Pharmaceutical expenditure under control

Pharmaceutical spending review

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Executive summary

Pharmaceutical expenditure has been rising rapidly and repeatedly exceeding the budget. Between 2015 and 2019, average public expenditure on pharmaceuticals amounted to EUR 1.06 billion and grew only marginally. However, since 2019 it has increased by EUR 560 million, reaching EUR 1.65 billion in 2024. This significant growth of 51% was not driven by inflation, which does not directly affect medicine prices, nor by increased consumption. The main drivers were reforms adopted in 2018 and 2022 that opened the market to new medicines. These reforms were expected to have a neutral impact on the budget, as they were to be offset by ambitious savings measures. Although the anticipated savings were not realised, the entry of new medicines to the market was not restricted.

More permissive conditions for the listing of medicines for reimbursement have led to repeated budget overruns in breach of the law. According to legislation, when deciding on the reimbursement of medicines from public funds (through the reimbursement listing process, also referred to as categorization), the Ministry of Health must ensure that public resources are sufficient to cover these expenditures. In practice, however, the Ministry has previously adopted decisions that exceeded the available budgetary space. In 2022, actual pharmaceutical expenditure exceeded the budget by EUR 287 million. For 2023, the budget was increased to match the 2022 expenditure level, yet it was again exceeded by EUR 196 million. The objective of this review is to propose measures to adjust the reimbursement listing process so that pharmaceutical expenditure delivers the greatest possible health benefits for patients while remaining within the budget. Due to its limited scope, the review does not address other important challenges in pharmaceutical policy, such as the uptake of generics and biosimilars or the re-export of medicines.

Despite the significant growth in pharmaceutical expenditure, information on the benefits for patients is not available. Data on the benefits of medicines are not collected systematically, even though they are taken into account in reimbursement decisions. As a result, it is not possible to assess how many quality-adjusted life years new medicines were expected to deliver, to what extent they might reduce the number or duration of hospitalisations, or what other benefits for patients were anticipated. Information on expected benefits should also inform decisions regarding any increases in expenditure. In Slovakia, however, the most frequent topic of public debate and the main argument for further increases in spending is the limited availability of new medicines. Nevertheless, international comparisons of availability have significant limitations.

The objective of pharmaceutical policy should be to maximise the benefits of new medicines rather than their number on the market. Not all new medicines entering the market provide additional benefits compared to existing treatments. More than half of the medicines introduced to the German market between 2011 and 2017 did not demonstrate additional benefit compared to previously available therapies (Wieseler et al., 2019). Moreover, new medicines do not automatically generate greater benefits than other health interventions. Public resources are limited; decisions to reimburse medicines from public funds for one group of patients therefore often imply fewer staff, slower replacement of outdated equipment, or fewer services for other patients. According to a study published in The Lancet (Naci et al., 2025), resources spent on medicines in the United Kingdom between 2000 and 2020 would likely have generated greater value if allocated to other areas of healthcare.

A key instrument for sustainably improving access to medicines while maximising health outcomes should be the consistent application of cost-effectiveness assessment. Cost-effectiveness analysis evaluates whether the benefits of new medicines are proportionate to their costs. The greater the benefits, the higher the price a medicine can command while still being considered cost-effective. Cost-effectiveness is used to allocate resources more efficiently so that spending generates the greatest possible health gains for patients. Although cost-effectiveness assessment formally exists in Slovakia, its implementation could be more rigorous.

- **Slovakia is willing to pay more from public funds for the benefits of new medicines than other wealthy countries.** In Slovakia, the cost-effectiveness threshold (the maximum price for one additional quality-adjusted life year used to assess whether a medicine is cost-effective) is set higher than in comparable and even wealthier countries in relative terms (relative to GDP per capita), and even in absolute terms compared with many richer countries. A higher cost-effectiveness threshold subsequently translates into higher medicine prices, as medicines can more easily meet the cost-effectiveness criterion.
- **In the past, some medicines were granted reimbursement even though they would not meet today's cost-effectiveness requirements, and these decisions are rarely revisited.** Past decisions not only tie up resources

that could have been used elsewhere, but also increase the prices of new medicines in the future. The reimbursement level of new medicines is benchmarked against that of existing medicines. The more expensive older medicines are, the more expensive new ones will be.

- **In the past, the Ministry of Health often failed to negotiate the prices recommended by the institute assessing the value of medicines.** The National Institute for Value and Technologies in Healthcare (NIHO) evaluates the benefits and costs of medicines seeking reimbursement from public health insurance. The assessment typically includes a recommendation on the level of discount that the manufacturer should provide in order for the medicine to be considered cost-effective. About half of the medicines assessed by NIHO were eventually granted reimbursement at a higher level than recommended, with deviations reaching several tens of percent in some cases. If the conditions recommended by the institute had been applied to medicines listed between January 2022 and April 2025, public health insurance expenditure could have been about EUR 50 million lower per year. In practice, there may be legitimate reasons to deviate from the recommended price, but such decisions should be explained in a transparent, credible and understandable manner.
- **The standard reimbursement process and cost-effectiveness assessment are weakened by the widespread use of exceptions.** Health insurance companies can approve medicines for individual patients as an exception, even if they are not normally reimbursed from public funds. In Slovakia, almost half of approved exceptions concern medicines that are already reimbursed but used in indications other than those for which they were listed. If some of these uses were previously assessed and determined not to be reimbursed from public funds due to low effectiveness, poor cost-effectiveness or limited resources, such decisions should not be circumvented through the use of exceptions.

Effective budget management requires clear information on the financial impact of new medicines, as well as continuous data on their utilisation. Information on the financial impact of reimbursement listing decisions remains unclear, even though these decisions affect public expenditure by tens of millions of euros each year. Public oversight is further constrained by the confidentiality of information on the benefits and actual prices of medicines. Transparency is additionally reduced by the different ways in which discounts are granted and presented across various Ministry of Health documents. It is often unclear whether the reported impact of medicines takes into account manufacturer discounts, the maximum reimbursement allowed by health insurance companies, or potential savings from substituted treatments. At the same time, decisions in other policy areas with significantly smaller impacts on public finances are required to include transparent and publicly available analyses of their fiscal and budgetary implications.

- **The impact of reimbursed medicines on the budget cannot be tracked based on published materials.** Although a large amount of information on each reimbursement listing decision is publicly available, its usefulness for assessing the impact on public expenditure and public health is very limited. A standardized table published as an annex to each reimbursement listing decision would ensure a comprehensive collection of key information on the impact of each medicine on the public health insurance system.
- **The confidentiality of manufacturer discounts[1] is justified, but it is necessary to reconsider which information can be disclosed and who should have access to it.** Medicine prices differ across countries, and disclosure could weaken a company's negotiating position in countries where it has room to secure higher reimbursement. Manufacturers are therefore more willing to provide discounts when they are kept confidential. However, the confidentiality of sensitive information appears to be overused. Not only unit price data but also information on the benefits of medicines is withheld. In addition, the Ministry of Finance historically did not have access to information on the budgetary impact of new medicines, which complicated the preparation and ongoing monitoring of the budget.

[1] The review uses the term *medicine manufacturer* to refer to the pharmaceutical company authorized to act on behalf of a specific medicine. The more precise term, which is also used in the process of including medicines in the reimbursement list, is the marketing authorisation holder. In some cases, the marketing authorisation holder may be a different company from the one that manufactures the medicine, as the authorisation holder may rely on the manufacturing capacities of another company. For the sake of simplicity and readability, the *term medicine manufacturer* is used throughout the review to refer to the marketing authorisation holder.

- **Paybacks need to be better monitored and enforced.** If the agreed reimbursement limit for a specific medicine is exceeded, the manufacturer should return the excess funds to the health insurance companies. However, the success of enforcing paybacks in Slovakia has historically been very low. Between 2018 and 2022, health insurance companies had claims to paybacks amounting to EUR 53 million. Active steps by the Ministry of Health to settle these claims were not taken until 2025.

Public resources could be freed in Slovakia through the de-listing of medicines that are not reimbursed even in other countries, and through a review of the co-payment system and exemptions, which are currently set in a non-targeted manner. The amount of resources available for new medicines is also influenced by the share of costs borne directly by patients. Patient co-payments for medicines in each country are determined by the scope of reimbursed medicines (which medicines the country can fund from public sources), the co-payment system (whether and how much a patient contributes for a given medicine), and exemptions from co-payments (how the country protects vulnerable population groups).

The review proposes 23 measures that could sustainably contribute to increasing access to effective medicines and improving health outcomes in Slovakia. Adherence to the pharmaceutical budget, as well as better information on the benefits that spending generates for patients, should be ensured through amendments to the law, as well as by defining the objectives of pharmaceutical policy and measurable indicators (measures 1–3). The consistent application of cost-effectiveness assessment (measures 4–9) should create fiscal space for the reimbursement of additional medicines. Improved data collection and transparent publication (measures 10–19) should increase predictability of processes for all stakeholders and enable more efficient management of pharmaceutical expenditure. Finally, creating space for new medicines could also involve shifting part of the costs to households (measures 20–23).

Table 1: Proposed Measures of the Spending Review

No.	Chapter	Name of measure	Description of measure	Savings potential (EUR million)
1	1.1	Ensure the reimbursement listing of medicines is consistent with the budget	Amend Act No. 363/2011 Coll. to specify how the reimbursement listing of medicines must be aligned with the approved budget.	
2	1.2	Define the objectives of pharmaceutical policy and set measurable indicators	The objectives of pharmaceutical policy should be clearly defined and accompanied by measurable indicators. These should be reported regularly, for example within the general government budget documentation. Policy priorities could be set according to unmet medical needs identified by experts in the respective therapeutic areas.	
3	1.2	Make reimbursement of selected medicines conditional on treatment outcomes	For medicines where this is appropriate (e.g. gene or cell therapies) and where treatment outcomes can be clearly measured, reimbursement from public funds should be conditional on the effectiveness of treatment.	
4	2.1	Consider lowering cost-effectiveness thresholds and discount rates*	Consider lowering cost-effectiveness thresholds, for example to the levels applied in neighbouring countries. The discount rate used in pharmacoeconomic assessments could also be reduced.	
5	2.2	Assess the cost-effectiveness of medicines that have not undergone NIHO assessment	All medicines with a significant budget impact (above EUR 1 million) that have not previously undergone cost-effectiveness assessment by NIHO should be assessed. Medicines that are not cost-effective should remain on the reimbursement list only at reimbursement levels that meet cost-effectiveness criteria.	0 – 110
6	2.2	Regularly review the cost-effectiveness of the most expensive medicines	Cost-effectiveness rules change over time. Medicines previously considered cost-effective may no longer meet these criteria after methodological changes. Expensive medicines (e.g. with annual expenditure exceeding EUR 1 million) should therefore be reassessed every five years.	
7	2.3	Renegotiate agreements that deviate from NIHO recommendations	Agreements that deviated from the conditions recommended by NIHO in the past should be renegotiated. The Ministry of Health may request a pharmacoeconomic analysis at any time (Act No. 363/2011 Coll., §93(1)), which can serve as justification for reopening negotiations.	
8	2.3	Publish the extent and justification of deviations from NIHO recommendations	Reimbursement listing decision of medicines should state not only the justification but also the extent of any deviation from the unit	

No.	Chapter	Name of measure	Description of measure	Savings potential (EUR million)
			reimbursement recommended by NIHO or from the reimbursement level consistent with cost-effective treatment.	
9	2.4	Limit reimbursement under the exceptional regime if the manufacturer does not apply for reimbursement listing*	Reimbursement under the exceptional regime should be limited if the manufacturer does not apply for reimbursement listing within a defined period, for example within 24 months of the registration of the medicine or indication.	
10	3.1	Introduce a standardised impact clause	Each reimbursement listing decision should include a standardised impact clause containing key information: unit reimbursement of the medicine (before and after discounts), the estimated number of patients, the treatment being replaced, and the reimbursement limit.	
11	3.1	Update the baseline scenario for medicine expenditure after each reimbursement listing decision	The consistency of a reimbursement listing decision with the budget should be demonstrated through an updated baseline scenario of medicine expenditure over the budget horizon.	
12	3.2	Review access to confidential information*	Reassess which information must remain confidential and determine which institutions should have access to it.	
13	3.2	Expand the categorization committee to include a representative from the Ministry of Finance*	Since the inclusion of medicines in the reimbursement system often has an impact of tens of millions of euros, the Ministry of Finance should be represented in the categorization committee.	
14	3.2	Publish an annual report evaluating the reimbursement listing process	Prepare and publish an annual analytical report evaluating reimbursement listing decisions in the previous year. In addition to budgetary impacts, the report should also include information on the declared benefits of newly listed medicines.	
15	3.3	Publish information on accrued and paid paybacks	Publish annually the amount by which the reimbursement limit for each medicine was exceeded in each relevant period, together with information on paybacks paid. The information should cover both clawbacks and adjustment payments.	
16	3.4	Prefer upfront discounts*	Ensure cost-effectiveness primarily through upfront discounts applied to the price per package. Limit the use of discounts provided through reimbursement limits.	
17	3.5	Ensure the effective functioning of patient registries	Improve estimates of the eligible patient population by automatically collecting treatment data in patient registries.	
18	3.5	Refine indication restrictions for selected medicines	Indication restrictions should be refined for expensive medicines where the estimated number of treated patients has been significantly exceeded or where off-label use may occur. Restrictions should be designed so that health insurance companies can easily verify compliance.	
19	3.5	Introduce horizon scanning	Use horizon scanning to anticipate the entry of new medicines and prepare the system for their potential budgetary impact.	
20	4.1	Reconsider the reimbursement listing of low-cost medicines with limited benefits	De-listing low-cost medicines with limited clinical benefits that patients can reasonably afford to purchase themselves.	0 – 50
21	4.2	Consider introducing a fixed co-payment	Introduce a fixed co-payment per package to make the system more transparent for patients, for example by adopting a system similar to that used in Germany with minimum and maximum co-payment levels.	
22	4.3	Repealing full exemptions from co-payments	Reintroduce quarterly caps on co-payments for vulnerable population groups instead of full exemptions from co-payments.	40
23	4.3	Redefine vulnerable groups	More precisely define the population groups eligible for protective limits on medicine co-payments, taking into account their socio-economic circumstances.	

**The measure is subject to an amendment of Act No. 363/2011 Coll., which, at the time of publication of the expenditure review, is undergoing inter-ministerial consultation.*

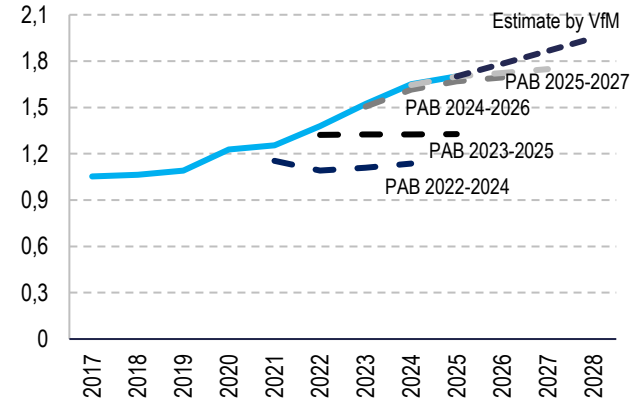
1 Pharmaceutical expenditure is rising and repeatedly exceeding the budget. However, it is not always clear what benefits they deliver

Pharmaceutical expenditure has increased by 51% since 2019, although consumption has remained almost unchanged. Despite this significant growth, information on their benefits for patients is not available due to a lack of data collection. Public discourse still focuses on the issue of medicine availability rather than on their actual benefits. Experience from abroad suggests that limiting the discussion to the introduction of new medicines is insufficient. More than half of the new medicines entering the market in Germany have not demonstrated greater benefits compared to existing treatments. In the United Kingdom, additional healthy life years would likely have been achieved if the country had invested in other areas of healthcare rather than in new medicines.

Rapid growth in pharmaceutical expenditure[2] has repeatedly led to budget overruns in the past. Between 2015 and 2019, expenditure ranged from EUR 1.02 to EUR 1.09 billion. Since 2019, however, spending has increased by 51%, even though the consumption of pharmaceuticals (measured in number of packages) covered by public health insurance (PHI) remained virtually unchanged until 2024. Expenditure has grown faster than GDP, reaching EUR 1.65 billion in 2024. This level of spending exceeds that allocated to culture (including local governments, EUR 1.5 billion) or the environment (EUR 1.3 billion). While pharmaceutical expenditure is not low by international standards, comparability across countries is limited (Appendix 1).

