Organisation for Economic Co-operation and Development

DAF/COMP/GF/WD(2025)31

Unclassified English - Or. English

7 November 2025

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

Global Forum on Competition

Competition in the Healthcare Sector – Contribution from Serbia

- Session II -

1 December 2025

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

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

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JT03576379

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Challenges of Exclusive Distribution on the Pharmaceutical Market[1]

1. Legal Framework of The Market

1. One of the most extensive areas of activity of the Commission for Protection of Competition **(the Commission)** concerns individual exemptions of restrictive agreements from prohibition. A significant number of these cases relate to exemptions of exclusive distribution agreements for human medicines on the territory of the Republic of Serbia. Through its practice, the Commission has shown particular interest in exclusive distribution of prescription-only medicines **(Rx medicines)**, with special attention devoted to those procured through public tenders.

2. Monitoring of the pharmaceutical market and the healthcare services market as a whole by the Commission is evidenced by the Sector Inquiry into the Competitive Landscape in the Private Healthcare Services Market[2], which was conducted and covered the period 2019–2023. In addition, the ongoing Sector Inquiry into the Pharmaceutical Market was launched recently, with significant influence by the wholesale distribution model of medicines.

3. The market for human medicines in the Republic of Serbia can be freely described as the most heavily regulated product market.[3] In such a regulatory environment, it is necessary to carefully assess the state and conditions of competition, with the aim of achieving economic progress, social welfare, and consumer benefit. This requires a refined and sensitive approach, often differing from other markets due to the need to ensure security of medicine supply.

4. Although all procedures for market entry (both for market participants and for individual medicines) are transparent and predefined, entry is possible only for adequately prepared entities and typically requires considerable time for product placement, which somewhat limits market development. These barriers are primarily administrative in nature. Economic barriers, while present and seemingly high, should not represent a major obstacle given the significant revenues achieved on the pharmaceutical market.

5. Wholesale trade in medicines may be performed only by entities granted a special wholesale license **(wholesalers)**[4] by the Ministry of Health, upon

[1] This contribution has been prepared by Mr. Miki Vidaković, Senior Adviser in the Restrictive Practices Division and Ms. Sunčica Đorđević, Senior Adviser in the Division for Assessment of Concentrations of the Commission for Protection of Competition of the Republic of Serbia. The views expressed herein are those of the authors and do not necessarily reflect the official position of the Commission for the Protection of Competition.

[2] https://kzk.gov.rs/komisija-je-sprovela-sektorsku-anali

[3] The principal piece of legislation governing the market for human medicines is the **Law on Medicines and Medical Devices** ("Official Gazette of the Republic of Serbia", No. 30/2010, 107/2012, 113/2017 – other law, and 105/2017 – other law). In addition to this law, the area is regulated by approximately 40 other laws and by-laws.

[4] Specific conditions prescribed by the **Rulebook on the Conditions for Wholesale Trade in Medicines and Medical Devices, the Data Entered in the Register of Issued Wholesale Licences**

verification of compliance with a range of conditions (related to premises, equipment, personnel, etc.). Licenses are issued for specific ATC classes of medicines. The circle of suppliers and buyers of a wholesaler is regulated: wholesalers may procure medicines only from other wholesalers, certified manufacturers, or licensed importers, and may sell only to pharmacies, healthcare institutions, private practices, and other wholesalers. Wholesalers are obliged to maintain adequate stocks of licensed medicines and to ensure continuous supply, including urgent delivery to healthcare institutions or private practices when necessary to protect life and health. Wholesalers must comply with the Guidelines on Good Distribution Practice[5].

6. The marketing of each individual medicine is conditioned upon the issuance of a marketing authorization by the Medicines and Medical Devices Agency of Serbia **(ALIMS)**. Marketing authorization holder **(MAH)** must be a company established in Serbia and is responsible for the quality, safety, and efficacy of the medicine. Marketing authorization holders are responsible for all batches of the medicine released to the market. While the regulations do not explicitly require the MAH to also possess a wholesale license, they do impose the obligation to ensure continuous market supply and maintain adequate stocks, as well as to have contracts with customers, making the MAH an undisputed participant in medicine distribution.

