, sales volumes, or future product launches can create the appearance or risk of coordination. An effective compliance framework sets out internal rules on data confidentiality, communication protocols, and restrictions on informal exchanges with competitors. Employees at all levels must be trained to recognize red flags, especially in interactions that may blur the lines between regulatory collaboration and commercial coordination.

Another critical component of compliance relates to procurement and tender participation. Tenders of medicinal products, particularly for hospitals, represents an important market segment, that compliance manuals may assist undertakings in ensuring that tender participation does not involve collusive bidding, bid rotation, or coordinated withdrawal.

Effective compliance in pharmaceutical markets cannot be achieved solely through written manuals. It demands internal structures capable of monitoring and enforcing compliance obligations. This includes setting up dedicated compliance officers or internal units responsible for overseeing competition-related procedures, approving contractual terms, and providing guidance to employees with regular training sessions. Documentation also forms a core element of compliance as undertakings should keep accurate records of decisions related to supplier selection, inventory allocation, pricing policies, and communication with regulatory bodies. This serves two purposes: ensuring transparency and enabling undertakings to demonstrate compliance if they are subject to investigation by the ACA.

7. Final remarks

The pharmaceutical sector in Albania requires a powerful compliance framework due to the complex interplay of regulatory obligations, market structure, and competition-law risks. A well-designed compliance manual serves as the foundation for ensuring lawful conduct, guiding undertakings through their distribution systems, vertical agreements, procurement procedures, and internal governance. It helps them understand the boundaries within which they operate and supports the creation of a stable, transparent, and competitive market environment.

Compliance is not only a formal requirement but an essential component of safeguarding public trust, ensuring fair access to medicinal products, and supporting a competitive ecosystem in a sector where consumer welfare is directly linked to availability, affordability, and safety. Strengthening corporate compliance structures, investing in continuous training, and engaging proactively with regulatory and competition authorities will be crucial for the sector's sustainable development, as well as contribute to Albania's long-term integration into the EU internal market.

Barriers to Parallel Import of Medicines to Bulgaria

Vesselka Kosserska
State Expert, Bulgarian Commission on Protection of Competition

The Bulgarian Commission on Protection of Competition initiated ex-officio competition advocacy proceeding in 2023 to assess the impact on competition of the legal provisions in Bulgaria regulating the parallel import of medicines. The proceeding was initiated following media reports on alleged normative and administrative barriers to import and trade with mainly prescription medicines, most of which are reimbursable medicines. Media reports revealed cases where prescription reimbursable drugs (e.g. human insulin), that are temporarily not available in Bulgaria, are already imported from other EU Member States but cannot be distributed from the warehouses and reach the patients due to administrative and legal obstacles.

The main focus of the CPC competition advocacy proceeding was to analyze the applicable to the parallel import of medicines legal framework in the country. As a rule, the use and trade with medicines for human use is strictly regulated legal area in all countries. Such regulation includes provisions on production, authorization for use, distribution, safety requirements, etc., as well as rules on pricing and reimbursement. Bulgaria, as EU Member States, applies the respective EU legislation in the area of medicines, as well as the EU rules on internal market and competition.

The relevant product market during the proceeding was identified as the market for medicines for human use that are identical or similar (as regards their active substance) to medicines already registered for use in Bulgaria and other EU country/ies, but imported in Bulgaria outside the usual distribution chain. The usual distribution chain of medicines includes the Marketing Authorization Holder (MAH) – wholesale distributors – retailers (pharmacies) or hospitals. For the sake of exactness, parallel trade with medicines, authorized for use by the European Medicine Agency (EMA) under the centralized EU procedure, is defined as parallel distribution, but medicines, authorized for use under the national authorization procedures of EU Member States, are defined as parallel trade within the internal EU market. The CPC examined both hypothesis without making distinction, as unobstructed (parallel) trade with goods and services within the internal EU market is one of pillars of the EU freedom of movement principles.

In the case of parallel import of medicines, the medicines are not imported in Bulgaria from the MAH, but from undertakings, having received authorization from the Bulgarian Drug Agency for import of particular medicine from another EU Member State, usually from wholesale distributors in that Member State. Once the medicine enters Bulgaria, the distribution chain is the same as the one for the medicines, imported from the MAH.

The parallel trade with medicines, specifically those, that are reimbursable, is driven by the different levels of reimbursement in EU Member States and therefore, the different reimbursement prices across the European Union. This distribution channel is supplementary in its' nature to the main source of medicines in EU countries in terms of quantities, operated by the MAH. In the case of Bulgaria, however, which is a small country and therefore small and not very attractive market for the medicines producers, such supplementary distribution channel could be beneficial for patients. As part of the CPC proceedings, patient associations expressed opinion that parallel trade was vital for supplying specific medicines to the Bulgarian patients. These associations pointed out that Bulgarian patients benefited through the years from the parallel trade to Bulgarian market of two main groups of medicines – in case of shortages in the EU market due to production reasons of some originator proprietary medicines and, on the other side in terms of prices– some cheap generic medicines, that are discontinued for supply by the MAH in Bulgaria due to low reimbursement levels.

When the CPC examined the applicable legal provisions regulating the parallel import of medicines in Bulgaria, it was established that there are generally three consecutive stages of administrative permissions to obtain in order to import and release specific medicine to the distribution chain in the country.

At the first stage, the parallel importer must obtain permission/authorization and generated authorization code for the medicine from the Bulgarian Drug Agency (BDA) for parallel import of specific medicine from specific EU country. The legal deadline for issuing this authorization is 45 days and this period could be extended to another 45 days, if the BDA does not obtain the requested information from the corresponding medicines authorization authority of the respective EU Member State, where the medicine

is exported from. The authorization obtained is valid for 5 years and after its' expiry the parallel importer should initiate new request and new authorization procedure.

At the next stage the parallel importers should apply to the Bulgarian national authority that sets the reimbursement price of the imported medicine and generates a reimbursement code for this specific medicine. The regulatory deadline for this procedure is 30 days, but this deadline could also be extended if the requested information is not supplied or received in time.

At the third and final stage, after receiving authorization for import and setting reimbursement price and code, the parallel importer should apply to the National Health Insurance Fund (NHIF), which is the public health insurance fund in Bulgaria, to receive generated reimbursement code to be filled in the prescriptions and in the pharmacies software when dispensing this medicine. The deadline for having this code generated is 14 days.

As it could be seen, the total minimum time needed for all administrative procedures in order to import and release to the distribution channel parallel import medicines in Bulgaria is 89 days and the maximum is 164 days. Parallel importers and associations asked for opinion during the CPC proceeding reported that the actual deadlines are much longer, varying from 180 to 390 days only for receiving the authorization permission.

Thus, the CPC identified the long deadlines and/or delays for receiving the necessary permissions for the actual release of medicines from parallel import as the first administrative obstacle. The other legal and administrative obstacle for the parallel import of medicines to Bulgarian market is the fact that at each stage of the administrative procedure and each of the three involved state authorities issue different codes for the specific product. It was established as well that even in the case of import of medicine with the same trade name from the same producer, the codes for the imported medicine are different from the ones, applicable for the medicine, supplied by the MAH. The reimbursement price also may be different. Different codes for one and a same product have direct implication for the prescription and sale of the product to the patient, as the pharmacies should dispense and get reimbursed only for this medicine with the specific code as chosen by the doctor, even though the active substance is the same, and even the producer and the trade name of the medicine may be the same. Thus, even though a medicine from a parallel import is available at the pharmacy, it cannot sell it to the patient if the doctor had checked in the prescription the code of medicine imported from the MAH (that could not be available in the pharmacy).

The CPC considered that these legal and administrative barriers to the parallel importers of medicines to the Bulgarian market are restricting competition in the Bulgarian market of medicines, especially reimbursable medicines. Evidence for these restrictions is the fact that in the period 2019-2023 only four parallel importers received authorization from the BDA and were actually operating in this market. The authorizations for parallel import of specific medicine imported from particular EU Member State were also not significant as number, ranging from 49 to 80 per year.

In its' **Decision No 1122/2024** on this issue, the CPC recommended to shorten the legal deadlines for issuing the necessary authorizations for parallel import of medicines. The Commission also considered that instead of generating different codes by the different competent authorities, it is more feasible to have a unified compound code for specific medicine (with the same active substance and dose), whose different parts and the corresponding information on the MAH or importer and the distributors should be generated by the respective state body and visible for them. The CPC also recommended to extend the authorization period for medicines from parallel import from 5 to 10 years, with a possibility for further prolongation under a simplified procedure as applicable to the same medicines supplied by the MAH. The CPC pointed out in its' decision as well that the rules on reimbursement levels should be clarified as the current rules allow different interpretations by state bodies and by the undertakings concerned which delays and, in some cases, discourages potential parallel importers of medicines in Bulgaria. More active parallel import of medicines to Bulgaria will benefit Bulgarian patients with access to medicines that are not otherwise economically attractive for MAH to supply to Bulgarian market.

Excessive Pricing in Pharmaceutical Market: GCCA's Experience

Mariam Berulava
Deputy Head of the Strategic Markets Monitoring Department, Georgian Competition and Consumer Agency

Introduction

The pharmaceutical market plays a critical role in ensuring public access to safe, effective, and affordable medicines. Given the essential nature of pharmaceutical products, pricing practices in this sector are of particular importance, as they directly affect both consumer welfare and public health outcomes. Pharmaceutical markets present particular vulnerability to exploitative abuse due to barriers and inelastic demand. For this reason, the pharmaceutical sector is widely regarded as one of the most highly regulated industries. Maintaining effective competition in this market has long posed a challenge for regulators and competition authorities. Although the entry of an increasing number of generic products would be expected to foster competition and reduce profit margins, but markets characterized by limited competition, or the presence of dominant undertakings remain susceptible to excessive pricing. Such practices may result in unjustifiably high costs for consumers and impose a significant burden on healthcare systems. Taking into account the significance of the pharmaceutical market and the aforementioned characteristics, the Agency devotes considerable attention to this sector. The Agency has conducted comprehensive market monitoring and, as a result, has identified various issues of concern, for which it has issued appropriate recommendations. Furthermore, in 2025, the Agency concluded an investigation initiated in relation to the alleged abuse of a dominant position.

Background

The Law of Georgia on Competition establishes the legal framework addressing unfairly high pricing, in particular Article 6, paragraph 2, subparagraph "a". Following the signing of the Association Agreement, amendments made to the Law in 2014 Article 6 aligned with Article 102 of the TFEU. Under the applicable legislation, pricing practices are expressly recognized as forms of abuse of a dominant position.

The Agency initiated an investigation based on a referral from the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia. The referral indicated that, during the period 2021–2023, eight undertakings applied high mark-ups to medicinal products (ranging from 300% to 3000%) across the supply chain, from importation to retail sale.

Based on the correlation between the factual circumstances outlined in the referral and the additional evidence reviewed by the Agency, the standart of reasonable suspicion of a potential infringement of the Law was met. Consequently, the Agency initiated a formal investigation into a possible violation of Article 6 of the Law by the eight respondent companies.

Relevant market

Given that the subject matter of the investigation concerned an alleged abuse of a dominant position and that excessive pricing analysis is only meaningful once dominance has been established, the Agency, as a preliminary step, conducted an assessment to identify and define the relevant market in accordance with applicable competition law principles and established methodologies.

In this case, each of the eight companies under investigation was active in the wholesale marketing and distribution of medicinal products, supplying them to pharmacy chains. After considering all relevant factors, including market dynamics, regulatory framework in Georgia, demand-side substitution, and the fact that patents for all relevant drugs had long expired, the Agency defined the product market at the molecule level (ATC 5 classification). In light of the foregoing, the Agency determined that four of the eight companies held a dominant position in their respective markets.

Methodology for assessing excessiveness

In evaluating the conduct of the companies, the Agency applied best practices developed by the executive and judicial bodies of the European Union within this legal framework, in particular test for assessing excessive pricing established by the ECJ in the United Brands case, which consists of two limbs:

- Limb 1: Whether the difference between the costs actually incurred and the price actually charged is excessive ("Excessive Limb");
- Limb 2: Whether the price is unfair, either in itself or when compared to competing products ("Unfair Limb").

Both limbs must be satisfied for a price to qualify as abusive.

For the purpose of establishing the costs incurred by the respondent undertakings during the relevant period, as well as determining an appropriate and reasonable profit margin, the Agency applied the cost-plus methodology. This method involves comparing the costs incurred by the undertaking with the price charged for a specific product to determine whether the price is excessive. It requires: (1) identifying the costs actually incurred (such as import costs, distribution costs, administrative expenses, etc.), and (2) assessing whether the resulting price may be considered excessive.

With regard to costs, both direct costs attributable to the product and indirect costs that can reasonably be allocated to it must be considered, using an appropriate proportion. Importantly, only costs incurred in a reasonable and efficient manner may be taken into account when determining product-specific costs. Accordingly, the Agency adjusted certain cost elements reported by the companies. For the purpose of allocating wholesale costs to a single package of a specific medicine, the GCCA applied an output-based method, distributing costs based on volume.

Following the determination of total costs, the "plus" element of the cost-plus margin - namely, a reasonable profit margin or reasonable rate of return - must be established. The resulting figure is then compared to the actual price. If the price exceeds the cost-plus benchmark, the difference is assessed to determine whether it is substantial and sufficiently high to be considered excessive.

During the investigation, after establishing reasonable margins for each pharmaceutical product, the Agency found that, in certain cases, actual prices significantly and persistently exceeded the cost-plus benchmark by 140.7%, 115%, and 96.6%, respectively.

Furthermore, while excessive pricing does not automatically constitute a violation of the Law, an undertaking holding a dominant position bears responsibility for assessing the risk that such pricing may be deemed unfairly high. In this context, the Agency evaluates whether the price is unfair in itself or in comparison with competing products or services. The existence of either condition is sufficient to establish a violation. The second step of the test involves two alternatives: (1) assessing whether the price is unfair in itself, or (2) whether it is unfair when compared to competing products. The GCCA examined both alternatives.

Under the first alternative, the Agency assessed whether: the excess was economically justified; objective reasons existed for higher margins; or cost shocks explained the deviation. No such factors such as innovation, improvements, investments, R&D expenditure, specific commercial risks, or regulatory pressures were identified to justify the excessive prices. Moreover, the economic value of the products did not exceed the cost-plus benchmark. In the absence of objective justification, the pricing was deemed exploitative.

This alone provided a sufficient basis for the Agency to conclude a violation of the Law. Nevertheless, given the high standard of proof required, the Agency also examined the second alternative of the second step.

Under this alternative, none of the comparison methods applied to the prices of five pharmaceutical products was found to provide a reliable benchmark. Accordingly, for those products, the Agency relied solely on the results obtained under the first alternative. For the remaining two pharmaceutical products, the Agency determined that comparing the disputed prices with prices from a previous period constituted an appropriate method. This analysis demonstrated that the price increases lacked an economic basis, they were not driven by cost increases, were disproportionate to cost variations, and were therefore unjustified.

Conclusion

During the investigation, it was established that the imposition of unfairly high prices by the companies constituted a violation of Article 6, paragraph 2, subparagraph (a) of the Law, which prohibits the fixing of unfair prices by undertakings holding a dominant market position.

According to the Agency's decision, four respondent companies were fined. In addition, the Agency issued a binding recommendation addressed to the undertakings concerned, as well as to other relevant market participants and potential entrants. Specifically, it emphasized that pricing policies for products and/or services within the relevant market must be designed to ensure that potential anti-competitive risks are assessed and taken into account prior to price setting.

Competition Policy in Kazakhstan's Pharmaceutical Sector: From Antitrust Enforcement to Pro-Competitive Reform

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The pharmaceutical sector is among the most sensitive industries for competition policy. The degree of competition in the markets for medicines and medical devices directly affects access to healthcare, the pace of innovation, and the efficiency of public expenditure. Kazakhstan's experience demonstrates that the sustainable development of competition requires a combination of antitrust enforcement, regulatory reform, and the digitalisation of market-entry procedures for pharmaceuticals.

One of the largest segments of Kazakhstan's pharmaceutical market is public procurement of medicines under the guaranteed volume of free medical care and the compulsory social health insurance system. Public spending in this area increased from USD 784.4 million in 2022 to USD 979 million in 2024. Today, the public segment accounts for roughly 40% of the country's entire pharmaceutical market.

The scale of public expenditure creates heightened risks of anti-competitive conduct. Enforcement practice of the Agency for Protection and Development of Competition of the Republic of Kazakhstan (hereinafter – the Agency) shows that the most common infringements include bid-rigging arrangements, horizontal price-fixing among competitors, market allocation by territory or customer, and the exclusionary procurement design through procurement documentation tailored to specific suppliers.

These problems have been particularly acute in the market for storage and transportation services for pharmaceuticals. Despite the presence of a significant number of potential market participants, procurement contracts for many years were concentrated among a narrow group of companies. In 2023, the Agency concluded an investigation against several major market players for sham competition in tenders conducted by the single distributor. The findings of the competition authority were subsequently upheld by the Supreme Court of the Republic of Kazakhstan.

At the same time, the analysis showed that limited competition was driven not only by the conduct of market participants but also by specific features of the regulatory framework. Procurement of storage and transportation services was conducted as a single lot, while existing requirements restricted the use of alternative logistics routes and created barriers to entry for new providers.

As part of a broader package of pro-competitive measures, the procurement design was revised. The number of lots was increased, allowing a wider pool of bidders to participate and creating conditions for the entry of new logistics providers. In addition, contract terms were reviewed, including contract duration and the mechanisms used to determine service prices.

Alongside improvements to the procurement system, an important pillar of Kazakhstan's competition policy has been the digitalisation of market-entry procedures for pharmaceuticals. In May 2024, under the Presidential Decree "On Measures to Liberalise the Economy", and at the initiative of the Agency, a comprehensive digital transformation of key procedures governing the circulation of medicines and medical devices was launched.

In cooperation with the Ministry of Health of the Republic of Kazakhstan and the Ministry of Artificial Intelligence and Digital Development, the government is implementing the "Single Window" project, which provides for the automation of several regulatory processes, including price notification, amendments to registration dossiers, expert assessments, and inclusion of medicines in the national formulary. The deployment of digital solutions is expected to reduce the time required for market entry from several years to 100 working days.

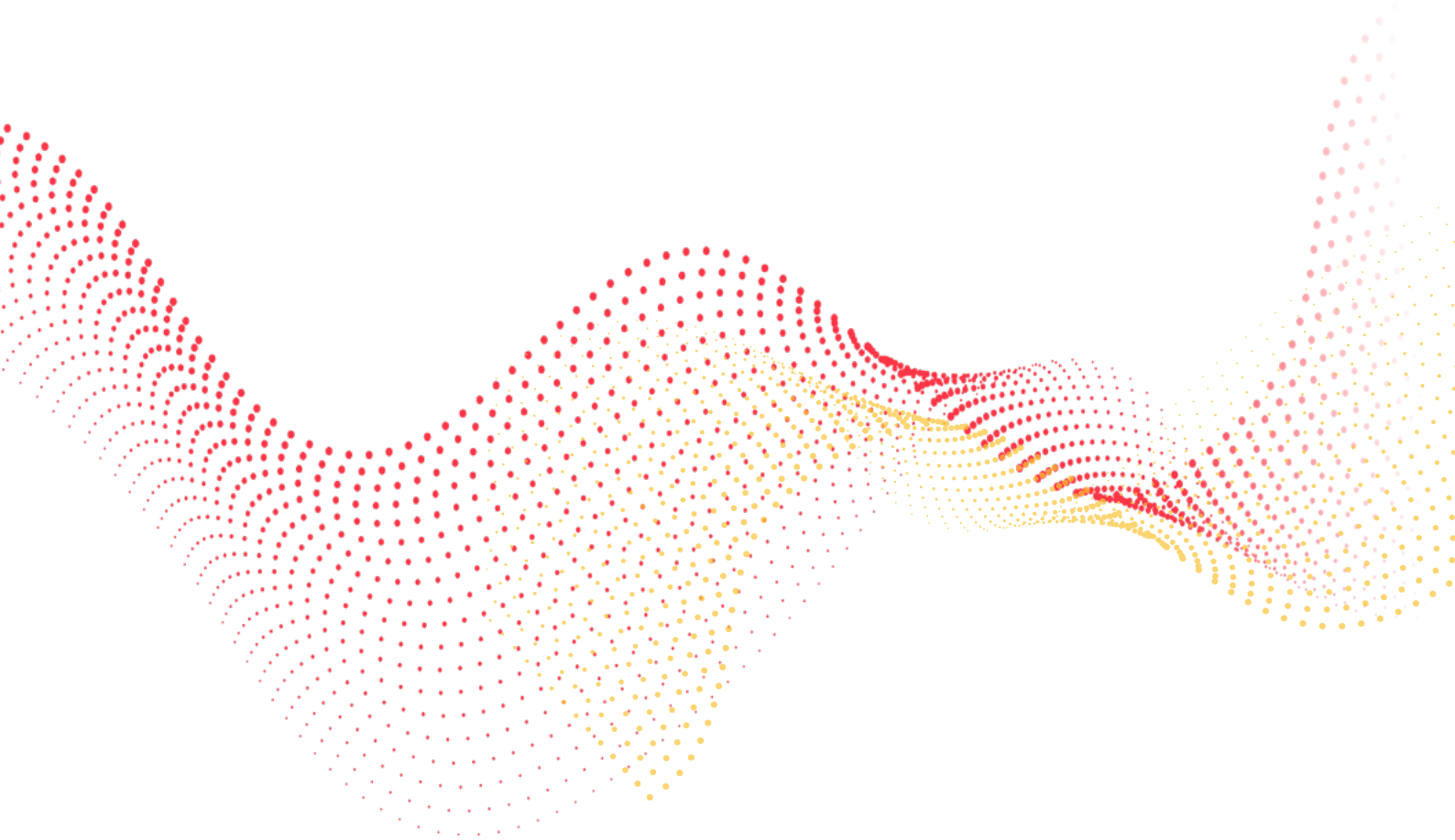
This reform has significant competition implications. In practice, manufacturers often waited one to two years – or longer – for their products to be included in public procurement lists. Such delays restricted patient access to new treatments, reduced the sector's investment attractiveness, and hindered the entry of new market players. Reducing administrative barriers will accelerate the introduction of innovative medicines and enhance competition in the market.

Another important direction of reform has been the phased deregulation of medicine prices. Under the Competition Development Roadmap for the Healthcare Sector adopted in 2022, Kazakhstan began to phase out excessive state price regulation in the commercial segment. The first stage, launched in 2023, covered a number of over-the-

counter (OTC) medicines. Although prices rose briefly following the removal of price controls, the subsequent development of competitive pricing mechanisms contributed to their stabilisation.

The second stage, implemented in 2025, extended deregulation to all OTC medicines. The results showed price reductions across a significant share of products, confirming that competitive market forces are capable of ensuring efficient price formation without administrative intervention. The third stage of the reform – now underway – provides for the gradual deregulation of prices for prescription medicines.

Kazakhstan's experience demonstrates that effective competition policy in the pharmaceutical sector goes far beyond detecting and sanctioning cartels. Long-term results are achieved through the removal of regulatory barriers, the digitalisation of government services, the reduction of administrative burdens on businesses, and the creation of conditions for open and non-discriminatory market access. It is precisely the combination of antitrust enforcement and pro-competitive regulatory reforms that improves access to medicines, encourages investment, and supports the sustainable development of the healthcare sector.



Future of Exclusive Distribution in the Pharmaceutical Market under New Regulation on Vertical Agreements in Serbia

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Introduction

The Republic of Serbia represents a jurisdiction in which restrictive agreements that do not qualify for block exemption must be subject to prior individual exemption approval by the competition authority. Unlike the EU system of self-assessment, undertakings in Serbia are required to obtain a formal decision from the Commission for Protection of Competition (the "Commission") before implementing such agreements.

Within this framework, a particularly notable share of exemption requests concerns the pharmaceutical sector, and more specifically, exclusive distribution agreements for human medicines. This concentration is not incidental. It reflects both the structural features of the pharmaceutical market and the incentives of market participants operating within a highly regulated environment.

Recent decisional practice shows that the Commission has adopted an increasingly stringent approach toward such agreements when they affect public procurement channels. This shift underscores the need to carefully reassess the role of exclusive distribution in a market where competition, regulation, and public health objectives intersect.

At the same time, the Serbian legal framework has been further aligned with EU standards through the adoption of a new Regulation on vertical agreements[1], bringing it closer to the current Vertical Block Exemption Regulation (VBER). A particularly relevant feature of this alignment is the explicit possibility for a supplier to appoint up to three exclusive distributors (previously it was one) for a given territory or customer group, while restricting active sales by other direct buyers that are not appointed distributors. While this model aims to balance efficiency and competition in general markets, its application in the pharmaceutical sector in the context of public procurement — will have to remain under the close scrutiny of the Commission.

Structural Characteristics of the Pharmaceutical Market in Serbia

The pharmaceutical market in Serbia is one of the most heavily regulated product markets. Regulation affects virtually all aspects of market activity, including:

- entry conditions for companies and products,
- licensing requirements for wholesalers,
- pricing of medicines, and
- distribution channels.

Wholesale distribution is limited to licensed entities and subject to strict conditions, including compliance with Good Distribution Practice and obligations related to maintaining supply continuity.

In parallel, each medicine must receive marketing authorization, and the marketing authorization holder (MAH) bears responsibility for quality, safety, and supply continuity. This introduces a dual-layer structure in distribution, where both wholesalers and MAHs play critical roles, but with asymmetric responsibilities, particularly regarding supply security.

A defining feature of this market is price regulation. Maximum prices of prescription-only (Rx) medicines are determined through a reference pricing system, while wholesale margins are capped. In practice, market participants *de facto* treat those maximum prices as fixed prices, which leads to limiting price competition, especially in public procurements.

These regulatory constraints significantly shape competitive dynamics. While administrative barriers to entry are substantial, they are complemented by structural features that reduce the scope for price-based competition and shift competitive parameters toward access to supply and participation in procurement processes.