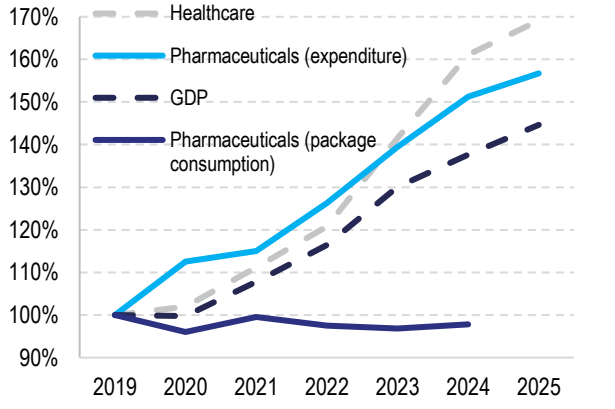
The public health insurance (PHI) budget did not anticipate the growth in pharmaceutical expenditure. In 2022, actual spending on medicines exceeded the budget by EUR 287 million. For 2023, the budget was increased to the 2022 level but was still exceeded by EUR 196 million. As total healthcare expenditure is capped, exceeding the pharmaceutical budget may reduce funds available for other healthcare areas.

Figure 1: The PHI budget for medicines is regularly exceeded, in EUR billion



Source: Public Administration Budget (PAB), processed by VFM

Figure 2: Pharmaceutical expenditure is growing faster than GDP, 2019=100%



Source: processed by VFM

Compared with other areas of healthcare, pharmaceutical policy is supported by a limited set of indicators, which provide insufficient guidance for public debate. Medicines constitute a core component of modern healthcare systems, alongside healthcare personnel and medical infrastructure. They contribute to longer life expectancy, improved quality of life and the prevention of hospitalisations. However, unlike in outpatient or hospital care—where indicators such as the number of visits or the number and length of hospitalisations are widely discussed—publicly available information on the benefits and cost-effectiveness of medicines remains limited. As a result, it is difficult to assess whether increases in pharmaceutical expenditure translate into measurable improvements in population health.

[2] The review primarily focuses on prescription medicines that were at least partially reimbursed from public health insurance. It covers the segment that is budgeted separately and accounts for 91% of public expenditure on medicines. These expenditures do not include medicines used in hospitals, which are reported as part of hospital services and budgeted within inpatient healthcare.

Box 1: Specific characteristics of the pharmaceutical market and the need for regulation

Pharmaceutical policy is one of the most heavily regulated areas of public finances. The pharmaceutical market is characterised by several structural market failures, which the state attempts to address through a range of regulatory and policy instruments. These market characteristics and policy responses differ depending on whether the medicines concerned are new (innovative) products or older medicines that have lost patent protection**.**

For innovative medicines, the pharmaceutical market is primarily characterised by the manufacturer's temporary monopoly resulting from patent protection, as well as by significant information asymmetry.

- **The reimbursement of medicines from public funds is regulated, and manufacturers cannot easily adjust prices to reflect inflation.** The price of innovative medicines is not determined in a competitive market but is the outcome of negotiations between the state and the manufacturer. In many cases, the actual prices of medicines are subject to confidential discounts and agreements, which reduces transparency and complicates international price comparisons. External price referencing therefore relies on official list prices, as actual transaction prices remain confidential. Any increase in the price of a medicine requires negotiation with the authorities.
- **Manufacturers typically possess more information about the effectiveness and risks of a medicine, while the state and the public operate under uncertainty which create information asymmetry.** This is particularly relevant for medicines entering the market on the basis of limited clinical evidence. As a result, negotiated prices and reimbursement conditions should be able to respond to new evidence on the real-world effectiveness of medicines over time.
- **The consumption of medicines is decoupled from their reimbursement**, as physicians decide on prescriptions, while the costs are borne by the public health insurance system.

The state addresses these market failures through a combination of regulatory and policy tools, including the marketing authorisation process, health technology assessment conducted by National Institute for Value and Technologies in Healthcare (NIHO), review activities of health insurance companies, negotiations on price and reimbursement conditions, cost-effectiveness thresholds, reimbursement limits, and risk-sharing arrangements through managed entry agreements (MEA contracts).

For medicines whose patent protection has expired, market dynamics change significantly with the entry of generic and biosimilar products. Their introduction creates a more competitive environment which, together with external price referencing, contributes to a gradual decline in prices. In this respect, the pharmaceutical market differs from most other goods and services, where prices tend to increase over time due to inflation. Nevertheless, inflationary pressures can also affect medicines—particularly older and low-priced products whose prices are already close to production costs.

1.1 Include medicines in the reimbursement listing only in accordance with the budget

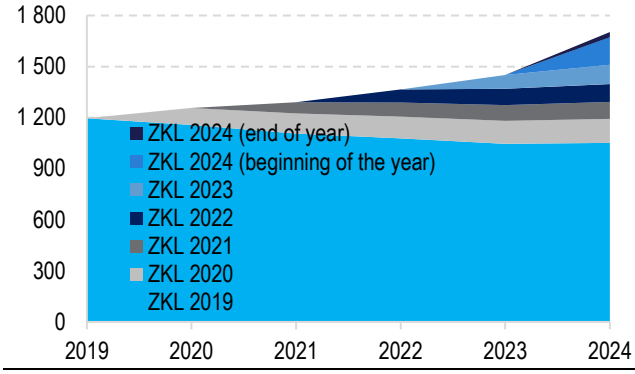
Repeated budget overruns in public health insurance (PHI) are primarily driven by the introduction of new medicines that are directly reimbursed through the categorisation process. Categorisation is the process of determining reimbursement listing. It is the principal instrument used by the Ministry of Health of the Slovak Republic (MoH SR) to expand the availability of medicines in Slovakia (Box 3). Categorisations implemented in 2023 and 2024 have had the most significant financial impact. The introduction of new medicines is gradual, with the full effect on pharmaceutical expenditure typically materialising in the third year after their inclusion.

Expenditure on older medicines declines gradually over time. In contrast to general goods and services, where spending rises even in the absence of volume changes due to inflation, the prices of specific medicines tend to decrease over time[3] (Figure 3; see Appendix 2 for further detail). This price reduction reflects external price referencing against other EU countries

[3] This does not always apply. In particular, for lower-cost medicines, where a large portion of the price reflects production costs, prices can be sensitive to increases in manufacturing expenses—such as wages, energy, or raw materials—which may in turn drive their overall price upward.

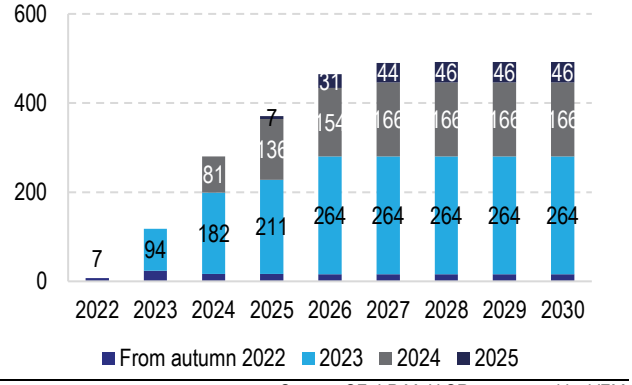
and the progressive entry of lower-cost generics and biosimilars. The recent growth in pharmaceutical expenditure is therefore largely attributable to the accelerated categorisation of new medicines since 2022 (Figure 4).

Figure 3: Development of expenditure on older medicines, in EUR million (ZKL = list of reimbursed medicines at the beginning of the year)



Source: Quarterly reports on pharmaceutical consumption by the NCZI, processed by VfM

Figure 4: Net financial impact of the categorisation of new medicines by year of categorisation, in EUR million



Source: SFaLP MoH SR, processed by VFM

The expenditure associated with the 2022 amendment to the law was to be covered by ambitious savings, which ultimately failed to materialise. The 2018 and 2022 pharmaceutical reforms aimed to improve the availability of new medicines and medicines for rare diseases (Box 2). Savings were to be made by restricting the use of medicines subject to exemption and by the arrival of generic and biosimilar medicines (medicines with the same active ingredient as the original medicines whose patents have expired). Overall, savings of almost EUR 230 million were expected by 2025 compared to 2021, which was to fully cover the expected expenditure on new medicines (EUR 229 million) (NR SR, 2022). Not only did the savings fail to materialise, but categorisation was also greater than expected, and budgeted expenditure between 2022 and 2025 increased by up to EUR 400 million (Appendix 3 discusses the reasons for the increase in expenditure until 2024, for which complete microdata from the NCZI's quarterly reports on medicine consumption for the whole year are available).

Box 2: Intended outcomes of the 2018 and 2022 pharmaceutical reforms

The 2018 amendment to Act No. 363/2011 Coll. was intended to improve the availability of new medicines. In addition to increasing availability, the amendment was intended to make the medicine categorisation process more transparent. Threshold values (maximum reimbursements for the additional benefits of new medicines) were increased, a new categorisation process was defined, and cost-sharing and risk-sharing agreements (MEAs, or *managed entry agreements*) were introduced, which enabled a more systematic distribution of costs between health insurance companies and pharmaceutical manufacturers (marketing authorisation holders) for new and budget-significant medicines.

Despite this, Slovakia lagged behind other countries in terms of medicine availability, and many medicines continued to be reimbursed on an exceptional basis. In response, an amendment was introduced in 2022. The new mechanism was designed to ensure that most medicines reimbursed on an exceptional basis by insurance companies were included in the list of reimbursed medicines (ZKL). In addition to improved availability, the process was intended to ensure more favourable conditions for public funds (cost-effectiveness, which is not evaluated in the case of exceptions) and equal access for patients (exceptions led to unequal access to medicines and health insurance reimbursements). The key changes were the transfer of the conclusion of MEA contracts from insurance companies to the MoH SR, the adjustment of the threshold value calculation, the obligation to submit pharmacoeconomic analyses demonstrating cost-effectiveness, and regular referencing.

The 2022 amendment was costly, but it was expected to deliver significant health benefits. Its actual impact will need to be carefully evaluated. According to an impact study analysing the effects on the PHI, which the MoH SR submitted to parliament, the new medicines were expected to significantly improve the performance of the Slovak healthcare system by 2030 (NR SR, 2022). Mortality preventable by healthcare was expected to fall by 34.3 per 100,000 inhabitants, and life expectancy was expected to increase by up to 2.6 years for men, for example.

Efforts to increase the availability of medicines should be consistent with the budget, and the current legal provisions do not ensure this. The Medicines Act explicitly states that the MoH SR should categorise medicines (and medical devices, special medical supplies and dietary foods) so that public funds are sufficient to cover their costs. Despite this, it has made decisions in the past that were not covered by the budget.

Table 2: Measure from subchapter 1.1

Measure	Description
Ensure the reimbursement listing of medicines is consistent with the budget	Amend Act No. 363/2011 Coll. to specify how the reimbursement listing of medicines must be aligned with the approved budget.

Box 3: Process of classifying medicines as directly reimbursed by the PHI – categorisation

Categorisation is the main tool for listing medicines among those directly reimbursed by public health insurance (PHI). It is a process in which the MoH SR decides on the conditions for reimbursement of medicines (when they can be reimbursed, what the patient's co-payment will be, how much the medicine will cost). If a medicine appears on the list of reimbursemented medicines, doctors can prescribe it under the conditions defined in the list, and insurance companies should reimburse its cost.

The application for inclusion of a medicine on the list of reimbursemented medicines is submitted by the manufacturer (marketing authorisation holder). After independent assessment by NIHO (National Institute for Health and Technology Assessment), the submitted applications are discussed once a month by the categorisation committee, which provides recommendations to the Minister of Health. The commission has 15 members, 6 of whom are nominated by health insurance companies, 3 by professional societies, 4 by the MoH SR, and 1 each by NIHO and a non-profit organisation representing patient organisations. The commission's decisions can be followed on official websites (categorisation portal/NIHO). However, only official prices and reimbursements are often published, on the basis of which it is not possible to estimate the impact on the budget (the discount negotiated between the MoH SR and the manufacturer ranges from 5 to 70%, usually around 30%). The actual impact of a particular medicine on the budget is the result of negotiations between the MoH SR and the manufacturer of the medicine and is not disclosed to the public. The impact of the medicine on the budget is gradual, as patients already undergoing treatment gradually switch to the new medicine (treatment with the previously available medicine (the so-called comparator) is not automatically discontinued). Medicine consumption and the impact on the budget usually stabilise around the third year.

Diagram 1: Process of categorising a new medicine in Slovakia

1. The manufacturer submits an application for inclusion, along with supportin documents, trought the medicines categorization portal.
2. NIHO assessment (130 calendar days for evaluation, but it is usually paused whenever additional information is required, so the process typically takes around 180 days).
3. The Ministry of Health of the Slovak Republic (MoH SR) invites the manufacturer to negotiate a confidential agreement (so-called MEA contract) within 7 days of the publication of the assessment.
4. Proposed MEA agreement.
5. The categorisation committee evaluates the submitted applications (it is not obliged to follow NIHO's opinion).
6. Recommendation to the Minister (minutes of the categorisation committee meeting including the recommendation and individual members' votes with comments).
7. Minister's decision (the Minister is not required to follow the committee's recommendation, although this rarely happens).
8. Inclusion in the List of Categorised Medicines (approximately 2.5 months after the Minister's approval).
9. **The full budgetary impact of a categorised medicine is realized after approximately 2–3 years. Once categorised, its impact on the budget is almost irreversible.**

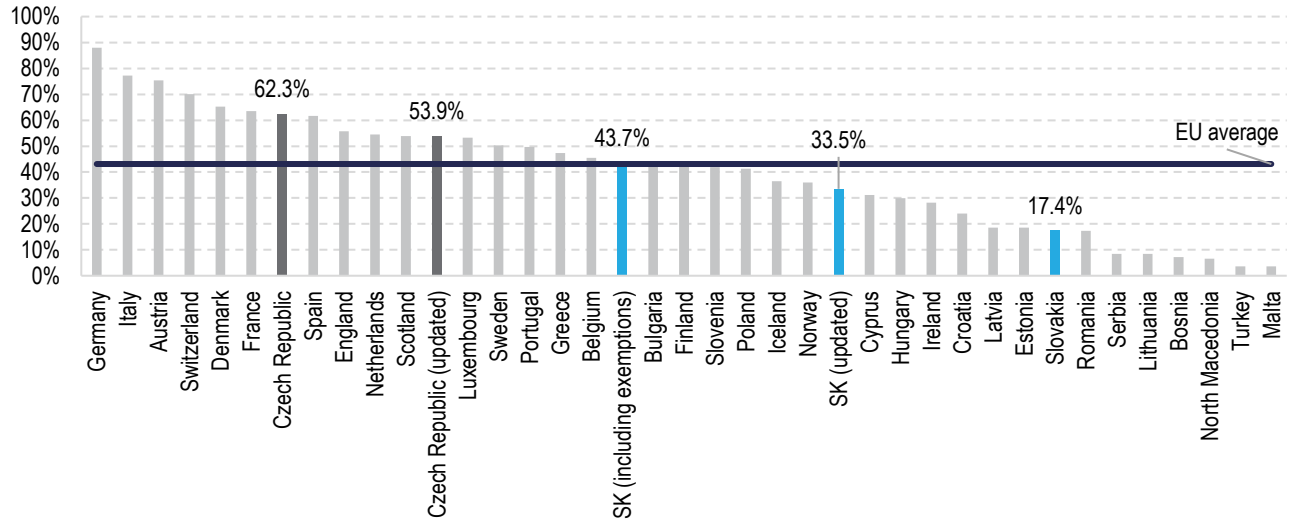
1.2 Systematically monitor the benefits of reimbursed medicines, not only their availability

Public debate in Slovakia continues to emphasise the availability of medicines rather than their benefits, largely because comprehensive information on the clinical and economic value of new medicines is not publicly accessible. Historically, increasing medicine availability has been the primary justification for growth in pharmaceutical expenditure, and it remains a key focus today. However, policy discussions should extend beyond the mere expansion of the medicine list to consider the tangible benefits these medicines provide. While ensuring access to selected medicines is important, international experience indicates that no country is required to finance all existing medicines indiscriminately.

