

Unclassified

English - Or. English

18 May 2026

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE**

Working Party No. 2 on Competition and Regulation

Competition and Regulation in the Healthcare Sector – Note by Romania

22 June 2026

This document reproduces a written contribution from Romania submitted for Item 7 of the 81st meeting of Working Party 2 on 22 June 2026.

Federica MAIORANO
Federica.Maiorano@oecd.org

JT03587162

Romania

1. At a time of rising healthcare costs and constraints on public finances, can competition help deliver better outcomes in the healthcare and pharmaceutical sector? What is the experience with past procompetitive reforms? What does the evidence show?

2. First of all, competition can improve outcomes in healthcare and pharmaceuticals if carefully designed and regulated. Competition advocacy in the healthcare sector has played a key role in improving the regulatory framework, enhancing market functioning, and ensuring better access to medicines for patients. In this context, the advocacy initiatives undertaken by the RCC have focused on measures aimed at strengthening the legal framework, with particular emphasis on taxation mechanisms, medicine availability, pricing policies, and fostering greater competition between innovative and generic medicines.

3. Among the advocacy actions with a notable market impact are:

1. Amendments to the Clawback Tax Framework

4. 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.

5. Previously, the clawback tax applied to generic medicines was also differentiated based on the country of manufacture. Generic medicines produced in Romania were subject to a lower clawback rate compared to those manufactured outside the country. This approach raised concerns regarding market distortions and unequal treatment.

6. The current system shifts the focus toward a more balanced and competition-friendly mechanism, aligning the tax burden more closely with the characteristics and pricing of medicines.

The Immunoglobulin Case

7. In relation to the clawback tax, an important example of how pricing and regulatory policies can directly impact the availability of essential medicines - through the adoption of anti-competitive conduct on the market - is the RCC *Immunoglobulin* case (Decision No. 101/2021). This case stands out as a landmark case for the Competition Authority,

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.

particularly in light of its serious impact on patients and the substantial fines imposed (approximately 71 million EUR).

8. 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.

9. 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.

10. 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.

11. The coordination of the manufacturers' behavior 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.

12. 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 favorable decisions for the producers of plasma-derived therapies.

13. 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.

14. The parties challenged the RCC's decision, and the case is currently pending before the court.

2. Elimination of Price Discrimination Between Off-Patent Innovative and Generic Medicines

15. Another significant advocacy outcome has been the removal of price discrimination between off-patent innovative medicines and their generic equivalents by aligning them at the same price level. In this context, the RCC successfully promoted the adoption of equal pricing rules for both categories.

16. Following the RCC's recommendations, the prices of innovative medicines whose patents have expired were reduced to the level of the corresponding generic reference price. As a result, the previous price gap of 35% between off-patent innovative medicines and generics has been eliminated. Manufacturers of off-patent innovative products are now required to align their prices with those of the generic medicines entering the market.

17. From a competition perspective, the RCC emphasized that market power is primarily linked to patent protection while it is still in force, rather than to the distinction between original and generic medicines after patent expiry. Once generics enter the market, maintaining different pricing levels for medicines with the same International Nonproprietary Name (INN) can lead to unjustified distortions.

18. At the same time, the RCC highlighted the need for carefully calibrated price reductions, supported by impact assessments, as excessive or unsustainable decreases could lead to the withdrawal of certain medicines from the market and ultimately harm patient access. In this context, the RCC emphasized that pricing policies should strike a balance between accessibility and the economic sustainability of producers, for both innovative and generic medicines. It therefore recommended a differentiated approach: maintaining prices in the Public Price Catalogue at a level that allows Romania to remain a reference country for other states, while setting reimbursement at a lower level, adapted to budgetary constraints and access objectives. This approach would support both the availability of medicines on the market and the efficient use of healthcare resources.

3. Improved Regulation of Public Service Obligations

19. Following recommendations from the RCC, the Ministry of Health strengthened the legal provisions governing the availability of medicines, particularly through a clearer definition and enforcement of public service obligations.

20. Under the Health Law³, the public service obligation requires „*The obligation of marketing authorisation holders (MAHs) (or their representatives) and wholesale distributors to continuously ensure an adequate range of medicines to meet the needs of a defined geographical area, and to deliver the requested quantities across that area as quickly as possible after receiving orders, as well as the obligation of pharmaceutical units to procure medicines when they are not available in stock at the time of request.*”

21. Further clarification was introduced through Order of the Ministry of Health No. 269/2017, which establishes concrete obligations:

- MAHs must ensure a minimum monthly stock level⁴ equivalent to the average monthly turnover for each authorized medicine;
- Wholesale distributors must maintain safety stocks at the level of the average monthly turnover;
- Wholesale distributors are required to fulfill all justified orders from healthcare units and pharmacies within agreed delivery terms⁵;
- Healthcare units and pharmacies must submit justified orders to their contracted distributors at least once per distributor until the order is fulfilled.

³ Law No. 95/2006 on Healthcare Reform, republished in the Official Gazette of Romania, Part I, No. 652 of August 28, 2015.

⁴ the average monthly turnover of the respective medicine over the last three months.

⁵ a maximum delivery time of 24 hours for justified orders related to medical prescriptions for acute and subacute conditions, and 48 hours for justified orders related to prescriptions for chronic conditions.

22. These measures aim to prevent medicine shortages and ensure continuous patient access to essential treatments.

4. Study on the analysis of the production and marketing markets for OTC medicines and food supplements.

23. Within the study, it was observed that manufacturers' communication strategies are primarily directed towards the general public, with audiovisual media representing the most important form of advertising and accounting for the largest share of marketing budgets. Compared to 2015, advertising expenditures in the audiovisual sector increased in 2019 by 58% for OTC medicines and by approximately 157% for food supplements. At the same time, the analysis of the legal framework applicable to OTC medicines and food supplements highlighted the need for issuing new regulations and amending certain existing requirements.

24. As a result of the analysis conducted, the RCC issued a set of recommendations, such as:

- Revising the legislation on the advertising of OTC medicines in the online environment. According to the national legislative framework, advertising addressed to the general public via social media networks or mobile applications is prohibited. In this context, the RCC recommended revising the legislation on medicinal product advertising, in order to establish specific requirements for social media and outdoor advertising, so that these communication channels may also be used;
- Improving the legislation in the field of e-commerce for OTC medicines by introducing clarifications regarding the possibility of carrying out this activity both through the pharmacy's own website and through intermediary platforms, including both marketplace-type platforms and on-demand delivery platforms, provided that these meet all the requirements applicable to the sale of medicines via the pharmaceutical unit's own website;
- Monitoring and moderating user-generated content on websites selling food supplements and on social media platforms;
- Establishing a list of ingredients/substances that may be used both in the manufacture of food supplements and in the production of medicines, as well as the maximum permitted quantities for each product category.

5. Conclusions

25. These advocacy actions illustrate how competition policy can complement sector-specific regulation in healthcare. By promoting fair taxation, improving supply obligations, and ensuring non-discriminatory pricing, the RCC has contributed to a more efficient, transparent, and patient-oriented pharmaceutical market.

26. Overall, the RCC's experience shows that competition can play a meaningful role in improving outcomes in the healthcare and pharmaceutical sectors, particularly in a context of budgetary constraints. Through targeted advocacy measures - such as eliminating unjustified price differences between off-patent innovative medicines and generics, and promoting a more equitable, differentiated clawback tax - the RCC has contributed to a more balanced and efficient market.

27. In this context, competition policy remains an essential complementary tool for achieving better healthcare outcomes while ensuring the sustainability of public finances.