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**GENERIC PHARMACEUTICALS**

-- Note by Romania --

**18-19 June 2014**

*This document reproduces a written contribution from Romania submitted for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014.*

*More documents related to this discussion can be found at <http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm>.*

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## **1. Recent developments in the competition enforcement.**

1. The latest EU economic crisis has been exercising a great strain on both national healthcare systems and pharmaceutical industry. In Romania, the Ministry of Health (hereinafter MoH) has endeavored to identify and implement cost control measures, in order to increase consumer welfare and ease the burden on the healthcare budget.

2. Romania understands the potential offered by the generics industry in terms of accessibility and cost control and has taken steps to encourage the industry and to obtain these benefits. Although some measures have been implemented, there is still room for improvement and further options are currently being envisaged by the authorities.

3. In 2009, the Romanian Competition Council (hereinafter RCC) has signed a collaboration protocol with the Romanian Medicines Agency (hereinafter NMA), agreeing to cooperate in any problem that could arise in the pharmaceutical field, such as producing, marketing, import and distribution, as well as the use of medicines, market studies and the general functioning of the market. A great emphasis was put on the collaboration between the bodies concerning existing regulation and possible regulatory remedies for a better functioning of the market. The protocol is still in place and has allowed members of the two authorities to meet and discuss problems that have arisen in the sector and to identify together the best solutions.

4. In Romania, the market authorisation for a drug will be granted upon request to the NMA, with the exception of medicines already authorised through the European Medicines Agency.

5. By derogation, an applicant for a market authorisation will not have to provide the NMA with preclinical and clinical trials' results, if it can prove that the medicine is a generic for a drug that has been authorised in Romania at least 8 years before, or in another EU member state, or through the centralised procedure, thus creating an incentive to entry the market. A generic will not be marketed in Romania before the passage of 10 years since the authorisation of the original drug. This also applies if the original drug was not authorised in Romania, but the applicant needs to point out the country in which the original was marketed.

6. After the attainment of the marketing authorisation for a prescription drug, its holder will apply for a price decision with the MoH.

7. The whole process, including both market authorisation and price decision, takes about ten months. The price should be less than or equal to the lowest price of the same product sold in the countries on the comparison list: the Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece and Germany. For generic medicines, the reference price is proposed by the holder of the market authorisation of the first generic medicine, by comparison with the prices of the same medicine in the countries on the list, without exceeding 65% of the price of the corresponding innovative medicine in Romania. If the price of the generic is lower than 65% of the original's price, the original medicine's price needs to be lowered, so as not to exceed the price of the generic with more than 35%.

8. The Romanian Association of Generic Producers has welcomed this new regulation, as the previous one contained a circular reference, stating that the generic's price had to be lowered again after the lowering of the price of the innovative. The argument of the association was that this circular reference allowed the producers of innovative medicines to drive the generics out of the market, lowering their price so that the generics producers should do the same accordingly, thus lowering the prices below the profitability threshold.

9. Any time during the period for which the price is valid, the holder of the marketing authorisation or its representative may diminish, for generics, the producer price initially approved by the MoH. The producer price thus decreased will be communicated to the MoH for the establishing of wholesale and retail prices accordingly, in order to include them in the National catalogue of medicine prices.

10. The distribution and pharmacy margins for medicines below 300 RON is computed as a percent of the producer's price, while for medicines over 300 RON, the margin is capped at 30 RON for wholesalers and 35 RON for pharmacies.

11. RCC has repeatedly advocated for measures that would increase the generic consumption in Romania. One of the proposals made by RCC was that the clawback tax paid by generic companies should be lower than the one paid by the innovative companies, thus encouraging consumption for the products of the former.

12. In 2010, RCC concluded a sector inquiry, which was focused on identifying problems in the pharmaceutical sector and finding solutions to these problems that would lead to a better functioning of the market.

13. The sector inquiry comprised chapters that dealt with the production of medicines, their distribution and legislative provisions that could affect these activities. The first objective was to conduct an in-depth analysis of the Romanian regulations that could affect the distribution activity, such as the way the national health programs are organised and function, the way of drafting the National Reimbursed Medicines List, the way the medicines used in hospitals are bought, as well as the regulation concerning the parallel trade.