Regular reports on the limited availability of new medicines in Slovakia are based on statistics with certain limitations. IQVIA (2024, 2025) annually evaluates the availability of selected medicines (167 medicines in 2024 and 173 in 2025) that the European Medicines Agency (EMA) approved in a certain period prior to that (for 2024, this is 2019 to 2022, Figure 5). However, the statistics have several limitations that reduce their comparability and informative value:

- for Slovakia, only medicines included in the categorisation list are taken into account, while in other countries (e.g. the Czech Republic) all medicines submitted (including exceptions) are reported
- they do not take into account the accelerated categorisation in Slovakia in 2024 – after the update on medicines included as of February 2025, Slovak availability doubled,
- The statistics do not take into account whether new medicines are better than existing ones.
- Different medicines are monitored each year – in 2025 (Appendix 4), 36 medicines from 2024 were removed and 42 new ones were added[4].
- Delays in the availability of a medicine may also be caused by factors such as the manufacturer's reluctance to enter the market (the manufacturer may prefer to enter larger and richer markets first, or may not have sufficiently adapted production capacities).

Figure 5: Share of new medicines approved by the EMA in 2019-2022 that were available at the beginning of 2024



Note: original – original availability in IQVIA, updated – availability in ZKL in February 2025, including exceptions – including medicines reimbursed on an exceptional basis.

Source: IQVIA, NCZI, MZ SR, VFM

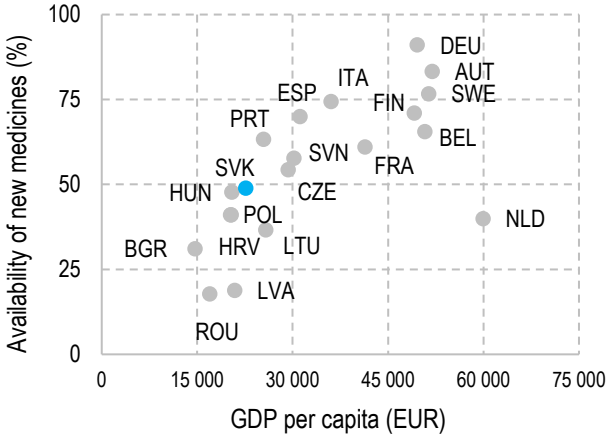
The availability of new medicines and their delayed entry is likely related to the economic development and market size. Delays in the entry of medicines onto the market may be influenced not only by a country's medicine policy[5] , but also

[4] When assessing availability, approximately 170 medicines are monitored, depending on how successful manufacturers are in developing them and obtaining approval from the EMA. In Slovakia, patients have access to over 1,700 medicines through the list of categorized medicines, corresponding to 4,469 products in different forms and strengths.

[5] The Ministry of Health of the Slovak Republic should ensure that deadlines are met and not delay decisions on the inclusion of medicines in the list of medicines reimbursed by the PHI (categorisation list). Adherence to deadlines shortens the time it takes for new medicines to arrive and at the same time reduces pressure on the budget through the possible financing of the use of medicines through exemptions, which are decided by the insurance company until the Ministry of Health agrees with the manufacturer on cost-effective conditions.

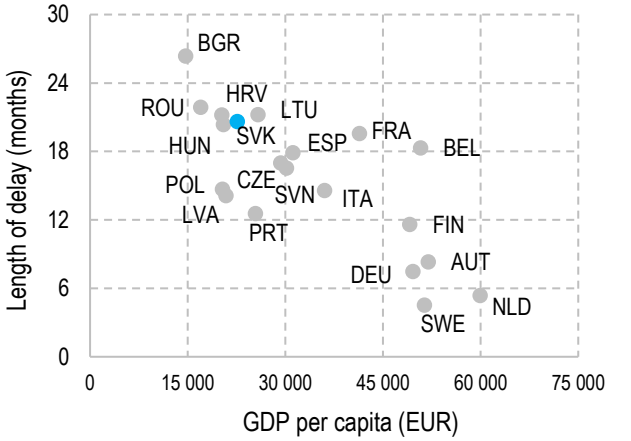
by the reluctance of medicine manufacturers to enter small markets (OECD, 2024). As with other goods and services, medcine manufacturers seek to establish themselves as soon as possible in larger and richer markets, which generate the highest revenues. Richer countries can afford to finance a larger number of medicines and are therefore more attractive to manufacturers. Smaller markets become saturated later, partly because production capacity is ramped up gradually.

Figure 6: Availability of new medicines from 2015 to 2017 (in %) and GDP per capita (in EUR)



Source: Bussgen and Stargardt (2022), Eurostat, VFM

Figure 7: Average delay in the arrival of new medicines (in months) and GDP per capita (in EUR)



Source: Bussgen and Stargardt (2022), Eurostat, VFM

Not all new medicines entering the market deliver substantial therapeutic benefits compared with existing treatments. Globally, pharmaceutical regulation is evolving to accelerate the development and approval of new medicines. However, the literature (Davis et al., 2017; Brinkhuis et al., 2024) indicates that only a subset of these medicines demonstrates meaningful advantages over current therapies. According to the German medicine agency IQWiG[6] (Wieseler et al., 2019), more than half of the medicines introduced to the German market between 2011 and 2017 (125 out of 216) offered no additional benefit compared with treatments already available.[7]

New medicines do not automatically provide greater health benefits than other healthcare interventions. Public resources are limited, and the decision to reimburse medicines for one patient group often reduces services (fewer staff, slower renewal of equipment, fewer examinations) for other patients. New medicines that introduced between 2000 and 2020 generated 3.75 million additional healthy years of life (QALYs), while the same resources allocated to existing services could have yielded 5 million QALYs (Naci et al., 2025).

Figure 8: Additional benefits of new medicines entering the German market, 2011–2017

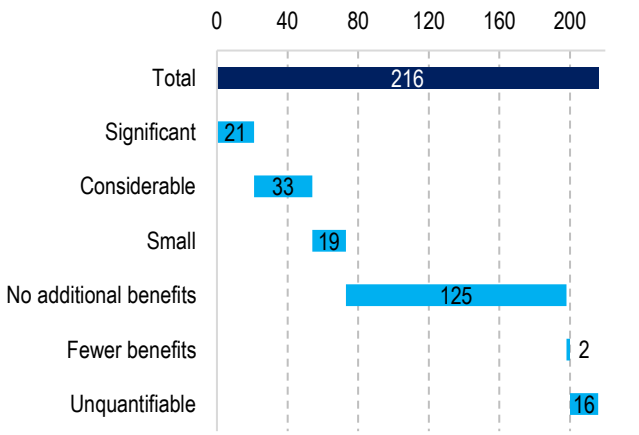
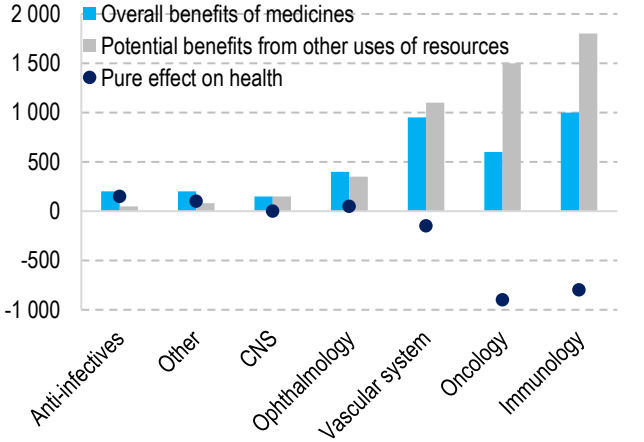


Figure 9: Health benefits of new medicines in the United Kingdom, 2000–2020, in thousands of QALYs



[6] The Institute for Quality and Efficiency in Health Care (IQWiG) is a German HTA agency which, like the Slovak NIHO, evaluates health technologies and their cost-effectiveness (HTA – Health Technology Assessment).

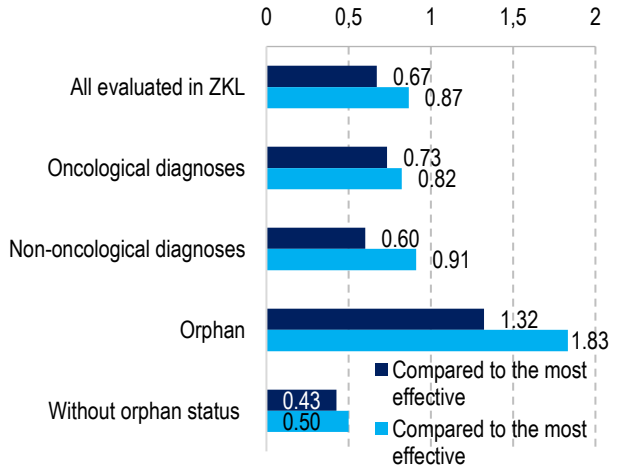
[7] New medicines have virtually free access to the German market. The German HTA agency evaluates them on an ongoing basis. If no agreement on cost-effective reimbursement is reached with the manufacturers, the medicines will no longer be financed from public funds. In the Slovak context, they would be removed from the list of reimbursed medicines.

Source: Wieseler et al. (2019), processed by VFM

Source: Naci et al., 2025, processed by VFM

In Slovakia, new medicines assessed by NIHO up to October 2025 are expected to provide, on average, less than one year of life in good health. Multiple medicines may be available for a single diagnosis, serving as comparators for the costs and benefits of new medicines. Assessments by NIHO (Figures 10 and 11) assess medicines either against the most effective treatments in the system or the most cost-effective options. Orphan drugs for rare diseases generally provide the highest average benefit but are also the most expensive, with prices reaching up to 10 times GDP per capita (228,105 euros per additional QALY) (see Chapter 2 for further cost-effectiveness analysis).

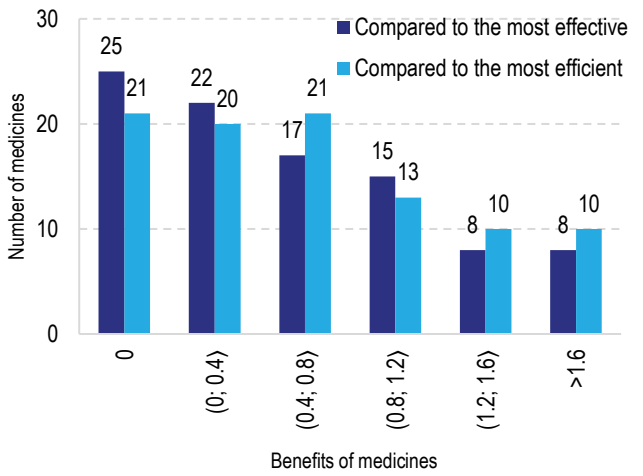
Figure 10: Benefits (change in QALY) of medicines evaluated by NIHO, which were categorised



Note: List of reimbursemented medicines (ZKL)

Source: NIHO, processed by VFM

Figure 11: Distribution of benefits (change in QALY) of NIHO-evaluated medicines that were categorised



Source: NIHO, processed by VFM

Box 4: Reimbursement of certain high-cost medicines should be linked to treatment outcomes

Costly innovative treatments, including cell and gene therapies, are increasingly being introduced into healthcare systems. While they offer the potential for long-term or even permanent effects, they are associated with substantial uncertainty, primarily because long-term outcomes cannot be fully captured in relatively short clinical trials and must therefore be estimated (Dabbous et al., 2020).

To mitigate risks to public finances, risk-sharing agreements can link reimbursement from public funds to treatment outcomes. Given the high costs and uncertain outcome, it may be disadvantageous for the state to pay for treatment with a given medicine for all patients, even if the manufacturer offers a discount. Risk-sharing agreements are not suitable for all medicines, as it is easy for the potential savings to be outweighed by the administrative costs (Dabbous et al., 2020). Their use is therefore particularly suitable for medicines (Reyes-Travé et al., 2021)

- which are used by a small number of patients,
- for which measurable outcomes can be defined and monitored (e.g. patient survival, growth by a certain number of centimetres, etc.),
- with a high impact on the budget.

A similar form of risk-sharing is already used in Slovakia. For one of the more expensive medicines,[8] which is covered by public funds in Slovakia, the pharmaceutical manufacturer is obliged to refund the money if the patient dies within a certain period of time after taking the medicine.

[8] It is not possible to disclose the name of the medicine, as the clause is marked as confidential in the contract.

Table 3: Measure from subchapter 1.2

Measure	Description
Define the objectives of pharmaceutical policy and set measurable indicators	The objectives of pharmaceutical policy should be clearly defined and accompanied by measurable indicators. These should be reported regularly, for example within the general government budget documentation. Policy priorities could be set according to unmet medical needs identified by experts in the respective therapeutic areas.
Make reimbursement of selected medicines conditional on treatment outcomes	For medicines where this is appropriate (e.g. gene or cell therapies) and where treatment outcomes can be clearly measured, reimbursement from public funds should be conditional on the effectiveness of treatment.

2 Stronger adherence to cost-effectiveness would create fiscal space for reimbursing more medicines

Adherence to cost-effectiveness principles should ensure that pharmaceutical expenditure delivers the greatest possible health gains for patients. However, several factors weaken cost-effectiveness in Slovakia and may lead to higher reimbursements. Slovakia pays more for the declared benefits of medicines than some wealthier EU countries, both in relative terms (to GDP) and in absolute terms. Reimbursements may also be driven up by expensive medicines that entered the system in the past without necessarily meeting cost-effectiveness criteria. These medicines now serve as comparators in the assessment of new medicines, thereby increasing the reimbursement granted to them as well. Given the relatively high threshold values and the use of costly comparators, it is relatively easy for a new medicine to meet the cost-effectiveness requirement. Despite this, reimbursements that the NIHO considered cost-effective were often not negotiated by the MoH in the past. As a result, the health system frequently pays even more for new medicines than would correspond to their (already relatively high) cost-effective price.

Ensuring cost-effectiveness maximizes health benefits for patients. In Slovakia, NIHO (Box 5)[9] evaluates whether the costs of new medicines correspond to their expected benefits. Using public funds for cost-ineffective medicines may constrain other healthcare resources, affecting hospital quality, staffing, or waiting times.

The cost-effectiveness threshold defines the maximum amount a country (society) is willing or able to pay for a patient to gain one additional year of healthy life, relative to treatments already available in the system. It does not define the price of the medicine, but rather the maximum reimbursement per unit of its benefit. It is compared with the ratio between the additional costs and benefits of the medicine. For common diseases providing more than 0.33 QALYs, the threshold in Slovakia is three times GDP per capita—EUR 68,400 per QALY in 2025 (Table 4). A medicine yielding 1 additional QALY may therefore have costs up to EUR 68,400 higher than existing reimbursed treatments.

In Slovakia, cost-effectiveness thresholds depend on the type of disease, the type of medicine, and the relative benefit of the medicine, as in other countries. It is also common internationally for the willingness to pay for new medicines to vary according to factors such as expected benefit or disease rarity. In Slovakia, thresholds are determined by the expected benefit of the medicine and whether it is for a common or rare disease (orphan) or represents an innovative treatment. The lowest threshold, twice GDP per capita, is applied only to a small number of medicines with very low benefits, and the same applies to three times GDP per capita applies to orphan and innovative medicines.

Table 4: Conditions for determining the threshold value for a new medicine in Slovakia in 2025

Change in QALY	Common disease (multiple of GDP/person)	Rare disease or innovative treatment (multiple of GDP/person)	Common disease (euros/QALY)	Rare disease or innovative treatment (euros/QALY)
0 to 0.33	2	3	45,621	68,432
0.33 to 0.5	3	5	68,432	114,052
0.5 and above	3	10	68,432	228,105

Note: GDP per capita was calculated as the ratio of GDP in 2023 to the number of people as of 1 January 2023. *Source: Decree No. 298/2022 Coll., Eurostat, VFM*

In the proposed amendment to the Medicines Act, the MoH SR proposed lowering the threshold values.

Box 5: How to measure the benefit and effectiveness of a medicine

The benefit of a medicine is defined as the change in QALYs (quality-adjusted life years) compared with its comparator. If a new medicine provides a patient with a total of 6 QALYs, while the comparator (an existing medicine in the system) provides 5.3 QALYs, its additional benefit is 0.7 QALYs. The QALY indicator has two dimensions: survival time and quality of life. If the medicine prolongs a patient's life by one year, but their quality of life is only 30% of full health, the

[9] Act No. 363/2011 Z. z. states in § 2 that cost-effectiveness is the ratio between the total costs incurred by public health insurance when using a medicine, medical device or dietary food and the total benefits of using this medical intervention; when comparing several medical interventions, the ratio between the difference in the total costs incurred by public health insurance for these interventions and the difference in the total benefits of using these medical interventions.

benefit is 0.3 QALY. It is also possible that a medicine does not extend survival but significantly improves quality of life, for example by enabling the patient to return to work. QALY captures both of these effects.

