

HALMED – Agency for Medicinal Products and Medical Devices of Croatia

c/o: Prof. Siniša Tomić, PhD, Head

Zagreb, January 10, 2023

Request to Impose a Moratorium on the Annual Calculation of Medicinal Product Prices Due to the Increase in Production Costs and Inflation

Dear Prof. Tomić,

On behalf of the American Chamber of Commerce in Croatia (AmCham), we would hereby like to issue a request to impose a moratorium on the annual calculation of medicinal product prices, which is performed by HALMED pursuant to the Ordinance on the criteria for determining the highest permitted price of medicinal products in wholesale and exceptionally a price higher than the highest permitted price of medicinal products in wholesale and the yearly calculation of the price of medicinal products.

As it stands, pharmaceutical companies, members of AmCham, are under great pressure from increased production costs and record inflation, and it is unsustainable for their business to further lower prices in such conditions through the process of referencing and annual calculation. Due to financial pressures on their business, there is a justified fear that there will be serious disruptions in the supply of medicinal products for patients in the Republic of Croatia.

The Draft Ordinance on the inclusion of medicinal products on the list of the Croatian Health Insurance Fund (HZZO) currently in the consultation process is extremely unfavorable in its current state. In addition, the HZZO is drafting financial contracts for manufacturers of medicinal products for 2023, which, as a rule, always additionally lowers the price. All this, combined with the implementation of the referencing procedure and annual calculation carried out by HALMED, practically prevents manufacturers of medicinal products from dealing with the current crisis.

Other branches of industry are free to form prices and adapt their operations to the market situation, thus ensuring their survival in times of crisis. The prices of almost all products have been on the rise during the past year. The pharmaceutical industry is deprived of this option, considering that the prices of medicinal products are the most regulated prices of any product in the Republic of Croatia. The regulator failed to provide a mechanism for raising the prices of medicinal products due to the enormous increase in production costs. The only mechanisms outlined in the regulations are mechanisms for lowering prices, disregarding the extremely unfavorable economic situation.

This year in June, the Government of the Republic of Croatia adopted a Conclusion calling on the construction sector to address the contracting authorities in public



procurement procedures with a request for payment of the price difference for unperformed public procurement contracts, in order to mitigate the consequences of the global disruption in the markets of building materials and products. The post-earthquake reconstruction process in the City of Zagreb, Zagreb County, and Banovina has been greatly facilitated by this Conclusion, and the Government correctly recognized the consequences of the crisis in the construction sector. Global disruptions in the pharmaceutical manufacturing sector are equally challenging. After the crisis caused by the pandemic, the war in Ukraine had an additional impact on the increase in inflation, which is now as high as 13.5% in Croatia. The costs of raw materials in the production of medicinal products increased from 50 to 160%, transportation costs up to 500%, and energy prices by 250%.

Even much wealthier European nations, such as Germany and Switzerland, have been forced to cope with shortages of medicinal products. Considering the extremely low prices of medicinal products in Croatia, especially generic and biologically similar medicinal products, and taking into account the fact that Croatia is a small market in terms of volume, the production of certain medicinal products for our market will no longer be sustainable. Germany responded to the acute crisis by passing a law prescribing a moratorium on medicinal product prices until 2026. A number of other European countries have also been working on finding a financing model for medicinal products that would take into account the enormous increase in the cost of manufacturing medicinal products, ensuring supply and preventing shortages.

Therefore, we ask that the Agency, in agreement with the Ministry of Health and the Government of the Republic of Croatia, refrain from performing the procedure of referencing and annual calculation of medicinal product prices in 2023.

Thank you in advance.

Kind regards,

A handwritten signature in black ink, appearing to read 'Doko Jelušić'.

Andrea Doko Jelušić
Executive Director

