President Mr. Gitanas Nausėda

Speaker of the Parliament Mrs. Viktorija Čmilytė-Nielsen

Prime Minister Ms. Ingrida Šimonytė

Minister of Health Mr. Arūnas Dulkys

Minister of Economy and Innovation Ms. Aušrinė Armonaitė

Brussels, May 8th, 2023

Subject: Medicines Security of Supply

Dear President Mr. Gitanas Nausėda,

Dear Speaker of the Parliament Mrs. Viktorija Čmilytė-Nielsen

Dear Prime Minister Ms. Ingrida Šimonytė,

Dear Minister of Health Mr. Arūnas Dulkys,

Dear Minister of Economy and Innovation Ms. Aušrinė Armonaitė,

Medicines for Europe represents manufacturers of generic, biosimilar, and value-added medicines, and we work closely with VGA – the Lithuanian Association for Generic, Biosimilar and Value-Added Medicines. Our industry supplies close to 70% of prescription medicines which deliver sustainable access to patients. We are concerned about the Lithuanian Government pharmaceutical policy where unjustified price reduction policies undermine the secure supply of essential medicines.

Our sector operates in a highly regulated market where prices are set by national pricing and reimbursement authorities and are subject to automatic price reduction measures known as reference prices.

Over the last 10 years, regulations on medicines have continued to increase while prices of generic medicines have been reduced by unfavourable policies. This downward spiral reached its peak with the emergence of the COVID-19 pandemic and the war in Ukraine, which put immense pressure on the generic medicines industry, with increasingly stringent regulations, low prices for generic medicines and rapidly rising manufacturing and supply costs.

The situation in Lithuania is one of the most difficult in Europe, as the price for generic medicines is based on an external reference price system using data from EURIPID, which is the database used for price comparisons. Unlike in other countries, the price of a medicine is calculated by taking the average price of the five EU countries

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

with lowest INN (International Non-proprietary Name or Active Pharmaceutical Ingredients) prices from EURIPID. This has led to price freezing for generic medicines in Lithuania since 2019 leading to an unsustainable market, as manufacturing and supply chain prices continue to rise. Manufacturers do not have the opportunity to adjust prices making prices in Lithuania lower than the average prices of other EU countries threatening the sustainability of the market and patients' access to medicines.

We underline that pharmaceutical policy experts strongly oppose the use of external reference pricing (ERP) for off-patent medicines because this leads in effect to a double price reduction. The generic medicine is a fraction of the reference product price in the country which is subject to ERP and then a second ERP related price cut is applied to the already reduced generic medicine price. This is why even EURIPID strongly advises member states not to apply ERP to off-patent medicines.

Given these circumstances, we are deeply concerned about the sustainable security of supply of medicines in Lithuania, which is why a different policy is urgently needed.

As this complexity is already known throughout Europe, countries such as Portugal or Sweden have already initiated a reform of their generic medicine pricing systems to take account of inflation and security of supply. Furthermore, other countries such as Romania, Germany or France are already paving the way for a similar reform.

We therefore call on the Lithuanian government to take action to address this difficult situation by paving the way for sustainable patient access to medicines in Europe. In this regard, we strongly recommend adopting the following principles in accordance with the "EURIPID[1] Guidance Document on External Reference Pricing (ERP)[2]":

1. ERP is an important policy tool that should be used in a mix with other instruments and not as standalone policy tool.
2. ERP should take place on a single product basis rather than by indices.
3. The aim of the national pharmaceutical policy should determine the selection of reference countries.
4. Evidence has shown that ERP is most effective when applied to pharmaceuticals without generic or therapeutic competition.
5. The comparison of prices of medicinal products should be done on the first price (type) in the pharmaceutical distribution chain.
6. Competent authorities should apply clear and transparent procedures to determine which pharmaceuticals are considered as comparable.
7. The pricing formula applied for ERP should reflect the national pricing policy objective.
8. ERP procedures should be performed with the highest possible accuracy and completeness of data sources.
9. If price information is adjusted to national requirements, it should be done in a transparent and sustainable manner.
10. ERP activities need careful planning and should also be considered as a policy tool for price revisions and monitoring.
11. The procedures and price inputs to ERP should be transparent to ensure predictability and effectiveness.

[1] European Pharmaceutical Pricing Database (EURIPID)
[2] euripid (d3erarkwm819zv.cloudfront.net)

12. Policymakers should consider strengthening their cooperation, in particular through the contribution and benefits of existing policies.

Our sector has a moral and a legal obligation to maintain the supply of essential medicines to Europe and we are fully committed to do so. However, our industry cannot operate in an environment combining rampant cost inflation with policies that continuously lower prices. This is why a change in the legislative framework is required to make this task fundamentally possible.

Medicines for Europe is committed to patient access and security of supply of medicines in all European countries. In that light, we would like to kindly request a meeting with you soon to discuss how to improve the security of supply of medicines for Lithuanian patients.

Sincerely,

Adrian van den Hoven
Director General
Medicines for Europe