When evaluating the cost-effectiveness of a medicine, the ratio of its additional costs to additional benefits is calculated, indicating the cost of achieving its incremental effect. If treating one patient with a new medicine costs EUR 285,000, while treatment with the comparator costs EUR 250,000, the additional costs amount to EUR 35,000. The cost per additional QALY would therefore be EUR 50,000, as the new medicine provides 0.7 QALYs more than the comparator (EUR 35,000/0.7 QALYs).

$$\frac{Cost\ of\ medicine\ B - Cost\ of\ medicine\ A}{Benefits\ of\ medicine\ B - Benefits\ of\ medicine\ A} = \frac{285\,000\ EUR - 250\,000\ EUR}{6\ QALY - 5{,}3\ QALY} = 50\,000\ EUR/QALY$$

A cost-effective medicine is one whose ratio of incremental costs to benefits falls below the threshold value. If the medicine is for a common disease and its benefit exceeds 0.33 QALY, the Slovak Ministry of Health decree sets the threshold at three times GDP per capita for 2023, i.e., EUR 68,432 per QALY (Table 4). A cost of EUR 50,000 per additional QALY would be considered cost-effective, and the medicine could be categorised.

2.1 Consider lowering the cost-effectiveness threshold values

Cost-effectiveness thresholds for medicines in Slovakia are likely higher compared with those in other countries. In wealthier countries such as Norway and the Netherlands, the thresholds are lower for all types of medicines (for both common and rare diseases), both in absolute terms and as a multiple of GDP. The United Kingdom has a higher threshold in absolute terms for innovative medicines (but not as a multiple of GDP per capita). Compared with Slovakia, this threshold in the UK applies to only a small proportion of medicines.

Table 5: Conditions for determining the cost-effectiveness threshold of a new medicine in Slovakia in 2025[1]

Country	Threshold value (specified)	Threshold value (in EUR)	Multiple of GDP per capita
Slovakia (before 2022)	28 to 41 times the average wage	40,040–58,630	1.76–2.57
Slovakia (since 2022)	**2 to 10 times the GDP per capita[1]**	**45,621 – 228,105**	**2 to 10**
Hungary	1 to 10 times GDP per capita[1]	21,515 – 215,145	1 to 10
Poland	3 times GDP per capita[1]	61,376	3
Czech	1.2 million CZK[1]	47,770	1.63
Latvia	3 times, EUR 300,000[1]	62,728 – 300,000	3 to 14.35
Netherlands	EUR 20,000 and EUR 80,000[1]	20,000 – 80,000	0.33 to 1.33
Norway	NOK 275,000 to 825,000	23,648 – 70,943	0.30 to 0.91
United Kingdom	GBP 20,000 to 300,000[1]	23,623 – 354,350	0.52 to 7.77

[1] Notes to the table are provided in Appendix 5. *Source: NIHO, VFM*

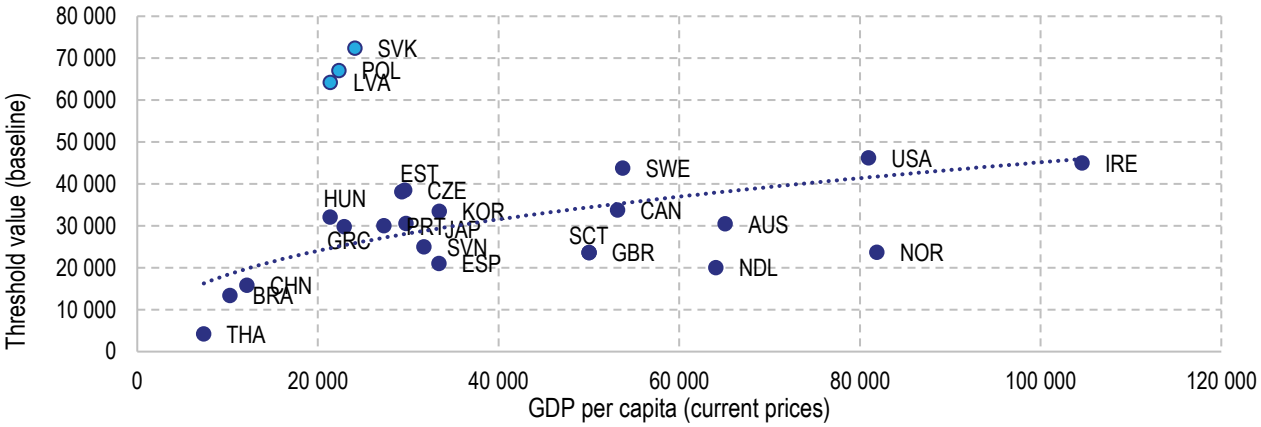
Slovakia's cost-effectiveness thresholds exceed the level consistent with the country's economic status. Threshold levels generally reflect a country's wealth. According to a study by the Austrian HTA agency (Strohmaier and Zechmeister-Koss, 2024), wealthier countries typically have higher absolute thresholds. Slovakia, Poland, and Latvia deviate from this pattern, with commonly used thresholds significantly higher than those in countries with similar GDP per capita. The MoH SR has proposed reducing thresholds in its draft amendment to the Medicines Act; however, the new thresholds would still remain among the highest in Europe.

Moreover, the cost-effectiveness threshold in Slovakia has increased over time, contributing to higher prices for new medicines. After linking the threshold to GDP in 2022, three times GDP per capita corresponded to EUR 50,604. By 2026, it had risen by 42% to EUR 72,043. In contrast, in developed countries such as the Netherlands, Norway, and the United Kingdom, thresholds are fixed. Increases in these countries do not occur automatically but are subject to public debate (Box 6).

A higher threshold may incentivize pharmaceutical manufacturers to enter the market, as it allows them to secure more favourable reimbursement conditions. However, the effectiveness of this approach is uncertain. It is unclear how many medicines would actually not enter the market at lower thresholds, for example at the levels used in neighbouring

countries. On the other hand, higher thresholds influence the expectations of manufacturers during negotiations, potentially increasing unit reimbursement even for medicines for which manufacturers would have accepted lower reimbursement

Figure 12: Baseline threshold values and GDP per capita at current prices in 2024



Note: The Figure shows the basic thresholds, i.e. those used for medicines with relatively common benefits. In Slovakia, this is three times the GDP, as twice the GDP is only used for medicines with very small benefits.

Source: VFM according to Strohmaier and Zechmeister-Koss (2024)

Box 6: The UK has lower cost-effectiveness thresholds than Slovakia, but they might still be relatively high

Although the United Kingdom's cost-effectiveness thresholds are lower than Slovakia's, they are still likely high relative to the potential benefits of alternative healthcare investments. A recent study published in The Lancet (Naci et al., 2025v) indicates that the most commonly used threshold in the UK, approximately EUR 23,600–EUR 35,400, may be high compared with other areas of healthcare. The authors evaluated 276 medicines recommended for categorisation by the UK's NICE between 2000 and 2020. These new medicines added roughly 3.75 million additional quality-adjusted life years (QALYs) for nearly 20 million patients at a cost of more than £75 billion. If the same funds had been allocated to other healthcare services, such as outpatient or institutional care, the system could have gained an additional 1.25 million QALYs. The empirically derived threshold would correspond to £15,000 (EUR 17,700).

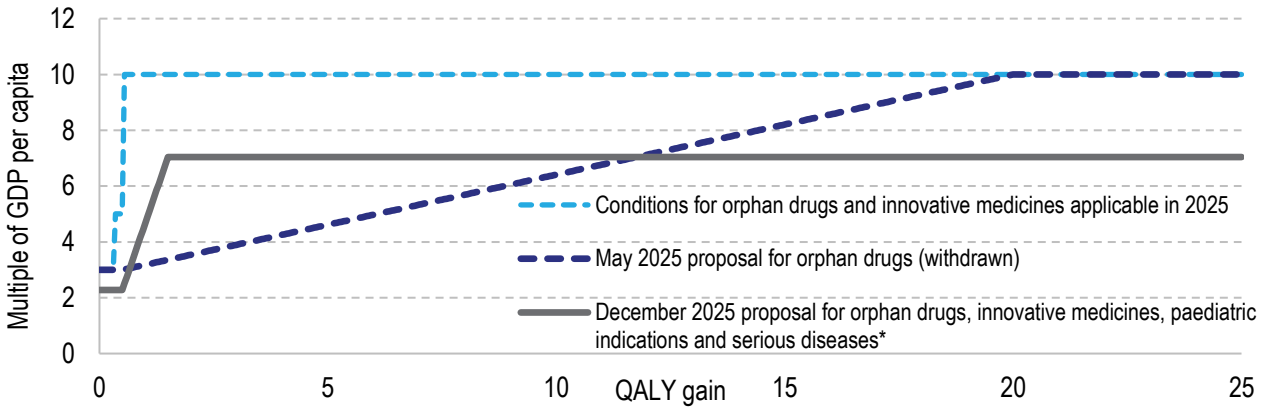
However, the UK's National Institute for Health and Care Excellence (NICE) recognises that the pharmaceutical industry is substantially more innovative, which may justify higher payments. NICE is therefore considering raising thresholds to £25,000–£35,000 (EUR 29,500–EUR 41,300). Even these proposed thresholds remain lower than Slovakia's lowest threshold (EUR 45,600, applied only to medicines with minimal benefit) and the more frequently used EUR 68,400 threshold.

Medicines are important, but other, often less expensive interventions can also provide significant benefits and may be underutilised in Slovakia. For serious and life-threatening diseases, it is critical to follow international recommendations, for example regarding the timing of surgery and follow-up treatment. In oncology, evidence shows that patient outcomes improve when care is managed by well-functioning multidisciplinary teams of doctors (Pangarsa et al., 2023). Such teams are gradually being established in Slovakia, but monitoring their functioning is more complex than monitoring medication use. In addition to appropriately tailored treatment, encouraging patients to exercise regularly or engage in other forms of physical activity can be highly beneficial (NCI, 2020). Medication remains important, but its reimbursement should reflect its actual benefits.

To encourage the introduction of medicines with greater benefits, the MoH SR has previously proposed slowing the growth of the cost-effectiveness threshold in line with the increasing benefits of medicines. Currently, the threshold for orphan drugs and innovative treatments also rises with their benefits, but it is rapidly approaching 10 times GDP per capita. The highest threshold is therefore applied regardless of whether a medicine provides 0.5 or 20 QALYs, meaning treatment yielding 0.5 QALYs may cost up to EUR 114,000, while treatment yielding 20 QALYs may cost EUR 4.56 million. In May 2025, the Ministry submitted a proposal to modify the inter-ministerial consultation process, aiming to lower thresholds and better link GDP multiples to benefits for orphan drugs. Under this approach, thresholds would increase linearly with additional benefits (for example, 3.2 times GDP per capita for 1 QALY, 4.6 times for 5 QALYs). Following opposition from part of the

public, the Ministry withdrew the proposal and, as part of the planned amendment to the Medicines Act, prepared a new proposal that also covers innovative treatments, paediatric indications, and rare diseases.

Figure 13: Entry conditions for medicines for rare diseases and innovative treatments valid in 2025 and proposals by the MoH SR



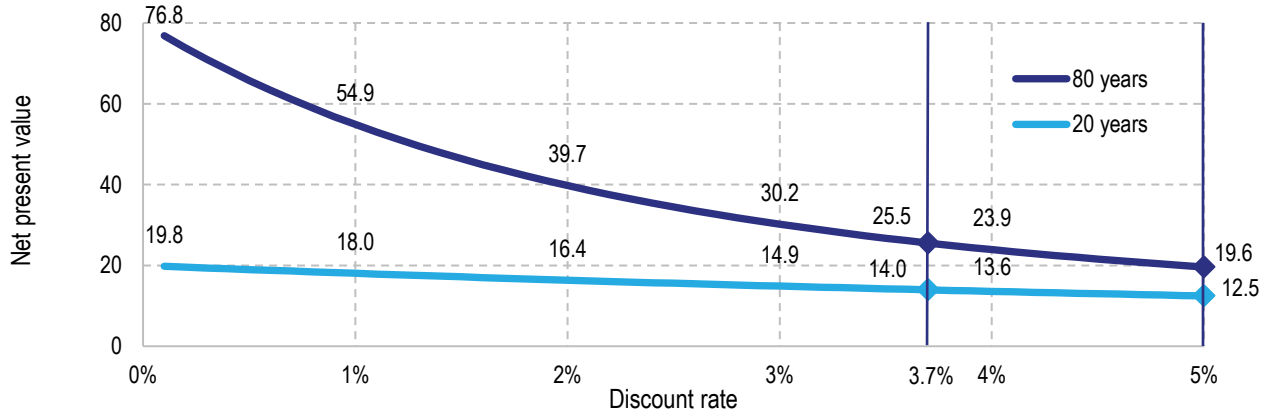
**The December 2025 proposal no longer uses multiples of GDP, but values in euros, which have been converted in the Figure to multiples of GDP from 2023.*

Source: VFM according to Decree 298/2022 Z. z., draft Decree 298/2022 Z. z and the prepared amendment to 363/2011 Z. z.

The cost-effectiveness of a medicine is determined not only by the threshold value but also by the discount rate. If a medicine has effects lasting more than one year, its total benefits and costs are calculated as the net present value by discounting future benefits and costs. The rate at which the value of future cash flows is reduced is called the discount rate. NIHO applies a 5% discount rate in its assessments[10], similar to other institutions evaluating infrastructure projects, such as motorway or hospital construction. For example, an exceptional medicine that saves the lives of newborns and enables them to live to age 80 in full health would yield only 19.6 QALYs at a 5% discount rate, compared with 30.2 QALYs at a 3% rate (Figure 14).

A higher discount rate may disadvantage medicines with long-term effects. Expressing medicine benefits in present value is particularly important when comparing different medicines. Valuing immediate benefits more than future benefits is a generally accepted principle, reinforced in the case of medicines by the uncertainty in estimating long-term effects. However, if the discount rate is set too high, it can hinder the introduction of medicines that have the potential to significantly extend patient survival. For instance, if a new medicine prolongs life by 80 years compared with a comparator that extends life by 20 years, the difference in present value at a 5% discount rate would be only 7.1 QALYs. If the rate were reduced to 3.7% (as proposed by the MoH SR in May 2025, alongside an adjustment of threshold values), the benefit of the new medicine would increase to 11.6 QALYs. This represents a substantial difference in terms of cost-effectiveness assessment[11].

Figure 14: Relationship between the discount rate and the net present value of a life-extending medicine (80 vs. 20 years)



Source: processed by VFM

[10] In the Czech Republic, SÚKL uses 3% and in England, NICE uses 3.5%.

[11] If the price of a new medicine were EUR 1 million higher than the price of the comparator, its relative price would be EUR 140,000 at a 5% rate and EUR 86,000 at a 3.7% rate. The relative price (ICUR) is the ratio of additional costs to additional benefits of the medicine and is compared to the threshold price in the cost-effectiveness assessment.

Table 6: Measure from subchapter 2.1	
Measure	**Description**
Consider lowering cost-effectiveness thresholds and discount rates	Consider lowering cost-effectiveness thresholds, for example to the levels applied in neighbouring countries. The discount rate used in pharmacoeconomic assessments could also be reduced.

2.2 Reassess expensive comparators from the past that inflate the reimbursement of new medicines

Between 2018 and 2022, medicines with annual expenditures in the tens of millions of euros could be granted reimbursement without demonstrating cost-effectiveness. In 2018, the definition of orphan medicines was expanded, and until 2022, such medicines were not required to demonstrate cost-effectiveness when entering the market. More favourable conditions for orphan medicine entry are important and commonly applied in other countries. However, the rules in place until 2022 were very permissive. The definition was overly broad, based on the incidence of the indication (Box 8), and no threshold was applied to medicines defined in this way. This allowed several medicines to enter the market without ever demonstrating cost-effectiveness.[12]

Table 7: Legislative changes affecting the entry of medicines for rare diseases

	2017	2018 2019 20 2021	2022 2023 2024 2025
Definition of orphans	Prevalence lower than 1:100,000	Indication lower than 1:50,000	Medicine classified as orphan by the EMA[13]
Cost-effectiveness assessment	No		Yes
Threshold value – orphan	No threshold		172,816 – 228,105 euros
Threshold value – common disease	EUR 40,040 – EUR 58,630		51,845 – 68,431 euros

Source: processed by VFM

Cost-ineffective medicines approved in the past not only tie up public resources but also increase the cost of future medicines. Cost-effectiveness is determined by the costs and benefits of existing treatments (example in Box 7). The higher the cost of older medicines (comparators), the higher the cost of new medicines will be. In the past, NIHO (2025) highlighted this in one of its assessments. The discount required from the manufacturer to achieve cost-effectiveness was lower than it would have been if the pair of comparators had been categorised with the NIHO-recommended reimbursement.

