Comment on the Draft of the Ordinance amending the Ordinance establishing the criteria for the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund and the method of reporting

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AmCham

American Chamber of Commerce in Croatia Američka gospodarska komora u Hrvatskoj

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Introduction

On October 28, 2022, the Ministry of Health submitted for public consultation the Draft of the Ordinance amending the Ordinance establishing the criteria for the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund and the method for determining the pricing of medicinal products paid by the Croatian Health Insurance Fund and the method of reporting (hereinafter: the Draft of the Ordinance).

The amendments to the ordinance in question were not included in the Plan of Consultation Activities of the Ministry of Health for 2022 from September 2022, but they should have been under Article 11, paragraph 5 of the Access to Information Act. As a result, companies were unable to plan their budgets and activities in relation to medicinal product prices and the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund. In previous years, the Ministry of Health has established work groups for drafting new laws and ordinances, which included the relevant stakeholders of the healthcare system, which agreed on the contents of new regulations by reaching a consensus through informed discussions. We believe that the procedure of preparing a document of utmost importance for the healthcare system should include all the stakeholders of that system from the very beginning.

The proposed Draft of the Ordinance introduces many amendments which are certain to put access to medicinal products at risk, and thereby also the outcomes of patient treatment in the Republic of Croatia. This contradicts the publicly presented objectives of the comprehensive healthcare system reform, which places Croatian users of the healthcare system and services at its center.

We would also like to point out that decreasing medicinal product prices is unsustainable amid the situation of growing inflation and the enormous increase in raw material and transport prices.

Taking into consideration the sizeable and significant changes that the Draft of the Ordinance proposes regarding price determination of medicinal products and the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund, as well as the fact that the procedure was not conducted in accordance with the Access to Information Act, we suggest that the **Draft of the Ordinance be withdrawn from public consultation** and that **a working group be formed which will include all relevant stakeholders**, and as a result, include **the representatives of AmCham's Healthcare Committee**, and that such a draft of the ordinance be submitted for a new public consultation procedure.

Comments

Article 4 of the Draft of the Ordinance

In the proposition of Article 4 of the Ordinance, after subparagraph 5, subparagraph 6 is added, reading as follows:
"- the medicinal product in question contains a new active substance authorized for marketing in a centralized procedure without a clinical equivalent on the medicinal products list, where the applicant is unable to provide evidence that the proposed medicinal product is funded by the national health insurance provider in at least 10 member countries of the European Union when submitting the request for the inclusion on the medicinal products list."

Adding this new criterion for the inclusion of the medicinal product in the reimbursement list of the Croatian Health Insurance Fund, which requires evidence that the proposed medicinal product is funded by the national health insurance provider in at least 10 member countries of the European Union, sets a **technical obstacle to ensuring faster medicinal product availability for patients in the Republic of Croatia.**

This proposal directly places patients in the Republic of Croatia **at a disadvantage** in relation to other citizens of the European Union, which directly contradicts the objectives and values of the European Union. Namely, the implementation of this requirement will lead to a significant delay (of possibly up to several years) in the inclusion of the medicinal product in the reimbursement list of the Croatian Health Insurance Fund, which will result in a deterioration of patients' health due to poorer treatment outcomes caused by the inability of timely treatment implementing new treatment advancements.

We believe that the aforementioned amendment contradicts the European Parliament's resolution on options for improving access to medicines from 2017, as well as Europe's Beating Cancer Plan and the Pharmaceutical Strategy for Europe. The recommendations in the aforementioned documents highlight the need for **consistent and timely access to medicinal products** and the **reduction of current major disparities in treatment options for patients** between different countries in the European Union. Article 35 of the Charter of Fundamental Rights of the European Union, guaranteeing the right to high-quality healthcare taken into consideration in defining and implementing all of the policies and activities of the European Union, should also be mentioned in this context.

This requirement also poses an obstacle to the **free movement of goods**, in this case, medicinal products. This measure is interpreted as a technical obstacle,

whereas the European Union has implemented the principles of mutual recognition, removal of physical and technical obstacles, and the promotion of standardization in order to ensure a single internal market of the European Union (Article 26 and Articles 28-37 of the Treaty on the Functioning of the European Union (TEFU)). This requirement not only prevents Croatian patients from being treated with the use of new therapeutic advancements but also prevents businesses in the European Union from operating in the Republic of Croatia in the same way as in other member countries.

It should be noted here that the marketing authorization obtained in a centralized procedure at the European Medicines Agency takes effect at the same time for all member states of the European Union, including the Republic of Croatia.

Following all of the above, we propose that **Article 1(6) be deleted** (10 countries limit).

Article 5 of the Draft of the Ordinance

Since most of the databases concerning the funding of medicinal products in member states of the European Union are not publicly available, i.e. access is charged, and/or a certificate is needed, and many do not include information on the level of funding or specific indications of the medicinal product in question, we propose that the following text **be deleted from item 7**: *"and evidence that the medicinal product is funded by the national health insurance provider"*.

In some countries of the European Union, medicinal products are not equally available in different areas of the country (for example, in different regions or cities), which means that this amendment would require all-year access to the databases of the national health insurance providers in all EU countries, as well as to the databases in specific regions and cities in some countries. Furthermore, the justification and the possibility of a pharmaceutical company sharing bought data with third parties are questionable.

Article 6 of the Draft of the Ordinance

Since the conditions which clearly define the guidelines and the parameters for the cost and cost-effectiveness analysis / cost-utility analysis are yet to be determined, we propose that **Article 16(a) be deleted** or that a **transitional period** be determined during which the aforementioned conditions should be defined, and during which period, the documentation from Article 16 does not have to be delivered.

