

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 Romania

- Session II -

1 December 2025

This contribution is submitted by Romania 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.

Mr Antonio Capobianco [Antonio.Capobianco@oecd.org]

JT03576376

Romania

1. Advocacy

1. The advocacy actions carried out by RCC involve measures aimed at improving the legal framework in the healthcare sector, with special attention being given to enhancing competition between innovative and generic medicines.
2. Among the advocacy actions that have had a significant impact on the market are intensive recommendations addressed to the regulator to eliminate the price discrimination between off-patent innovative medicines and their generic counterparts. In this respect, RCC successfully advocated for an equal pricing treatment of off-patent innovative medicines and their generic alternatives. Thus, whereas prior to the implementation of the RCC recommendations there was a 35% price difference between off-patent innovative medicines and generics, this gap has now been eliminated, the innovative medicine manufacturer being required to reduce the price of the off-patent product to the level of the generic medicine that entered the market.
3. In the same context of innovative vs. generic competition, RCC has been actively involved in amending legal provisions governing the application of the clawback tax¹. RCC recommendations called for a differentiated clawback tax application, depending on the type of medicine: innovative or generic². A uniform application of the clawback tax disproportionately affects generic medicines compared to more expensive, innovative ones. It is typically the consumption of innovative medicines that leads to the budget cap being exceeded, resulting in an unfair distribution of the fiscal burden. Therefore, while the clawback tax was previously applied uniformly to both innovative and generic medicines, it is now applied proportionally, based on the price positioning of medicines: innovative vs. generic as well as off-patent innovative medicines that already face competition from generics on the market.

2. Infringement decisions

4. The improvement and protection of competition on the pharmaceutical market have also been pursued through investigative means.
5. In this regard, Decision No. 91/2019 is worth mentioning. It is a decision through which RCC sanctioned Roche Romania SRL for engaging in an abusive market exclusion practice targeting the generic versions of the innovative off patent medicine Tarceva (Erlotinib).

¹ The clawback tax is state measure to control the budget expenditure , which requires pharmaceutical manufacturers to return to the state a part of the revenues earned from the sale of medicines that exceed the allocated amount from the National Health Insurance Fund (FNUASS).

² including also innovative medicines that are off-patent and have a generic alternative.

6. Tarceva and its generic versions are prescription-only medicines used in the treatment of cancer patients. According to the law, prescribing doctors must issue prescriptions using the international non-proprietary name (INN) of the active substance, not the brand name.

7. Roche's strategy implied steering patients toward purchasing Tarceva (via the Roche Patient Card and Roche Call Center) and covering the co-payment for Tarceva, to the detriment of the available generic alternatives:

- Upon issuing the prescription, the prescribing doctor would also hand the patient a Patient Card from Roche, bearing the message: "Your doctor has prescribed a Roche medicine. In order to receive the Roche medicine prescribed by your doctor, please contact the Roche Call Center." The patient would then place the order via the Roche Call Center rather than requesting it directly from the pharmacy. This limited the pharmacy's ability to inform patients about the available alternatives containing Erlotinib, favoring Roche's product over its generics.
- Roche covered the financial contribution (co-payment) that patients were required to pay when purchasing Tarceva. In doing so, Roche eliminated patients' financial incentive to choose cheaper generic alternatives³, whose visibility was already reduced due to the use of the Patient Card and the Roche Call Center mechanism.
- This strategy effectively undermined the state's regulated price control policies, by preventing pharmacies from presenting patients with lower-cost medicinal alternatives containing the same active substance.

8. By employing this strategy, Roche restricted the range of options available to patients for medicines containing Erlotinib, thereby limiting patients' freedom of choice and preventing direct competitors—the generic versions of Tarceva—from developing their sales under normal competitive conditions.

9. Although Roche challenged the decision, the High Court of Cassation and Justice (ICCJ) upheld the Competition Council's ruling.

10. Also, in 2019, through Decision No. 92, the same company, Roche Romania SRL, was sanctioned for another abuse of dominant position. Roche's strategy consisted in eliminating the ability of distributors to compete on the hospital supply market within the framework of the national oncology program, with the aim of excluding competition from biosimilar products.

11. The evidence in the case file showed that Roche had deliberately implemented a strategy designed to hinder and delay the market entry of biosimilar versions of the molecules rituximab, trastuzumab, and bevacizumab.

12. In anticipation of the entry of biosimilar versions of rituximab, trastuzumab, and bevacizumab onto the Romanian market, Roche deployed a market-securing strategy targeting hospitals, based on a pricing practice with exclusionary effects. In hospital procurement procedures, the products are requested based on their International Non-proprietary Name (INN), pharmaceutical form, and concentration. Therefore, both originator and biosimilar products—having the same INN—are in direct competition.

³ Cheaper at that time.

13. Roche's exclusionary behaviour consisted in participating in tenders with bid prices lower than the prices at which it sold the same products to its own distributors, who were also competing in those procurement procedures. Roche's objective was to preserve its market position, given that the success of a distributor in winning a tender could result in the replacement of Roche's brands with incoming biosimilar products.