Box 7: Illustrative example of how reimbursing cost-ineffective medicines affects the cost of future medicines

Medicine A is a treatment for a rare disease (orphan) and was the first to enter the Slovak market. Since the diagnosis had previously been treated only with symptomatic therapy, it was evaluated against that standard. Its benefit is 1 QALY.

In Example 1, Medicine A did not have to meet any cost-effectiveness requirements and was categorised at a cost of EUR 300,000 per patient treated. The medicine then serves as a comparator for assessing the cost-effectiveness of other medicines. Medicine B, which provides an additional 0.5 QALY, seeks entry at a cost of EUR 400,000. Since the ratio of its additional costs to additional benefits (EUR 200,000) is below the orphan threshold (EUR 228,000), Medicine B is considered cost-effective. Both medicines subsequently serve as comparators for Medicine C, which is cost-effective at a treatment cost of EUR 700,000.

If Medicine A had been required to meet the cost-effectiveness condition upon entry (Example 2), it would have been categorised at a maximum cost of EUR 228,000 (the threshold level). In this scenario, Medicine B, with a cost of EUR 400,000, would not meet the cost-effectiveness condition because the ratio of its additional costs to benefits exceeds the threshold based on the new price of Medicine A. Medicine B would therefore need to offer a discount, reducing its price from EUR 400,000 to at least EUR 342,000. Similarly, Medicine C would also be required to offer a discount.

[12] Some might not even get the MEA designation of a medicine for a rare disease today.

[13] The EMA grants orphan designation to medicines. These must meet three conditions: 1. they are intended for the treatment, prevention or diagnosis of a life-threatening or chronically debilitating disease; 2. the prevalence of the disease in the EU is no more than 1:50,000, or it is unlikely that the costs of developing the medicine will be recovered by the company after it is placed on the market; 3. there is no therapeutic alternative, or the medicine has a significant therapeutic advantage over existing treatments.

Table 8: Cost-effectiveness of new medicines depending on the price of their comparator

Example 1 – Medicine A did not have to meet the cost-effectiveness condition, which makes medicines B and C more expensive		
	QALY	Costs (in EUR)
Medicine A	1	300,000
Medicine B	1.5	400,000
Additional benefits and costs compared to medicine A	0.5	100,000
Proportion of additional costs and benefits		200,000
Threshold		228,000
Medicine C	3	700,000
Additional benefits and costs compared to medicine B	1.5	300,000
Proportion of additional costs and benefits		200,000
Threshold		228,000

Example 2 – Medicine A had to meet the cost-effectiveness condition, which also pushes down the prices of medicines B and C		
	QALY	Costs (in EUR)
Medicine A	1	228,000
Medicine B	1.5	400,000
Additional benefits and costs compared to medicine A	0.5	172,000
Proportion of additional costs and benefits		344,000
Threshold		228,000
Medicine B - after discount	1.5	342,000
Change	0.5	114,000
Share of additional costs and benefits		228,000
Threshold		228,000
Medicine C	3	700,000
Additional benefits and costs compared to medicine B	1.5	358,000
Proportion of additional costs and benefits		238,667
Threshold		228,000

Reimbursements for medicines that no longer meet cost-effectiveness criteria should be reviewed. Health insurance reimbursement should be limited to the cost-effective amount. If the manufacturer does not agree, the remaining cost may be borne by the patient. Reimbursement of cost-ineffective medicines ties up resources that could be used for more effective medicines or other areas of healthcare, while also increasing the cost of new medicines. Following the 2022 amendment to the Medicines Act, the MoH SR has the authority to remove medicines that do not meet current conditions from the categorisation list. According to §17(5a), the Ministry can do so only if it does not endanger patient life or health, which, under a strict interpretation of the law, makes de-categorisation practically impossible.

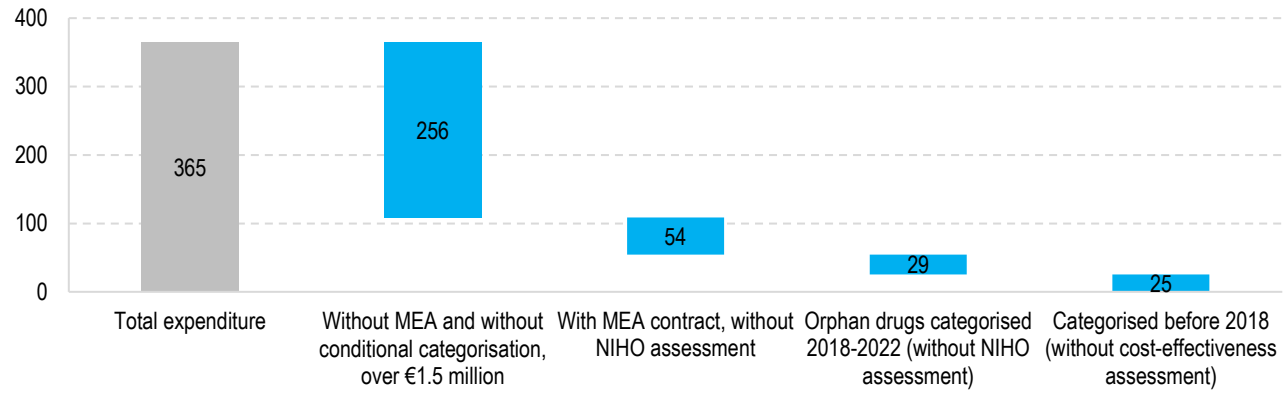
The review identified four groups of medicines that failed the cost-effectiveness assessment in the past, where a price reduction of 10–30% could generate savings of EUR 36.5–EUR 109.5 million. Discounts can be up to 70%, most commonly around 30%. The potential savings should be determined following a cost-effectiveness reassessment of the relevant medicines. In total, 61 medicines could be re-evaluated[14], with annual expenditure of EUR 365 million:

- Medicines with an impact of over EUR 1.5 million, without a concluded MEA contract and no history of conditional categorisation (21 medicines);
- Medicines with an MEA but without a NIHO assessment (9 medicines);
- Orphan drugs categorised between 2018 and 2022 but without a NIHO assessment (22 medicines);
- Other medicines categorised before 2018 without a NIHO cost-effectiveness assessment[15] (9 medicines).

[14] Due to current legislation and concluded MEA agreements, it is not possible to disclose the names of the medicines concerned.

[15] Until August 2024, cost-effectiveness assessments for medicines with a relatively low budget impact were carried out directly by the MoH (OPS FE of the MoH SR).

Figure 15: Expenditure on medicines that should undergo cost-effectiveness assessment, in EUR million, 2024



Source: Health insurance companies

Table 9: Measure from subchapter 2.2

Measure	Description
Assess the cost-effectiveness of medicines that have not undergone NIHO evaluation	All medicines with a significant budget impact (above EUR 1 million) that have not previously undergone cost-effectiveness evaluation by NIHO should be assessed. Medicines that are not cost-effective should remain on the reimbursement list only at reimbursement levels that meet cost-effectiveness criteria.
Regularly review the cost-effectiveness of the most expensive medicines	Cost-effectiveness rules change over time. Medicines previously considered cost-effective may no longer meet these criteria after methodological changes. Expensive medicines (e.g. with annual expenditure exceeding EUR 1 million) should therefore be reassessed every five years.

Box 8: Changes in the legal definition of medicines for rare diseases

As a result of the inappropriate legal definition of medicines for rare diseases in 2018, medicines with annual expenditures of EUR 74 million were included in the reimbursement system, even though they were not required to demonstrate cost-effectiveness. On 1 January 2018, an amendment to Act No. 363/2011 Coll. came into force. One of the objectives of the amendment was to enable more patients with very rare diseases to access reimbursed treatment. Manufacturers of certain medicines for rare diseases (so-called ultra-orphans) were not required to demonstrate standard cost-effectiveness in order for their medicines to be reimbursed by public health insurance (i.e., included in the ZKL).

Rare diseases were defined by indication rather than prevalence. Meeting the prevalence criterion is more difficult than meeting the registered indication criterion, as an indication can be defined as a subset of a disease (patients may have a non-rare disease but with rare complications). This change in definition significantly increased the number of medicines that could enter the ZKL without demonstrating cost-effectiveness.

Source: compiled according to Healthcare Spending Review II

2.3 Adhere to cost-effective reimbursement recommended by the NIHO

NIHO assessments support the MoH SR in negotiating the most favourable reimbursement terms for medicines. These assessments analyse the benefits and costs of medicines and, if necessary, include recommendations on the discount manufacturers should offer to achieve cost-effectiveness. NIHO prepares detailed assessments that provide the MoH SR with evidence-based arguments for negotiations with medicine manufacturers.

The MoH SR is responsible for conducting negotiations and determining their outcomes. NIHO assessments involve a high degree of uncertainty, which naturally arises from the use of statistical methods applied to data of varying quality[16]. Deviations from NIHO's recommended prices may therefore be justified in certain cases. The negotiated terms depend on the Ministry's willingness to enter into conflict and bear political costs if manufacturers do not accept the recommended discount. For example, in one case, the MoH SR disagreed with modifications made by NIHO to its pharmacoeconomic model, which increased the estimated benefits of the medicine and consequently reduced the required discount**.** In another case, the Ministry disagreed with the comparator price used by NIHO and opted to use the higher official price from the ZKL. This made the medicine cost-effective even with a lower discount.

The reasons for deviations from NIHO assessments may be difficult for the general public to understand. Therefore, it would be appropriate to also publish the impact of such deviations on public finances. Differences often arise from varying assumptions and parameters in the pharmacoeconomic model. Even if the Ministry explains why it favoured parameters proposed by the manufacturer, the public cannot independently assess the validity of the decision. In such cases, the Ministry could complement the justification with a quantification of the impact on PHI expenditures relative to the original proposed reimbursements, while avoiding the disclosure of confidential information.

Box 9: The importance of negotiations with pharmaceutical manufacturers is increasing

When purchasing common goods and services, such as cars, computers, or licenses, the state generally knows the estimated prices in advance and decides whether to proceed with the purchase, including whether to launch a public tender. The estimated contract value (ECV) should be set as close as possible to the final price, signalling how much the state is willing to pay. The ECV affects the final price—if set too high, the state may overpay—but for common goods with multiple suppliers, the tender should yield the lowest possible price.

Procurement of new, innovative medicines is significantly more complex. These medicines are purchased under non-public conditions directly from specific manufacturers holding temporary monopoly positions. There is no public competition, and official list prices do not reflect actual prices, as they incorporate confidential discounts, sometimes as high as tens of percent. Media reports of an innovative medicine not being categorised in Slovakia do not necessarily indicate that the MoH SR is unwilling to include it; rather, negotiations for cost-effective reimbursement corresponding to the medicine's benefits may not yet have concluded.

Pharmaceutical manufacturers use various negotiation tools to maximise the prices of medicines. Key strategies include:

- **Media pressure** – Manufacturers can influence public opinion even before market entry, often through patient organisations. The pressure from patient organisations to have a new medicine categorised as quickly as possible is understandable and legitimate. However, it typically does not account for the costs to PHI, which reduces the Ministry's negotiating flexibility.
- **Confidential discounts** – Prices agreed with the Ministry of Health remain confidential, limiting public oversight. Confidential discounts allow manufacturers to secure the highest possible prices in each country, maximising profits. While wealthier countries are expected to pay more to finance innovation (Persson and Jonsson, 2016)[17], international comparisons show that in some EU countries, poorer countries may pay more per unit of benefit (Figure 12).
- **Threat of market withdrawal** – Manufacturers may demand improved terms under threat of leaving the market if agreed conditions become disadvantageous, for example, if more patients consume the medicine than initially forecast.

As new medicines with significant benefits enter the market, the importance of negotiations will increase. The Ministry of Health should therefore be in the strongest possible position. Large manufacturers of new original medicines

[16] The degree of certainty depends on the quality of the data, but it will never be 100% because estimates from clinical studies with a certain statistical error are used.

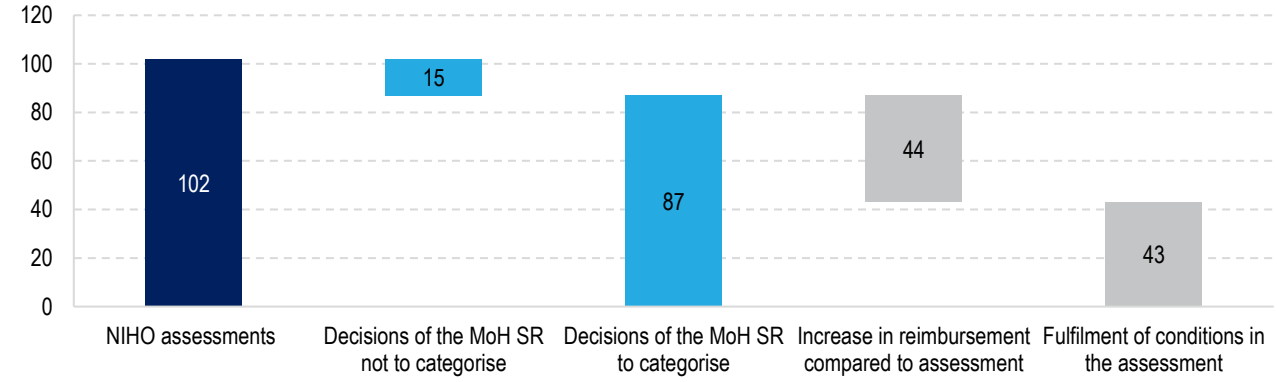
[17] In the academic literature, this is referred to as Ramsey pricing, according to which wealthier consumers are less sensitive to higher prices. A manufacturer with a monopoly position may use this principle in its pricing strategy and set higher prices in markets with higher income levels.

are regularly involved in negotiations on new medicine entry, extensions of MEA contracts, or expanded indications for already categorised medicines. Repeated interactions teach both parties how the other responds to various strategies—for instance, if the Ministry concedes to a threat to withdraw a medicine, it may face similar pressure in the future. Several principles should guide the MoH SR in negotiations (see IMF, 2025c):

- **Transparency and communication** – The MoH SR communicate pharmaceutical policy decisions more effectively. Not all new medicines provide significantly greater benefits than existing therapies, but the public often only hears about unavailability, without understanding the true therapeutic value.
- **Reputation and credibility** – The MoH SR should establish a reputation as a confident institution that follows NIHO recommendations in negotiations, is not intimidated by threats of market withdrawal, and is willing to de-list cost-ineffective medicines if no agreement on reimbursement reductions can be reached with the manufacturer. Frequent past deviations from NIHO recommendations or excessive responsiveness to pressures from manufacturers (such as media campaigns or withdrawal threats) may weaken the Ministry's negotiating position in future discussion.
- **Risk-sharing** – Where appropriate, MEA contracts should link reimbursement to treatment effectiveness or outcomes (see Box 4). This reduces uncertainty for the state.
- **Horizon scanning** – The Ministry should utilise information on anticipated market developments and prepare in advance for medicines expected to enter the market.

In the past, reimbursements negotiated by the MoH SR deviated from NIHO assessments in up to 50% of cases. Up to half of the medicines assessed by NIHO were categorised with a reimbursement higher than recommended, which, in the long term, increases PHI expenditure by EUR 50 million per year. Between its inception in January 2022 and April 2025, NIHO published assessments of 87 medicines that were subsequently categorised. In 44 cases, the medicines were categorised with a reimbursement exceeding the cost-effective level recommended by NIHO.

