Healthy Future of Slovakia
by Future Slovakia Forum

# PHARMACEUTICAL POLICY AND HTA IN SLOVAKIA IN THE CONTEXT OF SYSTEMIC HEALTHCARE REFORM

Position Statement by Healthy Future of Slovakia, expert group of Future Slovakia Forum for healthcare, September 2025

## Healthcare at a Crossroads

This position statement on pharmaceutical policy and HTA is part of a broader initiative by Future Slovakia Forum (FSF), which is preparing a comprehensive reform of Slovak healthcare. Pharmaceutical policy is not an isolated problem – it directly affects treatment outcomes, accessibility, and financial sustainability.

The FSF expert group (Babela, Polák, Dvorový, Petrík, Smatana, Mišík, and others) uses, among other analytical frameworks, the Healthcare Financial Sustainability Index (HFSI)[1] – an index for Central and Eastern European countries, evaluating four pillars:

1. Current fiscal burden
2. Demographic pressure on the system
3. Capacity and infrastructure
4. Economic viability

According to HFSI, Slovakia ranks among the lagging countries, and maintaining current trends threatens a permanent widening gap with regional leaders.

## 1. Stability and Predictability as Foundation

Stability and predictability are crucial for pharmaceutical policy. These were briefly achieved in August 2022, mainly due to the approval of pharmaceutical policy reform. Since August 2024, new procedures for health technology assessment, developed by the Ministry of Health SR and HTA agency NIHO, have taken effect.

However, the changes themselves are insufficient if they don't improve time-to-patient and value for money.

## 2. New HTA Procedures – Technocratic Tightening

After just one year, new HTA procedures are being proposed again, which technocratically tighten criteria for new medicines and indications entering the Slovak market. This creates another barrier in the legislative chain, complicating access to treatment innovations – without clear connection to better health outcomes or budget stability.

Specific problematic points:

1. Mandatory list price in base-case (§3.2): Ignoring negotiated discounts artificially inflates ICER. Example: a generic with 50% discount appears as full price in the model – unfair comparison to innovations.
2. PSA not mandatory for high uncertainty (§3.4.2): For ATMP/orphan, uncertainty is highest; precisely here probabilistic analysis should be mandatory.
3. Missing process timelines (SLA) and "stop-the-clock": Without time frameworks, shortened reimbursement pathways cannot be expected.

Consequence: Worsened predictability and longer access times to cost-effective therapies → higher long-term costs (complications, hospitalizations, disability).

## 3. The 2022 Reform – What It Brought

The law effective since August 2022 does not require fundamental amendments. The reform enabled access to missing therapeutic alternatives that have long represented standard treatment in neighboring countries. Published drug expenditure data clearly showed this is the most efficiently managed item within total healthcare costs, with a declining budget share.

This indicates the problem is not legislation, but the ability to actually comply with and implement pharmaceutical policy in practice. And not only for new medicines.

We see failure rather in implementation and enforcement of rules (across pharmaceutical policy, not only for new medicines).

## 4. Absence of Vision and Professionalism

A key problem in current pharmaceutical policy is the lack of long-term vision and unprofessional approach by the Ministry of Health SR and NIHO. The primary strategy appears to be delaying entry of new molecules and limiting treatment accessibility – without clear justification.

Postponement and restriction prevail without clear cost-benefit analysis. This contradicts the goal of healthier aging – the core of fiscal sustainability:

- More complications and hospitalizations
- Higher long-term costs for chronic conditions
- Lower productivity
- Risk of re-exports and unavailability

Moreover, proposed solutions open wide possibilities for medicine "re-export."

## 5. Slovakia Lags in Treatment Accessibility – Facts

Slovakia significantly lags behind the rest of the EU and is also an extreme outlier within the CEE region. While the average availability time in Central and Eastern European countries is approximately 356 days (CEE average, EFPIA WAIT 2024), the Slovak average is 797 days – worst along with Poland. This means Slovakia itself significantly drags down the regional

average. Only 27% of new medicines registered by EMA are available (vs. 46% in EU, 40-50% CEE, and 70-80% in developed EU states/UK).

Even when treatment is eventually included in Slovakia, patients in Bratislava access it faster than in peripheral regions. This phenomenon deepens patient distrust and inequality in access to innovations – a challenge that must be addressed not only by the HTA process but also implementation practices of insurers and providers.

EFPIA WAIT 2024 (IQVIA):

- EMA → availability time: 797 days (SR) vs. 578 days (EU average)
- New medicine availability (2020-2023): 27% (SR) vs. 46% (EU)
- Within EU, Slovakia ranks among the slowest countries (only Poland is worse – 804 days)

Eurostat 2024: Consequently, Slovaks live on average 3.1 years shorter than EU residents (78.6 vs. 81.7 years; Eurostat 2024). While this difference has multiple causes, delayed access to innovative treatment – including oncological, cardiovascular, and orphan therapies – is a documented contributing factor.

## 5A. Specific Problem of Small Country with Global Impact

Slovakia as a small country faces a paradox: Decision-making bodies approach medicine evaluation with extremely restrictive criteria that don't consider the country's actual size or market potential.

