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# How low pricing of generic and biosimilar drugs relates to their shortage

*The continuous increase in the prices of input raw materials as well as the increase in the cost of production and transport of medicines are in direct contrast to the ongoing price reduction of generic and biosimilar drugs in the Slovak Republic. The consequence is a rising shortage of medicines for patients. Even a short interruption in the availability of medicines can have a major impact on a patient's health and life. Every patient has a right to certain access to the medicines they need. This access is a fundamental aspect of providing quality healthcare.*

All countries strive to ensure a sustainable healthcare system. New measures and innovative rules are adopted in order to maintain and improve the availability of treatments for patients. Slovakia is one of the countries suffering significant medicine shortages. This summer, Adrian van den Hoven, Director General of Medicines for Europe, called on the Slovak government "to align its actions with the EU's pharmaceutical strategy and to prioritise political interventions that will increase the penetration of generic and biosimilar medicines, which will guarantee a long-term sustainable healthcare system and will ensure the supply of medicines for all Slovak patients."

Experts have been consistently proposing solutions to the situation in Slovakia, and a consensus was reached during a meeting of the Expert Forum in Bratislava.

## Solutions for Slovakia

A well-adjusted, stable drug policy system can withstand even unpredictable fluctuations of the external environment. Pushing generic drugs out of the reimbursement system and the subsequent non-systematic extra import of uncategorised drugs will place an extreme burden on public resources for the health system. It will not guarantee continuous availability nor generate resources for reinvestment in the health system. "The aim of our association is to achieve the implementation of conditions that ensure fair and timely access to high-quality treatment with generic and biosimilar medicines for all Slovak patients", says **Terézia Szádočka**, President of the GENAS Association. "Therefore, we consider it necessary to remove the major legislative barriers: harmonise external referencing (comparison of drug prices in the EU) according to the international recommendation of EURIPID, allow the increase of the drug price through referencing and cancel the non-systemic exemption from the fixed surcharge, which prevents the penetration of generic

and biosimilar medicines on the Slovak market."

### Continued price erosion of drugs

Despite several legislative changes, pharmaceutical policy in Slovakia is still notably overregulated. "Slovakia is among the countries with the strictest price regulation of medicines in the EU and the lowest officially determined drug prices. However, the flip side is the unavailability of some medicines on our market," states **Dušan Zachar** from INEKO. "In addition to various global production or distribution outages, unavailability can also be caused by our strict drug pricing system at the level of the average of the three lowest prices in the entire EU, which, unlike many other countries, does not allow price increases, even if the reference prices in other countries have increased. The effect of the lower attractiveness of our relatively small market for drug suppliers is further enhanced by the fact that Slovakia is very often a reference country for determining prices in other EU countries. To change this and contribute to better accessibility, especially for the cheapest medicines for patients, while maintaining fiscal responsibility, let's start considering adjustments to our system of international drug price referencing. One of the initial solutions could be enabling price increases for the cheapest drugs from generic drug groups, if the average price of the medicine is increased in the reference three cheapest countries,' adds Zachar."

"Pharmacists are on the front line of the problem of unavailability of medicines and are confronted with the dissatisfaction of patients, especially those who get their medicines abroad and rightfully question why these are not available in Slovakia, as they are in other EU member countries," says **Miroslava Snopková**, Vice President of the Slovak Chamber of Pharmacists. "Following legislative reforms, we perceive the reality that it is often easier to ensure innovative treatments for patients rather than the treatment of common ailments with ordinary drugs priced in units of tens of euros."

Generic and biosimilar drugs contribute to the development of a competitive environment in the pharmaceutical market. When there is sufficient and fair competition, the market naturally drives down drug prices while ensuring their availability, even without artificial referencing. Numerous European studies indicate that 'Biosimilar drugs contribute to the development of a competitive environment in the pharmaceutical market, thereby aiding the establishment of sustainable healthcare financing. It is therefore necessary to shorten the process of determining prices and reimbursement for biosimilar drugs,' stated **Tomáš Tesař** from the Pharmaceutical Faculty of Comenius University.

### Medicines for Europe's solutions

"Our industry exists to supply generic and biosimilar medicines to patients in Slovakia and the EU. We want to make sure that this supply is as secure as possible, but we face persistent challenges with the pricing policies that are applied to essential medicines. Mechanisms, such as external reference pricing, result in a downward spiral in medicine prices. This really matters, because prices have increased on every component needed to make a medicine, but the price of the medicine itself continues to decrease. For older medicines that have been subjected to unsustainable policies for years, this has resulted in economic unviability. This consequentially leads to market withdrawals and supply insecurity. At Medicines for Europe, we want to see the value of secure supply reflected in pricing policies, by allowing adjustments to price based on inflation, exploring new pricing models, and ending the use of external reference pricing policies for generic and biosimilar medicines that damage healthy competition, driving down prices but ignoring the value of the medicine to patients," states **Maja Graf** from Medicines for Europe.

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