7. New medicines may enter the market only after ALIMS issues a marketing authorization and determines the dispensing category (OTC or Rx[6]). For Rx medicines, the MAH must obtain from the Government the maximum allowed price, calculated based on reference prices in Slovenia, Greece, and Italy. Wholesale margins are capped at 6%, which includes distributor profit. [7] In practice, wholesalers tend to treat these limits as fixed prices, a position often cited in exemption requests. The retail price of Rx medicines is also subject to restrictions.

8. If an Rx medicine is to be used by public health system institutions and the cost needs to be covered by the Republic Health Insurance Fund (RFZO) or Fund for Social Insurance of Military Insured Persons (SOVO)[8], the MAH must apply for its inclusion on the RFZO Medicine List, during which RFZO sets the price it

for Medicines and Medical Devices, and the Manner of Entry ("Official Gazette of the Republic of Serbia", No. 10/2012, 17/2017, 84/2018), adopted pursuant to **Article 121 of the Law on Medicines and Medical Devices**.

[5] Published in "Official Gazette of the Republic of Serbia", Nos. 13/2016 and 44/2016 – correction. These Guidelines are harmonized with the **EU Directive on the Community Code relating to Medicinal Products for Human Use (2001/83/EC)** and the **EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)**.

[6] There are different Rx categories, but this is not relevant for the purposes of this text.

[7] **Regulation on the Criteria for Forming the Prices of Medicines for Human Use Subject to Prescription** ("Official Gazette of the Republic of Serbia", Nos. 86/2015, 8/2016, 14/2018, 18/2019, 48/2021 and 93/2023). This is only after the **amount is reduced by the value of the control stamp.**

[8] **RFZO** is the institution responsible for **mandatory health insurance** in the Republic of Serbia, along with SOVO as special institution responsible for military personnel and their families. SOVO uses RFZO Medicine List as their list of medicines.

is willing to pay. This price is usually somewhat below the maximum retail price and often serves as the ceiling price in public tenders. MAH is responsible for ensuring the security of supply to the RFZO, which is not a direct obligation of wholesalers (including an exclusive distributor, unless they are also the MAH at the same time) toward the RFZO.

2. Value of Rx Medicine Market

9. According to IQVIA data[9] (September 2024), the Serbian pharmaceutical market grew by 11% over the previous 12 months, with 55% of growth attributed to Rx medicines. The total Rx medicines market value is €1.85 billion, divided between healthcare institutions[10] and pharmacies. Considering the level of (under)development of the private healthcare system, it can be concluded that the indicated percentage provides a reasonable approximate indicator of the value of medicines procured through public tenders for healthcare institutions that are part of the public healthcare system. The value of medicines procured through public tenders was approximately 42%, which comes to €0.77–0.78 billion (September 2023 – September 2024).

10. Medicines dispensed in pharmacies at the expense of the mandatory health insurance public funds (RFZO and SOVO) are not procured through public tenders, but they are included in the reimbursement system at the prices set by the RFZO when the medicine is placed on the RFZO Medicine List, or at the price achieved in centralized public procurements (if a lower price was obtained)[11].

11. This is particularly important because, although public procurements do not directly affect the commercial distribution of medicines by wholesalers to pharmacies, they have an indirect but immediate impact: the price achieved in public procurements influences the prices of medicines dispensed at the expense of mandatory health insurance in pharmacies. In other words, these medicines must be competitively priced in wholesale so that pharmacies have a financial incentive to dispense them at the expense of the health insurance system.