A key characteristic of the Serbian pharmaceutical market is the dominant role of public financing through the Republic Health Insurance Fund (RFZO). Inclusion on the RFZO reimbursement list is essential for any medicine intended for widespread use. Without such inclusion, medicines are effectively excluded from the publicly financed system and must be purchased directly by patients, which significantly limits demand. The RFZO list has several important implications:

- market access gatekeeper;

[1] Regulation on categories of vertical agreements exempted from the prohibition of restrictive agreements ("Official Gazette of the Republic of Serbia" no. 27/2026), entered into force on 28.03.2026.

- only medicines included on the list can be widely dispensed within the public healthcare system;
- price benchmarking function;
- the reimbursement price set by RFZO often becomes the effective ceiling price in both public procurement and commercial distribution;
- demand structuring effect;
- pharmacies are incentivized to dispense medicines covered by public insurance, meaning that demand is largely concentrated around reimbursed products.

Public procurement represents a major distribution channel, with tenders typically structured under a "one lot – one medicine" principle or narrowly defined specifications. Moreover, prices achieved in public tenders have a spillover effect on the commercial segment. Even medicines dispensed outside tenders must remain competitively priced relative to tender outcomes in order to remain viable within the reimbursement system. This creates a tightly interconnected system in which procurement design, pricing, and distribution models jointly determine competitive outcomes.

Exclusive Distribution in the Pharmaceutical Sector

Exclusive distribution agreements are a common feature of vertical relationships in the pharmaceutical sector. In Serbia, however, their implementation is subject to strict scrutiny due to the requirement of individual exemption. The Commission assesses such agreements using criteria aligned with EU competition law, examining whether they:

- contribute to efficiencies or improvements,
- allow consumers a fair share of benefits,
- are indispensable, and
- do not eliminate competition.

In practice, most exemption requests in the pharmaceutical sector relate to exclusive distribution arrangements, either for individual medicines or entire portfolios. Recent cases indicate that the Commission has adopted a more restrictive stance, particularly where exclusivity affects participation in public tenders.

Comparison of two regulatory approaches in light of competition concerns from the past

The identified competition concerns must be assessed not only in light of market characteristics, but also in the context of the evolution of the legal framework governing vertical agreements. Under the previous regulation, exclusive distribution was effectively structured as a system in which the supplier appointed a single exclusive distributor for a given territory or customer group. In practice, this model frequently resulted in a complete elimination of intra-brand competition in public procurement. Under the new Regulation on vertical agreements, aligned with the EU Vertical Block Exemption Regulation (VBER), exclusive distribution system is defined as a system whereby a supplier allocates a specific territory or group of customers exclusively to itself or to up to three immediate buyers-distributors, while restricting other buyers from engaging in active sales into that territory or customer group.

Although it introduces a more flexible approach by allowing the appointment of up to three exclusive distributors, its actual impact on competition in the pharmaceutical sector remains uncertain and must be assessed in light of the specific market constraints set out in this paper.

Under the previous "single distributor" model, intra-brand competition was eliminated, considering the design of public procurement. In practice it resulted in situations where only one bidder could effectively participate. The new framework, by allowing up to three exclusive distributors, theoretically creates room for limited intra-brand competition. The Commission views the future implementation of this framework with optimism, as the presence of multiple distributors is expected to foster effective intra-brand competition on public procurements of Rx medicines. However, in practice, several structural factors significantly constrain this potential: wholesalers remain dependent on authorization by the MAH and parallel import is not feasible like in the EU internal market, thereby removing an external source of competitive pressure.

Previously, exclusive distribution frequently resulted in *de facto* foreclosure, due to restricted access to supply and bidding opportunities. This model also led to bidding prices aligned with maximum permitted levels. The new regulation could, in principle, mitigate foreclosure by enabling more distributors to participate, and is a step towards creating a stronger level playing field for enhancing price competition when exclusive distribution is granted. However, this depends critically on whether all appointed distributors are granted comparable commercial conditions, and they are genuinely independent in their bidding behavior. If one distributor retains structural advantages (e.g., better pricing, priority supply, or stronger contractual ties), the presence of additional "exclusive" distributors does not automatically eliminate foreclosure risks.

Under the single-distributor model, supply chains were highly concentrated, which could amplify risks in case of disruption. The new framework has the potential to improve supply resilience by allowing multiple distribution channels.

However, this benefit is conditional, as the misalignment between the MAH and distributor may persist unless one of the distributors also assumes the role of MAH. Such integration, however, carries its own risks for effective competition in public procurement markets, given that contracting authorities typically require authorization from the MAH, thereby potentially reinforcing the competitive advantage of that entity. Notably, this risk is not new, as under the previous regime the exclusive distributor frequently also acted as the MAH, further consolidating control over both supply and market access.

Under the previous regulatory framework, the Commission consistently emphasized the importance of ensuring that the widest possible number of wholesalers could participate in public procurement procedures. Accordingly, even in cases where exclusive distribution agreements were granted individual exemptions, such approvals were typically subject to conditions aimed at preserving market access. In particular, it was required that other wholesalers be allowed to procure relevant medicines from the exclusive distributor, and that the marketing authorization holder (MAH) issue authorization statements enabling their participation in public tenders. This approach effectively sought to mitigate the restrictive effects of exclusivity by safeguarding a minimum level of intra-brand competition in procurement procedures. Under the new Regulation on vertical agreements, the legal structure of exclusive distribution has been modified in line with the EU VBER, including the possibility to restrict active sales by non-appointed buyers. As a result, other direct purchasers, even where they exist, may be prevented from actively marketing or bidding the product, which in practice can limit their effective participation in public procurement. However, the new framework does not restrict the ability of buyers of the exclusive distributor to actively offer the products, meaning that secondary distribution channels may still formally exist. In this sense, the Commission's previous practice of imposing conditions - such as ensuring access for wholesalers and requiring MAH authorization statements - may remain conceptually relevant even under the new regime, as a tool to preserve a minimum level of competitive access in procurement markets.

With the introduction of the new regulation, the Commission is likely to place greater emphasis on: actual effects on competition in practice, rather than formal compliance with the "three distributor" threshold, and the functioning of competition in public procurement as the key assessment benchmark. This suggests that the mere existence of multiple exclusive distributors will not be sufficient to justify exemption, particularly where market outcomes do not demonstrate effective competition. This will require a period of monitoring market dynamics under the new framework.

Conclusion

The transition from a single-distributor model to a system allowing up to three exclusive distributors represents a step toward closer alignment with EU competition rules. While its practical impact on the Serbian pharmaceutical market will need to be assessed over time, the reform has the potential to introduce a more balanced distribution structure if multiple exclusive distributors are appointed.

At the same time, its ability to generate effective intra-brand competition in public procurement of medicines will depend on how these changes operate in practice within a highly specific market environment. Structural features such as strong regulatory constraints, centralized procurement, and limited scope for parallel trade may still limit the speed and intensity with which formal changes translate into competitive outcomes. However, they do not exclude the possibility of gradual improvements in competitive dynamics over time.

In this context, the Commission's focus will remain on assessing actual market effects rather than the formal design of distribution arrangements. A data-driven, effects-based assessment will therefore be essential in order to capture both the constraints and the potential benefits of the new framework as it develops in practice.

2. International Expert Contributions

The Former Andalusian System for the Selection of Medicines: Competition Engineering in a Regulated Pharmaceutical Market

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In regulated sectors, competition does not disappear; it is shaped by law. The Spanish pharmaceutical retail market offers a paradigmatic example of how regulatory design determines the locus and intensity of rivalry. The former Andalusian system for the selection of medicines – no longer in force – provides a valuable case study of how competitive mechanisms can be introduced without altering administratively fixed prices.

1. Competition Under Regulation: The General Spanish Model

The outpatient pharmaceutical benefit financed by the Spanish National Health System (SNS) operates under a dense regulatory framework. The consolidated text of the Law on Guarantees and Rational Use of Medicines (Royal Legislative Decree 1/2015) establishes the core legal architecture governing pricing, financing and dispensing conditions[2].

This framework includes:

- Administrative price setting.
- A reference pricing system.
- Prescription by active ingredient[3].
- Regulated pharmacy margins.

Under this structure, the retail price of publicly financed medicines is not determined by market forces. Autonomous Communities lack competence to regulate or modify pharmaceutical prices, which remain within State authority. Traditional price competition at the retail level is therefore structurally constrained.

However, prescription by active ingredient introduces a decisive competitive variable. When several medicines within a reference group share the same regulated price, the system leaves open a crucial question: which specific brand will actually be dispensed?

In the general Spanish model, this decision largely rests with the pharmacy, within the regulatory framework governing substitution and dispensing[4].

From a competition perspective, this margin of discretion is economically significant. When prices are equal, competition shifts from price to selection. The right to be dispensed becomes the relevant scarce asset.

Competition therefore persists – but it operates upstream and indirectly.

2. The Former Andalusian Reform: Competition "for" the Market

The former Andalusian system was introduced through Decree-Law 3/2011 of 13 December, amending the Law 22/2007 on Pharmacy of Andalusia, incorporating Articles 60 bis to 60 *quinquies* regulating the selection mechanism[5].

The system applied when medicines were prescribed by active ingredient and operated through public calls for specific active ingredients. For each formulation of an active substance or combination of active substances, the medicine to be dispensed in Andalusian pharmacies for a period of two years shall be the one submitted by the pharmaceutical laboratory whose proposal represents the lowest final cost to the Andalusian Health Service for the corresponding prescription among those submitted. Furthermore, in order to guarantee continuity of supply, participating pharmaceutical laboratories were required to demonstrate sufficient prior production capacity for medicines of the same pharmaceutical form as the one proposed, as well as to submit an express declaration undertaking to ensure its adequate and uninterrupted supply.

Any Laboratory worldwide could submit proposals (competing to be selected by offering economic benefits), and the medicine selected was the one whose offer represented the lowest final cost for the Andalusian Health

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[2] Royal Legislative Decree 1/2015, of 24 July (BOE No. 177, 25 July 2015), https://www.boe.es/buscar/doc.php?id=BOE-A-2015-8343
[3] Article 87 RLD 1/2015.
[4] Law 16/1997, of 25 April (BOE No. 100, 26 April 1997), https://www.boe.es/buscar/doc.php?id=BOE-A-1997-9029
[5] Decree-Law 3/2011, of 13 December (BOJA No. 246, 19 December 2011), https://www.juntadeandalucia.es/boja/2011/246/BOJA11-246-00002-19799-01_00004184.pdf

Service (SAS). Pharmacies were required to dispense the selected product.

Several clarifications are legally and economically relevant:

- The calls were open to all pharmaceutical laboratories meeting statutory requirements.
- No retail price was modified; the national price-setting framework remained intact.
- The mechanism was not a classical public procurement auction.
- It derived directly from statutory authorization.
- Supply guarantees were embedded in the design.
- The SAS did not act as a purchaser competing in the reference market.

The distinction between regulatory intervention and public procurement was addressed in early procedural challenges, including the Resolution 21/2012 of the Andalusian Administrative Tribunal for Contractual Appeals (8 March 2012)[6].

The reform did not deregulate the pharmaceutical market nor modify the content of the pharmaceutical benefit. Instead, it reallocated the competitive margin.

The system structured rivalry *ex ante* among laboratories. It transformed competition "in the market" – limited by regulated prices and the choice of the brand to be dispensed by pharmacies on non-transparent grounds – into competition "for the market."

3. Judicial Review and Legal Boundaries

The former Andalusian system generated significant constitutional and administrative litigation.

In Judgment 210/2016, the Spanish Constitutional Court upheld the constitutionality of the selection mechanism[7]. The Court confirmed that the Autonomous Community acted within its healthcare management competences and did not invade State powers over price regulation or pharmaceutical legislation.

Earlier, the Court had lifted the suspension of the challenged provisions through Order 238/2012[8].

Subsequent Supreme Court case law confirmed the regulatory nature of the mechanism and its distinction from classical public procurement, notably in Judgment 852/2021 (15 June 2021)[9].

From the perspective of Law 20/2013 on Market Unity[10], the mechanism did not restrict freedom of establishment or free movement. Andalusia maintained dispensing under the same national legislative framework applicable throughout Spain, thereby preserving the unity of the pharmaceutical market.

The controversy therefore concerned not market access in a classical sense, but the internal allocation of economic advantages within a regulated structure.

4. Competition Analysis: Structural Effects

The former Andalusian model raises broader doctrinal questions for competition policy.

In regulated price systems, rents may arise not from pricing power but from selection power. Where the right to supply depends on decentralized or opaque decision-making, competition may be fragmented and indirect.

By formalizing selection through transparent calls, the Andalusian system aimed to:

- Increase transparency in transactional conditions.
- Reduce informational asymmetries.
- Provide greater certainty of demand for selected laboratories.
- Internalize economic surplus within the public healthcare budget.

Publicly reported estimates attribute approximately €755 million in revenues to the Andalusian Health Service between 2012 and 2018, with annual figures in later years reportedly exceeding €180 million[11].

The former Andalusian model was also examined by the Spanish National Commission on Markets and Competition (CNMC) in its *Study on the Wholesale Distribution of Medicines in Spain (E/CNMC/002/17)*. The CNMC expressly referred to the Andalusian selection system as the only regional experience of competitive tendering for medicines dispensed through community pharmacies between 2012 and 2019. While acknowledging that the system generated competition among laboratories during the selection procedure and could potentially deliver significant savings through demand aggregation, the CNMC also noted that the award mechanism granted a temporary exclusive position to the selected laboratory. Crucially, the report situates the Andalusian experience within the rigid Spanish

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[6] Resolution 21/2012, Andalusian Administrative Tribunal for Contractual Appeals (8 March 2012).

[7] Constitutional Court, Judgment 210/2016 (BOE No. 16, 19 January 2017), https://www.boe.es/buscar/doc.php?id=BOE-A-2017-645

[8] Constitutional Court, Order 238/2012.

[9] Supreme Court, Judgment 852/2021 (ECLI:ES:TS:2021:2499).

[10] Law 20/2013, of 9 December (BOE No. 295, 10 December 2013), https://www.boe.es/buscar/doc.php?id=BOE-A-2013-12888

[11] Forest Partners report as cited in national media: *La Vanguardia*, 13 February 2019: https://www.lavanguardia.com/local/sevilla/20190213/46443602733/un-informe-cifra-en-755-millones-los-ingresos-para-el-sas-del-sistema-de-subasta-de-medicamentos-desde-su-implantacion.html *Europa Press*, 17 March 2019: https://www.europapress.es/andalucia/noticia-subastas-medicamentos-podrian-generar-mas-1000-millones-ahorro-cuatro-anos-informe-20190317103434.html

regulatory framework, where Autonomous Communities cannot intervene in price-setting. In that context, the Andalusian system can be interpreted as an attempt to introduce the highest degree of competitive pressure legally possible without breaching State competences or disrupting market unity – a point consistent with the Constitutional Court's validation of the model[12].

From a competition standpoint, the mechanism did not eliminate rivalry. It redirected it. Laboratories competed to secure predictable regional demand under regulated price conditions. The economic incentive shifted from influencing dispensing discretion to offering structured economic improvements to the public authority.

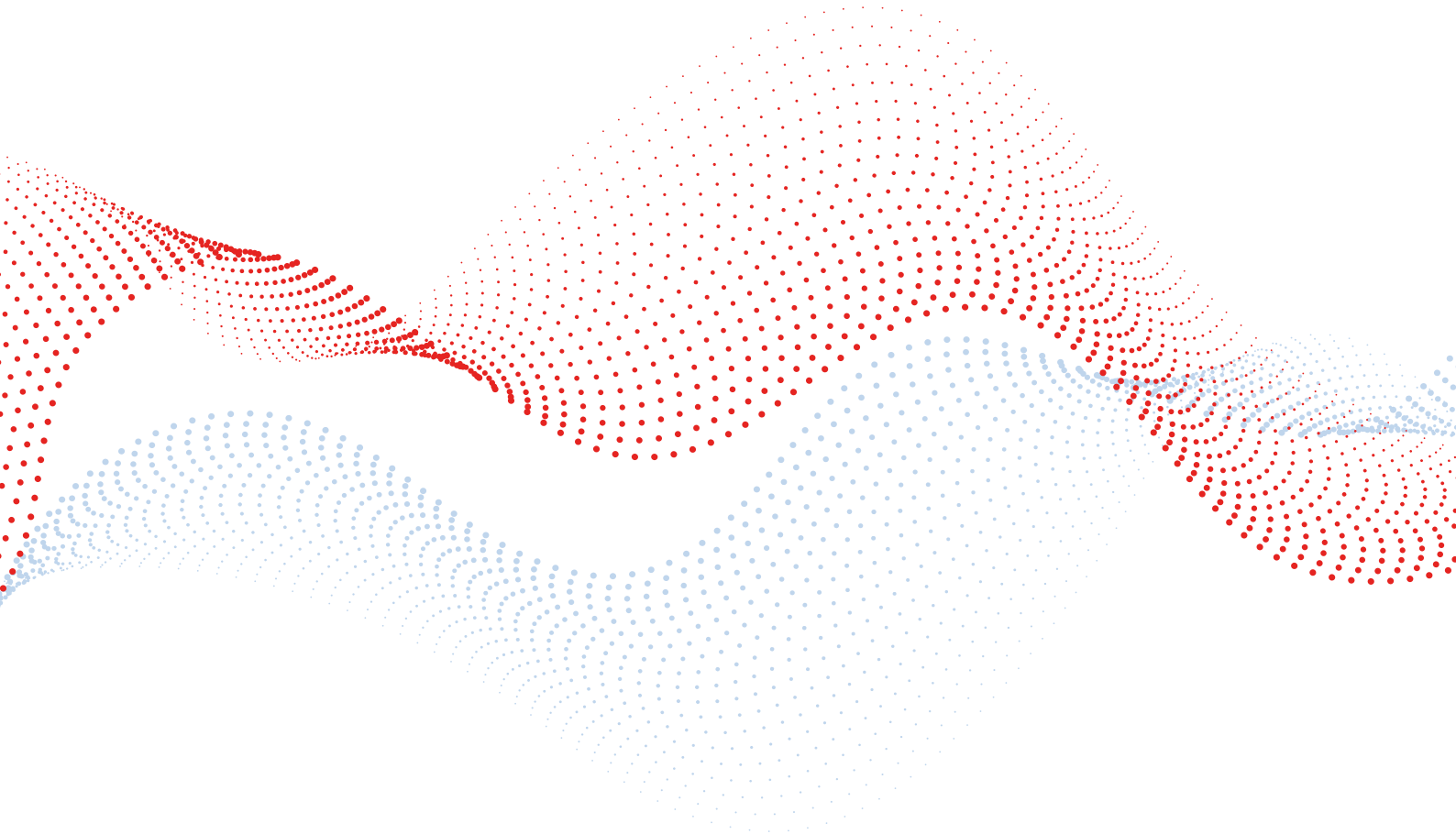
5. Conclusion

The former Andalusian system for the selection of medicines represents a notable example of competition engineering within a highly regulated healthcare market.

It did not alter retail prices. It did not modify the nationally defined pharmaceutical benefit. It did not introduce discriminatory barriers to entry. Instead, it redefined where and how competitive pressure operated.

Under the general Spanish model, prescription by active ingredient leaves the decisive competitive variable at the dispensing level. Under the former Andalusian system, that variable was relocated to a structured public selection process. In doing so, the mechanism formalized rivalry among laboratories and redirected the associated economic surplus toward the public budget.

Although the system is no longer in force, its doctrinal relevance remains. It provides a concrete illustration of how regulatory design shapes competitive interaction, reallocates rents, and influences market dynamics within publicly financed sector.



[12] CNMC, *Study on the Wholesale Distribution of Medicines in Spain*, E/CNMC/002/17, 2017, pp. 57 (note 142) and 132–134, available at: https://www.cnmc.es/sites/default/files/1619673_1.pdf

Combination Therapies and Mixed Bundling as Promising Candidates for Clinical (Competition Law) Trials

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Introduction

Since at least the early 2010s, the pharmaceutical sector has been subject to intense scrutiny under competition law, and all the more so in Europe, where authorities, unlike their counterparts in the United States, rigorously enforce (also) the prohibition on excessive pricing. Given that the existing case law has already been extensively surveyed in the literature, this article instead adopts a forward-looking perspective.

Building on a broader article (Arnaudo 2025a) addressing combination therapies (CTs), and taking into account more recent developments, the focus here is on possible developments concerning mixed bundling cases, namely commercial practices whereby sellers offer products both individually and as part of a package, with the bundle usually priced at a discount relative to purchasing the components separately. This is, it should be made clear, an exploratory exercise, which does not purport to offer conclusive findings on the topic but is instead offered to the reader's curiosity – and willingness to pursue further exploration.

CTs: A Taxonomy of Opportunities and Competition Risks

At the forefront of both scientific research and market development, CTs involve the use of two or more therapeutic agents to treat a disease, typically comprising a "backbone" drug together with one or more add-on components. Their use has expanded significantly over time: in 2023, the WHO Model List of Essential Medicines included 55 combination therapies out of 635 listed medicines (8.7%), compared with only 5 out of 208 medicines (2.4%) in 1977. This growth reflects well-recognised clinical advantages, including enhanced efficacy through multi-pathway targeting and improved patient adherence facilitated by single fixed-dose combinations.

Alongside these benefits, CTs also generate significant complexities for pricing and reimbursement negotiations, as well as for marketing strategies, since the relevant drugs may be owned either by different firms or concentrated within a single company, under a variety of possible exclusivity-rights configurations.

As regards pricing negotiations, authorities confronted with CTs often seek bundled discounts, which the holders of the individual components may lack either the incentive or the practical ability to provide, with the consequence that the availability of such combination products to patients may be more difficult to secure.

From an antitrust perspective, CTs create structural incentives for potentially anticompetitive conduct based on the leveraging of one or more exclusivity rights. On the one hand, firms may simultaneously cooperate in the development and marketing of a CT while competing in the markets for the individual components, thereby providing a particularly salient illustration of the concept of "coopetition." On the other hand, a single firm may develop complex recombinatory strategies across therapeutic components in order to sustain and extend its dominant position.

For instance, where all CT components remain under exclusivity and are held by different firms, horizontal coordination may delay or prevent entry of cheaper alternatives through "no-generic restraints" agreements concluded in anticipation of impending patent cliffs affecting one of the components. Anticompetitive arrangements may also arise between originator and generic firms that are jointly "on board" a CT, for example through mutual commitments not to use or supply products in alternative combinations, thereby restricting output, limiting competition, and sustaining high prices.

On a unilateral basis, a firm holding exclusivity over all components, or at least over the "commanding" backbone, may foreclose competition by strategically delaying the introduction of new treatments based on that backbone as part of a long-term product-launch strategy designed to preserve its competitive advantage in the relevant (disease) market. It may also engage in "product hopping," shifting demand away from products facing imminent generic entry and toward newly protected combinations. To be noted, although these practices are typically characterized as uni-

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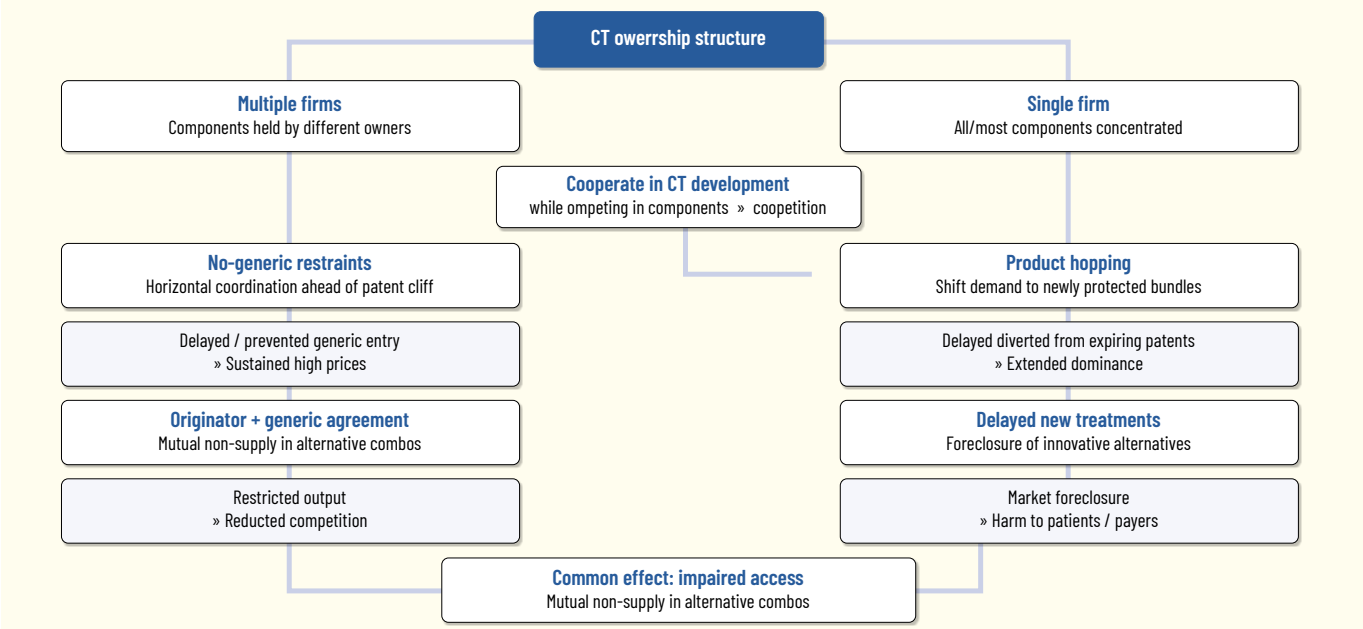
lateral conduct, they may equally be pursued by firms that are parties to a CT, provided that they are able to sustain a particularly effective form of strategic cooperation.

Given the relative complexity of the "combinations" available, an illustrative table of possible conducts and consequences is provided below.