Consequence for Slovak patients: Pharmaceutical company headquarters won't approve entry to the Slovak market under such conditions because:

- Restrictive HTA evaluations create precedents for other countries
- Low prices negotiated in Slovakia spread to the entire region via external reference pricing (ERP)
- Confidential discounts negotiated in Slovakia should become, according to prepared legislation, the basis for further price reductions for new indications

Paradox: Slovakia's long-term ultra-restrictive policy not only harms its own patients but also negatively affects treatment access in other EU and non-EU countries in parameters such as:

- Pricing (via ERP mechanisms)
- Confidentiality of conditions (prepared legislation requires disclosure of confidential prices)
- Entry conditions (strict HTA criteria create precedents)

## 5B. New Threat: Unprofessional HTA Evaluations with Global Impact

Now it's also unprofessional NIHO evaluations that are internationally available and often have nothing in common with modern and professional approaches to technology assessment in the EU or globally.

Critical connection to prepared legislation: The proposed law amendment introduces so-called "entry discounts" – a mechanism where confidential prices will be significantly reduced based on Slovak HTA evaluations at first inclusion. This means:

1. First inclusion: Slovak HTA determines "fair price" → manufacturer must provide high discount
2. New indications: This discounted price becomes basis for further reductions → cumulative effect
3. Regional impact: Low Slovak price spreads to neighboring countries via ERP

### Result:

- For Slovak patients: Even lower manufacturer motivation to enter market → decline from 27% to potentially <20% availability
- For region: Slovakia becomes "toxic market" for innovative companies
- For system: Apparent short-term savings in pharmaceutical policy translate to higher hospital care costs (late diagnosis, complications, hospitalizations)

### Financial Paradox:

While drug expenditures decline as a healthcare budget share (most efficiently managed item according to published data), total healthcare costs rise due to inefficiencies in other areas and late access to prevention and early treatment.

## 6. Recommendations for NIHO

We propose that NIHO follow universally applicable and modern HTA procedures when evaluating medicines, implemented by an erudite team with demonstrable education, skills, and experience, documented by specific projects and publications.

### A) HTA Methodology

- Implement MCDA as mandatory layer alongside ICER (clinical benefit, severity, unmet need, patient voice, budget impact)
- PSA mandatory for high-uncertainty evaluations (ATMP, orphan, oncology)
- Allow "dual base-case": list price and net-of-rebate (consistently in BIA too)

### B) Process and Transparency

- Timelines & SLA: max. 90 days + stop-the-clock, mandatory annual report of average durations
- Team qualification: demonstrable HTA skills (education, projects, publications)
- Public "HTA Transparency Report": durations, success rates, BIA deviations (±10%), outcome-MEA share, §88 variability between insurers

### C) System Integration

- Clear methodological connection to §88
- RWE minimum dataset (diagnosis, line, baseline, PROMS/PREMS, AEs, continue/stop; quarterly reports)
- Coordination with financing (multi-year budgets; spending review; value-for-money)

## 7. Call for Transparency and Cooperation

We demand that NIHO begin transparently communicating its proposals and conclusions with manufacturers and other relevant stakeholders. Cooperation is essential for optimizing

treatment accessibility conditions. Merely presenting general guidelines won't change the amateur and unprofessional pharmaceutical policy management.

Stakeholder participation is a necessary quality condition. Countries like Estonia or Lithuania show that an open process accelerates innovation introduction without budget threat.

## 8. Impact on Citizens' Lives and Economy

Such an approach, without strategic and holistic thinking, negatively affects patients' lives and has a highly negative impact on the country's economic growth.

Without strategic, data-driven approach, quality of life will worsen, long-term costs will rise, and the convergence gap with EU leaders will deepen.

"Anyone who is healthy today may need standard treatment tomorrow, which may not be available in Slovakia, harming not only the patient and their loved ones, but indirectly the entire society."

## CONCLUSION: Window of Opportunity 2025-2030

We don't demand more bureaucracy – we demand professional processes and faster, fair access to effective therapies. Pharmaceutical policy is an investment in healthier aging, not just a cost.

### Key FSF Messages:

1. The 2022 reform doesn't need "tightening" but quality implementation
2. NIHO should strengthen methodology, capacities, and transparency, not barriers
3. Slovakia must accelerate accessibility while guarding the budget – via MCDA, outcome-MEA, RWE, and SLA
4. Goal: converge to EU standard – for patients and sustainable finances

### KPI – Measurable Goals by 2029

| Indicator | Baseline | Target 2029 | Source |
|---|---|---|---|
| EMA → availability time (days) | 797 | ≤ 530 | EFPIA WAIT |
| Innovation availability (%) | 27% | ≥ 40% | EFPIA WAIT |
| Outcome-MEA share | n/a | ≥ 30% | MH/Insurer report |
| §88 variability between insurers | high | ≤ 20% | MH/Insurer report |
| BIA vs. plan deviation | n/a | ≤ ±10% | MH/NIHO |
| Average HTA duration (days) | n/a | ≤ 180 | NIHO |
| Healthy life years (men) | 56.8 | ≥ 60 | Eurostat |
| HFSI | baseline 2025 | +≥ 20 points by 2030 | HFSI |

## Sources:

- [1] Babela R, Kocis M: Healthcare Financial Sustainability Index 2025. Project HealthCare, 2025. Available online: https://www.projecthealthcare.sk
- EFPIA Patients W.A.I.T. Indicator 2024 (IQVIA)
- Eurostat – Life expectancy/Healthy life years (2024)
- FSF reform framework
- Other publicly available and relevant sources

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