It should be taken into consideration that it will take time for the physical and legal subjects preparing the analyses to adapt to the Croatian Health Insurance Fund's requirements, and if sufficient time is not provided, there will be further

delays for the inclusion of the medicinal products in the Fund's list, and none of the stakeholders will benefit from that.

Furthermore, the way in which this article is set out indicates the possibility of favorable treatment and violations of the principles of the free market because **it is unacceptable that the Fund determines which legal or physical persons registered to perform pharmaceutical-economic analyses will prepare the analysis** to be paid by pharmaceutical companies. In a free market, the only condition that the legal or physical person should meet is having the appropriate registered business activity and the quality of service, but such a category of business activities for the performance of pharmaceutical-economic analyses does not yet exist in the national economic activity classification system.

By introducing this analysis, the cost of preparing the documentation for including the medicinal product in the Croatian Health Insurance Fund list is further increased, which was not planned for in the budgets of the companies performing this business activity.

Article 8 of the Draft of the Ordinance

In paragraph 3, it is proposed that **subparagraph 3 be amended** by **replacing the proposed text with the following**: "- *evidence on the level of recommendation of Croatian, European or American clinical guidelines*".

Namely, the criterion "the highest level of recommendation according to Croatian clinical guidelines" **cannot be a funding requirement** for medicinal products from the list of high-cost medicinal products because the Croatian Medical Association and other professional associations are yet to define this list, and therefore it has not yet been implemented in the Croatian clinical guidelines, unlike the European or American guidelines.

In addition, there are no legal or any other obligations for Croatian medical associations to issue guidelines, and therefore there is no uniform practice among them. Many areas of therapy do not have Croatian clinical guidelines. Consequently, doctors primarily use European clinical guidelines since Croatia is part of the European Union, but they also use American clinical guidelines.

It is also necessary to **further clarify paragraphs 1 and 2** since it is not clear if it is possible to submit an application for the inclusion of a new medicinal product in the list of the Croatian National Insurance Fund and the list of high-cost medicinal products at the same time (according to paragraph 1, or if the medicinal product to be included in the list of high-cost medicinal products should first be included in the list of the Croatian National Insurance Fund (according to paragraph 2). If the correct procedure is the one described in paragraph 2 (2-step procedure), we want to express our concern that such an amendment will further

delay access to new therapeutic advancements for patients in the Republic of Croatia. We are of the opinion that **the current Ordinance and the current practice of the Croatian National Insurance Fund (simultaneous application submission for the high-cost medicinal products list and the Fund's list) should not be changed.**

Article 8 states that the Fund can remove a medicinal product from its list if the authorization holder does not provide consent to the price recommended by the fund. In the spirit of partnership, we believe it is crucial to **determine a reasonable deadline** for the provision of the consent **no shorter than 30 days**, primarily because of the companies which do business in Croatia on behalf of the authorization holder.

Paragraph 13 states that "*the Fund shall continuously monitor the efficiency of the medicinal product from the List using short-term measurable parameters, and, if the medicinal product does not produce the effect presented by the Authorization Holder upon the inclusion of the product in the list during its application in treatment, the Committee may suggest removing the medicinal product from the list*".

We believe it is necessary **to define those "short-term measurable" parameters and analyses** which must be based on scientific methods. It is also important to give authorization holders the option **to view or provide statements** regarding the aforementioned analyses. If this is not possible, we propose that **paragraph 13 in question be deleted**.

Article 16 of the Draft of the Ordinance

This article of the Draft of the Ordinance **puts additional pressure on the prices of medicinal products** upon their inclusion on the Fund's list compared to the current Ordinance. We believe this is neither justified nor sustainable during hyperinflation and the enormous increase in raw material and energy prices that the medicinal product producers are now facing. While many producers and service providers have increased the prices of their products and services in accordance with the current situation, the prices of medicinal products in the Republic of Croatia have not increased but have, in fact, been continuously decreasing due to (a) annual price coordination, (b) therapy price referral, and (c) the public procurement procedures for medicinal products in hospitals. It is necessary to **define mechanisms** which will allow for the adjustment of the pricing policy for medicinal products in line with the tremendous escalation of the prices of goods caused by inflation; if not, we will face the risk of shortages and disruption in the availability of medicinal products in the Republic of Croatia.

Resulting from all of the above, we propose that the Ordinance **determine the mechanism for the coordination of prices of medicinal products in the**

years when inflation is more prominent and that in the medicinal product pricing segment, **the provisions of the current Ordinance apply**.

It is important to note that **medicinal products comprise only a smaller share of the total cost of healthcare**, so our opinion is that savings should be made in other, less regulated and controlled segments of the healthcare system.

Article 15 of the current Ordinance

Article 15(2) of the current Ordinance reads as follows:

"*The submission, i.e. the proposal, as well as any amendments, shall be delivered to the Fund in an appropriate Application form in electronic and paper form.*"

Further to the aforementioned article, the companies submitting the proposal and amendment documentation to the Fund must make a copy of the documentation on portable memory devices or CDs, and deliver them to the Fund alongside the documentation in paper form.

In practice, due to digital security concerns, many companies strictly limit the use of external memory devices, and CDs are no longer used in many companies. There is also the concern of documentation confidentiality, i.e. the possibility that, after the transfer of the electronic document from the USB device at the Fund, the content may be deleted, and that upon its disposal as waste or for other purposes, the documentation may be inspected by unauthorized persons.

Therefore, we propose that **a digital platform be implemented**, where the companies can submit only the electronic version of the proposal and amendment documentation in a protected virtual storage space in a safe and secure way.

Therefore, we propose **Article 15(2) be amended to read as follows:**

"*The submission, i.e. the proposal, as well as any amendments, shall be delivered to the Fund in electronic form.*"

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