Source: design developed by the author using various AI tools

To the author's knowledge, no competition authority has yet brought proceedings specifically targeting CTs; however, an intricate U.S. private litigation "saga" concerning CTs for the treatment of HIV offers a useful illustration of the issues outlined above (In re HIV 2019).

In a nutshell, Gilead and Teva disputed patents concerning two of Gilead's major anti-HIV blockbusters, Truvada and Atripla, both based on the same active ingredient, tenofovir. After patent challenges and counter-litigation, the companies reached a settlement in 2013 under which Teva agreed to delay generic entry. Plaintiffs alleged a "pay-for-delay" scheme extending Gilead's monopoly by six months beyond 2021 and causing approximately $3.6 billion in overcharges. In June 2023 a jury found no liability, concluding that neither market power nor a payment-for-delay arrangement had been proven; an appeal is currently pending. A related class action, alleging the existence of "no-generic restraints" preventing the use of generics in CTs involving Gilead and other originator companies (BMS, Janssen), resulted in a series of settlements.

The litigation knot just described is highly intricate, and the settlements reached preclude further examination of the underlying details. Nonetheless, these cases underscore the relevance of strategic corporate conduct and its potential anticompetitive effects—which, as if that were not enough, concern CTs that constitute essential medicines for the treatment of severe diseases.

Recent Developments, Regulatory Experiments, and Future Perspectives

Since the principle of strategic product combination examined thus far is grounded in mixed bundling, it is worth mentioning a case opened in May 2026 by the Italian Competition Authority (ICA), which concerns the interaction between a pharmaceutical product and a diagnostic test (ICA 2026).

Following patent expiry of an originator drug marketed by Biogen for the treatment of a severe disease, multiple sclerosis, Sandoz sought to introduce a biosimilar. However, Biogen is also alleged to hold a dominant position in a diagnostic test required both for preventive screening and for routine monitoring of the risk of a rare adverse effect associated with the active ingredient used in both the originator and its biosimilar competitor. According to the ICA, Biogen's test – until 2022 the only authorised screening tool and still a *de facto* clinical standard – may facilitate the foreclosure of competition, insofar as Biogen refuses to supply it for patients treated with the biosimilar, thereby potentially restricting Sandoz's market entry.

As noted, the opening of the Italian case is very recent: therefore, any further assessment and comment must for the time be suspended. It is nonetheless reasonable to view it as illustrating the relevance of mixed bundling in the pharmaceutical sector, extending the scope of strategic product recombination even beyond CTs. The fact that, as is often noted in the specialised literature, there is an increasing

convergence between drugs and medical devices can only make the issue even more significant in the future.

Returning to CTs, but from a broader perspective beyond strict antitrust enforcement, it is also worth considering the recent emergence of a form of "quasi-regulation" aimed at striking a balance between competition law principles and the practical necessities of price negotiation, in order to identify operational solutions to the issues concerning the availability of products supplied to national healthcare systems recalled at the outset.

The UK Competition and Markets Authority paved the way in this direction in November 2023 by issuing a "Prioritisation Statement" indicating that it would not prioritise investigations into collaborations aimed at making CTs available to UK patients, provided certain conditions are met (CMA 2023). This innovative soft-law framework allows contribution payments from backbone drug suppliers to add-on suppliers in order to ensure cost-effectiveness for NHS reimbursement, subject to strict limits on the exchange of price information. Building on the UK model, the Belgian Competition Authority issued guidance in September 2025 on information exchange in CT reimbursement applications (BCA 2025). The guidance confirms that such exchanges may fall within Article 101(1) TFEU, while also specifying permissible categories of information in submissions to the national reimbursement authority.

Both of the negotiation frameworks discussed above raise broader questions about how to balance traditional competition principles with the promotion of coopetitive pharmaceutical innovation within national reimbursement systems aimed at supporting product availability. Subject to the need for further verification of their practical implementation – which, at present, does not appear to have been documented – in both cases there remains the impression that a strict emphasis on preventing the exchange of pricing information may inherently constrain the practical scope of these regulatory models.

For what it is worth, and in an effort to combine a pro-competitive approach to pricing and reimbursement challenges, the author of this article has undertaken a thought (and a very modest software) experiment aimed at envisaging innovative regulatory tools that could function as a "coopetitive black box," including AI-based systems capable of processing sensitive pricing inputs without mutual disclosure (Arnaudo 2025b). From a horizon-scanning perspective, encouraging developments can also be identified in the fields of blockchain and confidential computing—technologies that protect data during processing and are emerging as tools to enable the combination of sensitive information (e.g. pricing data) while preventing mutual disclosure between parties (Yager 2026).

To conclude, time will tell which solutions will ultimately prevail in practice in striking the necessary balance between competition and coopetition within the pharma-biotech sector, particularly with regard to pricing strategies, and, even more so, how technological innovation will contribute to such outcomes. In any event, the combination of pharmaceutical products is likely to remain central from an industrial standpoint and to play an increasingly significant role in the development and enforcement of competition law.

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Pharmaceuticals and Competition in Turkey

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The Turkish Competition Authority is active in pharmaceutical sector. By 2024, the number of decisions issued by the Turkish Competition board concerning pharmaceutical industry reached 18. Although the overall number of decisions slightly decreased compared to previous years, proportion of the merger control cases increased, accounting for 14 cases.

Following the amendments introduced to the merger control regime in 2020, the Board expanded its jurisdiction to cover undertakings operating in sectors such as "digital platforms, software and gaming software, financial technologies, biotechnology, pharmacology, agrochemicals, and health technologies". The inclusion of "pharmacology" within the scope of the amended regulation reflects the Authority's intention to scrutinize potential "killer acquisitions" more closely in the pharmaceutical industry. Accordingly, transfers of pharmaceutical licenses between undertakings may also fall within the scope of merger control review, even where the relevant transaction thresholds are not formally met.

The Competition Board also launched pharmaceutical sector inquiry as of late 2021 and recently composed a preliminary report. During the investigation process, the Board, sent numerous requests of information to pharmaceutical companies, suppliers, pharmacies, unions of undertakings, public bodies etc. In its pharmaceutical sector inquiry, the Authority sought to develop a comprehensive understanding of the pharmaceutical market, including the impact of public authorities, regulatory frameworks, pricing mechanisms, reimbursement systems, and market dynamics affecting competition in the sector.

In pharmaceutical cases, the relevant product market is generally defined on the basis of ATC-3 and ATC-4 classifications. Although the Board frequently accepts ATC-3 classification as the primary reference point for market definition, in certain cases ATC-3 or ATC-4 classifications may prove overly broad and may fail to reflect actual competitive dynamics accurately. This is particularly relevant in public hospital tenders, where demand is often shaped by the requirement for the same active ingredient. In such circumstances, competition may primarily occur at the level of the active ingredient rather than solely within the broader ATC classification.

In addition to ATC classifications, the Board also considers several other factors when assessing the relevant product market and competitive relationships between pharmaceutical products. These include the therapeutic characteristics of the medicine, physicians' prescribing habits, the stage of treatment at which the medicine is prescribed, the existence of off-label alternatives, the financial comparability of medicines, and whether the products are included within the reimbursement system.

One of the most notable recent cases involved Novartis and Roche. The Authority found that the companies had infringed Turkish competition law by coordinating their conduct to promote the use of the more expensive eye-treatment drug Lucentis over Altuzan, despite the medicines being considered interchangeable for certain ophthalmological indications. According to the Board, the parties engaged in a concerted practice aimed at discouraging the use of Altuzan through misleading statements, legal actions, and strategic conduct directed at physicians and public authorities.

In reaching its decision, the Board relied on scientific evidence, foreign precedents, and market data demonstrating that Altuzan represented a lower-cost yet effective alternative. The Authority concluded that the conduct restricted competition, increased healthcare expenditures, and ultimately harmed consumers. The parties' arguments concerning the absence of direct evidence of coordination and the alleged irrelevance of foreign precedents, particularly the Italian case law, were rejected. Consequently, the Board imposed administrative fines on both undertakings and determined that the infringement had continued for more than seven years.

The pharmaceutical sector inquiry also addressed practices commonly referred to as "evergreening", namely strategies aimed at artificially extending patent protection periods beyond their intended scope. In addition, the Authority collected and reviewed extensive data regarding patent disputes between originator and generic pharmaceutical companies.

As is well known, agreements between originator and generic manufacturers designed to delay generic market entry beyond the ordinary scope of patent protection are commonly referred to as "pay-for-delay" agreements. The European Commission has previously investigated and sanctioned several pharmaceutical companies for engaging in such conduct. Recognizing the significant anticompetitive risks associated with these arrangements, the Turkish Competition Authority devoted particular attention to this issue during the sector inquiry. In this context, the Authority reviewed a substantial number of patent disputes and settlement agreements, assessing both their potential pro-competitive and anticompetitive effects. The findings of the sector inquiry are expected to be shared with the public in due course.

Foreclosure Through the Use of Public Reimbursements

Although the pharmaceutical sector in Türkiye has periodically been subject to competition law enforcement, there have recently been few examples involving the exclusionary conduct of a dominant undertaking. However, the recently initiated AVİXA/AVİGEM case by the Turkish Competition Authority contains a rather different allegation of abuse of dominance.

In summary, an investigation has been launched into allegations that the economic entity consisting of AVİXA/AVİGEM violated Law No. 4054 on the Protection of Competition by preventing competitors from entering the nasal spray market and by causing public harm through withholding from the market one of the nasal sprays distributed under a co-marketing agreement.

The allegations within the scope of the case include licensing two different nasal sprays with the same composition and preventing market entry by incorporating the two products into the public procurement reimbursement system with different discount rates. Findings were also obtained indicating that competitors' market entry was hindered, and that public harm arose from the failure to place the lower-priced product, distributed under the co-marketing agreement, on the market.

Within the scope of the ongoing investigation, it is being examined whether the economic entity formed by AVİXA/AVİGEM violated the Law by abusing its dominant position through exclusionary and exploitative practices.

The investigation is also noteworthy from the perspective of relevant market definition, which constitutes one of the fundamental aspects of abuse of dominance cases. The two pharmaceutical products in question are dual-active-ingredient products, distinguishing this case from others in terms of determining whether these products belong to the same market as single-active-ingredient nasal sprays.

Labor Cartel in the Turkish Pharmaceutical Sector

A competition investigation covering a large portion of companies operating in the pharmaceutical sector was recently concluded. In the relevant decision, it was determined that agreements existed between companies aimed at restricting employee transfers, and that such practices could negatively affect wages, mobility, and career opportunities in the labor market. The Competition Board particularly emphasized that competition in the field of human resources is also protected under competition law.

The investigation also examined the exchange of competitively sensitive information among the undertakings involved in the infringement, including wage policies, employee transfers, agreements not to hire personnel from competing companies, details regarding recruitment processes, and human resources strategies. The Board concluded that, as in other sectors, such information exchanges in this sector reduced independent competitive behavior. At the end of the investigation, administrative fines were imposed on numerous pharmaceutical companies, including Pfizer, Sanofi, Novartis, AstraZeneca, and Novo Nordisk. As a result of the investigation, administrative fines totaling approximately TRY 244.8 million were imposed on 17 undertakings.

In summary, the decision is significant from the perspective of competition law because it clearly demonstrates that labor markets in Turkish competition law will also be actively protected, that "no-poach" agreements will be treated similarly to classic cartel behavior, that human resources practices are subject to competition law scrutiny, and that competitively sensitive information is not limited solely to pricing or sales data.

Competition in the Dietary Supplements and Vitamins Markets

As in many countries, there is a distinction in Türkiye between dietary supplements, vitamins, and pharmaceuticals. However, since pharmaceutical undertakings also produce vitamins and dietary supplements, these products are sold in pharmacies similarly to medicines, and they are used alongside pharmaceuticals during treatment processes, they may be considered closely related markets to the pharmaceutical sector. Especially following the COVID-19 pandemic, the dietary supplements and vitamins sector has experienced continuous growth, and competition law violations have also increased in this rapidly expanding market.

In Türkiye, particularly in recent years, numerous vertical competition law infringements related to the sale of vitamins and dietary supplements have been identified. Looking at decisions involving companies such as Farmatek, Orzaks, Haks, and Sovital, it is generally observed that manufacturers intervened in the resale prices of distributors and restricted online sales. Although these types of infringements differ from those seen in the pharmaceutical sector, such decisions concerning vitamins and dietary supplements – which are part of the broader healthcare field – are also important from the consumer's perspective. Thanks to these decisions, consumers have gained greater opportunities to access treatment-supporting products more easily and at lower prices.

Innovation Competition and Technological Capabilities in Cross-Border Pharmaceutical Mergers: The Pfizer/Seagen Case

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Cross-border pharmaceutical mergers increasingly raise complex competition law concerns that extend beyond traditional product overlap analysis. Modern transactions often involve the acquisition of innovation capabilities, technological platforms, and global commercialization ecosystems that may significantly influence future market structures. The acquisition of Seagen by Pfizer in 2023 illustrates these challenges. The transaction combined one of the world's largest pharmaceutical companies with a leading biotechnology firm specializing in antibody-drug conjugate ("ADC") technology.

In March 2023, Pfizer announced its intention to acquire Seagen, a global biotechnology company specializing in cancer treatments and ADC technology, for approximately USD 43 billion. The transaction represented one of the largest pharmaceutical acquisitions in recent years and formed part of Pfizer's broader strategy to strengthen its position in the oncology sector. According to Pfizer, the acquisition would combine Seagen's ADC technology and oncology pipeline with Pfizer's global research, development, manufacturing, and commercialization capabilities. Pfizer emphasized that oncology remains one of the fastest-growing areas of the pharmaceutical industry and described the transaction as an opportunity to accelerate the development of next-generation cancer therapies.[14]

The transaction attracted regulatory scrutiny in several jurisdictions due to concerns regarding potential effects on competition and innovation in oncology markets. The European Commission ultimately approved the transaction unconditionally under the EU Merger Regulation.[15] In the United States, the Federal Trade Commission ("FTC") reviewed the merger and raised concerns relating to Pfizer's interests connected to the cancer treatment Bavencio.[16] To address these concerns, Pfizer agreed to irrevocably donate the U.S. royalty rights from Bavencio to the American Association for Cancer Research ("AACR").[17] Following the receipt of all required regulatory approvals, Pfizer completed the acquisition of Seagen in December 2023. Following the acquisition, Pfizer integrated Seagen into its oncology business and established a dedicated Pfizer Oncology Division combining oncology-related commercial and research activities from both companies.

One of the most significant aspects of the case concerns innovation competition. The European Commission expressly recognized that mergers may affect not only existing product markets but also future technologies, pipeline products, and broader innovation spaces.[18] In particular, the Commission acknowledged the possibility of a "structural reduction of the overall level of innovation," reflecting concerns regarding the concentration of research capabilities in the pharmaceutical sector. This approach is especially relevant in pharmaceutical markets, where competition frequently takes place through research and development activities long before products reach commercialization.

Unlike traditional merger cases, where competitive effects can often be assessed through existing market shares and product overlaps, innovation-driven mergers require competition authorities to evaluate future market developments that may remain uncertain for many years. Research programmes may fail, technologies may evolve in unexpected directions, and entirely new therapeutic approaches may emerge. As a result, assessing the impact of a transaction on future innovation inevitably involves a degree of predictive judgment. Competition authorities are therefore required to determine not only how firms compete today, but also how they may compete in the future.[19]

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[14] Pfizer, "Pfizer Invests $43 Billion to Battle Cancer," Press Release, 13 March 2023, available at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-invests-43-billion-battle-cancer.

[15] European Commission, Case M.11177 – Pfizer/Seagen, Commission Decision of 19 October 2023, C(2023) 7192 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023M11177.

[16] Gardner, J., "In Pfizer-Seagen Review, FTC Has Chance to Set New Pharma Precedent," BioPharma Dive, 14 March 2023, available at: https://www.biopharmadive.com/news/pfizer-seagen-ftc-antitrust-review-competition/630298/.

[17] Pfizer, "Pfizer Receives All Required Regulatory Approvals to Complete Acquisition of Seagen," Press Release, 13 December 2023, available at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-receives-all-required-regulatory-approvals-complete.

[18] European Commission, Case M.11177 – Pfizer/Seagen, Commission Decision of 19 October 2023, C(2023) 7192 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023M11177.

[19] European Commission, Case M.11177 – Pfizer/Seagen, Commission Decision of 19 October 2023, C(2023) 7192 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023M11177.

The Commission ultimately concluded that the Pfizer/Seagen transaction was unlikely to result in a loss of innovation competition. In reaching this conclusion, it relied on evidence indicating that oncology research remains highly competitive, with numerous pharmaceutical companies, biotechnology firms, academic institutions, and research organizations actively developing new therapies. The Commission also emphasized that several competitors were investing heavily in ADC technology and that Pfizer itself was not considered a leading player in this field prior to the transaction.[20]

However, the case raises broader questions regarding whether the existence of numerous competitors necessarily eliminates concerns relating to innovation competition. While the oncology sector contains a large number of participants, not all innovators contribute equally to technological development. Certain firms may possess unique scientific expertise, proprietary technologies, specialized research teams, or particularly promising innovation platforms. From this perspective, the competitive significance of a transaction may depend not only on the number of market participants that remain after a merger, but also on the strategic importance of the capabilities being acquired.

The transaction is particularly noteworthy because its strategic significance extended beyond existing pharmaceutical products. Through the acquisition, Pfizer gained access to Seagen's ADC technology, research expertise, scientific know-how, and innovation capabilities.[21] The merger therefore involved not only the acquisition of marketed products and development pipelines, but also the transfer of a leading innovation platform in the oncology sector.[22] This raises broader questions regarding whether traditional merger control frameworks, which remain largely focused on product markets and existing competitive overlaps, adequately capture the competitive significance of acquisitions involving technological platforms, research capabilities, and innovation ecosystems.

A further challenge concerns the assessment of future innovation effects. The Commission relied heavily on internal company documents, market investigations, and industry expectations indicating that the merger would either have a neutral effect on innovation or potentially increase research and development activity.[23] According to this view, the transaction would allow Pfizer to accelerate the development and commercialization of Seagen's technologies while generating efficiencies and research synergies.[24] Nevertheless, innovation-related effects are inherently difficult to predict, particularly in pharmaceutical markets where research outcomes, technological breakthroughs, and future competitive dynamics remain uncertain for many years. Consequently, innovation-focused merger review requires competition authorities to make judgments regarding future technological trajectories that may not become apparent until long after a transaction has been completed.

The case also highlights the increasingly global nature of pharmaceutical innovation and the fragmented nature of cross-border merger enforcement. The Commission's analysis referred to worldwide oncology research, global development pipelines, and international competitors.[25] Yet the transaction was reviewed separately by different competition authorities applying their own legal frameworks and analytical approaches. While both the European Commission and the FTC ultimately allowed the transaction to proceed, the case demonstrates the continuing challenge of assessing global innovation effects through jurisdiction-specific merger review systems. In this respect, Pfizer/Seagen provides a useful example of the difficulties competition authorities face when evaluating mergers driven not primarily by existing product overlaps, but by the acquisition of future innovation potential, technological capabilities, and strategic research assets.

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[20] European Commission, Case M.11177 – Pfizer/Seagen, Commission Decision of 19 October 2023, C(2023) 7192 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023M11177.

[21] Mullard, A., "Pfizer Bets Big on ADCs with $43-Billion Seagen Acquisition," Nature Reviews Drug Discovery, Vol. 22, 2023, p. 342, available at: https://www.nature.com/articles/d41573-023-00060-6.

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[23] European Commission, Case M.11177 – Pfizer/Seagen, Commission Decision of 19 October 2023, C(2023) 7192 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023M11177.

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[25] European Commission, Case M.11177 – Pfizer/Seagen, Commission Decision of 19 October 2023, C(2023) 7192 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023M11177.

Abuse of Dominance in the Pharmaceutical Sector: A Cross-Jurisdictional Analysis of the *Leadiant* Case in the Netherlands, Italy and Spain

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1. Abstract

This article examines the *Leadiant* case as a cross-jurisdictional example of excessive pricing enforcement in the pharmaceutical sector. The Dutch, Italian and Spanish decisions all concerned the pricing of an essential medicine used to treat a rare metabolic disease, but differed in their legal framing, factual emphasis and remedies. Taken together, the cases illustrate how competition authorities may apply Article 102 TFEU and national competition rules where regulatory exclusivity is used to support prices considered unjustified in light of the product's costs, risks and therapeutic value.

2. Introduction

Excessive pricing in pharmaceutical markets has become an increasingly important area of competition law enforcement. While Article 102 TFEU has traditionally been applied more frequently to exclusionary abuses, recent cases show a greater willingness by competition authorities to address exploitative conduct where it directly affects patients, insurers and public health systems.

The *Leadiant* cases are a particularly relevant example of this development. The Netherlands Authority for Consumers and Markets (Autoriteit Consument en Markt, ACM), the Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato, AGCM) and the Spanish Competition Authority (Comisión Nacional de los Mercados y la Competencia, CNMC) examined the pricing of chenodeoxycholic acid, or CDCA, an essential medicine used to treat cerebrotendinous xanthomatosis, a rare and serious metabolic disorder. Leadiant was the pharmaceutical company responsible for manufacturing and commercialising the CDCA-based product at issue. Although the national decisions differed in legal framing, institutional context and remedies, they all raised the same central question: whether Leadiant had used regulatory exclusivity and a position of effective market power over an old medicine to impose unfairly high prices.

This article analyses the three decisions in chronological order. It first sets out the factual and regulatory background, before comparing the authorities' approaches to market definition, dominance, abuse, sanctions and remedies. It then considers the broader significance of the *Leadiant* cases for excessive pricing enforcement in the pharmaceutical sector.

For ease of reference, the timeline below summarises the sequence of the Dutch, Italian and Spanish decisions discussed in this article.

3. Factual and Regulatory Background

CDCA is a bile acid that has been known for decades. Although CDCA-based medicines were originally authorised for the treatment of gallstones, medical practice established that CDCA was effective in treating cerebrotendinous xanthomatosis, or CTX. CTX is a rare, progressive and life-threatening metabolic disease. Patients generally require lifelong treatment, and the absence of adequate treatment can lead to severe neurological and systemic deterioration.

For many years, patients in several European countries were treated with CDCA-based medicines used off-label or, in some jurisdictions, with magistral or hospital pharmacy preparations. The active substance itself was not new, and the therapeutic usefulness of CDCA in CTX had long been recognised in clinical practice and scientific literature. This point became central to the competition law assessment in all three jurisdictions: Leadiant's product did not involve a genuinely new active ingredient or a substantial therapeu-

tic innovation compared with earlier CDCA-based formulations.

The regulatory turning point was Leadiant's decision to pursue orphan drug designation and marketing authorisation for CDCA in the treatment of CTX. Under the EU orphan drug regime, orphan designation may be granted for medicinal products intended to treat rare, life-threatening or chronically debilitating conditions, and successful authorisation can confer ten years of market exclusivity for the approved indication. Such incentives are designed to encourage the development of treatments for rare diseases, where ordinary market incentives may be insufficient. However, the *Leadiant* cases illustrate the risk that orphan drug incentives may be used not to reward genuine innovation, but to create or reinforce monopoly power over an already known and clinically established treatment.

4. The Leadiant Strategy

The competition authorities reconstructed a sequence of conduct that began well before the formal launch of CDCA-Leadiant. Although each national authority focused on the facts most relevant to its own market, the decisions reveal a common pattern: an old molecule, long used in clinical practice, was transformed into a protected orphan medicine and then sold at a price many times higher than previous CDCA formulations.

In the Netherlands the ACM focused primarily on Leadiant's price increases and its conduct in negotiations.[26], Since 2008, Leadiant had supplied a CDCA-based product after acquiring it from another manufacturer. The product was initially sold at around €46 per pack of 100 capsules. After the product was renamed Xenbilox, the price rose substantially. In 2014, following the orphan designation strategy, the price increased again. Once Leadiant obtained marketing authorisation and orphan exclusivity, CDCA-Leadiant was introduced in the Netherlands at a price close to €14,000 per pack.

A similar factual pattern appears in the Italian decision.[27] The AGCM found that Leadiant had charged the Italian National Health Service unfairly excessive prices for Chenodeoxycholic Acid Leadiant from June 2017. The Italian authority also described the abuse as being implemented through a multifaceted strategy, including dilatory and obstructive behaviour during price negotiations with the Italian Medicines Agency, AIFA. The initial Italian price was approximately €15,500 per pack and was reduced only after the opening of the AGCM proceedings, but the AGCM still considered the reduced price excessive.

In Spain, the CNMC described the conduct as part of a broader long-term strategy aimed at securing control over the CDCA market.[28] This included the acquisition or disappearance of alternative CDCA-based products, control over the active pharmaceutical ingredient, and arrangements that limited potential competitors' access to the clinical data or raw materials necessary to develop alternative formulations. Once those conditions were in place, Leadiant supplied CDCA-Leadiant in Spain at a price exceeding €14,600 per pack. The CNMC therefore treated the conduct not as a series of isolated acts, but as part of a single strategy designed to secure and monetise monopoly power over an essential medicine.

Across the three jurisdictions, the authorities therefore viewed Leadiant's pricing not as an isolated commercial decision, but as the outcome of a broader regulatory and commercial strategy. The precise legal characterisation varied from one jurisdiction to another, but the underlying concern was the same. Leadiant had secured a position of exceptional market power over an indispensable medicine and then used that position to impose prices that the authorities considered unjustified.

5. Market Definition and Dominance

All three authorities adopted a narrow market definition based on therapeutic substitutability and legal requirements. The relevant market was not defined by broad categories of bile acids or rare disease treatments, but by the manufacture and supply of CDCA-based medicines for the treatment of CTX.

