

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE****Working Party No. 2 on Competition and Regulation****Designing publicly funded healthcare markets – Note by Croatia****26 November 2018**

This document reproduces a written contribution from Croatia submitted for Item 4 of the 66th OECD Working Party 2 meeting on 26 November 2018.

More documents related to this discussion can be found at

<http://www.oecd.org/daf/competition/designing-publicly-funded-healthcare-markets.htm>

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Croatia

1. Based on the complaint made by the Croatian Employers' Association – Pharmaceutical Manufacturers Association, Innovative Medicines Initiative and Generic Drugs Manufacturers Association, the Croatian Competition Agency (CCA) carried out a legal analysis of the Croatian Health Insurance Fund (HZZO) Guide for the new referral model identifying the basic drugs reimbursement list and the criteria for prescribing prescription drugs.
2. HZZO as a compulsory insurance fund manages the compulsory health insurance in the Republic of Croatia. Among other activities, it ensures the right to health compulsory health insurance and defines the basic drugs reimbursement list and the supplementary drugs reimbursement list within the scope determined on the basis of separate laws regulating this area.
3. Prescription drugs amount to a significant medicines market share. A prescription form is a public document issued by a licenced doctor of medicine or dental medicine. This is the reason why a doctor, as an authorised person to prescribe a medicine, is a key person in drugs prescription, both from the basic and supplementary drugs reimbursed lists.
4. The access to the medicines market for the prescription drugs is realized by the licence holder (a pharmaceutical company) on the basis of the inclusion in the HZZO basic drugs reimbursement list and the supplementary drugs reimbursement list. The criteria for the inclusion are determined by law and transparent. Once the medicine of a particular undertaking is placed on the HZZO lists this means that the undertaking concerned gained access to the prescription medicines market under equal conditions.
5. HZZO ensures full reimbursement for the prescription drugs that have been included in the basic list whereas the final consumers participate in the price of the drugs placed on the supplementary list directly or indirectly by their contribution in the supplementary health insurance.
6. The Guide for the new referral model additionally works out the criteria for GPs – who are responsible for taking the final decision with respect to prescription drugs and the therapy they propose. The Guide recommends that a GP, in principle, should prescribe the cheapest medicine within the medicines group of the same composition.
7. Although the Guide seems to constitute a recommendation and therefore it should not be binding, in practice it defines the behaviour of GPs when prescribing drugs, which indirectly may affect the medicines market.
8. First, it must be taken into account that this is a highly regulated industry, given the specific nature of the product concerned (medicines), the features of the medicines market in prescription drugs and the administration of public health policy resting on the principles of universal coverage and solidarity. This is the framework in which competition in the medicines market is to a certain degree restricted.
9. Second, without prejudice to the power of the Croatian Health Insurance Fund (HZZO), which is one and only public institution managing the compulsory health insurance, or to its endeavour to optimize and keep the sustainability of the health care prescription drugs plan, on the basis of the analysis of the rules concerned the CCA concluded that the Guide may to some extent lead to restrictions on the medicines market,

concretely, such HZZO practice may have exclusionary effects on particular undertakings in the market concerned. We are talking here about undertakings whose products are currently identified on the basic drugs reimbursement list worked out by the HZZO but whose drugs are not of the lowest price within the therapeutic category at issue.

10. The CCA holds the view that the application of the Guide may have exclusionary effects on the medicine manufacturers whose products are placed on the basic drugs reimbursement list, but are not the cheapest within the particular therapeutic group. Thus, the manufacturers of the medicines of the same composition from the basic drugs reimbursement list are excluded from the market despite the fact that they are included in the basic drugs reimbursement list covering the drugs that are fully reimbursed by HZZO. In other words, currently the final consumer does not enjoy the right to choose the medicine from the basic drugs reimbursement list even if he/she might wish to compensate for the difference between the price of the medicine in question and the reference price of the drug. What is more, this medicine cannot be at the same time placed on the supplementary drugs reimbursement list where it is only available to the final consumer by his/her direct or indirect contribution on the basis of the supplementary health insurance plan. Consequently, such a situation currently significantly diminishes the final consumer's freedom of choice relating to the medicines from the basic drugs reimbursement list.

11. Therefore, it is the opinion of the CCA that the adoption of any new rules in the area of health care prescription drugs or any revisions thereof should be carefully studied and alternative solutions found in the drug prescription plan so that the access to the basic drugs reimbursement list is ensured to all undertakings specified under the valid basic list that are currently to some extent being excluded from the market.

12. The CCA also points out that the financial benefits and optimization of the drug prescription system may be carried out by removing of the barriers that, despite the regulated industry concerned, may lead to strengthening of competition.

13. The removal of these barriers would result in the same efficiencies whereas at the same time the basic principle of competition would be observed. The undertakings would be able to compete within the regulated market while the consumers would be ensured a fair share of benefit based on the wider choice of products.

14. This is particularly important in the medicines market where access and operation happen in a distinctly regulated environment where alternative access and distribution of products are doubtful.

15. Finally, for the purpose of this opinion the CCA also took into account the comparative practice in the area concerned of a number of EU Member States, such as the medicines market, the prescription drugs plans and prescription drugs reimbursement plans within the public health policies of Poland, Slovenia and the Czech Republic. In the listed Member States this is also a highly regulated industry where price competition is diminished so that the traditional market rules do not play as significant role as in other industries involving sales of product or provision of services. Given the fact that medicines are protected by exclusive rights the competition in this area is commonly restricted to innovation and generally rules out price competition. When patents or other periods of exclusivity expire and generic drugs come to the scene, the prices significantly fall. Yet, in accordance with the relevant data, the patients there may enjoy the freedom to choose among several drugs from the list of licenced drugs the cost of which are reimbursed or compensated by the patient for the difference between the price of the concrete medicine

and the reference price, depending on the public health insurance plan of a particular Member State.

16. This opinion of the CCA has been communicated to the Ministry of Health and HZZO.