

# Availability of Treatment in Slovakia within the framework of European Legislation - Expert Forum Brings Solutions

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*The international conference Expert Forum, organized by the GENAS association, attracted key healthcare players to Bratislava on Monday, including representatives from the European Commission (DG SANTE), the Permanent Representation of the Slovak Republic to the EU, Medicines for Europe, Slovak and European experts and analysts. The participation of significant stakeholders underscores the importance of the topic of treatment availability and the need for discussion on current challenges and solutions, all in the context of the ongoing revision of EU pharmaceutical legislation.*

"Slovakian patients deserve better and more secure access to medicines. The EU pharmaceutical reform should enable more access to medicines in Slovakia through regulatory incentives, a strong Bolar clause<sup>1</sup> for timely generic and biosimilar competition and incentives for affordable value added medicines innovation in Slovakia. For supply security, a future Critical Medicines Act<sup>2</sup> should encourage solidarity instead of national hoarding (stockpiling), investment in manufacturing resilience in the EU and clear security of supply rewards in pricing and procurement," states Adrian van den Hoven, Director General of Medicines for Europe.

## The Value of Generic Medicines

The sector of generic, biosimilar and added-value medicines has long been ensuring access to medicines, better health outcomes for patients, and the sustainability of the healthcare system. Generic medicines are now 70% of prescribed medicines in Europe while only accounting for less than 30% of pharmaceutical expenditure<sup>3</sup>. Over 90% of the EU critical medicines list are essential, generic medicines.<sup>4</sup>

Expenditures in the top 3 therapeutic areas have decreased from 37% to 8% since 2000 thanks to generic medicines, and future opportunities for small molecules losing patent protection by 2027 are estimated at nearly €10 billion<sup>5</sup>.

<sup>1</sup> [Factsheet-on-Bolar-Exemption-Medicines-for-Europe-April-2022.pdf \(medicinesforeurope.com\)](#)

<sup>2</sup> [Prvý unijný zoznam kritických liekov | ŠÚKL \(sukl.sk\)](#)

<sup>3</sup> [Medicines-for-Europe-Factsheets-on-Removing-barriers-to-equitable-access-for-timely-competition.pdf \(medicinesforeurope.com\)](#)

<sup>4</sup> [Press-release-Launch-Critical-Medicines-Alliance-24-April-2024.pdf \(medicinesforeurope.com\)](#)

<sup>5</sup> <https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/iqvia-true-value-of-generic-medicines-04-24-forweb.pdf>

## Drug Price Erosion

Despite several legislative changes, drug policy in Slovakia remains heavily overregulated. Slovakia is among the countries with the strictest price regulation of generic and biosimilar medicines in the EU and the lowest official drug prices, set at the average of the three lowest prices in the entire EU. Unlike many other countries, Slovakia does not allow price increase even when reference prices in other countries have risen. The lower attractiveness of our relatively small market for drug suppliers is further exacerbated by the fact that Slovakia is often a reference country for price setting in other EU countries.

## Pricing Requires Flexibility

"We need to start examining whether the current strict regulatory framework, especially for some of the cheapest medicines (generics), is having the opposite effect to what was the original intent. Instead of strengthening competition between multiple brands on the market, lowering prices and drug costs, and increasing drug availability for patients, some medicines are leaving the market, leading to shortages, reduced competition, and in the long run, concentration of stronger brands, ultimately resulting in higher prices and costs for society," says Dušan Zachar, Director of INEKO. "Let's analyze and consider whether making our rigid regulatory system more flexible, and allowing price increases for the cheapest generic medicines within international price referencing, if average prices have increased in other reference countries, could be a win-win solution. Currently, this is not possible in our price referencing system," continues Zachar.

"Our priority is to ensure fair and timely access to effective, safe, and high-quality treatment with generic and biosimilar medicines for all Slovak patients," said Terézia Szádocka, President of the GENAS association. "For this reason, it is essential to remove the main legislative barriers: to align external referencing (comparing drug prices in the EU) according to international EURIPID recommendations, to allow price increases through referencing, and to abolish the non-systemic exemption from the fixed co-payment, which limits the penetration of generic and biosimilar medicines on the Slovak market."

Tomáš Tesař from the Faculty of Pharmacy at Comenius University stated that "quality and affordable generics and biosimilars should be the preferred first-line treatment options, and therapeutic guidelines need to be revised when drug patents expire."

Adrian van den Hoven – Director General, Medicines for Europe, Brussels

Terézia Szádocka – President of GENAS Association

Tomáš Tesař – Faculty of Pharmacy, Comenius University

Dušan Zachar – INEKO

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GENAS – The Association for Generic and Biosimilar Medicines is a voluntary non-profit association of legal entities, bringing together manufacturers of generic and biosimilar medicines. The association was founded in 2000. Its goal, in addition to ensuring accessible and sustainable treatment, primarily for chronically ill patients, is to engage in expert discussions with key stakeholders in healthcare about meaningful savings related to the sustainability of the healthcare system. Better availability of generic and biosimilar medicines, alongside efficient financial resource allocation, will bring more health benefits to patients. Last year, generic medicine manufacturers supplied more than 49.1 million packages of medicines to the Slovak market, representing 17.8% of prescribed synthetically produced medicines in financial terms. The share of generic medicines in the treatment of chronically ill patients represents 61.6% of patient days (DOT/days of treatment) in the Slovak prescription drug market.<sup>6</sup> There is an 18-year experience in treating cancer and onco-hematology with biosimilar medicines in Slovakia. The use of biosimilar monoclonal antibodies for treating gastrointestinal diseases and rheumatoid arthritis has been a tradition in Slovakia since 2013. More information can be found at [www.genas.sk](http://www.genas.sk)

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<sup>6</sup> IQVIA – Rx Sell In databáza, 2023