In the Netherlands, Leadiant held a 100% share of the market for CDCA-based medicines used to treat CTX during the infringement period. Although other medicines were theoretically registered for CTX, they were not prescribed in practice, and patients were dependent on CDCA-Leadiant. The Rotterdam District Court later confirmed that the ACM had correctly assessed Leadiant's dominant position.[29]

In Italy, the AGCM similarly found that Leadiant held a dominant position in the Italian market for the production and sale of CDCA-based medicines used to treat CTX. The life-saving nature of the medicine and the absence of equivalent therapeutic alternatives meant that the Italian National Health Service had very limited countervailing

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[26] Netherlands Authority for Consumers and Markets (ACM), *Case no. ACM/20/041239 / Document no. ACM/UIT/659893 Leadiant*, 1 July 2021, https://www.acm.nl/system/files/documents/decision-of-abuse-of-dominant-position-by-leadiant.pdf.

[27] Italian Competition Authority (AGCM), *Order No. 30156*, 17 May 2022, https://en.agcm.it/dotcmsdoc/pressrelease/A524%20chiusura%20EN.pdf.

[28] Spanish Competition Authority (CNMC), *Resolución Leadiant S/0028/20*, 10 November 2022, https://www.cnmc.es/sites/default/files/4473155_0.pdf (in Spanish).

[29] District Court of Rotterdam, *Case No. ROT 23/5310 Leadiant v ACM*, 13 February 2025, https://uitspraken.rechtspraak.nl/details?id=ECLI:NL:RBROT:2025:1806 (in Dutch).

power. Even where a public purchaser is formally powerful, its bargaining position may be weak when patients depend on a single essential medicine.

In Spain, the CNMC defined the relevant product market as the manufacture and supply of medicines containing CDCA for the treatment of CTX. Other substances, such as cholic acid, were not considered effective substitutes in actual clinical practice. Magistral formulations were also not treated as effective market constraints because their availability was limited and, according to the CNMC, affected by Leadiant's conduct. The relevant geographic market was national, reflecting the national character of pharmaceutical pricing, reimbursement and authorisation procedures.

6. Abuse of Dominance: Excessive Pricing and Exclusionary Conduct

The central legal question in each jurisdiction was whether Leadiant's prices were excessive and unfair within the meaning of Article 102 TFEU and the national equivalents. The authorities relied, expressly or implicitly, on the two-stage test derived from *United Brands*: first, whether the difference between the costs incurred and the price charged is excessive; and second, whether the price is unfair either in itself or when compared with competing or comparable products.[30]

In the Netherlands, the ACM concluded that Leadiant's price was both excessive and unfair. The authority examined the costs and revenues attributable to the orphan designation and marketing authorisation project, the investments made, manufacturing and distribution costs, the risks associated with bringing the product to market, and the revenues generated before and during the infringement period. The ACM found that the project involved low costs, limited risk and very high returns. The price was therefore considered exorbitantly high.

The unfairness assessment in the Netherlands was closely linked to the lack of innovation. CDCA had been used effectively for CTX for decades, and Leadiant's authorisation efforts were considered largely administrative. The Rotterdam District Court accepted that obtaining marketing authorisation may justify some price increase,but held that the increase from approximately €46 to nearly €14,000 per pack was beyond reasonable justification. The Court famously described the conduct as a "textbook example" of abuse of dominance.

In Italy, the AGCM also found the price to be unfairly excessive. Its analysis emphasised the disproportion between Leadiant's costs and the price charged, the limited R&D activities undertaken, the old and well-known nature of the molecule, and the absence of therapeutic added value compared with previous CDCA-based medicines. The AGCM also considered the broader negotiation context: the Italian National Health Service was under pressure to ensure patient access, while Leadiant allegedly delayed and obstructed the AIFA pricing process.

The Spanish case went further in its legal characterisation. The CNMC treated Leadiant's conduct as a single, continuous and very serious infringement involving both exploitative and exclusionary abuses. On the exploitative side, the CNMC found that Leadiant imposed excessive and non-equitable prices on the Spanish National Health System. On the exclusionary side, it found that Leadiant's strategy restricted actual and potential competition, including through control over the active ingredient and clinical data, and by suppressing alternative low-cost formulations.

This is one of the most important differences between the jurisdictions. The Dutch case is principally an excessive-pricing case, with strong emphasis on Leadiant's special responsibility and lack of genuine negotiation. The Italian case is also centred on excessive pricing, although the AGCM's factual account highlights a broader strategy and obstructive negotiation conduct. The Spanish case, by contrast, explicitly integrates exclusionary and exploitative conduct into a single anticompetitive strategy.

7. Jurisdictional Differences

Although the three cases concern the same medicine and the same broad pricing strategy, the national decisions reflect differences in the organisation of healthcare systems and in national pricing and reimbursement procedures.

In the Netherlands, the harm was borne through the health insurance system. Dutch insurers continued reimbursing CDCA-Leadiant because patients depended on it and had no effective alternative. The burden therefore ultimately fell on insurers, premium-payers and the wider public. The ACM also criticised Leadiant's failure to engage meaningfully in negotiations: Leadiant made only vague calls for negotiation and did not present concrete proposals aimed at reaching a reasonable price.

In Italy, the key institutional counterpart was AIFA and the Italian National Health Service. The AGCM paid particular attention to the national pricing negotiation procedure and to Leadiant's conduct within that process. The Italian case shows that even where a price is subject to interaction with a medicines authority, competition law may still intervene if the outcome reflects an imbalance of bargaining power and leads to an unjustifiably excessive price.

In Spain, the CNMC focused on the Spanish National Health System and Leadiant's use of the foreign medication

[30] Court of Justice of the European Union, Case C-27/76 [1978] *United Brands v Commission*, ECLI:EU:C:1978:22, para. 252.

route. According to the CNMC, from June 2017 Leadiant supplied CDCA-Leadiant in Spain in a way that avoided ordinary pricing and reimbursement negotiations, while imposing a unilateral price exceeding €14,600 per pack. The CNMC also found that Leadiant deliberately delayed the national pricing and reimbursement procedure.

8. Sanctions and Remedies

The sanctions imposed across the three jurisdictions were substantial, although they differed in amount, scope and addressees.

The decisions are also notable for their application of the EU competition law concept of the undertaking as a single economic unit. In the Netherlands, the ACM identified the relevant undertaking as consisting of Essetifin S.p.A., Leadiant Biosciences S.p.A., Leadiant Biosciences Ltd. and Leadiant GmbH. Leadiant GmbH and Leadiant Biosciences Ltd. were considered directly involved in the infringement, respectively because Leadiant GmbH sold CDCA-Leadiant in the Netherlands and held the relevant marketing authorisation and orphan designation, while Leadiant Biosciences Ltd. determined the Dutch list price. In Italy, the AGCM imposed the fine jointly and severally on Leadiant Biosciences Ltd. and Essetifin S.p.A. In Spain, liability was attributed to ESSETIFIN S.p.A., Leadiant Biosciences Ltd. and Leadiant GmbH, reflecting their respective roles within the Leadiant group, including parent-company control, operational involvement and the holding of the relevant marketing authorisation. This confirms that, in complex pharmaceutical groups, liability may attach to the economic unit responsible for the conduct rather than only to the entity directly commercialising the product.

In the Netherlands, the ACM initially imposed a fine of approximately €19.57 million on Leadiant for charging excessive prices between 2017 and 2019. The fine was later reduced to around €17 million, and on 13 February 2025 the Rotterdam District Court largely upheld the ACM's decision, subject to a further limited reduction due to the length of proceedings.

In Italy, the AGCM imposed a fine of approximately €3.5 million. The AGCM also ordered the companies to comply with obligations aimed at defining non-excessive prices for CDCA-Leadiant and to refrain from similar conduct in the future.

In Spain, the CNMC imposed a fine of €10.25 million on Leadiant. The Spanish authority also imposed behavioural remedies requiring Leadiant to remove the exclusive control of the CDCA active ingredient and to market CDCA-Leadiant directly in Spain at a price negotiated with the Ministry of Health.

Taken together, these sanctions show a coordinated but not uniform enforcement response. Each authority applied Article 102 TFEU and the national equivalent in light of its national healthcare system, procedural framework and evidentiary record. The result is a set of decisions that are mutually reinforcing but legally distinct.

9. Broader Significance

The Leadiant cases are important because they show how competition law can respond when pharmaceutical regulation is used in a way that produces monopoly pricing without corresponding innovation. Orphan drug incentives are legitimate and socially valuable where they encourage the development of treatments for rare diseases. However, these incentives do not exempt pharmaceutical companies from Article 102 TFEU. Where a dominant undertaking obtains regulatory exclusivity over an old and clinically established medicine, it retains a special responsibility not to impose unfair prices or prevent the emergence of lawful alternatives.

The cases also demonstrate that excessive pricing analysis in pharmaceuticals is becoming more sophisticated. Authorities did not simply compare prices before and after orphan designation. They examined costs, risks, R&D investments, therapeutic value, internal rates of return, alternative products, negotiation conduct and the dependence of public purchasers. The Dutch and Italian authorities focused strongly on the absence of innovation and the disproportion between price and cost. The Spanish authority added a broader foreclosure narrative, treating excessive pricing as the final stage of a monopoly-building strategy.

The *Leadiant* cases also sit within a broader European enforcement trend concerning excessive pricing in the pharmaceutical sector. This trend is illustrated by the European Commission's *Aspen* investigation, which concerned several off-patent cancer medicines used to treat leukaemia and other haematological cancers. The Commission ultimately closed the investigation with binding commitments rather than a fine.[31] It is also reflected in the United Kingdom, where the Competition and Markets Authority (CMA) has pursued several excessive-pricing cases involving off-patent medicines, including *Pfizer/Flynn*[32] and *Liothyronine tablets*[33]. Taken together, these developments confirm that competition authorities are increasingly willing to address

[31] European Commission, *Decision Case AT.40394 – Aspen*, 10 February 2021, https://ec.europa.eu/competition/antitrust/cases/dec_docs/40394/40394_5350_5.pdf.
[32] Competition and Markets Authority (CMA), *Case 50908 – Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, 21 July 2022, https://assets.publishing.service.gov.uk/media/64c7d68a5c2e6f0013e8d7d8/Phenytoin_Decision_-_Redacted_1__.pdf.
[33] Competition and Markets Authority (CMA), Case 50395 – *Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK*, 29 July 2022, https://assets.publishing.service.gov.uk/media/61b8755de90e07043f2b98ff/Case_50395_-_Decision_final___.pdf

exploitative abuses where excessive pharmaceutical prices place pressure on patients, insurers and public health systems.

Finally, the *Leadiant* cases confirm that public health systems may be vulnerable purchasers even when they are large institutional buyers. In ordinary markets, a powerful buyer may discipline suppliers. In the case of an essential medicine for a rare disease, however, the buyer's legal and ethical obligation to secure patient access can substantially weaken its bargaining power. This was a recurring theme in the Netherlands, Italy and Spain.

10. Conclusion

The *Leadiant* cases provide a clear example of the growing role of Article 102 TFEU in addressing excessive pricing in pharmaceutical markets. Across the Netherlands, Italy and Spain, the authorities concluded that Leadiant had imposed unjustifiably high prices for an essential medicine whose active substance and therapeutic use were already well established.

The cases confirm that orphan drug exclusivity may reward genuine innovation, but it does not exempt dominant undertakings from competition law scrutiny. In this respect, the *Leadiant* trilogy is an important reminder that regulatory incentives must not be transformed into a basis for disproportionate pricing at the expense of patients and public health systems.

Relevant OECD Work

OECD, *Excessive Prices in Pharmaceutical Markets*, 2018, https://www.oecd.org/content/dam/oecd/en/publications/reports/2018/03/excessive-pricing-in-pharmaceuticals_1abdfb96/8e161f63-en.pdf.

Lobbying and Restriction of Competition: The Pharmacies Case

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Introduction

It is well established in the case-law of both the Court of Justice of the European Union (CJEU) and the national courts of the European Union (EU) Member States that pricefixing agreements constitute restrictions of competition by object under the EU and national competition rules.

Against this background, the Lithuanian Competition Council (CC) encountered a price-fixing agreement concluded in the context of a legislative process and was required to determine whether such conduct constituted an infringement of competition law or should instead be characterised as "mere lobbying", as argued by the undertakings involved. The CC concluded that the legislative context *per se* does not preclude the application of competition rules.

The court of first instance annulled the CC's decision, following which the CC appealed to the Lithuanian Supreme Administrative Court. It cannot be ruled out that the case may ultimately be referred to the CJEU. While the final judgment is still pending, the CC remains firmly of the view that the practices examined in the *Pharmacies* case are highly detrimental to competition and to consumers.

The *Pharmacies* case

In 2017, the Lithuanian Ministry of Health (Ministry) decided to assess retail and wholesale mark-ups for reimbursable medicines, which were established by the order of the Minister of Health. The Ministry informed the Lithuanian Pharmacies Association (LPA) that a working group would be shortly formed to evaluate the existing mark-ups. The Ministry requested the LPA to submit economically substantiated proposals for adjusting the markups, following the LPA's position that the existing markups were insufficient to cover market players' operational costs. At a later stage, the Ministry also requested calculations substantiating the need for changes to the markups, as well as data on the markup levels required for undertakings to operate in an economically rational manner. The LPA, with the consent of its members (the pharmacies) and member-affiliated companies (the wholesalers), jointly determined wholesale and retail mark-ups for reimbursable medicines and presented them to the Ministry as allegedly necessary to cover their operational costs. However, the CC found that the proposed mark-ups were not only intended to cover the operational costs of the undertakings concerned but were designed to ensure additional profits for all competing groups of companies.

In particular, after the Ministry requested the LPA to submit economically substantiated proposals for adjusting the markups, the LPA informed its members and member-affiliated companies thereof, and the companies decided to submit to the Ministry mutually coordinated[34] mark-ups for reimbursable medicines. On 5 June 2017, the LPA submitted to the Ministry the jointly agreed desired mark-ups for reimbursable medicines on behalf of its members and member-affiliated companies, presenting those mark-ups as being justified by operational costs. Subsequently, as the Ministry's working group was not persuaded by those proposals, the LPA and the companies jointly prepared[35] an additional document illustrating a "typical pharmacy", i.e. demonstrating the alleged costs and income of such typical pharmacy. This document was intended to substantiate the necessity of introducing the proposed mark-ups.

As already mentioned, during the investigation the CC's case handlers found that the calculations presented in the "typical pharmacy" document were prepared after the LPA had already decided on the mark-ups to be presented to the Ministry. In particular, the investigated undertakings were considering and adjusting various economic figures to align with those pre-determined mark-ups. The "typical pharmacy" document indicated that if the LPA's proposed mark-ups were adopted, the profit of the "typical pharmacy" would equal 0. However, internal individual communication of all three investigated company groups revealed that to each of them the adoption of the LPA's proposed mark-ups would have resulted in an increase in profit. When the CC requested information on how the LPA's proposed mark-ups and estimates provided in the "typical pharmacy" document were calculated, the investigated undertakings claimed that the LPA collected individual data of every competing company group and aggregated it. However, the CC found that these claims were invalid. Although the Min-

[34] The mark-ups were calculated by one of the competitors based on the desired profit of that company group, other competitors agreed to provide those mark-ups to the Ministry on behalf of the LPA.

[35] The document was prepared by one of the competitors; another competitor provided proposals to amend the document to demonstrate a less favorable financial state of the pharmacies.

istry's working group (technical staff) concluded that the LPA's proposed mark-ups would be detrimental to patients, since they would increase patients' co-payments for reimbursable medicines, the Ministry nevertheless continued negotiations with the LPA and assessed the data presented by the LPA.

In December 2017, the Ministry, the LPA and the wholesalers' association entered into a Cooperation Agreement. Under the agreement, wholesalers and pharmacies committed to recalculate, in a fair manner, the prices of non-reimbursable medicines following a value added tax reduction and to provide the Ministry with price information for non-reimbursable medicines for a six-month period. In return, the Ministry agreed to review and adjust the mark-ups for reimbursable medicines. The Minister of Health subsequently issued an order approving the new mark-ups for reimbursable medicines, which had been negotiated with the LPA.

In 2022, the CC issued a decision[36] establishing that the LPA and 8 pharmaceutical companies had entered into anti-competitive agreement and infringed the national and EU competition law when they agreed on the wholesale and retail mark-ups of reimbursable medicines, which were subsequently approved by the Ministry. The agreement was qualified by the CC as indirect price-fixing, i.e. competition law infringement by object.

The CC assessed that the Ministry bears responsibility for ensuring accessibility of medicines for Lithuanian patients and that, by submitting data on the alleged costs of pharmacies and the mark-ups required to cover those costs, the LPA exercised significant influence over the Ministry's decisionmaking process. As a result, the LPA's actions amounted to indirect pricefixing. The data provided by the LPA was used by the Ministry as the source of information regarding what level of mark-ups would allow companies to cover their operational costs and guarantee accessibility of reimbursable medicines. The investigated companies' internal documents and communication showed that they were seeking to demonstrate to the Ministry that if the Ministry refuses to adopt the mark-ups proposed by the LPA, the companies may experience financial difficulties, resulting in some pharmacies in rural areas being closed, etc.

The legal dispute

The LPA, its members and member-affiliated companies appealed the CC's decision in the *Pharmacies* case arguing, *inter alia*, that by issuing its decision the CC undermined their freedom of association and right to participate in the legislative process, lobby and represent their interests.

The court of first instance upheld the LPA's and pharmaceutical companies' appeal and annulled[37] the CC's decision. The court held that, in the case at hand, the undertakings' actions did not infringe competition rules, as they were carried out outside the market and did not constitute a restriction of competition by object, as well as that they were the result of the Ministry's actions. The CC appealed the court of first instance's decision to the Lithuanian Supreme Administrative Court.

In the CC's view, the mere fact that the companies' actions were carried out within the legislative process does not exempt those actions from having to comply with competition rules. Moreover, the CC did not conclude that the competition restriction arose from the fact that the LPA participated in the legislative process and submitted the mark-ups proposal *per se*. The CC's decision was based on the fact that competitors manipulated the data that was necessary for the Ministry to decide on the mark-ups to be adopted and subsequently applied in the market. This was particularly relevant given that the Ministry sought to assess what level of mark-ups would allow undertakings to cover their operational costs while ensuring accessibility of reimbursable medicines.

Contrary to the investigated companies' statements, the CC strongly believes that the freedom of association and right to lobby does not eliminate the undertakings' obligation to adhere to the competition rules. Moreover, the right to participate in the legislative process does not entail a right to manipulate that process by submitting to the decision-making authorities economic data distorted by an anti-competitive agreement between competitors.

Conclusion

As demonstrated in this article, price-fixing agreements may be concluded in various forms and contexts, including the legislative process. The CC believes that excluding such agreements from the scope of competition law would be detrimental to the effectiveness of competition rules and to consumer interests. However, enforcement decisions addressing such practices may nevertheless be appealed on grounds such as alleged restriction on the freedom of association. The final decision in the *Pharmacies* case may help shape substantive principles concerning the legal assessment of pricefixing agreements concluded in the legislative context.

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[36] The decision is available online: https://kt.gov.lt/uploads/docs/docs/5491_5e8421360b4f3b61c6678178fecf3a46.pdf.

[37] The press release is available online: https://www.teismai.lt/lt/regionu-administracinis-teismas-panaikino-konkurencijos-tarybos-nutarima-del-konkurencija-ribojancio-susitarimo-del-kompensuojamuju-vaistu-antkainiu/13536.

Innovation as the Market: The Illumina/Grail Saga and the Evolution of Merger Control

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1. Merger Control as a Tool to Preserve Innovation

Merger enforcement plays a critical role in preserving competitive markets and safeguarding the dynamic forces that drive economic progress. By preventing incumbent firms from increasing and entrenching their economic power, merger control is one of competition law's most powerful tools for driving innovation, preserving rivalry, and preventing anticompetitive concentration.

Across jurisdictions, merger control regimes are designed to intervene before competitive harm materialises. Their purpose is not limited to preventing immediate price increases. Rather, merger review seeks to preserve markets that remain open to future competition. In this sense, merger enforcement operates as a forward-looking safeguard, protecting competitive conditions in their incipiency rather than waiting until market power has already taken hold and dominance has become entrenched.

Protecting dynamic competition is particularly important in research-intensive markets such as biotechnology and pharmaceuticals. In these sectors, competition often unfolds not through existing products but through research efforts. Firms invest heavily in uncertain and long-term development pathways, racing to produce new therapies, diagnostic tools, and medical technologies. Independent research programmes pursuing similar scientific objectives create a form of rivalry that can accelerate discovery and expand the range of possible technological solutions.

Competition authorities have therefore long recognised that rivalry may arise not only between firms currently active in a market but also between firms that may become competitors in the future. Transactions involving potential or nascent competitors can alter this dynamic by removing emerging competitive threats before they fully materialise. When such transactions eliminate independent research efforts, they may reduce incentives to innovate and weaken the competitive pressures that drive technological progress.

The consequences for innovation can be significant. Acquisitions of emerging innovators may allow incumbent firms to discontinue overlapping research, absorb promising technologies, or redirect development away from disruptive innovations that threaten existing business models. In doing so, they can reduce the number of independent pathways toward technological discovery and narrow the scope of future competition.

Such acquisitions may also enable incumbents to shape the direction of innovation itself. By consolidating control over emerging technologies, a dominant firm may steer technological development along trajectories that reinforce its existing market position. Rather than multiple firms exploring competing scientific approaches, innovation may be channelled to align with incumbents' strategic priorities. The result can be slower progress, fewer breakthroughs, or the abandonment of promising technologies altogether.

These risks are particularly consequential in markets involving life-saving medical technologies. In such contexts, the stakes of diminished innovation are heightened. Breakthrough diagnostic tools and therapies often emerge from rivalrous innovation among independent research programmes. When mergers reduce that rivalry, the consequences may include delayed medical advances, reduced technological diversity, or lost opportunities to improve patient outcomes.

For these reasons, merger enforcement increasingly focuses on transactions that threaten potential competition and rivalrous innovation. Evaluating such risks requires authorities to look beyond current product offerings and near-term actual or potential competition to examine research pipelines, technological capabilities, and firms' incentives to innovate. Because these dynamics often emerge before products reach the market, they may be visible only through internal documents, R&D strategies, and strategic assessments of firms' capabilities.

The proposed acquisition of Grail by Illumina presented precisely these concerns. At stake was not only the structure of a nascent market for multi-cancer early detection tests, but also the future direction of innovation in cancer diagnostics. The United States (US) Federal Trade Commission (FTC) case, therefore, stands as a powerful precedent in modern merger enforcement, confirming that competition

[38] All views expressed herein are my personal views and do not necessarily reflect the views of the OECD or any of its members.

law can intervene to preserve competition where it centres on the development of new technologies rather than existing products.[39]

Few recent cases illustrate these dynamics more vividly than the attempted acquisition of Grail by Illumina, which placed questions of innovation rivalry, vertical foreclosure, and merger jurisdiction at the centre of modern antitrust enforcement.

2. The Illumina/Grail Transaction and the Emerging Market for Multi-Cancer Early Detection Tests

The proposed acquisition of Grail by Illumina arose amid rapid technological developments in cancer diagnostics. At the centre of the transaction was the emerging field of multi-cancer early detection (MCED) tests, a new generation of diagnostic tools designed to detect multiple forms of cancer from a single blood sample. By analysing fragments of circulating tumour DNA in the bloodstream through advanced genomic sequencing, MCED tests promise to transform cancer screening by enabling earlier and less invasive detection of a wide range of cancers.[40]

The potential public health implications of this technology are substantial. Early detection is widely recognised as one of the most effective ways to improve cancer survival rates.[41] Traditional screening methods typically focus on specific cancers and often rely on invasive procedures or imaging technologies. MCED tests, by contrast, seek to identify signals associated with multiple cancers through a simple blood draw, potentially allowing physicians to detect diseases at much earlier stages. As a result, the development of reliable MCED tests has been described as one of the most promising advances in cancer diagnostics.[42]

At the time of the transaction, several biotechnology companies were competing to develop MCED technologies, creating an innovation race in which the ultimate technological and commercial outcomes remained uncertain. Firms such as Grail, Thrive Earlier Detection, and Singlera Genomics were investing heavily in research programs to develop competing diagnostic platforms capable of identifying cancer signals in blood samples. Competition among these firms was therefore centred not on existing products, but on the race to develop new diagnostic technologies capable of transforming cancer detection.[43]

Illumina played a central role in this technological ecosystem. The company is the leading global supplier of next-generation sequencing (NGS) technology, enabling rapid analysis of DNA and other genetic material. NGS platforms are widely used across biomedical research and clinical diagnostics and constitute a critical input for companies developing liquid biopsy technologies, including MCED tests. As a result, all firms developing blood-based cancer detection technologies relied on Illumina's NGS platforms for sequencing.[44] Indeed, Illumina's sequencing platforms were widely regarded as the industry standard and served as a critical input for firms developing MCED tests.[45]

Grail was originally founded in 2016 as a subsidiary of Illumina and later spun out as an independent company. Following its spin-off, Grail focused on developing its flagship MCED test, known as Galleri, which aims to detect dozens of cancer types from a single blood sample. By the time Illumina announced plans to reacquire the company in September 2020, Grail had become one of the most prominent developers of MCED technology.[46]

The proposed transaction, therefore, involved a vertical merger between the dominant supplier of sequencing technology and one of the leading developers of MCED tests. While Illumina characterised the acquisition as a means of accelerating the development and commercialisation of Grail's diagnostic technology, competition authorities, including the US FTC and the European Commission (EC), expressed concern that the merger could alter the competitive landscape of the emerging MCED market.[47]

In particular, competition enforcers feared that Illumina's control over sequencing technology could allow the company to disadvantage rival developers of MCED tests that depended on its platforms. Such conduct could take many forms, including raising prices for sequencing inputs, limiting access to new technological developments, or otherwise impairing competing firms' ability to develop and

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[39] Illumina, Inc. v. FTC, No. 23-60167, slip op. at 12 (5th Cir. Dec. 15, 2023) ("Critically, because the Commission viewed the relevant product market as one for the research, development, and commercialization of MCED tests—not the existing commercial market for MCED tests—it based its market definition on what MCED-test developers reasonably sought to achieve, not what they currently had to offer. Each of Illumina's proposed bases for why the Commission's market definition fails springs from the presumption that the Commission should have defined the market based on the products that currently exist, not those that are anticipated or expected. We disagree.")