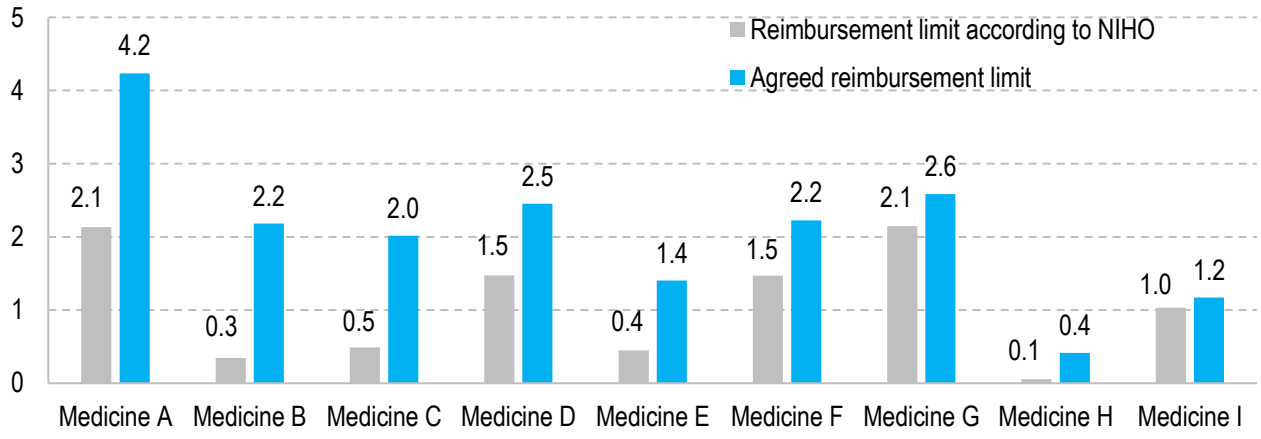
Figure 16: Number of NIHO cost-effectiveness assessments of medicines on which the MoH SR made decisions, January 2022–April 2025



Source: NIHO

The nine medicines with the largest percentage deviations alone could have generated annual savings of EUR 9 million. Data from health insurance companies indicate that some medicines are purchased at prices exceeding NIHO's recommended reimbursements by tens of percent. If these were the medicines with the highest budgetary deviations, potential savings would be even greater. According to NIHO, the top ten such medicines alone could account for EUR 39 million. Contracts for these medicines should be reopened and renegotiated, prioritising those with the greatest impact on the PHI budget.

Figure 17: Medicines with the highest percentage deviations from NIHO recommendations, in EUR million



Source: Health insurance companies

Exceptions to cost-effectiveness requirements have rarely been applied in the past, but the amendment may lead to broader use. Current legislative conditions (§7(5) of Act 363/2011 Coll.) allow certain new medicines to be exempt from cost-effectiveness requirements. This applies to medicines that have no therapeutic alternative and provide relatively high benefits. According to the MoH SR, since the 2022 amendment to Act No. 363/2011 Coll., only three medicines had been categorised under these conditions by January 2026, two of them in November 2025. In the draft amendment to the Medicines Act, the MoH SR tightens the requirements related to the benefits of medicines but expands the groups for which exceptions may be applied. Currently, exceptions apply only to orphan medicines and medicines for innovative treatment. According to the draft amendment, they would also apply to medicines for paediatric indications and for the treatment of serious diseases.

Table 10: Measures from subchapter 2.3

Measure	Description
Renegotiate agreements that deviate from NIHO recommendations	Agreements that deviated from the conditions recommended by NIHO in the past should be renegotiated. The Ministry of Health may request a pharmacoeconomic analysis at any time (Act No. 363/2011 Coll., §93(1)), which can serve as justification for reopening negotiations.
Publish the extent and justification of deviations from NIHO recommendations	Reimbursement listing decision of medicines should state not only the justification but also the extent of any deviation from the unit reimbursement recommended by NIHO or from the reimbursement level consistent with cost-effective treatment.

Box 10: Price referencing of new medicines is no longer as important as it was in the past

Price referencing of categorised medicines leads to gradual price reductions over time. Referencing is the mechanism used by the state to determine the maximum prices of medicines. The price of a given medicine is compared with prices in other countries (external referencing – in Slovakia against the three cheapest EU countries) or with prices of similar medicines on the domestic market (internal referencing). Together with competition between manufacturers and the entry of generics or biosimilars after patent expiry of original medicines, this contributes significantly to price erosion – a gradual decline in the unit prices of medicines over time (Appendix 2).

The importance of external price referencing is declining, mainly due to the increasing number of medicines categorised with confidential prices. New and expensive medicines enter national markets with undisclosed prices, so comparisons based on official list prices increasingly become an administrative exercise. The MoH SR negotiates the conditions for a medicine's entry with the manufacturer, and if an agreement is reached, an MEA contract is concluded. Most of the information in these contracts is confidential, allowing manufacturers to offer discounts on the official price. Manufacturers negotiate similar entry conditions in other EU countries. External referencing based on official prices abroad therefore has little effect on the actual prices of these medicines. Its importance is likely to decline further as innovation

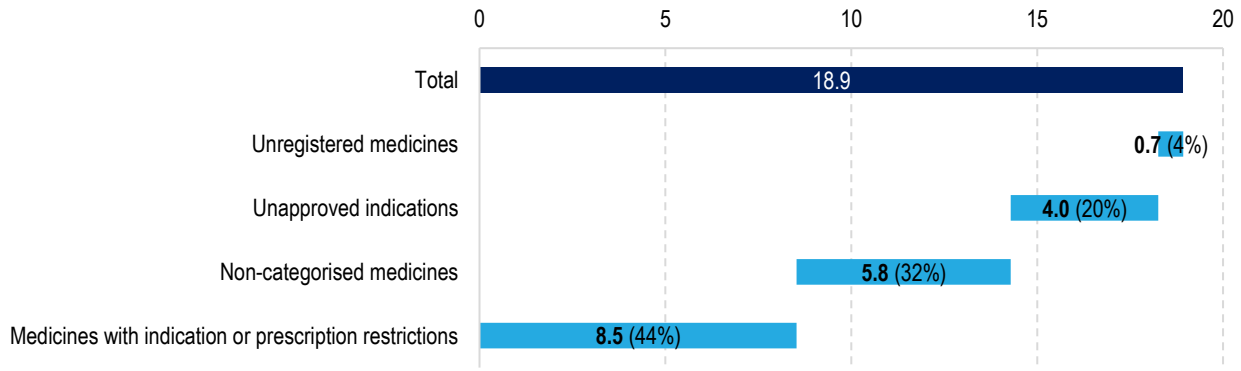
accelerates and new, high-cost medicines enter the market more rapidly, often requiring confidential discounts (Persson and Jonsson, 2016; IMF, 2025c; Dabbous et al., 2020).

2.4 Avoid bypassing cost-effectiveness requirements through exemptions

Medicines reimbursed on an exceptional basis are a common feature of pharmaceutical policy in many developed countries. There will always be situations that the standard categorisation process cannot fully address. In legitimate cases, health insurance companies may bypass categorisation and approve reimbursement for a medicine that is not normally reimbursed. For example, if available treatment is ineffective for a cancer patient and there is a registered[18] medicine that has not yet been categorised, the attending physician may submit a request for exceptional reimbursement. The physician does so based on clinical judgement to allow the patient to access the medicine before it is categorised. Early access or use outside approved indications (so-called off-label use) is also common practice abroad (Box 12).

The widespread use of exceptional reimbursement in Slovakia undermines the standard categorisation process. Almost half of the approved exceptions concerned categorised medicines used in indications other than those approved for reimbursement—for example, newly registered indications of already categorised medicines. This becomes problematic when such use occurs in cases where the MoH SR had previously decided during the categorisation process that the medicine should not be reimbursed for those indications, whether due to low efficacy, insufficient cost-effectiveness, or limited resources.

Figure 18: Number of approved reimbursed on an exceptional basis by type, 2023, in thousand



Source: ÚDZS (2024)

Box 11: Types of exceptional reimbursement in Slovakia

Act No. 363/2011 defines four types of exceptions under which a health insurance company may approve reimbursement of a medicine outside the conditions set out in the categorisation list. The request is submitted by the attending physician and must be duly justified. The health insurance company has 15 days to make a decision.

A. Unregistered medicines – Medicines that are not registered, meaning they have not yet been approved by regulatory authorities (in Slovakia, ŠÚKL or the EMA in the EU) for use on the Slovak or European market.

B. Unapproved indications – Registered medicines used for a therapeutic indication that is not specified in the marketing authorisation decision. In some cases, it is not possible to approve the use of a medicine for all patient groups (e.g. pregnant women or children). An exception may therefore be appropriate.

C. Non-categorised medicines – Medicines that are not included in the list of reimbursed medicines. Newly registered medicines may take time to enter the reimbursement system. Similar to point A, this mechanism can allow earlier patient access, but it is important that the categorisation process is not circumvented.

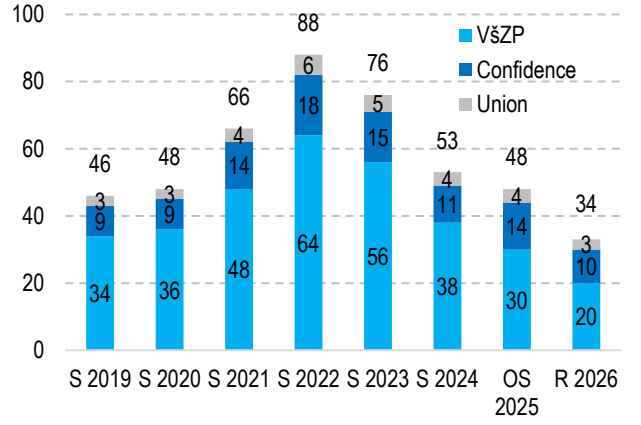
[18] The registration of a medicine or indication means that the manufacturer has been granted permission to market it and can start selling it in pharmacies. Such a medicine has been tested and proven to be safe and effective for the registered indication based on scientific evidence. Registration is granted by a regulatory authority, in Slovakia by the State Institute for Drug Control (ŠÚKL) and in the EU by the EMA.

D. Medicines with indication or prescription restrictions – Medicines included in the list of reimbursed medicines that are subject to prescription or indication restrictions. If a medicine is already categorised, it means that the MoH SR has defined the conditions under which cost-effectiveness is maintained. In some cases, an exception may still be justified (for example, if a medicine is approved for patients aged 12 and over and the patient is 11, but there is a high probability that the treatment would also be effective).

The 2022 amendment to the Medicines Act facilitated the expansion of indication-based categorisation, which was expected to reduce expenditure on exceptional reimbursement for non-categorised indications. Expenditure on exceptional reimbursement increased until 2022, reaching EUR 88 million. Following the reform, a number of medicines previously reimbursed through exceptional reimbursement were expected to enter the standard reimbursement system. At the same time, limits were introduced on the share of funds that health insurance companies could spend on exceptions. In 2023, this share was 3.9% of expenditure on medicines; in 2024 it was expected to fall to 2.9%, and from 2025 to 1.9%.

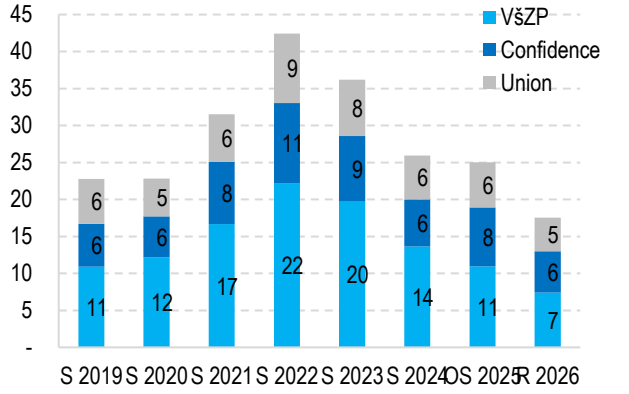
The shift of medicines from exceptional reimbursement to categorised medicines achieved only partial success. The reduction in the limit on health insurance companies' expenditure on exceptions was postponed by one year, with a share of 2.9% applying in 2025 instead of 1.9%. Medicines that were categorised were replaced by other exceptions, and expenditure therefore declined more slowly. Part of the increase reflects newly registered medicines, for which exceptional reimbursement should serve as a temporary access pathway. However, there may also be cases where manufacturers do not apply for categorisation even though the medicine has long been reimbursed through exceptions. This may suit manufacturers because categorisation would require them to demonstrate the medicine's cost-effectiveness. An example is a medicine for the treatment of achondroplasia, which was submitted for categorisation more than three years after its registration in Slovakia, even though it had already been reimbursed through exceptions for a prolonged period.

Figure 19: Expenditure on exceptional reimbursement by health insurance company, in EUR million



Note: Data for Union were only available for 2022-2023; for other years, estimates were used.
S – actual expenditure, OS – expected expenditure, R – budget

Figure 20: Expenditure on exceptional reimbursement per insured person by health insurance company, in EUR



Source: Health insurance companies, UDZS

The introduction of clearer rules for exceptional reimbursement would enhance predictability for patients in Slovakia. Currently, the decision to approve reimbursement of a medicine on an exceptional basis rests solely with the health insurance company. Decisions may vary between individual cases and across insurance companies. This creates inequalities that, according to the Public Defender of Rights, are unconstitutional and contrary to the International Covenant on Human Rights. In addition to defining clearer rules, it would also be appropriate to publish information on cases in which the insurance company granted an exception and those in which it refused to do so.

Requiring manufacturers to submit a categorisation request within a defined period after the first approval of exceptional reimbursement could limit circumvention of the categorisation process. In the proposed amendment to the Medicines Act, the MoH SR suggests requiring marketing authorisation holders to submit an application for categorisation if their medicine is repeatedly reimbursed through exceptions. This requirement would not apply to medicines for rare diseases, paediatric indications, or medicines registered for less than 24 months.

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Box 12: Other countries also use exceptional reimbursement, but the rules are more clearly defined than in Slovakia

Exceptional reimbursement is often granted on the basis of the named-patient principle, which involves a decision on an individual case. In the Czech Republic, the Health Insurance Act stipulates that exceptions may be granted only if they represent the only therapeutic option from the perspective of the insured person's health and if the case is truly exceptional. The interpretation of these conditions has subsequently been further developed through the case law of Czech courts. In Poland, reimbursement for non-categorised medicines may be approved within the framework of "emergency access to medicine technologies" (RDTL), where healthcare providers decide on the basis of a physician's request. In the case of unregistered medicines, the decision is made by the national medicines agency. Given that new medicines are generally more accessible in wealthier countries, the approval of exceptions often reflects a compassionate approach, providing access to medicines (or indications) that have not yet been registered (for more details, see IMF, 2025a).

Table 11: Countries granting named-patient exceptional reimbursement for uncategorized medicines

Country	Mechanism	Note
Italy	*Legge 648/96 – uso compassionevole*	Medicines that are unregistered may be used in life-threatening conditions. The scheme also allows access to medicines for which reimbursement has not yet been established.
Poland	*Emergency access to medicines – RDTL*	Decisions are made by physicians and healthcare providers, who operate within legal limits—up to 3% of the pharmaceutical budget. The criteria are established by law, and the Ministry of Health determines which medicines cannot be reimbursed through RDTL. Healthcare providers are allocated a specific budget for RDTL.
Czech	*Similar to Slovakia*	Insurance companies decide, the law defines the basic conditions, court decisions have determined the application practice.
Slovakia	*Act No. 363/2011 Coll., reimbursement of medicines for exceptions*	Insurance companies decide[19], the rules are flexible, there are no limits for decision-making.

Reimbursement of exceptional medicines is expected to undergo significant changes in 2026. The amendment to the Medicines Act, submitted by the MoH SR in December 2025, originally proposed to establish clearer rules for health insurance companies. Mandatory reimbursement would be linked to a demonstrably effective medicine, and the marketing authorisation holder would be required to submit an application for categorisation. Insurance companies would retain the option to reimburse medicines that do not meet the specified efficacy criteria, but the extent of public funding would be limited. The amendment also introduces group exemptions for relatively inexpensive medicines when there is a need to treat a group of patients with a medicine not reimbursed through the standard scheme. The current limit on the amount of exceptional reimbursement, expressed as a percentage, would be abolished, with available resources instead defined by a programme decree.

Table 12: Measures from subchapter 2.4

Measure	Description
Limit reimbursement under the exceptional regime if the manufacturer does not apply for reimbursement listing	Reimbursement under the exceptional regime should be limited if the manufacturer does not apply for reimbursement listing within a defined period, for example within 24 months of the registration of the medicine or indication.

[19] The amendment to Act 363/2011 Z. z. regulates the institute of exceptional medicines and sets rules for the reimbursement of these medicines to patients. At the time of publication, the amendment had not yet been approved.