14. The second objective consisted of the analysis of a representative sample, formed of 92 product markets defined at ATC4 level, which covered more than 70% of the total distribution market in 2008.

15. The sector inquiry has looked at distribution contracts for the best-sold medicines, to identify cases where the distribution was made through a small number of wholesalers or through just one exclusive wholesaler, and to determine the part of the market that was covered by such agreements.

16. Following the finding that most of the markets were highly concentrated, due to the high market shares held by innovative products, the sector inquiry next focused on the penetration rate of the generic medicines and the factors that led to the situation.

17. Regarding the innovative-generic relationship, RCC found that the legal framework was improved, due to the entry into force of a new regulation that states that doctors must prescribe medicines on the International Nonproprietary Name (hereafter INN), not on the brand name, as before. Also, the pharmacies will release the less expensive medicine, and will dispense the more expensive one only in special cases when the doctor prescribed the medicine on the brand name or the patient insists that he should get the more expensive drug.

18. RCC considered that the same principle should be applied to medicines dispensed through the national health programs, at least for INNs for which there is more than one drug on the market, in order to decrease the expenses with the medicines and to encourage the consumption of generics, as soon as these enter the market. This proposal was taken up by the Ministry of Health, and introduced in the regulation concerning the reimbursement of the medicines in the National Health Programs.

19. For this to happen, RCC proposed the introduction of criteria that should be used when drafting the reimbursement lists and that certain medicines should be automatically included in the reimbursement list after the MoH's decision of including that medicine in the reimbursement list.

20. In addition, RCC considered that further measures should be taken to encourage the consumption of generics. To avoid the influences on the prescription process, RCC recommended that the terms gifts, advantages in money or goods that have a “symbolic value” and “are not expensive” should be further defined to set bounds for the maximum value of these gifts received by the prescribing doctors.

21. The generics should get into the market as fast as possible, without unnecessary delays; therefore RCC has continued to monitor the generics’ penetration. To continue this analysis, RCC triggered another sector inquiry, in April 2013. The purpose of this inquiry is to continue the monitoring of the 92 product markets identified in the previous inquiry and to see how the changes in regulation have impacted the market. The findings of the inquiry will serve to further investigate if there are cases of unilateral practices or any agreements of the “pay-for-delay” type and to tackle these as well.

22. The investigation will also look at generic entry on the market since 2009 and the market shares acquired since then. The inquiry also investigated the prescription process and will seek to identify new ways to increase generic consumption, starting at the prescription level and continuing at pharmacy level. A questionnaire has been sent to the pharmacies that will show how many of the prescriptions are on the INN and how many on the brand name, and which are the factors that influence the dispensing of the innovatives to the detriment of generics.

23. The sector inquiry will also look at the price levels of the medicines, to ascertain if the level of influence the entry of a generic drug on a market has on the price of an innovative medicine.

24. Since 2009, RCC has also observed an improvement in the payment terms of the Romanian Health Insurance House to the actors in the pharmaceutical industry, as they have evolved from one year in the previous year to 60 days at the present time. This is an important factor to be taken into consideration, as it increases the predictability of the system and improves the cash-flow of companies, helping especially the small actors, that don’t have access to bank or supplier credit.

## **2. Pharmaceutical companies’ practices under competition scrutiny.**

25. In May 2009, NMA reported and expressed concern to RCC about the actions taken by companies Novartis (Novartis GmbH and Novartis AG) by bringing a litigation action in the courts of common law in Romania, for the annulment of multiple marketing authorisations issued by the NMA for companies producing generic drugs.

26. NMA argues that this legal approach is promoted by ignoring and even against the *acquis communautaire* in force, since Novartis (Novartis AG and Novartis GmbH) claim that the original drugs are under the protection of the patent. According to EU regulations, patents are irrelevant to the analysis of the legality of such authorisations by the NMA.

27. NMA has pointed out the negative impact such an action implies, since it represents a clear anticompetitive practice, highlighted also in the European Commission preliminary report on the inquiry on the pharmaceutical sector.

28. For the pharmaceutical sector there are three types of rules: patent rules, market authorisation rules and rules concerning the prices and reimbursement.