14. Roche challenged this decision as well, but the High Court of Cassation and Justice (ICCJ) upheld the Competition Council's ruling.

15. Another decision concerning innovative–generic competition is Decision No. 270/2024, through which the RCC fined the company Boehringer Ingelheim RCV GmbH & Co KG. The investigated behaviour involved a complex strategy aimed at limiting the development of generic competition on the market, through actions such as influencing prescription practices.

16. Spiriva is an innovative medicine produced by Boehringer Ingelheim, based on the active substance tiotropium. According to international guidelines and national protocols, Spiriva is indicated as a first-line treatment for COPD (chronic obstructive pulmonary disease).

17. On the Romanian market, Spiriva was protected by patent until 2016. In 2017, the first generic version of Spiriva began to be marketed in Romania. At the same time, Boehringer registered a new product, based on the combination of tiotropium and olodaterol, under the name Spiolto—first launched globally in 2015, and marketed in Romania starting with 2017. Spiolto is also recommended for COPD treatment, but it is intended as a second-line therapy.

18. Anticipating the expiration of Spiriva's patent protection, Boehringer adopted a strategy to limit the market penetration of tiotropium generics, by shifting COPD patients from Spiriva to its newly launched product, Spiolto.

19. Boehringer implemented intensive marketing efforts, including multi-channel communication campaigns—direct interactions with doctors, digital communications, and the organization of scientific and medical events such as conferences, congresses, workshops, and more. Through these communication channels, Boehringer aggressively promoted a change in the therapeutic algorithm for COPD, encouraging doctors to prescribe Spiolto as a first-line treatment, in contradiction with both international guidelines and the Romanian national protocol.

20. Boehringer Ingelheim's behaviour was motivated by the intention to mitigate the risk of losing Spiriva's market share to tiotropium generics, and to redirect the revenue stream generated by this blockbuster drug toward the newly introduced product, Spiolto.

21. Boehringer challenged the Competition Council's decision, and the case is currently pending in court.

22. Although it does not concern innovative–generic competition, the Immunoglobulin case (Decision No. 101/2021) stands out as a landmark case for the Competition Authority, particularly in light of its serious impact on patients and the substantial fines imposed (approximately 71 million EUR).

23. The investigation was launched following public information about a crisis on the market for products derived from human blood or plasma, specifically human immunoglobulins. At the same time, the Ministry of Health submitted a request to the Competition Council, asking for support to ensure the availability of essential products for patients by enforcing competition rules.

24. The investigation focused on the conduct of the main immunoglobulin suppliers—Baxalta GmbH, CSL Behring GmbH, Biotest AG, Kedrion SpA, Octapharma AG—as well as the sector’s representative association (PPTA). The case concerned a coordinated strategy aimed at restricting or even interrupting the supply of immunoglobulins to the Romanian market, with the goal of pressuring authorities to suspend the clawback tax for medicines derived from human blood or plasma. Through this strategy, the companies sought to gain a commercial advantage, specifically to improve their profit margins.

25. In the second half of 2015, the main manufacturers—who covered over 95% of the national demand for immunoglobulins—joined a working group (ROTF) established and coordinated by the PPTA, with the aim of obtaining an exemption for plasma protein therapies (PPTs) from the clawback tax in Romania.

26. The coordination of the manufacturers’ behaviour took place through repeated communications within the ROTF, during which a strategy emerged to limit the supply of immunoglobulins as a coercive tool to pressure authorities into amending the legislation on the clawback tax.

27. The evidence in the case file indicated that the decisions to withdraw from the market were interdependent, based on a common understanding, and amounted to a boycott. The crisis it generated among patient-consumers was severe enough to force public authorities to adopt economically favourable decisions for the producers of plasma-derived therapies.

28. The lack of access to immunoglobulins, essential medicines used to treat various serious conditions, endangered patients’ lives and prompted the authorities to take emergency measures, including activating the European Union Civil Protection Mechanism. This underlined the seriousness of the situation on the national market.

29. The parties challenged the Competition Council’s decision, and the case is currently pending before the court.

3. Future work

30. In the context of the actions undertaken by RCC to ensure a normal competitive environment, it is worth mentioning the ongoing sector inquiry into pharmaceutical retail. This investigation is currently in progress and focuses on identifying factors that may limit patients’ access to medicines dispensed through pharmacies. The goal is to find the most effective methods to improve the availability of these products at patient level.

31. Additionally, the Competition Council plans to expand the Price Monitor platform to include OTC (over-the-counter) products and dietary supplements sold

through major pharmaceutical chains across Romania. Currently, patients do not have easy access to centralized and updated information regarding the availability and prices of OTC pharmaceutical products and dietary supplements. Furthermore, due to price differences between pharmaceutical chains, consumers often lack the ability to make an objective comparison before making a purchase. This lack of transparency may lead to market imbalances, potential unfair commercial practices, and ultimately hinder access to essential health and preventive products.