3 Monitoring and reporting of pharmaceutical expenditure is opaque

The information provided by the MoH SR on the impacts of categorization is opaque, despite these impacts amounting to tens of millions of euros over the coming years. The confidentiality of a large amount of critical data—such as negotiated prices of new medicines, consumption estimates, or reimbursement limits after discounts—complicates the monitoring of expenditure. Transparency is further reduced by the varied methods of providing discounts, their presentation in Ministry documents, and the collection of rebates from manufacturers. It is often unclear whether the reported impact takes into account the discounts granted, the maximum reimbursement by health insurers, or savings from displaced treatments. Meanwhile, decisions in other areas with significantly smaller impacts on public finances are required to include transparent and publicly available analyses of their budgetary effects and implications.

Resources for new medicines are limited, so simply reducing unit prices is insufficient to maximise their benefits. Resources must be allocated and planned to deliver the best value for money. When considering the categorisation of a new medicine, clear information on its budgetary impact and continuous monitoring of consumption of other medicines are required. Incorrect estimates of a new medicine's impact may unnecessarily block or delay the categorisation of other medicines, reducing the predictability of the process for all stakeholders.

Monitoring pharmaceutical expenditure is complicated by confidential discounts, inaccurate patient number estimates, and inconsistent methodologies across health insurers. The large volume of non-public information and the complexity of discounts—particularly those applied ex post—makes budget preparation and monitoring challenging for both the MoH SR and insurance companies. Some discounts are applied only after annual settlement through manufacturer refunds, while others involve advance payments, further complicating expenditure tracking throughout the year.

Table 13: Types of discounts and challenges in monitoring pharmaceutical expenditure

Type of discount	Description	Challenge for reporting
Upfront discount	The health insurance company reimburses the pharmacy for the discounted price of the dispensed medicine.	• The discount is confidential.
Rebate	The health insurance company reimburses the pharmacy at the undiscounted price and subsequently claims a rebate from the medicine manufacturer.	• The discount is confidential. • Ongoing medicine consumption must be adjusted to account for future rebates. • Some health insurance companies may receive ongoing advance payments from pharmaceutical manufacturers. If the MoH SR is unaware of this, it may overestimate the expected rebates.
Discount linked to reimbursement limit	The pharmaceutical manufacturer may provide part of the discount within a reimbursement limit that is lower than the agreed unit price multiplied by the estimated consumption. The discount is only activated once the agreed medicine reimbursement limit (i.e., the total amount of pharmaceutical expenditure reimbursed by PHI) has been exceeded. A 100% discount is applied to each package above the limit.	• The discount provided within the reimbursement limit is a rebate; therefore, the same reporting requirements apply. • The payback is paid in a different year than the expenses were incurred. • Currently, there is no coordination between health insurance companies and the MoH SR in monitoring rebates. Although the reimbursement limit is shared across all health insurance companies, each insurer only sees its own expenses and therefore lacks information on whether, and to what extent, it is entitled to a payback.

Source: processed by VFM

To compile a credible budget, the Ministry of Finance requires access to accurate data on the impact of medicine categorisation. Control over pharmaceutical expenditure is further limited because, when preparing the annual budget, the MoH SR typically includes only the impact of newly categorised medicines for the upcoming year as part of policy changes.

However, the full budgetary effect of medicine categorisation usually materialises over three years.[20] For instance, in its 2025 programme decree, the MoH SR estimated the impact of newly categorised medicines at EUR 70 million, whereas the actual impact over three years may reach EUR 140–210 million. Historically, the Ministry of Finance lacked reliable information on the timing of these expenditures. As a result, the MoH SR often requested additional resources during subsequent budget processes as a "categorisation catch-up." At that stage, neither the Ministry of Finance nor the MoH SR has effective options to reverse the growth of these expenditures.

3.1 Standardize the impact clause for the categorization of a medicine

Although the categorisation of a medicine can affect the budget by tens of millions of euros, information on these impacts remains unclear. It is currently impossible to track the effect of categorised medicines on public expenditure using published materials. While the categorisation portal provides extensive details on each procedure, its usefulness for assessing the impact on the budget or public health is limited.

Publishing a standardized table as an annex to each medicine's categorisation decision would ensure comprehensive recording of key information. The budgetary impact of the categorisation of each new medicine (or indication) should be included as a mandatory annex to the MoH SR's decision. This approach is analogous to the impact clause in the legislative process, which requires quantifying effects over the entire budget horizon. Although many new medicines are categorised through confidential MEA agreements, making full public disclosure difficult, completing the table would still improve record-keeping and increase transparency in decision-making.

Table 14: Draft impact clause in categorization decisions for medicines or indications

*Reported for the fiscal year, only for categorisation cases	Year 0	Year 1	Year 2	Year	Maximum annual impact
Unit price without discount	4,150	4,150	4,150	4,150	
Unit price with discount	2,490	2,490	2,490	2,490	
Estimated number of patients	50	100	170	190	220
Estimated consumption per package	200	400	680	760	880
Reimbursement limit for medicine (indication) without discount (thousand euros)	830	1,660	2,822	3,154	3,652
Reimbursement limit for medicine (indication) with discount (thousand euros)	**498**	**996**	**1,693.2**	**1,892.4**	**2,191.2**
Replaced treatment (savings) (thousand euros)	**80**	**160**	**272**	**304**	**352**
Expected decrease in the number of patients in replacement therapy	**40**	**80**	**136**	**152**	**176**
Expected decrease in packaging consumption in replacement therapy	**240**	**480**	**816**	**912**	**1,056**
Net impact on PHI without discount (thousand euros)	750	1,500	2,550	2,850	3,300
Net impact on PHI with discount (thousand euros)	**418**	**836**	**1,421.2**	**1,588.4**	**1,839.2**
Benefit of the medicine per patient (iQALY)	**0.2**				
Total benefit of the medicine (iQALY × number of new patients[1])	**10**	**11**	**16**	**7.4**	**16**
ICUR[2] of the medicine without discount	75,000				
ICUR[2] of the medicine after discount	**41,800**				
Threshold price of the medicine	**45,621**				

Note: Fields marked in bold may be public. *Source: VFM*

[1] The example assumes that 10% of patients from the previous year will discontinue treatment.

[2] ICUR stands for Incremental Cost-Utility Ratio, i.e. the ratio of added utility (benefits) to added costs.

[20] All documents from the Ministry of Health of the Slovak Republic, including those from its advisory bodies (e.g., NIHO, the categorisation commission), use a three-year horizon for the gradual introduction of medicines. This approach reflects practical constraints: it is not possible to change the treatment of all patients simultaneously, some physicians require time to familiarise themselves with new medicines, and manufacturers may not be able to supply the entire market in the first year.

It is unclear from the published documents whether the budget actually provides sufficient resources for the categorised medicines. The law stipulates that categorisation must be carried out in accordance with the budget.[21] However, in its decisions, the MoH SR merely states that there is scope for the inclusion of the medicine (Appendix 7). While the table shows the total expenditure for the entire categorisation in a given year, it does not provide information on the impact of a specific medicine or the resources available. The table also presents the impact only for the following year, despite the gradual introduction of medicines. Furthermore, the reported expenditure on medicines for the current and subsequent year does not correspond to the adopted budget or programme decree[22], further reducing transparency[23].

Figure 21: Example of a table used by the MoH SR to declare the compliance of medicine categorisation with the budget

Odhad výdavkov na lieky z rozpočtu VZP / mil. €	2024	2025
Očakávaná skutočnosť - všetky lieky	1 661,280 €	1 786,541 €
Dietetické potraviny	39,000 €	40,000 €
Vplyv liekov zaradených do ZKL (Y)	36,931 €	99,953 €
Vplyv osobitnej cenovej regulácie	3,639 €	4,683 €
Úspora generiká a biosim., úsporné politiky	- 47,486 €	- 47,486 €
SPOLU OS Lieky + DP	**32,084 €**	**97,150 €**
SPOLU OS Lieky	**- 6,916 €**	**57,150 €**

Source: decision on medicine categorisation

The decision of the MoH SR on the categorisation of a medicine should include the expected development of pharmaceutical expenditure, broken down into its projected trajectory without the categorisation and with the change resulting from the decision to categorise the medicine. Adopting a categorisation decision constitutes a policy change for which the MoH SR allocates a defined portion of the medicine budget. The baseline expenditure scenario (Table 15) allows monitoring of the remaining space for categorising other medicines in a given year. Monitoring should cover at least a three-year horizon due to the gradual introduction of medicines into the system. A policy change also affects the terms of MEA contracts upon expiry. MEA contracts typically last three years, after which terms—such as the reimbursement limit—may be adjusted. If the MoH SR and the manufacturer cannot agree on the adjustments, the terms from the third year of the contract continue to apply. For instance, manufacturers may request an increase in the number of patients based on previously inaccurate estimates, sometimes coupled with the threat to exit the market.[24]

Table 15: Proposed table structure for presenting the compliance of medicine categorization with the budget, with illustrative impacts, in EUR million

	OS 2025	2026	2027	2028
Approved budget	**1,600**	**1,700**	**1,800**	**1,900**
Expenditure without categorisation of new medicines (continuously updated according to PHI monitoring)	1,550	1,650	1,700	1,750
Space for categorisation of new medicines approved in the budget	50	50	100	150
Medicines already categorised during 2025	*10*	*20*	*30*	*40*
Remaining space	*40*	*30*	*70*	*110*
Effect of the assessed medicinal product	***0.418***	***0.836***	***1.421***	***1.588***

Note: OS – expected expenditure. *Source: VFM*

[21] §90(1) of Act No. 363/2011 Coll.: Categorisation of medicines, medical devices, special medical materials, and dietary foods shall be carried out in such a way that public funds managed by health insurance companies are sufficient to cover the costs of medicines, medical devices, dietary foods, and healthcare services reimbursed under public health insurance.

[22] Decree determining the minimum expenditure of insurance companies on individual segments of healthcare. Although it only specifies minimum amounts, the accompanying documentation from the Ministry of Health of the Slovak Republic also forecasts total expenditure in individual segments. The highest priority areas have a defined minimum amount that is almost identical to the forecast (100%), e.g. for medicines, the match was 97% in the decree for 2025.

[23] Since the summer of 2025, the Ministry of Health has been providing the impacts of categorisation from previous years on the budget horizon.

[24] In the programme decree for 2025, the Ministry of Health announced an increase in reimbursement limits in MEA contracts after the end of the reference period in the amount of EUR 15 million, arguing that there was a threat of medicines leaving the market.

Table 16: Measure from subchapter 3.1

Measure	Description
Introduce a standardised impact clause	Each reimbursement listing decision should include a standardised impact clause containing key information: unit reimbursement of the medicine (before and after discounts), the estimated number of patients, the treatment being replaced, and the reimbursement limit.
Update the baseline scenario for medicine expenditure after each reimbursement listing decision	The consistency of a reimbursement listing decision with the budget should be demonstrated through an updated baseline scenario of medicine expenditure over the budget horizon.

3.2 Reassess which information must remain confidential and who should have access to it

There are valid reasons for maintaining the confidentiality of discounts provided by pharmaceutical manufacturers. Medicine prices differ across countries and disclosing them could weaken a manufacturer's negotiating position in markets where higher reimbursements are possible. Manufacturers are therefore more willing to offer substantial discounts when they remain confidential. Discounts from the list price can reach up to 70%, although the most common level is around 30%. In Slovakia, non-public prices are typically negotiated through MEA contracts**.**

Box 13: MEA agreements

The MEA agreement is a confidential contract on the controlled entry of medicines between pharmaceutical manufacturers and the Slovak MoH. In Slovakia, it is primarily used for the introduction of expensive medicines with an annual budgetary impact exceeding EUR 1.5 million. MEA agreements are also employed when reimbursements based on official prices do not meet cost-effectiveness conditions, allowing the manufacturer to negotiate a confidential discount with the MoH SR. A key feature of these agreements is the total reimbursement limit for a specific medicine, which enables the Ministry of Health to manage budgetary risks. If consumption exceeds the agreed limit, the manufacturer must return the excess to public health insurance (PHI). The agreed discounts and refunds remain confidential, which manufacturers justify due to international price referencing. As a result, the actual price is typically tens of percent lower than the official estimate provided by the manufacturer.

The secrecy of data has arguably gone too far and should be reviewed. Not only is information on unit reimbursement and medicine prices—critical for transparency—kept confidential, but entire pages of documents are redacted (Appendix 8). For example, the net impact on PHI expenditure or the declared benefit of a medicine (multiplied by the number of patients) should be disclosed. According to the Medicines Act, the MoH SR has the authority to assess whether all information considered confidential by the manufacturer meets the criteria for trade secrets (§75a(3)). A review of the current approach to data confidentiality would increase transparency across the system. The forthcoming amendment to the Medicines Act proposes to explicitly exclude the benefits of a medicine from confidential classification. For example, clinical trial results, epidemiological data, and information on the efficacy and safety of a medicine would no longer be considered confidential.

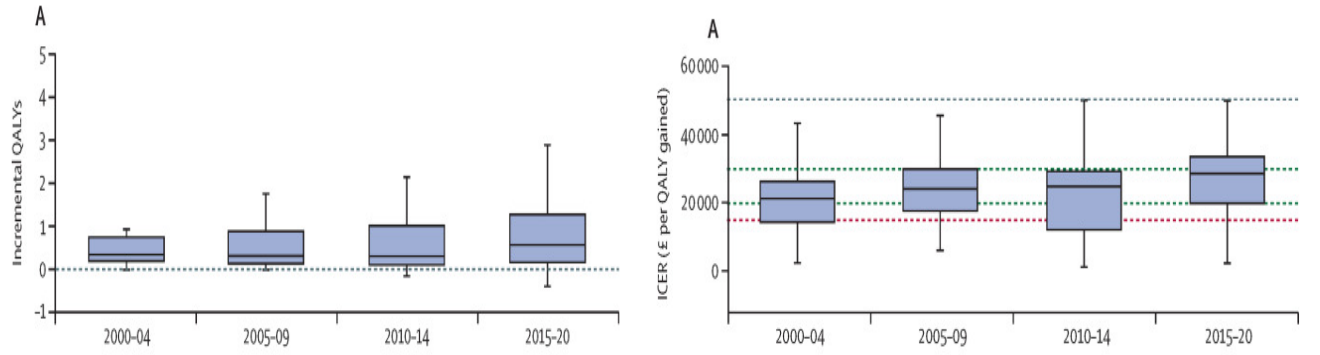
Certain data for medicines under MEA contracts must remain confidential, including the number of patients treated, the unit price after discount, and other variables that could be used to infer prices. Nevertheless, these data should be collected in a standardised form for budgeting purposes and for evaluating the benefits of categorisation.

The Ministry of Finance of the Slovak Republic must have access to the decisions of the Categorisation Commission and NIHO assessments to validate the MoH SR's data for budget preparation and monitoring. Currently, the Ministry of Finance only receives aggregated data and cannot independently verify or validate it. The proposed amendment to the Medicines Act would grant the Ministry of Finance membership in the Categorisation Commission with voting rights.

The costs and benefits of categorisation could also be published in a consolidated summary report. The benefits of medicines are rarely discussed in Slovakia, partly because the MoH SR does not publish relevant data or analyses. Given the importance of the issue and the significant growth in pharmaceutical expenditure in recent years, the Ministry could publish an annual summary report evaluating categorisation. This report should summarise the costs and benefits of categorised medicines, including the fulfilment of financial obligations arising from concluded contracts (e.g., refunds and their settlement

by manufacturers). For sensitive data, such as the benefits of individual medicines, effects could be presented in aggregate form, for example using Figures of added QALYs and ICURs (Figure 22). Preparing such a report would also ensure that the Ministry monitors the declared benefits of individual categorised medicines or indications, not just their budgetary impact, and tracks requests for extensions of indication or prescription restrictions.

Figure 22: Even confidential data can be presented without violating the terms of MEA contracts, for example through box plots for all categorized medicines in a given year, as demonstrated by Naci et al. (2025).



Source: Naci et al. (2025)

Table 17: Measure from subchapter 3.2

Measure	Description
Review access to confidential information	Reassess which information must remain confidential and determine which institutions should have access to it.
Expand the categorization committee to include a representative from the Ministry of Finance	Since the inclusion of medicines in the reimbursement system often has an impact of tens of millions of euros, the Ministry of Finance should be represented in the categorization committee.
Publish an annual report evaluating the reimbursement listing process	Prepare and publish an annual analytical report evaluating reimbursement listing decisions in the previous year. In addition to budgetary impacts, the report should also include information on the declared benefits of newly listed medicines.