[40] *Id.* at 1-2.

[41] In re Illumina, Inc. & Grail, Inc., Complaint, at 3, Docket No. 9401 (F.T.C. Mar. 30, 2021).

[42] *Id.* at 3-7. Although multi-cancer early detection tests remain an emerging technology and are still undergoing large-scale clinical validation, their potential to transform cancer screening has already reshaped the competitive landscape of cancer diagnostics. The Illumina/Grail merger was therefore not about an established product market, but about control over a technology that could define the future of cancer detection.

[43] *Supra* note 2, at 2-3.

[44] *Id.*

[45] *Id.*

[46] *Supra* note 4, at 15.

[47] *Supra* note 4; European Commission (2022), Mergers: Commission prohibits acquisition of GRAIL by Illumina, https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5364.

commercialise their own diagnostic tests.[48] Given the central importance of sequencing technology to the development of liquid biopsy diagnostics, these concerns raised the possibility that the merger could influence not only current market conditions but also the future trajectory of innovation in cancer diagnostics.[49]

3. A Transatlantic Enforcement Saga: The Interaction Between US and EU Merger Proceedings

The Illumina/Grail transaction quickly evolved into one of the most complex and closely watched merger challenges in recent antitrust history. Rather than being reviewed in a single jurisdiction, the transaction triggered parallel and partially overlapping proceedings in both the US and the European Union (EU), creating a rare situation in which two major competition regimes simultaneously assessed the competitive implications of the same emerging technology market.

The interaction between these proceedings ultimately shaped the trajectory of the case. In the US, the FTC challenged the merger under US antitrust law through administrative proceedings before its internal tribunal. In parallel, in Europe, the EC asserted jurisdiction through the controversial use of the referral mechanism under Article 22 of the EU Merger Regulation (EUMR). The resulting procedural overlap transformed the merger challenge into a transatlantic enforcement saga and raised broader questions about the role of merger control in innovation-driven industries, particularly how authorities should address transactions involving nascent competitors that fall outside traditional notification thresholds.[50]

The events unfolded rapidly following the announcement of the transaction in September 2020, when Illumina agreed to acquire Grail for approximately $8 billion. In March 2021, the FTC initiated administrative proceedings challenging the merger, arguing that the acquisition would allow Illumina to foreclose rival developers of multi-cancer early detection (MCED) tests by restricting access to its next-generation sequencing (NGS) technology.[51]

At roughly the same time, the EC began reviewing the transaction following a referral request from several Member States under Article 22 EUMR. This provision, sometimes referred to as the "Dutch clause," allows Member States to request that the EC examine a transaction even when it does not meet the EU's turnover thresholds.[52] Historically, Article 22 referrals were used primarily by Member States without their own merger control regimes. In this case, however, the EC accepted referrals from Member States that themselves lacked jurisdiction over the transaction under their national laws, marking a significant expansion in the practical use of the mechanism.[53]

The EC ultimately prohibited the merger in September 2022, concluding that Illumina would have both the ability and the incentive to foreclose competing developers of MCED tests that depended on its sequencing platforms.[54]

The EC's decision to assert jurisdiction over the transaction proved highly controversial. Because the merger did not meet either the EU's turnover thresholds or those of the referring Member States, the referral effectively enabled the EC to review a transaction that would otherwise have escaped EU merger control. Illumina challenged this interpretation before the General Court, arguing that the Commission's approach exceeded the intended scope of Article 22 EUMR. Although the General Court initially upheld the Commission's jurisdiction in July 2022, the issue ultimately reached the Court of Justice of the European Union (CJEU), which in September 2024 overturned that interpretation and annulled the Commission's assertion of jurisdiction under Article 22.[55]

The procedural interaction between the US and EU challenges became even more complex when Illumina completed the acquisition of Grail in August 2021, while litigation and appeals were still ongoing. In response, the Commission opened a gun-jumping investigation and imposed interim measures requiring the companies to maintain Grail as a separate and independent entity pend-

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[48] *Id*.

[49] *Supra* note 4, at 18.

[50] Following the Court of Justice of the European Union's (CJEU) *Illumina/Grail* judgment concerning Article 22 EUMR, several EU Member States have adopted or strengthened "call-in" powers enabling competition authorities to review transactions that fall below traditional merger notification thresholds where there is a risk of harm to competition. Such mechanisms have been introduced or expanded, inter alia, in Italy, Denmark, Hungary, Sweden, Ireland, Lithuania, Latvia, Slovenia and Cyprus. Although these regimes share the objective of capturing potentially problematic acquisitions that escape standard turnover thresholds, particularly transactions involving nascent or innovative firms, their legal design varies considerably across jurisdictions. Differences arise, for example, in the criteria that trigger review (e.g., turnover thresholds, market share indicators, or broader assessments of potential competitive effects) and in the time limits within which authorities may exercise these powers.

[51] *Supra* note 3.

[52] Rusu, C (2021), The Dutch clause revisited: new Commission guidelines on case referrals based on Article 22 of the EU merger control regulation, https://www.ru.nl/sites/default/files/2023-09/17%20 %20The%20Dutch%20clause%20revisited%20-%20new%20Commission%20guidelines%20on%20case%20referrals%20based%20on%20Article%2022%20of%20the%20EU%20merger%20control%20regulation%20-%20by%20Catalin%20S.%20Rusu%2C%205%20April%202021.pdf.

[53] Illumina, Inc. & Grail LLC v. European Commission, Joined Cases C-611/22 P & C-625/22 P, Judgment of the Court (Grand Chamber), Sept. 3, 2024, ECLI:EU:C:2024:67, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62022CJ0611.

[54] *Supra* note 10.

[55] *Supra* note 16 (holding that Article 22 EUMR referrals are only possible where the referring Member State has jurisdiction under national law).

ing the outcome of the merger review.[56] These measures effectively prevented the two firms from integrating their operations.

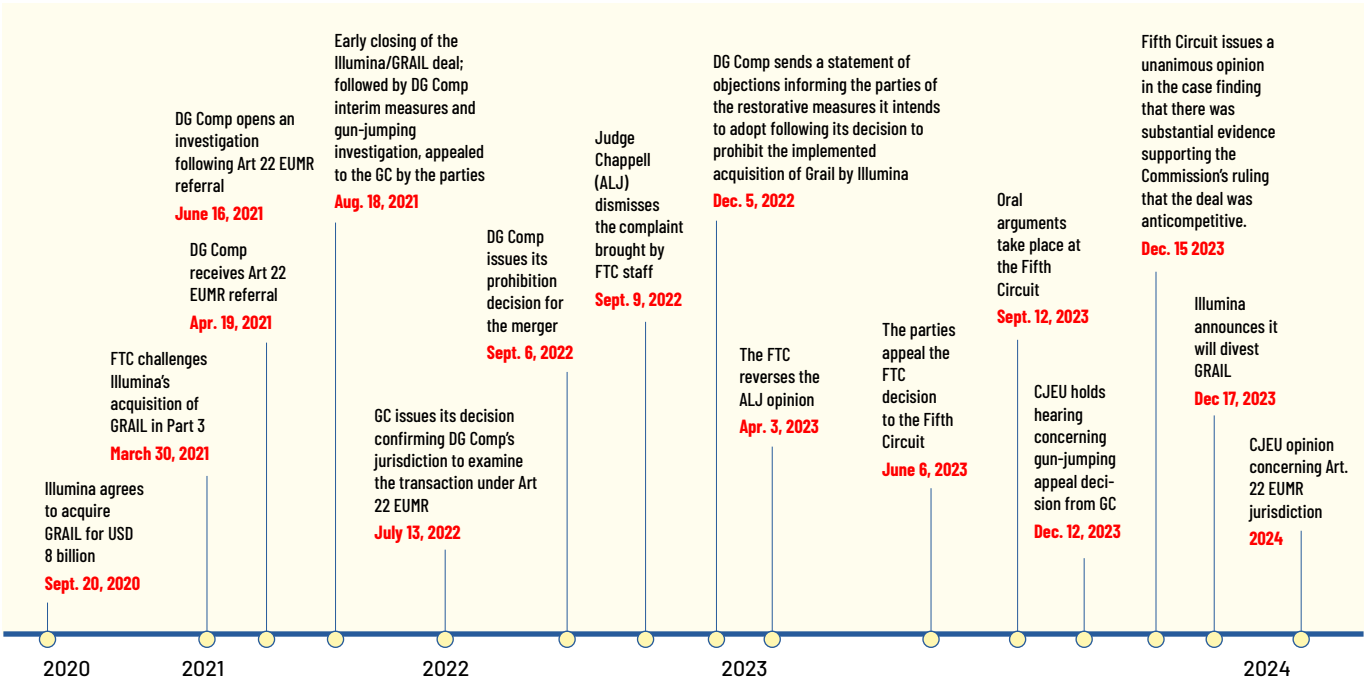
The hold-separate imposed in Europe had important consequences for the parallel proceedings in the US. By preventing the full integration of the companies during the review process, the EC's interim measures preserved the competitive status quo while the FTC pursued its administrative challenge. In doing so, the EU proceedings indirectly ensured that the market conditions underlying the FTC's case remained largely unchanged while the litigation unfolded.

Meanwhile, the FTC's case followed a different procedural trajectory in the US. In September 2022, the administrative law judge initially dismissed the complaint. The FTC, however, reversed that decision on appeal in April 2023 and ordered Illumina to divest Grail. The dispute ultimately reached the U.S. Court of Appeals for the Fifth Circuit, which in December 2023 vacated the FTC's order and remanded the case for reconsideration of Illumina's proposed behavioural remedy, while largely agreeing with the FTC's competitive analysis.[57]

Following the court's ruling, Illumina announced that it would divest Grail, and the separation was ultimately completed in June 2024, when Grail was spun off as an independent company.[58]

Taken together, these parallel proceedings illustrate the increasingly global nature of merger enforcement in innovation-driven markets. The Illumina/Grail case not only tested the boundaries of jurisdiction and procedure in both the US and the EU, but also demonstrated how multiple competition authorities, operating through different legal frameworks and procedural tools, can simultaneously shape the outcome of transactions involving emerging technologies.

The Illumina/Grail saga: Timeline



The US Court of Appeals for the Fifth Circuit's Decision and Its Significance

On review, the Fifth Circuit largely agreed with the FTC's competitive analysis.[59] The court concluded that the agency had presented substantial evidence demonstrating that Illumina possessed both the ability and incentive to foreclose competing developers of MCED tests by restricting access to its next-generation sequencing technology or degrading the terms on which rivals could obtain this critical input. In doing so, the court recognised that vertical integration involving a dominant supplier of a key tech-

[56] European Commission (2023), Mergers: Commission fines Illumina and GRAIL for implementing their acquisition without prior merger control approval, https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_23_3773/IP_23_3773_EN.pdf.
[57] *Supra* note 2.
[58] Grail (2023), Grail Statement of Divestiture, https://grail.com/stories/grail-statement-on-divestiture/.
[59] *Supra* note 2.

nological input can threaten downstream competition in emerging technology markets.

Importantly, the court rejected Illumina's argument that the merger should be viewed primarily as a pro-competitive integration that would accelerate the commercialisation of Grail's technology. Instead, the Fifth Circuit emphasised that the relevant competitive concern was the preservation of rivalry among multiple firms developing competing MCED technologies. Allowing the dominant supplier of sequencing platforms to acquire one of the leading developers of such tests, the court concluded, risked distorting the competitive conditions under which innovation in early cancer detection would occur.

Although the court remanded a narrow issue concerning the FTC's analysis of Illumina's proposed behavioural remedy, it otherwise affirmed the central findings of the FTC's decision. Faced with continued litigation and regulatory scrutiny, Illumina ultimately agreed to divest Grail, completing the separation through a spin-off in June 2024. Since then, Grail has continued to advance the development and deployment of its MCED technology independently, expanding the availability of its Galleri blood test and supporting ongoing clinical studies to improve early cancer detection. These developments suggest that innovation in this field has continued to progress without vertical integration with Illumina.[60]

The significance of the decision also extends beyond the fate of a single merger. Historically, modern U.S. merger enforcement has often focused primarily on price and output effects in existing product markets, with comparatively less emphasis on potential competition or competition in innovation. By recognising the risks that vertical integration posed to the development of competing MCED technologies, the Fifth Circuit reconfirmed that merger law can address harms that arise from the suppression or distortion of technological rivalry in emerging markets. This renewed attention to potential and innovation competition is also reflected in the 2023 U.S. Merger Guidelines, which place greater emphasis on technological rivalry, vertical foreclosure, and competition in emerging markets.[61] The OECD Council's revised Recommendation on Merger Review similarly emphasises attention to whether a merger has effects on innovation, including reducing incentives to innovate or dynamic competition.[62]

Viewed from a broader perspective, the decision also reflects an evolving convergence in how competition authorities address harms to innovation. European merger enforcement has long placed explicit emphasis on innovation competition, as illustrated by the EC's decisions in Dow/DuPont and Bayer/Monsanto, which examined how consolidation among major research-intensive firms could weaken incentives to innovate or eliminate competing research pipelines in highly concentrated R&D-driven industries. In those cases, the EC developed a theory of harm centred on the loss of rivalry between a small number of global innovation leaders and required structural remedies targeting not only overlapping products but also research capabilities and innovation pipelines.[63]

The Illumina/Grail decision can therefore be seen as part of a broader evolution in merger control toward recognising that competition law must protect not only current market rivalry but also the competitive processes that generate future technologies. In this respect, the decision revives a strand of U.S. antitrust doctrine dating back to the merger cases of the 1960s, in which courts acknowledged that mergers eliminating independent centres of research or potential future competitors could threaten the competitive process even before concrete product-market effects materialised. While concerns about innovation and potential competition featured prominently in cases such as United States v. El Paso Natural Gas and FTC v. Procter & Gamble, they played a more limited role in merger enforcement in subsequent decades.[64] The recent focus on emerging innovation markets can therefore be understood less as a doctrinal departure than as a renewed emphasis on principles long embedded in US antitrust law.

The case thus stands as an important precedent for modern merger enforcement, breathing new life into innovation-based theories of harm in US merger enforcement. It demonstrates that enforcers and courts are willing to intervene where a transaction threatens to distort the innovation process itself, particularly in sectors such as biotechnology, where the competitive stakes involve technologies with the potential to transform public health.

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[60] BioSpace (2025), Show Galleri ® Multi-Cancer Early Detection Blood Test Increased Cancer Detection More Than Seven-Fold When Added to USPSTF A and B Recommended Screenings, https://www.biospace.com/press-releases/grail-pathfinder-2-results-show-galleri-multi-cancer-early-detection-blood-test-increased-cancer-detection-more-than-seven-fold-when-added-to-uspstf-a-and-b-recommended-screenings.

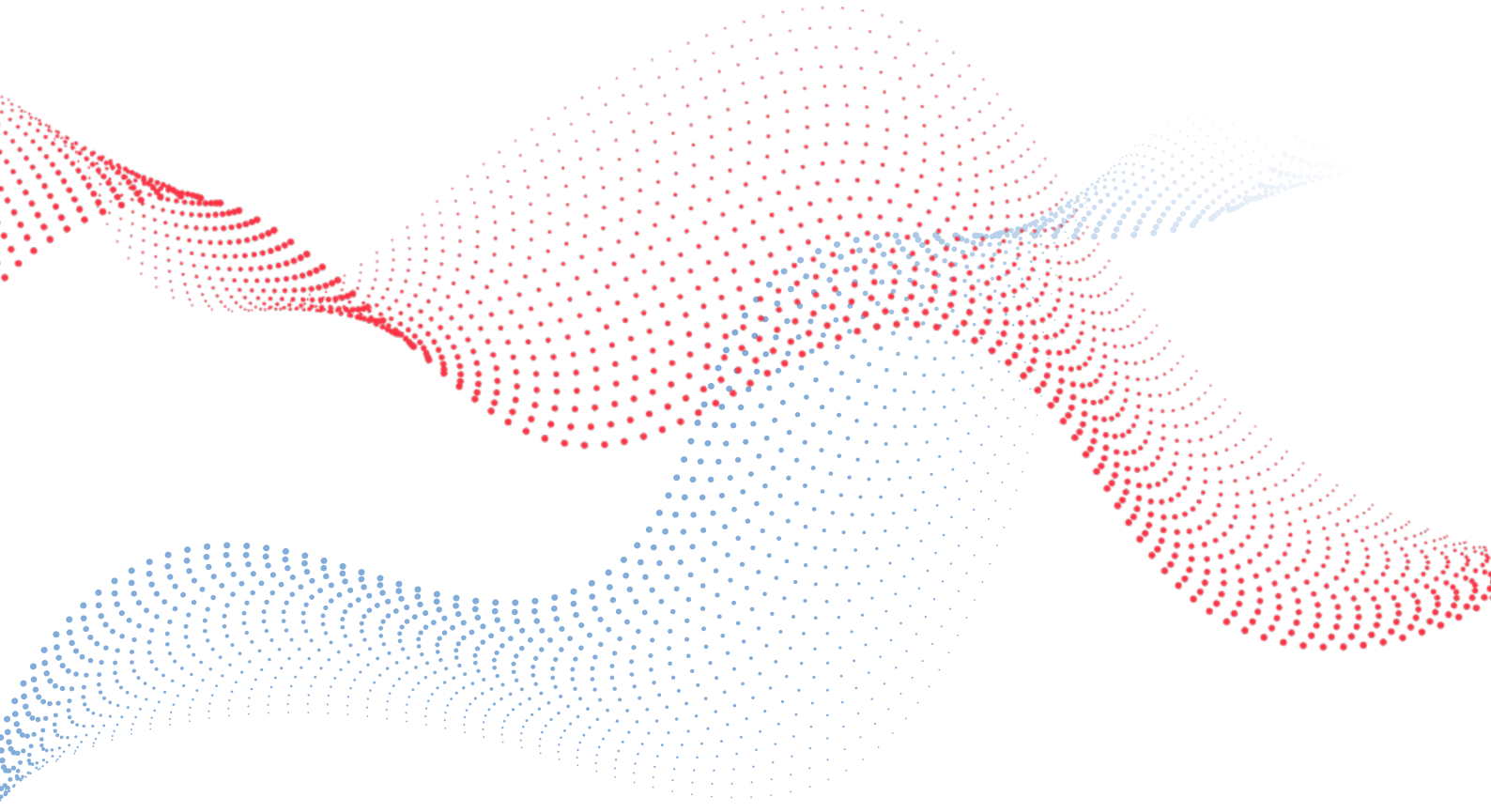
[61] U.S. Department of Justice and the Federal Trade Commission (2023), Merger Guidelines, https://www.justice.gov/atr/merger-guidelines.

[62] OECD (2025), OECD Council revised its Recommendation on Merger Review [OECD/LEGAL/0333].

[63] European Commission, Case M.7932 – Dow/DuPont, Commission Decision of 27 March 2017; European Commission, Case M.8084 – Bayer/Monsanto, Commission Decision of 21 March 2018.

[64] *United States v. El Paso Natural Gas Co.*, 376 U.S. 651 (1964); *FTC v. Procter & Gamble Co.*, 386 U.S. 568 (1967); see also *United States v. General Dynamics Corp.*, 415 U.S. 486 (1974).

More broadly, the Illumina/Grail saga illustrates the growing importance of merger control as a tool for protecting competition in innovation-driven industries. As technological progress increasingly depends on complex ecosystems of research platforms, data, and specialised capabilities, mergers may reshape not only existing product markets but also the conditions under which future technologies are developed. Ensuring that these innovation processes remain open to rivalry will therefore remain a central challenge for competition authorities. The case thus signals an important shift in modern merger enforcement: competition law is not merely concerned with prices or output, but with preserving the competitive rivalry that determines which technologies will shape the markets of tomorrow.



A Commitment Decision in an Abuse of Dominance Case on the Hungarian Soft Drinks Market

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1. Introduction

This article presents an abuse of dominance case concerning the Hungarian soft drinks market, which was ultimately resolved through the acceptance of commitments. The case illustrates the role of commitment decisions as a flexible and efficient enforcement tool in competition law, particularly in complex, multi-product settings.

In the proceedings, the Hungarian Competition Authority (GVH) investigated whether the Hungarian subsidiary of the Coca-Cola group leveraged its dominant position on the market for carbonated soft drinks into adjacent markets, including alcoholic beverages and other non-alcoholic drink categories.

2. Factual Background, Relevant market

In May 2019, the GVH initiated competition supervision proceedings against Coca-Cola HBC Magyarország Kft. (Coca-Cola Hungary). The investigation focused on a complex system of discounts and contractual conditions applied in agreements concluded with HoReCa (hotel, restaurant, and café/catering) outlets.

These agreements covered a wide range of products belonging to The Coca-Cola Company's (TCCC) portfolio, including carbonated soft drinks, mineral water, fruit juices, coffee, and alcoholic beverages. The GVH identified concerns that the structure of these agreements – particularly conditional discounts, stockholding obligations, and product bundling – could exclude competitors or hinder entry in certain beverage markets.

The theory of harm was based on potential leveraging. The GVH considered that Coca-Cola Hungary could leverage its position on the market for carbonated soft drinks through tying practices and portfolio-based discount schemes, thereby foreclosing competition in adjacent product markets. In essence, the case concerned the risk of foreclosure arising from the linking of commercially important products with less popular ones across different beverage categories.

The relevant product market was assessed from both a distribution channel and a product perspective. From the distribution side, a distinction was made between on-premise consumption (purchases for immediate consumption for example in HoReCa outlets) and off-premise consumption (purchases for later consumption). From the product side, in line with the European Commission's practice, carbonated soft drinks were considered to constitute a separate product market within the HoReCa sales channel, due to differences in consumption patterns, pricing, consumer target groups and consumer preferences compared to non-carbonated beverages.

The precise delineation of the market could be left open with regard to the differentiation of individual flavours (especially cola-flavoured carbonated soft drinks).

The relevant geographic market was defined as national since Coca-Cola Hungary operates with a nationwide pricing system and distribution structure, while marketing and branding activities are also organised at the national level. HoReCa operators are likewise primarily supplied by domestic distributors.

3. Legal Assessment

With regard to dominance, the GVH's analysis showed that between 2011 and 2022, Coca-Cola Hungary's volume-based market share was around 80-90% on the relevant market, and its turnover-based share was around 70-80%. External market data indicated somewhat lower but still substantial shares (volume-based market share 60-80%, turnover-based share between 60-80%) between 2014 and 2022. From 2020 onwards, Coca-Cola Hungary's market share increased slightly in both aspects.

Based on the responses of competitors, the barriers to market entry were high, and HoReCa outlets' buyer power was not considered a significant factor that could offset high market share and significant barriers to entry. The latter could be attributed, among other things, to the significant prestige of Coca-Cola as a brand, offsetting buyer power.

As regards Coca-Cola Hungary's conduct, based on internal documents and e-mail correspondence seized during dawn raid, the GVH could not exclude that the practices under investigation might constitute an infringement. In relation to the discounts applied by Coca-Cola Hungary in the agreements used for the sale of soft drinks, com-

petition concerns emerged regarding the listing and presentation of the various beverage products in the contract modules and their interpretation by HoReCa partners. The GVH found that the design of these modules could potentially incentivise HoReCa partners to purchase and stock the full range of products listed in a given category in order to qualify for discounts. This created a risk of tying or bundling effects. HoReCa operators purchasing carbonated soft drinks could potentially become commercially incentivised to source additional, less popular products from Coca-Cola Hungary rather than from competing suppliers. As a result, products competing in separate markets could be indirectly foreclosed.

The discounts applied by Coca-Cola Hungary could therefore potentially have a foreclosure effect on competitors present on the market for related products. Given that Coca-Cola Hungary's dominant position could not be excluded on the market for the tying products (i.e. the market for carbonated soft drinks), this tying raised the risk of foreclosing the market for other products forming part of the tied or bundled products and, indirectly, for the market for the tying product.

Competition concerns also arose regarding the company's periodic promotions, particularly in the case of discounts on mixed drinks (alcoholic cocktails). The GVH concluded that the terms and conditions of these discounts may have given partners the impression that they had to purchase both the alcoholic and non-alcoholic beverage products used for mixing from Coca-Cola Hungary.

In its defence, Coca-Cola Hungary contested both the market definition and the assessment of its conduct. First, the company argued for a significantly broader product market definition, encompassing essentially all non-alcoholic beverages. According to the company, consumer choice in the HoReCa segment is driven by factors atypical compared to retail, as consumers do not select venues based on the availability of specific soft drinks. Instead, soft drinks play a complementary role, and their absence is unlikely to affect consumer behaviour. As a result, different non-alcoholic beverages – including carbonated soft drinks, juices, iced teas, and mineral waters – as well as even homemade drinks (such as lemonades), should be considered substitutable to a significant extent. The company also argued that demand in the HoReCa segment is relatively insensitive to price changes, given that soft drinks typically represent only a small proportion of the total bill and their pricing is aligned with the overall positioning of the venue. On this basis, the company submitted that a broader market definition would imply lower market shares and, consequently, weaken any finding of dominance. It further challenged the reliability of the market share calculations, arguing that the available data did not allow for a clear separation between HoReCa and other consumption channels (such as on-the-go consumption), thereby limiting their probative value. With regard to dominance, Coca-Cola Hungary emphasized that high market shares alone are not determinative and argued that it does not operate independently of competitive constraints. In particular, it rejected the characterization of its products as "must-have" items, noting that consumers are generally willing to switch to alternative beverages if their preferred product is unavailable. It also argued that its market position is primarily explained by efficiency advantages, including a broad product portfolio and the ability to offer one-stop-shop solutions. As to the alleged conduct, the company maintained that its standard commercial agreements do not contain tying provisions. According to Coca-Cola Hungary, HoReCa partners often prefer sourcing multiple products from a single supplier in order to reduce transaction and administrative costs, independently of any exclusionary practices.