29. Art. 81 of the Commission’s regulation 726/2004 (market authorisation through centralised procedure) and art. 126 of the Directive 2001/83/CE (market authorisation through national procedures) state that the market authorisation will not be refused, suspended or revoked, except on the basis provided in the Regulation and in the Directive. Since the state of the patent is not included in the grounds provided

by the Regulation or the Directive, this cannot be used to refuse, suspend or revoke the market authorisation.

30. Therefore, the task of the public bodies in the field of marketing authorisation is to verify if a medicine is safe, effective and of good quality. Their main task is to ensure that the pharmaceutical products that reach the market are not harmful for the public health.

31. These types of litigations are used by the innovative companies to block or delay the access of the generic drugs after the patent expiry, and could represent an infringement of art 102 TFUE.

32. The respective INN was in the product market analysed at that time by the EC investigation, therefore RCC could not act at the moment. However, EC was made aware of the facts of the case.

33. For a behaviour to enter the scope of the abuse of dominance provisions, 3 conditions need to be cumulatively met: the company should have a dominant position on the concerned relevant market, the company should abuse that position by resorting to anticompetitive acts and these acts should have as an object or as an effect the impairment of economic activity or the consumer harm, especially by eliminating undertakings from the market.

34. In December 2009, Actavis lodged a complaint at RCC against Novartis Pharma GmbH and Novartis AG, alleging infringement of articles 5 and 6 of the Romanian Competition Law.

35. Novartis owned a patent in Romania for Valsartan (which is the active ingredient for its drug Diovan) valid until February 2011. Thus, Actavis would have been able to market its generic version for Valsartan after the patent expired.

36. Actavis obtained marketing authorisation granted by the Romanian Medicines Agency for its generic version of Valsartan in June 2008. According to the national law, the marketing authorisation is valid three years from the date it is granted, even if the product is not actually marketed. Further, a prescription medicine with a marketing authorisation can be marketed only after obtaining a price decision by MoH.

37. Although “patent linkage” is unlawful under European rules, in February 2009 Novartis initiated an administrative complaint (litigation) against NMA and the generic companies for the annulment of the marketing authorisations obtained by Actavis and another generic company, Belupo. Novartis alleged illegality of the marketing authorisations on grounds of patent infringement.

38. On such circumstances, in May 2009 Novartis sent a letter to Actavis with a proposal to withdraw the litigation against Actavis, provided that Actavis should take certain commitments not to apply for a price decision from the MoH with more than 90 days prior to the expiration of the patent, as well as restraining from manufacturing, disposing of, offering to sell, selling or importing in view of disposing of, offering to sell or selling any products for which Actavis obtained the marketing authorisations. Actavis did not accept the signing of those commitments. Accordingly there was no agreement.

39. At that moment, the price mechanism set by the Romanian law established a so called “double referencing rule” (the price of the first generic medicine which obtains price approval becomes the “generic reference price”). The generic reference price cannot be higher than 65% of the original’s price. If the generic reference price approved by MoH was smaller than 65% of the original’s price, the original’ price for the drug in question had to be lowered in 60 days and could not exceed the generic reference price with more than 35%).

40. In other words, due to the existence of a “double referencing rule” in price regulation, even though the patent for a drug was still valid and the generic cannot be marketed, the price of a generic with marketing authorisation could have influence (lower) the price of the original.

41. The time limit within which MoH issues a price decision is of 90 days from the date of the application. Thus, for the generic to be launched (first sale) without delay from patent expiry date, it is necessary and sufficient for the generic company to submit the price application with 90 days prior to patent expiry, so MoH could grant the decision around the date patent expires. Therefore Novartis’ actions did not delay generic entry.

42. It appears that Novartis’ actions (trying to prevent generic companies to apply for a price decision until the date which is 90 days prior to the patent expiry date) had the aim to preserve its regulated price, at least until the patent had expired, at the level initially approved by MoH.

43. As regarding the existence of a dominant position held by Novartis in the market for Valsartan, the information provided by Actavis did not support that claim. According to Actavis, there were other INNs substitutable with Valsartan, all included in the same ATC 4 class (e.g. Telmisartan, Candersartan Cilexetil, Irbesartan, and Losartan). Furthermore, Novartis had dropped the litigation and withdrew its administrative complaint against Actavis and NMA on November 2009.

44. Romanian Competition Council concluded that there are no sufficient grounds for further investigation.