12. Based on available data, it can be conservatively concluded that the share of Rx medicines dispensed in pharmacies compared to total RFZO expenses on medicines is between 35–40%[12], representing a value of €0.64–0.75 billion. It can also be concluded

[9] IQVIA is a global company engaged in the analysis and research of the pharmaceutical market, health data, and medical studies (https://www.iqvia.com). The report was prepared for the Chamber of Commerce and Industry of Serbia and is publicly available at the following link: https://api.pks.rs/storage/assets/Serbian%20Pharma%20Market%20Overview%20Sep_2024.pdf

[10] Although pharmacies may also be considered healthcare institutions, for the purposes of this text, the term **"healthcare institutions"** refers specifically to **primary healthcare centres, clinics, hospitals, and other facilities providing medical treatment by medical professionals**.

[11] More than 3,400 private pharmacies have concluded agreements with the public health insurance funds and are obliged to dispense medicines to patients presenting a prescription for medicines covered by the RFZO or SOVO, charging a co-payment if applicable. The pharmacies are then reimbursed by the RFZO and SOVO.

[12] The estimate of 35–40 % is based on IQVIA data (MAT August 2024), according to which the pharmacy channel accounts for around 58 % of the total prescription medicines market, and on the historical relationship between the value of reimbursed medicines and the total value of medicines paid by the RFZO in 2017 (29 %). The estimate also takes into account statements by the RFZO Director, indicating that the share of reimbursed medicines dispensed in private pharmacies

that the turnover of Rx medicines covered by mandatory health insurance amounts to approximately 80 % of the total Rx medicines market, i.e., around €1.49 billion annually, with an observed growth rate of 6 %.

13. At the same time, the undeniable importance of public procurements must be highlighted, both due to the volume of distribution and their impact on medicine prices, even in non-tender (commercial) distribution.

14. Public procurement of medicines is almost always organized under the "one lot – one medicine" principle. Lots for procurement of generic medicines typically are defined by brand-name medicines and additional criterions ATC5 class, INN, dosage form, strength, and packaging. Such design of the lot eliminates inter-brand competition. In other tenders, lots are designed by INN, allowing for potential competition between therapeutic equivalents only if several medicines of the same INN are on the RFZO Medicine List, and also ih they meet further specifications. All wholesalers are generally required to submit a statement from the relevant marketing authorization holder confirming that the supplier is authorised to offer the medicine in a specific public procurement **(an authorisation statement)**.

3. Exclusive Distribution of Medicines and Market Challenges

15. Manufacturers, MAHs, and wholesalers frequently submit to the Commission requests for individual exemption for exclusive distribution agreements. Over the past eight years, the Commission has begun to adjust its approach to relevant market definition.

16. Previously, the market was typically defined at the ATC3 level.[13] However, given the growing importance of public procurement, the Commission now distinguishes between sales within and outside public tenders. For non-tender sales, ATC3 is at this moment still generally accepted as adequate, because the Commission is accepting statements that on non-tender markets therapeutic interchangeability of a specific medicine is not in focus of wholesalers and pharmacies, as they have ability to market other similar products within its sales portfolio.

17. However, regarding public procurements, the Commission takes the view that competition in a public procurement is a fight for the market, and that the market is defined by the specifications of the procured item. Considering the described method of designing individual lots, the Commission defines relevant markets for medicines in public procurements by brand (protected) names, or by INN or ATC5 wherever possible,

experiences an annual expansion of around 10 %, attributed to the expansion of the private pharmacy network and the closure of pharmacies in the public healthcare system that were supplied through the RFZO. The assessment was carried out conservatively, with a regressive reduction in the annual growth rate over the period 2017–2024. Source: https://paragraflex.rs/dnevne-vesti/210717/210717-vest18.html?utm_source=chatgpt.com

[13] Decisions of the Commission no. 4/0-03-71/2014-11 of 03.04.2014, no. 4/0-03-658/2014-11 of 19.12.2014, no. 4/0-03-62/2016-8 of 15.03.2016, and no. 4/0-03-859/2017-10 of 03.03.2017. The Commission is not obliged to publish exemption decisions on its website. However, some decisions are occasionally published to inform market participants about specific rulings or changes in practice. Individual exemption decisions are available on the Commission's website: https://kzk.gov.rs/odluke/tipovi/odobreni-sporazumi.

reflecting the tender's specification and substitution possibilities[14]. In such cases, the Commission first assesses the possibility of intra-brand competition and then the possibility of inter-brand competition.