As the case was resolved through commitments, the GVH did not carry out a full legal qualification of the conduct and did not establish an infringement.

4. Commitments

Negotiations between Coca-Cola Hungary and the GVH regarding commitments began in 2022. The company revised and supplemented its proposals several times in response to feedback from the GVH.

A central element of the commitments was to clarify the wording of commercial agreements. The company undertook to clearly distinguish between carbonated soft drinks and other product categories, ensuring that the applicable commercial conditions are independent of one another. In order to draw the attention of the relevant trading partners to the amendments of the contracts concluded before the commitment period, the company undertook to highlight these amendments on the first page of new agreements and indicate them in bold in the contract text.

Coca-Cola Hungary has committed to amending its commercial agreements relating to non-alcoholic products by adding further explanatory and clarifying provisions that the commercial terms regarding carbonated soft drinks and other products distributed by Coca-Cola Hungary (including non-carbonated soft drinks and alcoholic products) are not dependent on each other. In order to visually separate the conditions, the company undertook to place the clarifying provisions in separate paragraphs (modules).

In addition, Coca-Cola Hungary also modified its agreements concerning alcoholic beverages with clarifying provi-

sions, including provisions on mixed drink promotions. The revised terms clarify that discounts related to mixed drinks are not conditional on sourcing carbonated soft drinks from Coca-Cola Hungary, thereby preserving the freedom of HoReCa operators to choose alternative suppliers.

Finally, Coca-Cola Hungary undertook to implement a compliance programme and to maintain the commitments for a period of three years.

Conclusion

In light of the commitments offered, the GVH considered that it was not necessary to reach a definitive conclusion on whether the conduct constituted an infringement. Instead, the authority accepted the commitments as an appropriate and proportionate means of addressing the identified competition concerns.

The commitments effectively eliminate the risk that contractual arrangements and discount schemes could tie the purchase of different product categories. They ensure the independence of commercial conditions across product groups and remove incentives that could lead to the foreclosure of competitors in adjacent markets.

The introduction of a compliance programme further supports the effective implementation of these changes in the company's commercial practices.

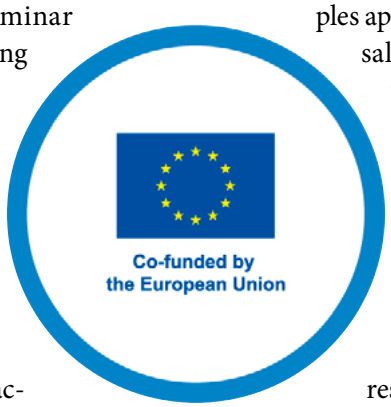
This case illustrates that competition law enforcement is not limited to punitive measures. Commitment decisions can provide a pragmatic and efficient solution to complex competition concerns, particularly in markets characterised by strong brands, broad product portfolios, and intricate commercial arrangements.

IV. CONFERENCES IN THE PAST SEMESTER

1. RCC Seminars

Judges Explore Vertical Agreements and Modern Distribution Challenges in Competition Law

In January 2026, judges from across Europe gathered in Budapest for the Competition Lab for Judges, a seminar dedicated to one of the most important and technically demanding areas of competition law: vertical agreements and vertical restraints. Funded by the European Commission's Single Market Programme, the seminar combined legal analysis, economic reasoning and practical case exercises to strengthen judicial understanding of how competition rules apply to distribution relationships in modern markets.



The programme focused on the framework used under European competition law to assess agreements concluded between companies operating at different levels of the supply chain, such as manufacturers, wholesalers and retailers. Participants explored the legal concepts that underpin the analysis of vertical agreements, including the notions of *agreement*, *restriction by object* and *restriction by effect*, as well as the role of the EU Vertical Block Exemption Regulation (VBER) in determining when such arrangements may benefit from a safe harbour.

A central message of the seminar was that vertical agreements are often fundamentally different from horizontal arrangements between competitors. While some vertical restraints may restrict competition, many can also generate efficiencies by improving distribution, preventing free-riding, encouraging investment and enhancing consumer welfare. Participants therefore examined the analytical frameworks used to distinguish pro-competitive arrangements from restrictions that may harm markets and consumers.

The economic rationale of vertical agreements received particular attention. Discussions highlighted how manufacturers and distributors frequently rely on contractual restrictions to organize distribution systems, protect brand value and ensure service quality. At the same time, participants considered circumstances in which such restrictions can reduce competition, foreclose rivals or partition markets, requiring closer scrutiny by competition authorities and courts.

Reflecting the growing importance of e-commerce and digital platforms, the seminar also examined the application of competition law to vertical restraints in digital environments. Through analytical frameworks and case studies, participants discussed how traditional competition principles apply to online distribution systems, platform sales, digital marketplaces and the increasing use of selective and exclusive distribution arrangements in the digital economy.

Several sessions focused on specific categories of vertical restraints that frequently arise in competition cases. Discussions on price restrictions in distribution networks, including resale price maintenance (RPM), considered why restrictions on distributors' pricing decisions are generally viewed as serious competition concerns, while also exploring the economic and legal arguments that may arise in particular circumstances. Case studies enabled participants to assess how courts and authorities approach these issues in practice.

On the second day, attention turned to territorial and product restrictions, two areas that continue to generate significant litigation and enforcement activity within the European Union. Participants examined the legal treatment of restrictions on cross-border sales, customer allocation mechanisms and limitations on the products distributors may sell. These discussions highlighted the importance of preserving the integrity of the internal market while balancing legitimate business objectives.

The seminar also addressed the increasingly relevant topic of collusion within distribution networks. Participants explored situations in which vertical relationships can facilitate coordination among market participants or support broader anticompetitive strategies. The discussions emphasized the need for courts to carefully assess evidence and economic context when determining whether distribution arrangements are serving legitimate commercial purposes or facilitating restrictions on competition.

A distinctive feature of the programme was its strong practical orientation. Throughout the two-day seminar, participants worked on a series of hypothetical cases that allowed them to apply the analytical frameworks discussed

during the presentations. These exercises encouraged active debate and provided an opportunity to test legal reasoning against realistic competition law scenarios involving distribution agreements and vertical restraints.

By bringing together judges, practitioners, economists and enforcement experts, the Competition Lab provided a forum for discussing how competition law continues to evolve in response to changes in business models and distribution systems. The seminar underscored the importance of combining legal analysis with economic understanding when assessing vertical agreements and highlighted the key role of judges in ensuring the consistent and effective application of competition rules across Europe.

Overall, the seminar reinforced the idea that vertical agreements remain one of the most nuanced areas of competition law, requiring careful balancing between restrictions that may harm competition and arrangements that can generate efficiencies, innovation and benefits for consumers.

Competition and Pharmaceutical Markets: Exploring Enforcement, Regulation and Advocacy

In February 2026, the OECD-GVH Regional Centre hosted a seminar in Budapest dedicated to one of the most challenging and socially important sectors for competition authorities: pharmaceutical markets. Bringing together experts from competition agencies, the European Commission and beneficiary authorities across the RCC region, the seminar examined how competition law and policy can contribute to affordable medicines, sustainable innovation and better outcomes for patients.

The programme highlighted the unique characteristics of pharmaceutical markets, where competition authorities must operate in an environment shaped by patents, intellectual property rights, strict regulation, public procurement systems and significant information asymmetries. Participants discussed how these features can both stimulate innovation and create risks of market distortions, requiring competition agencies to develop specialized expertise and enforcement strategies.

The seminar opened with an overview of the sector and the tools available to competition authorities. Discussions focused on the interaction between regulation and competition, the structure of pharmaceutical distribution chains, and the different approaches authorities may use to identify and address competition concerns in drug manufacturing, distribution and retail markets.

A major theme throughout the event was the relationship between regulation and anticompetitive conduct. Participants explored how regulatory frameworks can sometimes unintentionally facilitate collusion, create barriers to entry or shield market participants from competitive pressure. The Lithuanian experience provided insights into the detection and assessment of collusive practices in highly regulated environments and highlighted the importance of understanding industry-specific incentives and market structures.

The enforcement sessions examined some of the most significant competition cases in the pharmaceutical sector. Experts reviewed European Commission investigations and landmark cases involving strategies designed to delay the entry of generic medicines, including so-called pay-for-delay agreements, where originator companies provide incentives to generic manufacturers to postpone market entry. Participants also discussed the competition implications of patent-related practices, litigation strategies and conduct that may restrict innovation or reduce patient choice.

Special attention was devoted to exclusionary abuses and pricing practices. The seminar reviewed important European precedents, including the Aspen, Leadiant and CD Pharma cases, which addressed concerns relating to excessive pricing of pharmaceutical products. These discussions highlighted the delicate balance competition authorities must strike between preserving incentives to innovate and preventing exploitative conduct that may harm healthcare systems and patients.

Beyond pricing issues, participants explored a broader range of potentially anticompetitive behaviours in pharmaceutical markets, including abusive rebates, predatory pricing, bid rigging in public procurement, resale price maintenance, exchanges of commercially sensitive information, coordination between pharmacies and manufacturers, and practices that may limit production or reduce access to treatment alternatives. The seminar emphasized that competition agencies increasingly need sophisticated economic and legal tools to address these complex behaviours.

Another important topic was competition advocacy. Drawing on the experience of the Lithuanian Competition Authority and several beneficiary agencies, participants discussed how advocacy initiatives, market inquiries and engagement with policymakers can address structural barriers to competition that enforcement alone may not resolve. Speakers highlighted the value of providing evidence-based recommendations to governments, healthcare regulators and public purchasers in order to improve market functioning and increase access to medicines.

The programme also examined merger control in pharmaceutical markets through the lens of the widely discussed Illumina/Grail case. Discussions focused on the challenges of assessing innovation-driven mergers, the role of potential competition, and the need for authorities to evaluate not only current market effects but also the impact transactions may have on future innovation pathways and patient welfare.

Throughout the seminar, participants worked on hypothetical case studies designed to apply the concepts discussed during the presentations. These practical exercises encouraged exchanges of experience among agencies and provided an opportunity to explore enforcement and advocacy responses to realistic competition concerns arising in pharmaceutical markets.

The seminar concluded with a regional discussion on the future of competition advocacy in healthcare and pharmaceutical markets. Representatives from Bosnia and Herzegovina, Bulgaria and Georgia shared perspectives on the challenges faced by competition authorities in the region and highlighted the importance of market inquiries, regulatory cooperation and institutional dialogue in promoting competitive and patient-focused healthcare systems.

Overall, the seminar demonstrated that pharmaceutical markets require competition authorities to combine strong enforcement with effective advocacy and deep sectoral knowledge. By tackling exclusionary practices, scrutinizing mergers, addressing excessive pricing concerns and promoting pro-competitive reforms, competition agencies can play a crucial role in ensuring that pharmaceutical markets deliver both innovation and accessible healthcare for consumers.

Competition Agencies as Drivers of Growth and Welfare: Key Takeaways from the RCC Seminar in Yerevan

From 18–20 March 2026, competition officials and experts from across the RCC network gathered in Yerevan, Armenia, for a seminar dedicated to **"Competition Agency Tools for Promoting Growth and Welfare."** The event explored how competition authorities can support economic development through a wide range of instruments, including enforcement, advocacy, market studies, merger review, compliance initiatives and regulatory reform.

A central theme throughout the discussions was that competition authorities are no longer seen solely as law enforcers. While strong enforcement against cartels, abuses of dominance and other anticompetitive practices remains essential, agencies increasingly contribute to economic growth by identifying market barriers, promoting sound regulation and fostering a culture of competition across government and society.

Participants examined practical experiences from Armenia, Romania, Italy, Portugal, Albania and Paraguay, illustrating how competition tools can be adapted to different institutional and economic contexts. Case studies demonstrated how enforcement actions can open markets to new entrants, strengthen competitiveness and deliver tangible benefits to consumers.

Several sessions highlighted the growing importance of **competition advocacy**. Speakers shared examples of successful interventions aimed at removing unnecessary regulatory restrictions, reforming self-regulated professions and encouraging policymakers to adopt pro-competitive approaches. The discussions reinforced the message that some of the greatest gains for consumers and businesses can arise from improving the regulatory environment rather than from enforcement actions alone.

The seminar also addressed emerging areas of interest for competition authorities. Sessions on labour market competition explored how competition policy can protect worker mobility and improve labour market outcomes, while discussions on innovative markets focused on ensuring that competition frameworks remain effective in rapidly evolving sectors and digital environments.

Market studies featured prominently in the programme, with presentations on methodology and practical experiences in sectors such as finance and port services. Participants discussed how market studies enable authorities to identify structural problems, understand market dynamics and develop recommendations that improve market performance even where no infringement is found.

Other topics included competitive neutrality, merger control, compliance programmes and the role of evidence in demonstrating the benefits of competition policy. Together, these sessions highlighted the breadth of tools available to competition agencies and the importance of selecting the most appropriate instrument for each market challenge.

The seminar concluded with a broader reflection on the relationship between competition policy and other government policies. Speakers emphasized that achieving sustainable growth and welfare requires close cooperation between competition authorities, regulators and policymakers, ensuring that competition principles are embedded across the public policy framework.

Overall, the seminar underscored a clear message: modern competition authorities are key contributors to economic growth, innovation and consumer welfare, using a diverse toolkit that extends well beyond traditional enforcement.

Competition Lab for Judges Examining Contemporary Challenges in Abuse of Dominance Enforcement under EU Competition Law

On 14-15 May 2026, the Competition Lab for Judges brought together judges, legal practitioners, academics, economists and competition law experts in Budapest for a high-level seminar dedicated to abuse of dominance under Article 102 TFEU. Funded by the Single Market Programme of the European Commission and organised by the OECD-GVH Regional Centre for Competition in Budapest, a joint initiative of the Organisation for Economic Co-operation and Development and the Hungarian Competition Authority (GVH), the seminar provided participants with an opportunity to engage in in-depth discussions on exclusionary and exploitative abuses, evolving economic theories of harm and recent developments in EU competition law jurisprudence.

The programme focused on the key substantive and procedural developments in abuse of dominance cases under EU competition law and aimed to provide participants with a comprehensive analytical framework for assessing abusive practices. Particular attention was devoted to the concepts of dominance and abuse, exclusivity arrangements and exclusivity payments, excessive pricing, bundling and tying, as well as evidentiary standards in judicial review proceedings. The discussions drew extensively on EU case law and practical examples illustrating the evolution and application of Article 102 TFEU.

The seminar opened with welcome remarks delivered by Attila Sipos, Secretary General of the Hungarian Competition Authority, followed by an introductory questionnaire exercise designed to assess participants' existing familiarity with abuse of dominance concepts and EU competition law enforcement.

The first substantive session, titled "Dominance – Analytical framework and case examples – a Judge's view," was delivered by Mercedes Pedraz, Judge at the Spanish National High Court. The presentation examined the concept of dominance, the role of market definition and the notion of economic power under EU competition law. The session further explored collective dominance and reviewed landmark case law concerning predatory pricing, price discrimination, rebates, refusal to supply, margin squeeze and tying practices. Particular emphasis was placed on the judicial perspective in assessing dominance and exclusionary conduct under Article 102 TFEU.

The following session on "Abuse – Analytical framework and case examples" was presented by Maria Pilar Canedo, Senior Competition Expert at the OECD. The presentation focused on the analytical framework governing abuse of dominance under Article 102 TFEU and examined the interaction between legal doctrine, economic analysis and judicial interpretation. Discussions addressed how the concept of abuse has evolved through EU case law and increasingly requires competition authorities and courts to assess market realities, competitive effects and broader policy considerations. Practical examples from regulated sectors further illustrated the relationship between regulation and competition enforcement.

The afternoon session on "Refusal to deal – Analytical framework and case examples" was delivered by Giorgio Monti, Professor at Tilburg Law School. The presentation examined refusals to supply and refusals to grant access to essential facilities under Article 102 TFEU, with particular emphasis on the Bronner test and its interpretation in EU competition law. Discussions explored indispensability, elimination of effective competition and objective justification, while also considering the balance between preserving incentives for investment and innovation and ensuring market access for competitors. Using examples involving transport infrastructure and downstream markets, the session illustrated how refusal to deal cases increasingly require detailed assessment of market structure, consumer welfare and downstream competitive effects.

Another key session addressed "Exclusivity arrangements, exclusivity payments and rebate schemes" and was presented by Athanasia Gavala, Director General of the Hellenic Competition Commission. The presentation analysed exclusive dealing arrangements, fidelity rebates and conditional rebate systems from both legal and economic perspectives. Discussions examined explicit and implicit exclusivity, retroactive and incremental rebates and the different types of rebate thresholds and incentive structures commonly encountered in abuse of dominance cases.

Particular attention was devoted to the evolution of EU competition law from earlier formalistic approaches, particularly Hoffmann-La Roche, toward the increasingly effects-based methodology reflected in Intel and subsequent jurisprudence. The session also examined the As-Efficient Competitor (AEC) test and its role in assessing foreclosure effects arising from rebate schemes. Participants discussed the relationship between contestable demand, effective pricing and average avoidable costs, while also reflecting on the

limitations of purely quantitative analysis and the importance of broader market realities and competitive structure in rebate assessments.

The first day concluded with a hypothetical case exercise allowing participants to apply the analytical frameworks discussed throughout the day to realistic abuse of dominance scenarios involving complex market structures and exclusionary conduct.

The second day of the seminar opened with a session on "Bundling and tying – Analytical framework and case examples" delivered by Sven Frisch, Attaché de justice at the Luxembourg Administrative Tribunal. The presentation examined the distinction between contractual tying, technical tying, pure bundling and mixed bundling and analysed the economic theories underlying leveraging strategies by dominant undertakings. Discussions focused on both offensive and defensive leveraging theories and explored how tying arrangements may extend market power into adjacent markets or protect existing dominance from emerging competitive threats.

The session additionally reflected on landmark digital market cases, including Microsoft and Google Android, and discussed how technological integration, interoperability concerns and platform ecosystems increasingly challenge traditional competition law analysis. Participants examined the efficiencies potentially generated by tying and bundling practices while also considering the foreclosure risks associated with such arrangements in digital and technology markets.

The following session on "Excessive pricing – Analytical framework and case studies" was delivered by Lefkothea Nteka, Partner at Lambadarios Law Firm and former member of the Hellenic Competition Commission. The presentation focused on excessive pricing under Article 102 TFEU and examined the United Brands test, including the "excessive" and "unfair" limbs of the analysis. Discussions explored methodological challenges associated with price-cost comparisons, benchmarking exercises and the determination of economic value.

Participants additionally reflected on broader policy concerns associated with excessive pricing enforcement, including the risk of transforming competition authorities into de facto price regulators and the potential impact of intervention on investment incentives, innovation and market dynamics. The discussions highlighted the practical difficulties associated with distinguishing genuinely exploitative prices from temporary high prices resulting from competitive market conditions or innovation-based advantages.

Following an additional hypothetical case exercise, the afternoon session addressed "Evidentiary issues in abuse of dominance cases" and was presented by Yolanda de Muynck, Référendaire at the European Court of Justice. The presentation examined the European Commission's investigative powers under Regulation 1/2003, including requests for information, inspections and procedural guarantees available to undertakings during competition investigations.

The session further addressed standards of proof before EU courts and explored the role of direct, circumstantial and economic evidence in establishing infringements under Articles 101 and 102 TFEU. Particular attention was devoted to digital investigations, electronic communications, search terms and data-intensive evidence gathering, as well as the balance between effective enforcement powers and the protection of procedural rights and fundamental guarantees during judicial review proceedings.

Throughout the programme, speakers repeatedly emphasised the increasing sophistication of competition law analysis and the growing importance of interdisciplinary approaches combining legal doctrine with economic reasoning. Discussions highlighted that modern abuse of dominance cases frequently involve complex assessments of market power, foreclosure effects, efficiencies and long-term consumer welfare implications, particularly in rapidly evolving digital and innovation-driven sectors.

The seminar concluded with an interactive Kahoot exercise and a final questionnaire session designed to evaluate participants' understanding of the concepts and analytical frameworks discussed during the programme.

The Competition Lab for Judges therefore provided an important platform for professional exchange, comparative dialogue and deeper engagement with contemporary challenges in abuse of dominance enforcement under EU competition law. Top of FormBottom of Form.

2. OECD Conferences

OECD Competition Week (June 2026) Overview

OECD Competition Week – June 2026, held from 22 to 26 June 2026, brought together competition officials, policymakers, academics, and practitioners to discuss a broad range of contemporary issues in competition law and policy. Through working party meetings, roundtable discussions, and expert presentations, participants exchanged experiences and explored recent developments, emerging challenges, and evolving approaches to competition enforcement.

The following summaries provide an overview of the discussions and key insights from each session.

Institutional Arrangements, Competition Advocacy and Market Dynamics

The session of WP2 on Competition examined how different institutional arrangements shape the work and effectiveness of competition authorities across jurisdictions. Using examples from the Competition Bureau of Canada and Colombia's Superintendencia, the discussion explored the relationship between institutional design, enforcement priorities, and competition advocacy. Particular attention was given to the role of competition authorities in identifying and addressing regulatory risks, promoting competitive market dynamics, and engaging with policymakers to foster pro-competitive regulation.

The session also introduced the OECD Guide for Assessing the Impact of Competition Authorities' Activities, emphasizing that the performance of competition authorities should be assessed not only through enforcement outcomes, but also through their broader impact on deterrence, regulatory quality, and the development of more competitive markets.

Competition Assessment of Laws and Regulation in the Healthcare Sector

The roundtable examined the role of competition assessment in promoting efficient and competitive healthcare markets. Discussions focused on how laws, regulations, and public policies can unintentionally restrict competition, particularly through hospital mergers, regulatory barriers, and contractual practices limiting market entry and innovation. Drawing on recent enforcement actions by the U.S. Department of Justice and the Federal Trade Commission, speakers highlighted several high-profile healthcare cases involving hospital consolidation, labour market restrictions, and anticompetitive agreements.

The session also explored the use of Certificates of Public Advantage (COPAs), which allow certain hospital mergers to proceed under state supervision despite potential competition concerns, raising important questions about the balance between public interest objectives and the preservation of competitive market structures. In addition, participants reviewed recent empirical evidence on the deterrence effects of competition enforcement, emphasizing that effective antitrust intervention extends beyond individual cases by discouraging anticompetitive conduct and influencing business decisions before harmful mergers or practices materialize. Overall, the discussion underscored the importance of integrating competition assessment into regulatory design to ensure that healthcare policies promote innovation, efficiency, affordability, and consumer welfare while avoiding unnecessary restrictions on competition.

National Security Considerations in Competition Enforcement

This session explored the growing interaction between competition policy and national security in an increasingly fragmented geopolitical environment. Participants discussed how geopolitical tensions, technological rivalry, supply chain disruptions, and export controls are reshaping competition enforcement and expanding the role of national security considerations in economic policymaking. Particular attention was given to the challenges competition authorities face when assessing mergers, market conduct, and interventions involving strategically important sectors, while ensuring that competition law remains focused on preserving competitive markets.

The discussion also examined the concept of strategic autonomy and the increasing tendency of governments to support domestic industries and reduce dependence on foreign suppliers. While such measures may strengthen resilience and safeguard critical sectors, participants noted that they may also reduce competitive pressure, weaken incentives for innovation, and distort market outcomes if not carefully designed. The session concluded by emphasizing the importance of transparent decision-making, clear institutional boundaries, and close cooperation between competition authorities and national security bodies to balance legitimate security objectives with the long-term benefits of open and competitive markets.

Non-Compete Clauses and Labour Market Competition

The session focused on competition in labour markets, examining how contractual restrictions on employee mobility, particularly non-compete clauses, but also no-poaching and wage-fixing agreements, may reduce competition, productivity and innovation. The discussion highlighted growing evidence that these restraints have become widespread across sectors and often extend beyond their original purpose of protecting legitimate business interests.

Participants explored their impact on labour mobility, knowledge diffusion, business dynamism and wage growth, while emphasizing the increasingly important role of competition authorities in addressing anti-competitive practices in labour markets. The session also considered potential policy responses, including stronger enforcement against labour market restraints, improved regulatory frameworks, and the use of less restrictive alternatives, such as non-disclosure agreements, to balance legitimate business interests with competitive labour markets.

Competition and Consumer Policy in Digital Markets

The roundtable explored the increasingly interconnected nature of competition and consumer protection in digital markets, highlighting how digital platforms, algorithms, and AI systems influence both consumer behaviour and market outcomes. Participants discussed concerns related to personalised pricing, self-preferencing, data-driven lock-in, manipulative choice architecture, and the growing role of AI-driven recommendation and decision-making systems.

A key focus of the discussion was how regulators can respond more effectively to these challenges. Participants emphasized the need for closer coordination between competition, consumer protection, data protection, and digital regulatory authorities, including through joint priority-setting, policymaking, and enforcement initiatives. The discussion also highlighted the importance of integrating consumer agency considerations more systematically into enforcement frameworks to ensure that consumers can make informed and autonomous choices in increasingly complex digital environments.

Looking ahead, participants considered possible approaches to improving regulatory effectiveness, including better-designed remedies, stronger institutional cooperation, and greater transparency obligations for digital platforms and AI systems. The discussion also explored whether emerging tools, including AI-based solutions and new forms of remedial intervention, could help address harms arising from data-driven business models while preserving innovation and consumer benefits. Particular attention was given to the challenges posed by agentic AI systems and the need for coordinated responses that promote both consumer welfare and competitive digital markets.

Information Sharing in Competition Policy

The session examined the evolving role of information sharing in competition policy, highlighting both its efficiency-enhancing benefits and its potential risks for competition. Participants discussed how information exchanges can reduce uncertainty, support investment and innovation, and facilitate legitimate business cooperation, while also creating opportunities for collusion by enabling firms to monitor competitors, align their behaviour, or sustain coordinated conduct. The discussion emphasized that competition authorities should assess information exchanges based on their competitive effects and market context rather than relying on rigid classifications.

Particular attention was given to the growing role of digital platforms, algorithms, and data intermediaries, which have transformed the speed and scale of information exchanges and created new enforcement challenges. Participants stressed the importance of context-specific assessments and practical safeguards, including data aggregation, anonymisation, restricted access to commercially sensitive information, and appropriate disclosure delays. Overall, the session concluded that effective enforcement should preserve the legitimate benefits of information sharing while preventing practices that facilitate coordination and undermine competitive market outcomes.

Case Prioritisation and Prosecutorial Discretion

The roundtable explored how competition authorities determine which cases should be investigated and pursued in order to maximise the impact of limited enforcement resources. The discussion emphasized that case prioritisation is not an isolated decision but part of a broader enforcement framework, linking institutional goals and strategic priorities to project selection, case delivery, and ex post assessment. Participants examined the broad range of factors that influence prioritisation decisions, including the expected competitive impact of a case, the scale of consumer harm, the likelihood of successful enforcement, deterrence effects, legal significance, resource requirements, and overall strategic value.

The OECD Competition Secretariat also presented the findings of its 2026 survey on case prioritisation, which revealed considerable differences among competition authorities regarding prosecutorial discretion, transparency, internal guidelines, and decision-making processes.

While most authorities indicated that high-level organisational priorities play an important role in case selection, approaches varied between top-down leadership-driven models and bottom-up approaches led by operational teams. Overall, the session highlighted that effective enforcement depends not only on selecting the right cases but also on maintaining a coherent enforcement strategy that aligns institutional objectives, resource allocation, and impact evaluation, ensuring that competition authorities maximise their contribution to consumer welfare and well-functioning markets.

OECD Peer Review of Latvia

The roundtable was dedicated to the OECD Peer Review of Latvia, examining the effectiveness of the country's competition law and policy framework, institutional arrangements, and enforcement practices. Based on the findings of the OECD Secretariat's report, the discussion provided an opportunity for peer competition authorities to assess Latvia's progress and identify areas requiring further reform. Particular attention was given to the Competition Council's governance structure, the alignment of resources with strategic priorities, and the effectiveness of its enforcement activities. Participants discussed the relatively limited use of ex officio investigations, leniency and whistleblowing programmes, as well as concerns regarding the low level of sanctions and their deterrent effect.

The roundtable also examined the authority's economic expertise in complex investigations, particularly in abuse of dominance and digital markets, the limited use of interim measures and commitments, and the effectiveness of merger control. In addition, discussions addressed advocacy activities, market studies, cooperation with neighbouring competition authorities, the enforcement of competition rules against state-owned enterprises and municipalities, and the increasing role of private enforcement. Overall, the peer review recognised Latvia's significant institutional progress, while concluding that further reforms are needed to ensure that expanded resources translate into stronger, more proactive, and more deterrence-oriented competition enforcement.

Competition and Corruption in Public Procurement

The roundtable explored the close relationship between competition and corruption in public procurement, emphasizing the significant economic importance of public procurement, which accounts for a substantial share of public expenditure and plays a critical role in delivering public services. The discussion highlighted how corruption distorts competitive processes by reducing competitive pressure, discouraging innovation, increasing prices, and creating barriers to market entry, ultimately leading to greater market concentration. Particular attention was given to the interaction between corruption and bid rigging, noting that corrupt practices may facilitate collusion while making anti-competitive conduct more difficult to detect.

Participants also examined the legal and enforcement challenges arising from fragmented institutional frameworks, differences in evidence collection and procedural rules, and the need to balance transparency with confidentiality. Finally, the session stressed the importance of strengthening cooperation among competition authorities, anti-corruption agencies, procurement bodies, and law enforcement institutions through information sharing, coordinated investigations, and a whole-of-government approach to enhance prevention, detection, and enforcement in public procurement.

V. NEWS FROM REGION

Appointment of Alina Cebotariov as President of the Competition Council of the Republic of Moldova

Alina Cebotariov

President, Competition Council of the Republic of Moldova

She completed her studies in Business Administration at the British Business College in London, United Kingdom. She subsequently pursued further studies in Business Administration at the International Institute of Management in Chisinau, Republic of Moldova, and later specialised in Economics and Financial Administration at NOVA University of Applied Sciences in Amersfoort, the Netherlands.

Alina Cebotariov has over 18 years of professional experience in the regulation and supervision of the financial sector. She previously worked within the National Commission for Financial Markets, where she held a management position and was involved in complex regulatory and supervisory processes in the non-bank lending sector. Subsequently, she served as Deputy Director of the Organisation for Entrepreneurship Development, contributing to the development of financing and guarantee instruments for the business environment. She was appointed on 27 April 2026.

She has also been involved in strategic projects implemented in cooperation with various national and international partners.

She is a certified expert in sustainable finance from Frankfurt School of Finance & Management and holds academic qualifications in economics and financial management obtained in the Republic of Moldova and the Netherlands.

Her native language is Romanian, and she has advanced proficiency in both English and Russian.

For more details, please visit our official website.

VI. INSIDE A COMPETITION AUTHORITY: REPUBLIC OF KYRGYZSTAN

Agency Questionnaire

1. Relevant competition legislation

The competition law of the Kyrgyz Republic is based on the Constitution of the Kyrgyz Republic, international treaties to which the Kyrgyz Republic is a party that have entered into force in the manner prescribed by law, and consists of the Laws of the Kyrgyz Republic «On Competition», «On Natural Monopolies in the Kyrgyz Republic», and other regulatory legal acts of the Kyrgyz Republic governing relations related to the protection of competition.

The Law «On Competition» defines the organizational and legal foundations for the protection and development of competition and is aimed at preventing, limiting, and suppressing monopolistic activity and unfair competition, as well as ensuring conditions for the creation and efficient functioning of the markets of the Kyrgyz Republic.

The Law was adopted in 2011, and in 2015, its provisions were harmonized with the provisions of the Treaty on the Eurasian Economic Union and the Model Law «On Competition» approved by the decision of the EEC Council.

Subsequently, a number of additional amendments and supplements were introduced, including the establishment of an mechanism for preventing competition-law infringements, the clarification of requirements relating to abuse of dominance, anti-competitive agreements (cartels) and concerted practices, as well as state control over economic concentration.

2. Agency's competences

The Service carries out state control over compliance with the competition law of the Kyrgyz Republic, including:

- over the actions of an economic entity (group of persons) holding a dominant position, which have, or may have, the effect of restricting competition and/or infringing on the interests of other undertakings or individuals;
- over anti-competitive agreements (concerted practice) of undertakings that restrict competition;
- over acts and actions (inaction) of state bodies and local self-government bodies aimed at preventing, restricting, or eliminating competition;
- over antimonopoly requirements applicable to the procurement of goods;
- over the reorganization (merger, acquisition, transformation) of undertakings (their associations);
- carries out an analysis of the state of the competitive assesment of the relevant markets for goods, works, and services;
- exercises regulation and state control over the activities of natural monopoly entities, pursuant to the Law of the Kyrgyz Republic "On Natural Monopolies in the Kyrgyz Republic".

In addition to antimonopoly regulation, the Service:

- carries out state control over compliance with legislation on advertising and consumer protection within its competence;
- approves tariffs (prices) for services (works), except for educational ones, provided by state bodies, local self-government bodies and their structural subdivisions, organizations, and institutions, according to the established procedure;
- approves the cost of permits issued by executive authorities and their structural subdivisions, according to the established procedure;
- sets prices for socially significant goods in the event of the introduction of temporary state price regulation in accordance with legislation on pricing and carries out control over their application;
- carries out control over the correctness of the formation and application of regulated tariffs (prices), including for paid services (works) provided by state bodies, local self-government bodies and their structural subdivisions, organizations, and institutions;
- carries out state metrological supervision in accordance with the Law of the Kyrgyz Republic «On Ensuring the Uniformity of Measurements».

3. The Institution

A. Structure of the Agency

a. The Chairperson

Mamyraliev Aibek Abaskanovich, born in 1981, has a higher education.

In 2003, he graduated from the Kyrgyz National University majoring in «Jurisprudence».

In 2011, he graduated from the Academy of Public Administration under the President of the Kyrgyz Republic majoring in «Public Administration».

In 2012, he graduated from the Institute of Social Development and Entrepreneurship majoring in «Accounting and Auditing».

In 2014, he defended his PhD thesis on the topic: «Administrative and legal status of the antimonopoly authority of the Kyrgyz Republic», in which he

highlighted current problems related to the status of the antimonopoly authority of the Kyrgyz Republic that arise during the implementation of tasks and functions by the antimonopoly authority and proposed ways to solve them. He is a Candidate of Legal Sciences. He holds the civil service rank of «Class 3 State Civil Service Counsellor».

He has worked in the antimonopoly authority since 2005 in the following positions: leading specialist, head of department, deputy director, state secretary; he was appointed as the Chairperson of the Service on February 16, 2026.

b. Members of the Board

A board of 7 people is formed within the Service, consisting of the Chairperson of the Service, Deputy Chairmen, a representative of the Ministry of Economy and Commerce of the Kyrgyz Republic, as well as heads of structural divisions of the central office of the Service. 3 members of the board are appointed by the Chairperson of the Cabinet of Ministers of the Kyrgyz Republic and 4 by the Minister of Economy and Commerce of the Kyrgyz Republic.

c. Deputies

The Chairperson of the Service has two deputies:

1. Kadyrbekova Nurzhan Mainazarovna, born in 1980, has a higher education.

   In 2003, she graduated from the Law Faculty of the Kyrgyz National University named after Zh. Balasagyn majoring in «Jurisprudence».

   She began her career in 2003 as an assistant lawyer at the Sverdlovsk Legal Consultation Service.

   From 2007 to 2015, she worked at the Ministry of Justice of the Kyrgyz Republic.

   She has been working at the Antimonopoly Authority since 2015 in the following positions: leading specialist, sector of legal and methodological work, and authorized representative for anti-corruption issues. Appointed as Deputy Chairperson on April 1, 2026.

   She holds the civil service rank of «Class 1 State Service Counsellor».

2. Kokosherov Sanzharbek Sharshenalyevich, born in 1991, has a higher education.

   In 2012, he graduated from the Academy of Public Administration under the President of the Kyrgyz Republic majoring in «State and Municipal Administration».

   Began his professional career at the Antimonopoly Authority in 2013 and worked in the following positions: leading specialist, chief specialist, head of sector, head of department, head of directorate. Appointed as Deputy Chairperson on April 1, 2026.

   He holds the civil service rank of «Class 2 State Service Counsellor».

The Deputy Chairpersons report directly to the Chairperson and carry out their activities within the limits of the duties assigned to them.

d. Staff of the Agency

The total number of employees is divided into persons engaged in case handling/managers, and administrative/support staff.

The Service's staff consists of 86 civil servants (53 in the central office and 33 in territorial units) and 29 positions for technical and junior support staff.

The main functional duties of the Service are carried out by 5 directorates:

- directorate of investigations, control over compliance with competition law and advertising, 9 employees;
- directorate of legal support and consumer protection, 9 employees;
- directorate of regulated sectors, 7 employees;
- directorate of analysis, reporting, and interaction with the EEC, 8 employees;
- directorate of metrological supervision, 9 employees.

In addition, 9 territorial units carry out all functions of the Service locally, 33 employees.

Also, the structure of the Service includes: the human resources management, documentation support, and state language department, 5 employees, and the accounting and financial-economic activities sector, 2 employees.

B. Level of independence

a. System of appointment and detachment for the Chairperson and other key roles

The Chairperson is appointed to and dismissed from the position by the Chairperson of the Cabinet of Ministers of the Kyrgyz Republic upon the recommendation of the Minister of Economy and Commerce of the Kyrgyz Republic (hereinafter referred to as the Minister).

The Chairperson of the Service reports directly to the Minister.

The composition of the board members is approved by the Minister.

The Regulation on the Board of the Service is approved by the Chairperson of the Service.

The Deputy Chairpersons are appointed to and dismissed from the position by the Chairperson of the Cabinet of Ministers of the Kyrgyz Republic upon the recommendation of the Minister.

The Chairperson of the Cabinet of Ministers of the Kyrgyz Republic has the right to dismiss a Deputy Chairperson without the recommendation of the Minister.

The Chairperson, Deputy Chairpersons, and heads of territorial units make their own decisions regarding the implementation of the powers assigned to the Service.

However, the Service does not have the right to send letters directly to the Administration of the President of the Kyrgyz Republic, that is, letters shall be sent to the Administration through the Ministry.

b. Budgetary and structural issues

The Service is supported by the republican budget and other sources of financing not prohibited by the laws of the Kyrgyz Republic.

The Chairperson:

- decides on issues regarding bonuses for employees of the Service;
- is the chief administrator of funds with the right of first signature;
- manages the funds and property of the Service in the manner prescribed by the budget legislation of the Kyrgyz Republic;

c. Relations with other institutions

It cooperates with the Jogorku Kenesh of the Kyrgyz Republic during the review of draft laws.

Employees are involved in working groups of other ministries and departments when reviewing and solving issues in specific sectors of the economy.

Upon identifying decisions of ministries and departments that restrict competition, the Service sends them a warning or an order to cancel the decisions that restrict competition.

In addition, the Service approves tariffs for paid services provided by state bodies and verifies the correct formation and application of tariffs for paid services.

It submits, if necessary, materials on infringements of the competition law of the Kyrgyz Republic to law enforcement agencies; requests according to the established procedure and receives from state bodies, local self-government bodies the information necessary for the performance of its functions, including information of a confidential nature or constituting a commercial secret.

d. Accountability

The Service reports to the Ministry of Economy and Commerce of the Kyrgyz Republic on the implementation of the approved Action Plan of the Cabinet of Ministers of the Kyrgyz Republic regarding the performance of measures assigned to the Service.

The Service annually submits to the Administration of the President of the Kyrgyz Republic an Annual Report on the competition in the commodity markets of the Kyrgyz Republic and the measures taken to suppress infringements of competition rules therein, which is provided and posted on the official website of the Antimonopoly Authority on the Internet.

C. Decision-making

a. Internal procedure on competition cases

When considering cases on infringements of competition rules, the Service is guided by the Rules for considering cases on infringements of competition law of the Kyrgyz Republic, approved by Resolution No. 619 of the Cabinet of Ministers of the Kyrgyz Republic dated November 4, 2022, and the Procedure for considering cases on infringements of competition law in the field of unfair competition, approved by Resolution No. 362 of the Government of the Kyrgyz Republic dated June 2, 2012.

The Service's fundamental tool in achieving this objective is the collection of necessary information and evidence confirming or refuting the commission of an infringement.

All decisions (decisions on reviewing and suspending a case, issuing a warning or order, applying liability measures) when considering cases suggesting possible violation of competition legislation are made by the head, deputy head of the Antimonopoly Authority, or the head of a territorial unit.

Cases on violations of competition law are considered finally in the presence of the person (official representative) who violated the competition law. In the absence of this person, the case shall be considered only in the event where there is evidence of his/her timely notification of the place and time of the consideration of the case and no formal request for postponement of the case has been received from him/her.

During the consideration of the case, explanations of the person in respect of whom the case is being considered, testimonies of other persons participating in the consideration of the case, and explanations of experts shall be heard.

The operative part of the decision is announced immediately upon the conclusion of the case consideration.

A copy of the decision (warning, order, ruling) on the elimination of violations of competition law is handed over against signature or sent to the person in respect of whom it was issued, as well as to the applicant, within 3 working days. When sending a copy of the decision, a corresponding entry is made in the case file and a receipt of dispatch is attached.

In case of disagreement with the decision taken as a result of the consideration of a case on violation of competition law, the parties have the right to appeal it within 30 working days from the date of delivery of a copy of the decision (warning, order, ruling) or the announcement of the decision to the person in respect of whom the case was considered.

The above-mentioned regulatory legal acts also provide for administrative regulations for the implementation of the function of initiating and considering cases of violations of competition law, including the procedure for filing a complaint suggesting possible violation, conducting an analysis of the commodity market, if necessary, the procedure for conducting an investigation and preparing materials for the consideration of cases.

Separation between instruction and decision-making is not allowed.

b. Control of the decisions taken

The decision based on the results of the consideration of cases on violations of competition legislation should indicate the deadline for eliminating violations or the deadline for paying penalties; before the expiration of the deadline, the economic entity is obliged to report or submit a formal request for an extension of the performance period. In case of non-fulfillment within the deadline, the Service may take measures.

4. Enforcement over the last 24 months

A. Cartels

a. Dawn raids

The possibility for the Service to carry out dawn raids appeared only with the adoption of Resolution No. 713 of the Cabinet of Ministers of the Kyrgyz Republic «On approval of the Procedure of control by authorized state body on regulation and supervision in the field of the antitrust law of the Kyrgyz Republicc» dated November 25, 2024. However, according to the Constitutional Law of the Kyrgyz Republic «On the Prosecutor's Office of the Kyrgyz Republic», the prosecutor's office carries out the registration of inspections conducted by state bodies. Lawful and justified inspections are subject to registration.

The procedure for coordinating dawn raids is currently absent.

b. Main cases

In the Talas region, the purchase price of beans dropped to 25-26 soms per 1 kg, whereas previously the purchase price of unpeeled beans (from a combine harvester) was 32-36 soms per kg, with an average cost price of 27 to 30 soms per 1 kg depending on the region and the distance of arable land from water.

Purchase prices for unpeeled beans were reduced simultaneously by all purchasing organizations. One of the reasons for the reduction in purchase prices was the increase in transportation prices, however, this increase lasted for an insignificant amount of time. Bean purchasers, citing the increase in transportation prices, did not want to increase purchase prices, although tariffs for transport services had been reduced.

Thus, setting and maintaining low purchase prices would have led to appreciable losses for agricultural producers.

After the Service employees conducted explanatory work with the purchasing companies, the purchase price for beans was set at 35 soms per kg, that is, 9 soms higher than what had been set by the purchasing organizations previously.

Considering that approximately 50,000 tons of beans were sold by farmers at 35 soms per kg, additional revenues to farmers amounted to approximately 450 million soms.

B. Abuse of dominant position

a. Main cases

Pursuant to the Procedure for identifying an excessive price, the following were carried out:

- analysis of costs included in the cost price of PCR test services, with the aim of determining their economic justification;

- assessment of the costs and profits required for production and sales;
- an investigation was conducted to establish the facts confirming the actions of LLC «I.» and LLC «G.KG» in setting a excessive price.

The Service issued a ruling on the recovery from LLC «I.» of the revenue share obtained as a result of the violation of the Law of the Kyrgyz Republic «On Competition», by setting an excessive price, in the amount of 300 million soms.

During the analysis of the mobile telephone communication services market, conducted by the Service to assess the state and development of the competitive environment in this market, it was established that the market in question is an oligopoly, since, in accordance with clauses 4, 5, 6 of part 1 of article 4 of the Law of the Kyrgyz Republic «On Competition», the collective dominance of the three cellular companies CJSC «AT», LLC «SM» and LLC «NT» exceeds 50 percent and the relative sizes of the shares of these companies remain unchanged, and access to this market for new competitors is difficult.

The analysis showed that the cost of outgoing calls to numbers of other mobile operators, when the limits are exhausted (in the case of tariff packages) and according to direct billing by various mobile operators, in fact, for subscribers ranges from 4.18 to 5.04 soms/min excluding taxes, with a cost price of 1.5 soms/min.

The cost of outgoing calls directly depends on the tariff for the transmission of inter-network traffic (or interconnect rate), that is, the interconnect rate is the base rate when calculating the cost price of outgoing calls from the network of one mobile operator to the network of another mobile operator.

At the same time, an assessment of prices prevailing in reference markets was conducted. Markets for similar services in the EEU member states (Armenia, Kazakhstan, and Russia) were identified as reference markets. These markets meet the criteria specified in Article 3 of the Law of the Kyrgyz Republic «On Competition».

According to information provided by the antimonopoly authorities of the Republic of Armenia, the Republic of Kazakhstan, and the Russian Federation, inter-network connection rates between cellular operators are lower than in the Kyrgyz Republic; accordingly, the cost of outgoing calls to other mobile operators in these countries is lower.

Pursuant to Clause 7 of Article 6 of the Law of the Kyrgyz Republic «On Competition», actions of an economic entity occupying a dominant position, which have, or may have, the effect of restricting competition and/or infringing on the interests of other individuals, including the establishment or maintenance of an excessive price for services provided, are prohibited.

Thus, the cellular companies CJSC «AT», LLC «SM», and LLC «NT» have violated Clause 7 of Article 6 of the Law of the Kyrgyz Republic «On Competition», i.e., they maintain an excessive price for outgoing inter-network calls for subscribers.

Based on the results of the review, the Service issued an order to the cellular companies to eliminate the violation of the specified article of the Law of the Kyrgyz Republic «On Competition» by means of a phased reduction of economically unjustified high inter-network connection rates, which was performed.

Applications from insurance companies «AT», «AYu», «RK» regarding the actions of OJSC «NES» during the tender for the procurement of insurance services for motor-vehicle transport, drivers, and passengers against accidents resulting from traffic accidents, as well as third-party liability insurance, were reviewed. During the review of the applications, it was established that the qualification requirements for tender participants put forward by OJSC «NES» were discriminatory and established barriers for potential participants. During a working meeting, representatives of OJSC «NES» announced the voluntary elimination of the specified violations and notified about the cancellation of the tender.

During the pandemic, for the purpose of unjustified excessive pricing, the entity «FM», occupying a dominant position in the market, suspended the dispensing of medicines, despite having a significant supply in warehouses. The withdrawal of goods from circulation by the dominant entity led to the creation of an artificial shortage in the market and an increase in prices for medicines.

As a result of the investigation, the actions of the entity «FM» were recognized as a violation of Clause 2 of Article 6 «Abuse of dominant position» of the Law on Competition.

A warning was issued, and the violation was eliminated.

Upon the application of the company «M» and the Association of Telecom Operators, the Antimonopoly Authority reviewed a case against the company «KT», which occupies a dominant position in the market for fiber-optic cable laying services in tele-

phone conduits for telecom operators, regarding the creation of obstacles to market access for other undertakings and the imposition of conditions obliging them to conclude a contract only with a specific enterprise.

During the review of the case, it was established that for the implementation of technical specifications for laying fiber-optic cable in telephone conduits for telecom operators, the company «KT» proposed concluding a contract exclusively with its own structural divisions. At the same time, telecom operators having their own resources and licenses for the implementation of technical specifications were simply not allowed to lay cable in the telephone conduits. Moreover, there is no alternative to the telephone conduits of the company «KT», since the telephone conduits belonging to other telecom operators are either a continuation or a branch from the conduits of the company «KT».

The Antimonopoly Authority recognized the actions of the company «KT» to conclude a contract with telecom operators on the condition of including provisions in it that they are not interested in, as a violation of the Law on Competition, and issued a warning. As a result, the violation was eliminated.

The investment enterprise «P», occupying a dominant position in the market for intra-republican air transportation, upon entering this market, set a predatory price for an airline ticket at 900 som for a flight on the route Bishkek-Osh, which, in turn, undermined the competitive basis for domestic air carriers operating in the market. According to averaged data, at the time of setting the price, the average cost price for airlines for a flight on the route Bishkek-Osh was 1800 som. The dominant company «P», having significant financial resources, set the price at 900 som. This is a classic market conquest scheme, where a predatory price is set with the aim of eliminating competitors in the market.

The Antimonopoly Authority held meetings and explained the norms of competition law; as a result, the dominant company moved away from this principle and set a minimum price based on the average cost price of the flight, thereby establishing equal competitive conditions for entities in the market.

The economic entity «M», included in the Register of Dominants, refused to continue its activities with the company «R» regarding the acceptance of payments and the supply of equipment for payment terminals. Due to the fact that they had disputes regarding the cash acceptor under a previously concluded contract, the company «M» terminated the contract for carrying out activities related to the acceptance of payments in their favor.

The Antimonopoly Authority conducted an investigation, which proved the fact of an unjustified refusal to fulfill the terms of the contract by an entity occupying a dominant position in the market, not related to force majeure circumstances, and established a violation of competition law in the form of an abuse of a dominant position. Following the investigation and issuance of a warning, the payment acceptance contract with company «R» was renewed, and the issue of the quality of terminal supply for the company's purposes was resolved by mutual agreement.

A cement plant included in the Register of Dominant Companies manipulated and refused to supply cement, citing a loading plan with other consumers – entities carrying out the construction of social infrastructure facilities in the republic.

After the intervention of the Antimonopoly Authority, direct contracts were signed with construction organizations, and distribution volumes, given the limited production output, were evenly redistributed among all market participants.

The dominant economic entity «B», having significant market power among all counterparties, created favorable conditions for 2 counterparties regarding a return bonus for services rendered. Out of 23 counterparty organizations in the market, only two were given privileged conditions regarding the return bonus.

The Antimonopoly Authority carried out explanatory work, as a result of which equal conditions were established for all companies, which, in turn, established an equal competitive position for the undertakings that were competitors to each other throughout the entire chain.

A complaint was received by the Antimonopoly Authority from economic entity «X» regarding the setting of different prices for the same product. Economic entity «X», operating in the market, having approximately the same consumption volumes, fulfilling the conditions of entities for the acquisition of goods of the dominant entity «Y», received a commercial offer at a price 10% higher than other counterparties of this enterprise «Y».

The Antimonopoly Authority reviewed the complaint and clarified the essence of the complaint.