18. When making decisions, the Commission also considers the effects of previously approved exclusive distributions of medicines, particularly for the same medicines or the same parties. In cases where a medicine previously enjoyed intra-brand competition but, after the introduction of exclusivity, was dominantly offered by only one bidder (the exclusive distributor) at the maximum tender price, the Commission has tended not to approve such agreements. Such a shift in the Commission's practice has led not only to "rejection decisions" of the Commission, but was accepted by the parties after receiving statements of objections, and led to contract amendments, the abandonment of exclusive distribution in public procurement markets, and even the withdrawal of exemption requests.

19. Conversely, for new or rarely tendered medicines, the Commission may approve the exemption for a limited period, subject to conditions ensuring the MAH does not unjustifiably withhold authorization statements from other potential bidders. Such decisions, however, do not fully eliminate the risk of (hypothetical) situations that an exclusive distributor may grant a smaller rebate to a wholesaler who will be its competitor in a public procurement, while at the same time bidding with price lower than the selling price to competitor, which ultimately can potentially contribute to the creation of an appearance of competition.

20. The Commission's experience suggests that exclusive distribution in a highly regulated environment with price and margin caps constitutes a significant market restriction, incomparable to exclusivity in unregulated markets. Competing wholesalers often lack incentives to engage with such products, effectively withdrawing from tender competition. There are rare exceptions where exclusive distributors act only as intermediaries and do not participate in tenders, however, these cases are exceptional.

21. In some instances, the exclusive distributor becomes the MAH. In others, the manufacturer retains control of the MAH, while the distributor imports directly, bypassing the MAH. This raises supply security concerns, as only the MAH bears legal responsibility toward RFZO. If shortages occur under such arrangements, the medicine can even be removed from the RFZO Medicine List. These medicines than become unavailable to the wider patient population, even if sufficient quantities exist in the country, since the barrier is that they are not dispensed at the expense of mandatory health insurance, and they must instead be purchased directly by patients. If this situation persists, it may lead to an actual reduction in domestic supply, due to the lack of financial incentive to produce or import the medicine.

4. Concluding Observations

22. The pharmaceutical market, particularly the public procurement segment, requires careful evaluation of the potential effects of exclusive distribution to avoid jeopardizing the security of medicine supply.

23. The Commission's decisions reflect the current market conditions, which are undoubtedly influenced by factors such as the availability of substitute medicines on the RFZO Medicine List, the manner in which public procurements are conducted, and similar

[14] Decisions of the Commission no. 4/0-02-119/2022-11 of 13.07.2022, no. 4/0-02-243/2023-28 of 13.11.2023, and no. 4/0-02-21/2024-5 of 15.03.2024.

issues. We believe that the Commission's approach might have been different under different circumstances, which is why the aforementioned Sector Inquiry into the Pharmaceutical Market was initiated. This inquiry aims to determine whether it is possible to improve the current market situation — that is, whether the existing market conditions could be enhanced to ensure effective competition in the pharmaceutical market.

24. The authors' view is that in the future, improving market conditions will require efforts beyond the Commission's. Also, the authors expect the aforementioned inquiry might provide better perspective of whether contracting authorities in public procurement should reassess tender design practices that inherently limit competition, whether the roles and obligations of MAHs should be further clarified, and whether adjustment to the cap on wholesale margins could stimulate greater intra-brand competition, given that maximum prices are already regulated. Furthermore, the inquiry might give a clearer perspective on whether using therapeutic substitutability could serve as the cornerstone both for tender design and for relevant market definition outside tenders, since pharmacies increasingly dispense reimbursed medicines and can alternatively choose only among approved therapeutic alternatives — a factor that strongly influences wholesale demand and upstream supply structure.

25. For precise and official conclusions, it is necessary to await the completion of the Sector Inquiry into the Pharmaceutical Market, which, in line with the Commission's good practice, will also provide recommendations to relevant stakeholders.