The dominant entity «Y» justified its actions with prepayment conditions, the criterion of the acquirer's reliability, the acquirer's loyalty, but could not provide documentary evidence. Following the investigation and the issuance of a warning, the applicant economic entity "X" received a commercial offer with prices similar to those of other business entities.

b. Fines

A fine was imposed on 1 economic entity in the amount of 300.0 million soms.

c. Number of cases

Decisions on violations regarding abuse of dominant position, including:	5
with fines	1
without fines	4
decision on bringing to responsibility	-
decisions on non-infringement of rights	-
Other: warnings were issued, based on the results of which infringements were eliminated	5
Total	**10**

C. Other cases (unfair competition and others)

Over past 24 months, the Service reviewed cases of unfair competition aimed at:

- unauthorized copying of another economic entity's product, as well as its packaging and external design;
- direct reproduction of another economic entity's products by infringing its patent rights;
- illegal use of another's trademark, service mark, appellation of origin of goods, trade name, which could lead to confusion with the activities of another economic entity.

a. Main cases:

Some of the main cases on unfair competition are:

- Application from citizen M.V.V., owner of LLC «L.P.K.» (hereinafter referred to as LLC), which manufactures and sells cosmetic products under the trademark Califfornia, which is registered with Kyrgyzpatent. M.V.V. discovered the sale by I.Ch. and M.Z.A. of cosmetic products (foundation, makeup base) on the territory of the Dordoi market, using the name Califfornia. The specified goods are not products of the LLC. Following the review, the Service issued a warning on the necessity to cease actions violating clause 5 of part 1 of art. 8 of the Law of the Kyrgyz Republic «On Competition». This warning was fulfilled on time.
- Appeal from representatives by power of attorney of CJSC «B.K.I.» (hereinafter referred to as CJSC). According to the information set forth in the appeal, CJSC manufactures and sells tea products under the trademarks Champion, Bayce and others, on the territory of the FEZ «Bishkek». The trademarks of the products manufactured by CJSC were registered with Kyrgyzpatent in 2012. Representatives of CJSC discovered the sale of counterfeit tea on the territory of the Osh market under the trademark Champion, which is not a product of CJSC. Following the review, a warning was issued to citizen A.N.A. to cease actions that contained signs of violation of competition law, which was fulfilled on time.
- On December 16, 2024, JSC «BSK» filed an application against LLC «I» regarding the use of a trademark confusingly similar to the international trademark «Baking Soda» («Пищевая сода»), the copyright holder of which is JSC «BSK». Based on the results of the review of this application, the Service issued a warning on January 11, 2025, to cease actions (inaction) containing signs of violation of competition law not later than February 10, 2025. Due to failure to comply with the Service's warning dated January 11, 2025, in relation to LLC "I", pursuant to Part 1 of Article 434 of the Code of the Kyrgyz Republic on Offenses, a notice of infringement was issued on August 20, 2025, and a fine in the amount of 130 calculated indices was imposed.
- Law firm «L» filed an application against manufacturers «BL», «rim», «efx», «eco» and LLC «DK», which, according to the applicant, carried out unfair competition by selling products using the applicant's registered trademark. The right to the trademark is confirmed by a certificate. Following the review of the specified application by the Service, on the basis of article 289 of the Code of the Kyrgyz Republic on Offenses, a notice of infringement was issued against M.R.T. and a fine in the amount of 200 calculation indices was imposed. With regard to the remaining undertakings, administrative enforcement measures were not applied due to the lack of registration with tax authorities. In addition, liability measures were applied for the violation of Article 15 of the Law of the Kyrgyz Republic 'On Competition' for failure to provide information upon the Service's request.

b. Fines

Over two years, the fine for unfair competition amounted to 33.0 thousand soms, and for failure to provide information — 182.0 thousand soms.

c. Number of cases

Decisions on violations regarding unfair competition, including:	18
with fines	2
without fines	14
decision on bringing to responsibility	-
decisions on the absence of infringement of rights	2
Other (fine for failure to provide information)	14
Total	**32**

D. Merger Review

a. Number of cases

During the period under review, no formal requests for a merger were received.

At the same time, over 2 years, the Service reviewed formal requests from 75 undertakings for consent to reorganization (transformation). Positive conclusions were given.

In addition, administrative liability measures in the amount of 215 thousand soms were applied to two undertakings for violation of Article 11 of the Law of the Kyrgyz Republic 'On Competition', pursuant to which an economic entity is required to obtain prior consent from the Service to create an economic entity in which participants are persons and/or a group of persons affiliated with them.

5. Judicial review over the last 24 months

Based on a received complaint, the Service reviewed a case regarding the elimination of the Law of the Kyrgyz Republic «On Competition» by canceling a barrier in the form of an entrance fee in the amount of 20,000 soms for persons joining the Bar Association of the Kyrgyz Republic, and issued an order to eliminate the violation.

Article 19 of the Law of the Kyrgyz Republic «On the Bar Association of the Kyrgyz Republic and Advocacy» contains a list of requirements for candidates for the right to practice law. This list does not include the requirement for mandatory payment of an entry fee.

If a lawyer fails to become a member of the Bar Association within one month from the date of receipt of the license, the license shall be terminated in accordance with paragraph 6 of part 5 of article 22 of the Law of the Kyrgyz Republic «On the Bar Association of the Kyrgyz Republic and Advocacy».

The charging of an entrance fee of 20,000 soms by the Bar Association generates an income for the Bar Association and has signs of a barrier to entry into the advocacy market for newly licensed individuals, and is a discriminatory action on the part of the Bar Association.

However, the Bar Association of the Kyrgyz Republic did not recognize the legality and validity of the issued order, and, exercising its right to appeal, applied to the courts.

During the judicial proceedings, the legality of the issued order was confirmed. Thus, by the rulling of the Judicial Collegium for Administrative Cases of the Supreme Court of the Kyrgyz Republic, the resolutions of the 1st and 2nd instance courts were left unchanged, and the complaint of the Bar Association of the Kyrgyz Republic was dismissed.

The Service revealed that LLC «I.» had set an excessive price for PCR test services. Based on the results of the work carried out, the Service issued a resolution on the recovery from LLC «I.» of the revenue share obtained as a result of the violation of the Law of the Kyrgyz Republic «On Competition» in the amount of 300 million soms.

Disagreeing with the Service's decision, LLC «I.», pursuant to the Law of the Kyrgyz Republic «On the Fundamentals of Administrative Activity and Administrative Procedures», filed an administrative complaint with the Ministry of Economy and Commerce of the Kyrgyz Republic, as well as a complaint with the Public Prosecutor's Office of the Kyrgyz Republic against the actions of the Department's employees, who allegedly violated the requirements of the Decree of the President of the Kyrgyz Republic dated January 9, 2024, on introducing a moratorium on inspections of business entities until December 31, 2024.

The Prosecutor's Office of the Oktyabrsky district of Bishkek, after reviewing the above-mentioned complaint of LLC «I.», did not establish any violations of the requirements of the legislation of the Kyrgyz Republic.

By the decision of the Commission for the Review of Administrative Complaints of the Ministry of Economy and Commerce of the Kyrgyz Republic dated March 29, 2024, the administrative complaint of LLC «I.» on the cancellation of the Service's resolution on the recovery of the income obtained as a result of the violation of the Law of the Kyrgyz Republic «On Competition» was denied.

Disagreeing with the decision, LLC «I.» applied to the court; within the framework of judicial proceedings, on November 28, 2024, the Supreme Court of the Kyrgyz Republic ultimately upheld the decision of the appellate instance and recognized the Service's actions as lawful.

6. Advocacy work over the last 24 months

a. Initiatives related to public bodies

Competition advocacy contributes to the formation of a culture of competition in the economy, as well as to strengthening the authority and reputation of the Antimonopoly Authority. In this area, work is carried out in three main directions: raising awareness among state bodies, the business community, and the general public.

The Service provides official opinions on draft regulatory legal acts aimed at regulating business activities, for compliance with competition law, and, if any discrepancies are identified, an opinion on this is provided and taken into account. In addition, when developing regulatory legal acts, state bodies carry out a regulatory impact analysis (RIA). At the same time, the impact on competition is assessed, which is aimed at evaluating the risk of the emergence of conditions under which individual business entities (or groups of entities) receive unjustified advantages over other market participants. Representatives of business associations are involved in the working group for carrying out RIA.

Active interaction with business associations is also underway through the conclusion of an Agreement on Cooperation in the Market of Socially Significant Goods between the Service and associations within the framework of the Law of the Kyrgyz Republic «On Pricing.» The Agreement stipulates the obligations of business associations to comply with competition rules and prevent unjustified price increases on socially significant goods.

The Service, in order to ensure the principles of transparency of work, regularly carries out seminars, trainings, and round tables aimed at increasing the awareness of citizens and the business community about the benefits of competition, consumer protection, and measures to curb unjustified price growth for goods and services. All events are carried out with the participation of the media.

The Service also cooperates with universities of the republic; specialists of the Service carry out training courses on issues of competition, consumer protection, pricing, and advertising.

b. Market studies

The Service annually draws up a plan for the analysis of commodity markets. The Service also conducts market research on its own initiative or upon receipt of requests if there is an increase in prices or other circumstances suggesting that competition may be restricted or distorted.

The results of the analyses are submitted for discussion by the Commission. In case of identifying a dominant enterprise, a decision is issued to include it in the State Register of undertakings occupying a dominant position in the commodity market, in order to carry out economic and statistical monitoring of it.

Economic and statistical monitoring includes an assessment of the activities of the economic entity, including:

- changes in the volume of production and/or sale of goods (services);
- changes in prices for goods (services);
- changes in the level of profitability;
- changes in the share of the economic entity in the market;
- assessment of the behavior of the economic entity in the market and its influence on competitors and consumers;
- the influence of the economic entity on the competition (positive or negative).

In the event of a significant increase in prices, the reasons for such changes are examined on the basis of indicators of excessive pricing or predatory pricing, in accordance with Articles 4-1 and 4-2 of the Law of the Kyrgyz Republic "On Competition".

Interview with the Chairperson

1. How would you describe the mission of your agency and its social impact?

The main goals of the Antimonopoly Regulation Service of the Ministry of Economy and Commerce of the Kyrgyz Republic (hereinafter referred to as the Service) are to create conditions for fair competition, prevent unfair advertising, ensure consumer protection, and prevent unjustified price and tariff increases.

Thus, the mission of the Antimonopoly Authority is to ensure fair and efficient competition in markets, protect consumer interests, and create conditions for sustainable economic development.

In simple terms it means:

- preventing monopolies and abuse of dominant position;
- combating cartels;
- merger control;
- protecting consumer rights from unfair practices.

What is the social impact?

Firstly, it is fair prices. When there is competition, firms cannot raise prices indefinitely. People receive goods and services at a more affordable prices.

Secondly, it is the quality of goods and services. Companies are forced to compete not only on price but also on quality. As a result, consumers benefit.

Thirdly, business development. The Antimonopoly Authority protects small and medium-sized businesses, as it prevents them from being forced out of the market by strong players. As a result, the market becomes more open and dynamic.

Fourthly, social justice. Since it eliminates a situation where a few companies control the market and dictate terms. As a result, economic inequality is reduced.

Fifthly, trust in the state. Transparent market rules increase the trust of citizens and businesses in state institutions. Thus, the Antimonopoly Authority is not just a «regulator», but a key institution that shapes a healthy economic environment, protects the consumer, and stimulates innovation and development.

2. What is the level of competition awareness in your country? Do policymakers consider competition issues? Is competition compliance a significant concern for businesses?

The Service is actively carrying out work on competition advocacy.

Every year, the number of appeals (complaints) regarding signs of violations of the Law of the Kyrgyz Republic «On Competition» increases (111 appeals were received over 2 years), which indicates the level of awareness of the business community. In addition, complaints are received regarding consumer protection and advertising.

However, I can characterize the level of awareness as average with elements of insufficient depth of understanding.

Thus, large companies, especially in regulated sectors, are generally aware of the key requirements of competition law. Although small and medium-sized businesses demonstrate limited understanding of the rules, including the distinction between acceptable and prohibited practices. Attention to competition issues arises in connection with inspections or proceedings.

But, due to the recent adoption of amendments to the Law on Competition through the practice of implementing an antitrust compliance system, the level of awareness, I think, will become appreciably higher.

Do decision-makers consider competition issues?

Competition issues are considered, but not systematically, as mechanisms for assessing the impact on competition are applied to a limited extent. There is no systematic practice of assessing the impact on competition. Priority is often given to sectoral policy and social and economic tasks. The main problems are the state's participation in the

economy, the presence of administrative barriers, and the granting of advantages to individual entities.

Thus, competition is not yet integrated as a mandatory element of the decision-making process.

Is compliance with competition law a significant issue for business?

Large businesses consider antitrust risks, while small and medium-sized businesses, due to a low level of legal awareness, underestimate the risks.

A key direction for further development is:

- implementation of the principle of competitive neutrality of the state;
- development of antitrust compliance;
- increasing the level of legal and economic awareness.

3. Do you believe that the situation has changed appreciably since your agency began its work, especially after the publication of reports or the application of sanctions?

The Antimonopoly Authority was created after Kyrgyzstan's transition to a market economy (since 1991).

The Antimonopoly Authority played a major role in the transformation of the country, particularly in the privatization of state property, price liberalization, and the transition from a planned system to private entrepreneurship and the service sector.

The state ceased to be the monopoly owner of the means of production. Former state enterprises became private, and small and medium-sized businesses actively developed.

The abolition of state price regulation led to their formation based on supply and demand. Borders were opened for the free import and export of goods.

A legal framework for antitrust policy was created. The Antimonopoly Authority was the initiator of the development of a program to support and develop entrepreneurship, especially small and medium-sized businesses, in order to develop competition in commodity markets.

It also initiated the creation of a register of state paid services and the adoption of measures to reduce them for transition from a command-and-control system and deep state regulation of the economy to a more market-based system.

Yes, the situation has changed, but not radically. The publication of reports and decisions of the Antimonopoly Authority has made the topic of competition more public; businesses learn about risks more often through specific cases, and state bodies have come to understand that their decisions can be challenged. As a result, a deterrent factor has formed, albeit a limited one.

If previously the regulations were mainly «on paper», now in practice there are cases of abuse of dominant position, anti-competitive agreements are being considered, and merger control is being applied. Thus, the law has begun to be applied in practice, rather than just being declared.

The publication of reports and the application of sanctions have launched a process of change, but they are insufficient without the implementation of antitrust compliance, the strengthening of economic analysis, and the integration of competition into state policy.

4. What are the main challenges your agency is currently facing? What are your priorities for the near future?

The main challenges for the Antimonopoly Authority now are as follows:

Firstly, one of the problems is limited powers and problems with access to information. In practice, companies do not always provide the necessary information about prices and market behavior, which complicates investigations. As a result, the effectiveness of detecting cartels is reduced, and the possibility of conducting economic analysis is also limited.

Secondly, this is the high share of the state in the economy, the significant presence of the state in key sectors of the economy, and the combination of the functions of a regulator and a market participant. The problem is that the Antimonopoly Authority is forced to control the state as a violator, which is institutionally difficult.

Thirdly, the structural monopolization of markets. These are natural monopolies (energy, infrastructure), and high concentration in certain markets. And, as a consequence, there are limited opportunities for the development of competition; regulation often replaces competition.

Fourthly, a low level of antitrust culture. This is a weak understanding of the regulations among small and medium-sized businesses, and a lack of developed antitrust compliance, which leads to violations and a low level of voluntary compliance with the law.

Fifthly, these are anti-competitive actions by state bodies. The law also applies to government bodies; however, they continue to make decisions that restrict competition.

Sixthly, these are limited resources; personnel and analytical resources are limited, and economic analysis of markets is insufficiently developed. As a result, the focus shifts to formal violations, and the absence of complex cases (cartels, digital markets).

Seventhly, the Service is facing challenges related to changes in the digital economy. These challenges require the adaptation of antitrust regulation to new realities, taking

into account the specifics of the functioning of digital markets, and the coordination of antitrust policy at the international level.

The increase in the market power of digital platforms, which accumulate a large volume of users and can dictate their terms to suppliers of goods and services, thereby restricting competition, requires the Service to protect consumers from abuse in digital commodity markets.

The priorities of the antimonopoly authority are:

- Strengthening enforcement – detection of cartels, control of dominant entities, and development of sanction practices with the aim of increasing the deterrent effect.
- Reducing state participation in the economy – development of the principle of competitive neutrality.
- Development of antitrust compliance – implementation of programs for business, and advocacy work. Transition from punishment to the prevention of violations.
- Development of analytics and digital tools – economic analysis of markets, monitoring of prices and company behavior, and digitalization of the authority.
- International cooperation – cooperation within the framework of the EEU, and adopting best practices.

5. What are the main strengths and weaknesses of your agency?

The strengths of the Service are determined by its legal status and influence on the economy.

The Service not only monitors compliance with competition law, but also monitors compliance with advertising legislation and regulates natural monopolies, including control over the justification of tariffs for rail transport, airport and air navigation services, and centralized water supply and sanitation. At the same time, it ensures the optimization of expenses in regulated sectors, focuses on the interests of consumers, and also ensures the unified approaches to regulation and the accessibility of infrastructure on non-discriminatory terms.

In addition, it protects consumer rights, temporarily regulates prices for socially significant goods in the event of the introduction of temporary state price regulation in accordance with pricing legislation, and monitors compliance with established prices, which helps curb inflation.

Also, the strengths of the Service include the mandatory nature of the performance of its decisions. However, unlike many punitive bodies, the antimonopoly service often uses soft power: it issues a warning, and if the company eliminates the violation, no fine is imposed. This helps to quickly correct the situation in the market without long court proceedings.

A weakness of the Service is the lack of sufficient financial and human resources, which are key factors for the effective enforcement of competition law. Also, the status of the Service is not suitable for the full performance of its functional duties. Therefore, the Service is accused of failing to curb the growth of consumer prices and of promoting decisions that do not contribute to increasing competition.

Thus, the Antimonopoly Authority of the KR possesses the necessary basic tools and powers, however, its efficiency is limited by the institutional environment, the level of economic development, and insufficient integration of competition into state policy.

6. If you could make significant changes to the national competition legislation tomorrow, what would they be?

Currently, the draft Law of the Kyrgyz Republic «On Competition» in a new version has been adopted by the Jogorku Kenesh of the Kyrgyz Republic and sent to the President of the Kyrgyz Republic for signature. The proposed amendments contemplate significant changes in the draft law as well:

- the following concepts have been introduced: "countervailing buyer power", "network effect", "digital platforms" and in Article 6 the actions of the antimonopoly authority when conducting an analysis of the competition in the commodity market (commodity markets) where transactions between sellers and buyers are carried out through the use of a digital platform, which will enable antimonopoly regulation of the activities of digital platforms;
- the formation and maintenance of the State Register of undertakings occupying a dominant position in a commodity market is being abolished;
- internal compliance systems for competition law requirements or antitrust compliance are being implemented, which will reduce the risks of violating competition law and, as a consequence, the risk of negative consequences for the business entity (collection of fines, prosecution, etc.). At the same time, the draft Law provides for the right of undertakings to voluntarily organize compliance;
- ensuring the transparency of the provision of state aid or subsidies by creating and maintaining a register of undertakings that have been provided with state aid.

In addition, clarifying and specifying amendments are being made to the articles concerning abuse of dominant

position, and the prohibition of agreements, concerted practice of undertakings that restrict competition, with the exception of agreements that are recognized as admissible pursuant to the criteria of admissibility. Additionally, the law introduces exemptions and mitigations of liability for participation in agreements or concerted actions, and proposes increasing the statute of limitations for certain violations of competition law.

7. Which decisions taken over the last two years make you particularly proud? Are there any cases that, looking back, could have been carried out better?

A particular source of pride is the decision regarding the abuse by LLC «I.», which set an excessive price for PCR test services. Based on the results of the work carried out, the Service issued a resolution on the recovery from LLC «I.» of the revenue share obtained as a result of the violation of the Law of the Kyrgyz Republic «On Competition» in the amount of 300 million soms.

Moreover, over the last two years, a number of decisions and areas of work of the Antimonopoly Authority can be noted that can truly be considered significant from the point of view of protecting competition and consumers.

First and foremost, a certain pride is caused by the strengthening of control over socially significant markets – primarily in the areas of food, coal, cement, and medicines. The Antimonopoly Authority actively carried out price monitoring, responded to sharp price fluctuations, and strengthened control over dominant entities. In conditions of high inflation, this had important social significance.

Another important area has been the work on improving control and supervision procedures in the field of competition law. In 2024, a new Procedure of control by authorized state body on regulation and supervision in the field of the antitrust law of the Kyrgyz Republic was approved, which can be considered a step towards more systematic and transparent regulation.

If we talk about cases that, looking back, could have been carried out better, it is important to acknowledge here that antimonopoly practice is always connected with a very complex balance between the protection of competition, business interests, and public expectations. Some high-profile investigations, for example, in the field of medical and laboratory services, caused active discussions from the business side regarding the completeness of economic analysis and the quality of communication with the market.

Moreover, in a number of cases, society and business have not always provided sufficient openness and detailed explanations of the decisions being made. For the Antimonopoly Authority, it is extremely important not only to issue a decision but also to convincingly demonstrate to the market its economic and legal justification. It is precisely the transparency and predictability of enforcement that form trust in competition policy.

Therefore, one of the main lessons of recent years can be called the need for further strengthening of economic analysis, digitalization of investigations, development of forensic practice, and a more active dialogue with the business community.

8. Do you feel support from the state, citizens, and the business community?

Pursuant to Article 3 of the Constitutional Law of the Kyrgyz Republic «On the Cabinet of Ministers of the Kyrgyz Republic», the Cabinet of Ministers of the Kyrgyz Republic resolves all issues of state administration, with the exception of issues assigned by the Constitution and laws to the competence of the President and the Jogorku Kenesh, courts, other state bodies with special status, and local self-government bodies, including:

- ensuring the implementation of a unified antimonopoly and competition policy;
- ensuring the implementation of price and tariff policy.

The Cabinet of Ministers has entrusted these issues to the Service, which plays a crucial role in providing us with the necessary resources and strengthening the legal framework.

State support exists, but it is provided in different ways and depends largely on the specific sector and market situation.

In recent years, the state has shown an understanding of the importance of developing a competitive environment, especially in the context of the need to attract investment, ensure economic stability, and protect consumer rights. More attention is being paid to antimonopoly regulation in matters of pricing, public procurement, regulation of socially significant markets, and the digital economy. At the same time, the level of institutional support still needs to be further strengthened, both in terms of resources and in terms of the independence and powers of the Antimonopoly Authority.

Support from citizens usually increases when the activities of the Antimonopoly Authority are directly related to everyday issues: price increases, tariffs, quality of services, availability of goods, or consumer protection. However, society does not yet fully understand the exact role of the Antimonopoly Authority and competition policy, and how it affects the standard of living and economic development.

The business community perceives the activities of the Antimonopoly Authority more ambiguously. Fair business, as a rule, is interested in transparent and equal market rules, protection from unfair competition, and the reduction of administrative barriers. At the same time, some market participants may perceive the Antimonopoly Authority as a restriction on their economic interests, especially in cases of investigations, merger control, or regulation of a dominant position.

In general, I can say that the demand for an effective competition policy in Kyrgyzstan is gradually growing. However, to strengthen trust and support, it is important to increase the transparency of the Antimonopoly Authority's work, develop a legal culture of competition, and ensure the predictability of competition enforcement.

9. How useful do you consider international and regional cooperation? Does it work effectively?

International cooperation in the field of antimonopoly regulation in the context of economic globalization is a tool for protecting national interests and ensuring fair competition.

International and regional cooperation is becoming a necessary condition for an effective competition policy, as modern markets have long gone beyond national borders. Digital platforms, cross-border trade, e-commerce, international supply chains, and the activities of large multinational companies make it impossible to fully investigate many violations solely by the efforts of one state. In this sense, cooperation provides several practical advantages at once. This includes the exchange of experience and best investigation practices, access to market analysis and digital economy methodologies, coordination of actions on cross-border cases, staff training, and the formation of unified approaches within integration associations.

Interaction within the framework of the Eurasian Economic Commission is especially important for Kyrgyzstan. The common markets of the EEU require mutually agreed competition rules. For us, participation in these mechanisms allows to gain access to broader analytical and law enforcement experience.

However, I think it is too early to talk about the full efficiency of cooperation, since in practice serious limitations remain. These include differences in national legislation, varying levels of independence and resources of antimonopoly authorities, the complexity of the exchange of confidential information, and the lack of unified approaches to digital platforms and algorithmic pricing.

Furthermore, I believe that international cooperation is effective only when there is a strong and professional antimonopoly institution within the country. External support cannot replace domestic political will, forensic practice, and a real readiness to ensure competition even in sensitive sectors of the economy. Therefore, cooperation is undoubtedly useful and is becoming increasingly significant, however, its efficiency remains insufficient for now.

10. What is your opinion on the OECD-GVH Regional Centre for Competition? Do you have any suggestions for its improvement?

Participation in the seminars of the OECD-GVH Regional Centre for Competition is important for the activities of competition authorities.

The OECD-GVH Regional Centre for Competition in Budapest, in my view, is one of the most successful and practically oriented mechanisms of international cooperation in the field of competition policy for the countries of Eastern Europe, Central Asia, and the former Soviet Union.

Its key value is not so much in formal events, but in creating a professional community of antimonopoly authorities in the region. For us, this is especially important, as it allows us to gain access to the best practices of the OECD and the EC, train employees in modern methods of economic analysis, exchange investigation experience, discuss the problems of digital markets, state-owned companies, cartels, and abuse of dominant position, and strengthen links between regulators, courts, and the academic community.

In my view, possible areas for improvement could be the following:

- A more practice-oriented format. We especially need not only theoretical seminars, but also joint case studies, investigation simulations, training in digital forensics, and working with algorithmic pricing.
- Strengthening support for small antimonopoly authorities. For small countries, human and analytical resources are limited. It would be useful to develop a system of long-term expert support, rather than just short-term events.
- Pay more attention to digital platforms and AI. Today, it is digital markets that form the main challenges for competition policy.
- Development of joint regional research. For example, on EEU Cross-border markets, e-commerce, pharmaceuticals, transport, and public procurement. This would allow for the creation of not only a training platform but also an analytical one.

In this regard, we wish the RCC new projects that will contribute to the development of international cooperation and ensure conditions for fair competition in all countries.

VII. CONTACT INFORMATION

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