3.3 Ensure active enforcement of paybacks

Monitoring pharmaceutical expenditure is complicated by paybacks, which pharmaceutical manufacturers provide when the agreed reimbursement limit is exceeded. The reimbursement limit represents the maximum amount a health insurance company will reimburse for a medicine in Slovakia. It is typically calculated as a multiple of the agreed unit reimbursement (after discount) and the expected consumption of the medicine. The limit serves primarily as a tool for managing expenditure risks, with the pharmaceutical manufacturer assuming responsibility if more patients than expected use the medicine. The right to a payback arises when the agreed reimbursement limit is exceeded, obliging the manufacturer to return the difference between the agreed and actual reimbursement amounts. Between 2018 and 2022, such paybacks were referred to as adjustment payments, and since 2022, following the introduction of MEA contracts, they are referred to as clawbacks.

Budgeting for paybacks is unclear and entails several risks. Paybacks are not tied to the calendar year and, in the event of legal delays in their payment, planning the pharmaceutical budget becomes more difficult. Health insurance companies also face challenges in planning their expenditures. When managing their share of public health insurance (PHI) according to their insurance portfolio, they do not have information about the payments they can expect, as the agreed ceiling applies to all insured persons collectively. During 2025, the MoH SR revised the estimated amount of paybacks expected from pharmaceutical manufacturers several times. In the programme decree for 2025 approved in April 2025, it anticipated paybacks of EUR 71 million; in July the estimate was EUR 43 million, and in September EUR 51 million (Table 18).

Table 18: Expected paybacks in various documents of the MoH SR, in EUR million

Budget year	2025			2026		
Date of provision	April 2025	July 2025	September 2025	June 2025	July 2025	September 2025
Clawbacks	62.5	19	26.9	0	36	36
Adjustment payments	8.2	24	24	0	24	24
Total	**70.7**	**43**	**50.9**	**0**	**60**	**60**

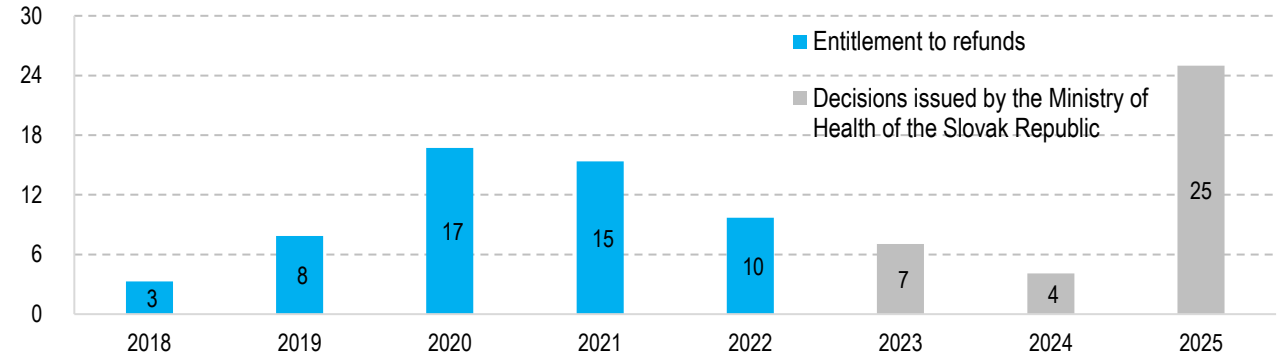
Source: MoH SR

Adjustment payments (2018-2022)

The success rate in recovering adjustment payments was very low. Adjustment payments arose when the actual reimbursement by health insurance companies for a medicine exceeded its conditional reimbursement level. In such cases, the manufacturer of the medicine was obliged to pay the difference to the health insurance companies. According to data from the MoH SR, as of July 2025 health insurance companies were entitled to adjustment payments amounting to EUR 53 million for the years 2018–2022. However, the MoH SR did not issue its first decisions until 2023, amounting to EUR 7 million. In 2025, the Ministry issued decisions totalling EUR 25 million and opened 22 new proceedings relating to the years 2018–2022.

The Supreme Audit Office (SAO) has repeatedly drawn attention to the long-term inaction of the MoH SR in recovering adjustment payments (2023, 2024). The Ministry issued decisions on adjustment payments in an unsystematic and inconsistent manner. For example, in 2022 the Ministry did not legally conclude a single proceeding concerning the payment of adjustment payments. The MoH SR only began to actively address the settlement of adjustment payments in 2025.

Figure 23: Entitlement to adjustment payments and decisions issued by the MoH SR, in EUR million



Source: MoH SR

Clawbacks (2022 - present)

Unlike adjustment payments, the MoH SR does not need to initiate administrative proceedings to enforce clawbacks. The 2022 amendment to the law introduced medicine reimbursement agreements (MEAs), which include a commitment by the pharmaceutical manufacturer to pay the difference between the actual expenditure on a medicine and the agreed maximum amount reimbursed by health insurance companies. Based on a request from the MoH SR, sent to both health insurance companies and pharmaceutical manufacturers, manufacturers automatically transfer the corresponding payments to health insurance companies.

A disadvantage of clawbacks is that health insurance companies do not have accurate information about the claims incurred during the year. The reimbursement limit is set jointly for all insurance companies, but each insurer has information only about its own reimbursements. For example, if the reimbursement limit for a medicine is set at EUR 1 million and VšZP reimburses EUR 0.8 million in a given year, it does not know whether it will ultimately be entitled to a retroactive payment.

Table 19: Measure from subchapter 3.3

Measure	Description
Publish information on accrued and paid paybacks	Publish annually the amount by which the reimbursement limit for each medicine was exceeded in each relevant period, together with information on paybacks paid. The information should cover both clawbacks and adjustment payments.

3.4 Prioritize upfront discounts

Part of the paybacks may also arise from discounts provided above the reimbursement limit. As a standard, the reimbursement limit should be calculated as a multiple of the agreed unit reimbursement (after discount) and the estimated number of packages based on the expected number of patients. However, manufacturers may provide part of the discount above the limit, meaning that the agreed limit is set below the level corresponding to the unit reimbursement multiplied by the expected number of packages.

However, discounts provided above the reimbursement limit may pose long-term risks for the MoH SR. They can lead to significantly higher volumes of paybacks, which are difficult for the MoH SR to monitor. At the same time, there is a risk that the manufacturer may request an increase in the reimbursement limit during the performance period (or after the contract expires, typically after three years), arguing that the conditions are unfavourable and threatening to withdraw the medicine from the market.

In the programme decree for 2025, the MoH SR announced an increase in reimbursement limits in MEA contracts amounting to EUR 15 million. The increase is justified in Table 7 of the explanatory memorandum to the decree specifically by the threat of medicines leaving the market. The MoH SR is at a disadvantage in contract negotiations because patients are already being treated with the medicines in question and need to continue treatment. It is reputationally more difficult to de-list a medicine that patients are already receiving than to prevent a medicine from entering the market in the first place. Consequently, it is advantageous for the manufacturer to offer a discount that is valid for only a few years in order to secure market access.

Table 20: Examples of different discount mechanisms

	Medicine A (discount via reimbursement limit)	**Medicine B** (discount via unit reimbursement)	**Medicine C** (combination of discounts)
List price reimbursement	1,000	1,000	1,000
Cost-effective reimbursement	600	600	600
Agreed reimbursement	1,000	600	800
Estimated number of packages	1,000	1,000	1,000
Agreed reimbursement limit	**600,000**	**600,000**	**600,000**
Actual number of packages	1,100	1,100	1,100
Cash expenditure on medicine	**1,100,000**	**660,000**	**880,000**
Entitlement to payback	**500,000**	**60,000**	**280,000**

Source: processed by VFM

The MoH SR should insist on discounts per medicine package at the point of dispensing. The agreed reduced payment per package is no longer subject to further deadlines and does not rely on estimates of the number of potential patients. Various mechanisms—such as adjustment payments and MEA contracts with retroactive payments—have been established in legislation for more than a decade to ensure risk sharing between pharmaceutical companies and the state for high-cost or uncertain medicines. However, experience has shown that successful recovery of funds when the agreed reimbursement is exceeded is not guaranteed and carries risks. The MoH SR is aware of this issue, which is why the current draft amendment to the Medicines Act introduces an upfront discount at market entry as a mandatory component of MEA contracts. While upfront discounts could theoretically facilitate the re-export of medicines, such practices are illegal and must be addressed separately rather than through complex exit discounts.

Table 21: Measure from subchapter 3.4

Measure	**Description**
Prefer upfront discounts	Ensure cost-effectiveness primarily through upfront discounts applied to the price per package. Limit the use of discounts provided through reimbursement limits.

3.5 Improve forecasting of patient volumes and the arrival of new medicines

The actual long-term impact of categorising a new medicine on the budget depends on accurately estimating the number of patients and the effect of replacing existing treatments. When concluding an MEA contract, the pharmaceutical manufacturer and the MoH SR assume a certain number of patients, from which the expected consumption of the medicine is derived, and set reimbursement limits accordingly. The final net effect on expenditure is also influenced by whether the medicine replaces another medicine or treatment.

Patient registries

Incorrectly estimating the number of patients can contribute to budget overruns. For example, six medicines exceeded their expected consumption due to a higher number of patients, resulting in health insurance expenditure of EUR 74 million in 2024. The total reimbursement limit for each medicine is set by the MEA contract. If this limit is exceeded, manufacturers are required to reimburse the excess expenditure. When the agreement is well designed, a low estimated number of patients only becomes a concern when negotiating its extension, as manufacturers may request an increase in the limit. Even a small error in estimating patient numbers can therefore have significant budgetary consequences in the future.

Incorrect estimates of replacement treatments can also lead to budget overruns. A new medicine may save public funds if it replaces a more expensive alternative. Consequently, in the budget impact section of their application, pharmaceutical manufacturers estimate the net impact of the new medicine. They typically assume a gradual roll-out, with full market penetration most often occurring in the third year, based on the expectation that their treatment will gradually gain a dominant position. If discounts linked to reimbursement limits are tied to these expectations, slower-than-expected market uptake—such as due to prescriber reluctance—may prevent these discounts from being realized.

Failure of the expected substitution creates significant budgetary challenges. The MoH SR should monitor the consumption of such medicine groups, while health insurance companies should identify the causes of insufficient substitution. Faster expenditure growth in medicine groups where substitution was anticipated leads to budget overruns and reduces the capacity to categorise new medicines. Once the budget is adopted, it is crucial that the estimate excluding new medicines is as accurate as possible.

Patient registries should be used to estimate the number of patients likely to use a new medicine. These registries are databases designed to collect data on the health status and treatment of patients with serious diseases or specific disease groups (see Appendix 6 for details). In addition to supporting clinical studies, registries are essential for identifying epidemiological trends, effectively planning preventive and screening programmes, and providing accurate data for pharmacoeconomic analyses. This information directly influences negotiations with pharmaceutical manufacturers and the setting of reimbursement limits.

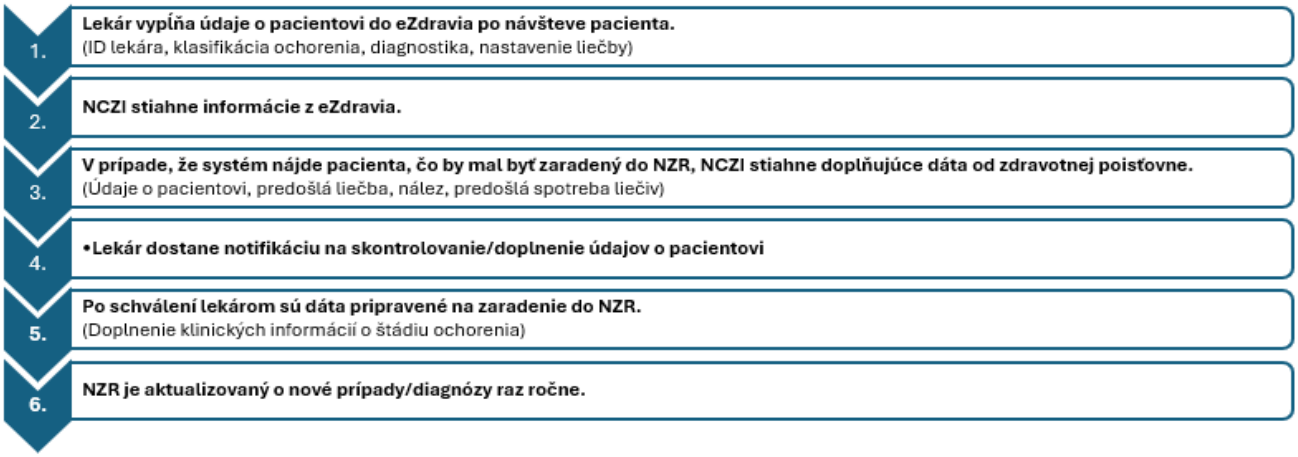
However, Slovak patient registries are not fully operational, including even the most important oncology registry. The data in these registries are not regularly updated, and compared to other countries, they are limited in coverage, both in terms of the range of diagnoses and socio-demographic information on morbidity. Consequently, they cannot be used to accurately estimate the budgetary impact of new medicines. Instead, surveys or data from the NCZI are used, which are less reliable.

Reporting to patient registries is not automated in Slovakia. Doctors must manually report data to the National Cancer Registry for each patient, in addition to reporting to the eZdravie system. The NCZI portal is used for this purpose, but the process of filling it out is complicated. Since the mandatory reporting obligation of doctors to the registers is not enforceable, systemic barriers reduce doctors' motivation to register patient data. The content of patient registers is regulated by Decree No. 74/2014, which specifies the monitored health parameters[25] as well as the reporting obligation for healthcare providers. This is set at 30 calendar days from diagnosis for all registers. However, data reported within this period is not automatically added to the registers, and the frequency of data updates by the NCZI is unknown (see Diagram 2).

[25] For each national health register (NZR), the scope of patient parameters is regulated by Act No. 153/2013. For example, the national oncology register should process basic socio-economic data (permanent residence, economic activity, employer) and surgical procedures, findings, patient progress in oncological classification with ongoing treatment evaluation.

Slovakia should implement automated reporting to patient registries through eHealth systems. The eHealth system has been operating in Slovakia since 2018, with over 12,000 healthcare providers currently reporting data. However, eHealth is not linked to the registries, which creates an additional burden for healthcare providers, who must enter duplicate data into multiple systems. Automatic updating of patient registries from eHealth would eliminate a significant portion of manually entered data on visits and diagnoses. Diagram 2 illustrates the reduction in workload for healthcare providers: with automation, they would only need to enter qualitative data into eHealth during consultations, in addition to standard patient information, if the patient is included in a registry based on their diagnosis. Currently, patient data are entered twice. Using available software for effective patient data collection would improve the reliability of data for pharmacoeconomic analyses and research (for examples of automated systems in Denmark, see Box 19).

Diagram 2: Visualization of Data Collection in the National Cancer Registry After Automation



Sources: VFM, NCZI

Horizon scanning

Given the expected pressure to further increase spending on medicines, it is essential to consider the medium- and long-term outlook when managing and planning the budget. The pharmaceutical industry is moving towards personalised medicine and the development of innovative therapies for small patient populations. These increasingly sophisticated medicines can place a significant burden on public finances. It is therefore necessary to prepare for their introduction in advance.

Horizon scanning is used to systematically anticipate the arrival of new, innovative, and often high-cost medicines. It involves collecting data from international databases, EMA registrations, clinical studies, and communication with pharmaceutical manufacturers to create a list of medicines likely to seek categorisation after EU registration (within 1–5 years). The expected price, clinical benefit, and budgetary impact of these medicines are estimated. Horizon scanning helps policymakers better prepare for the arrival of new medicines by providing answers to key questions:

- How should medicines with the highest clinical benefit and unmet medical need be prioritised for categorisation, given the available budget?
- Which generics are expected to enter the market, and what savings will their entry generate?
- What impact could medicines entering the market in the next 2–3 years have on ongoing negotiations?
- What are the known risks and benefits of future medicines, and how can this information be used in negotiations?

Box 14: Horizon scanning can help the MoH SR plan future pharmaceutical spending on new medicines

Horizon scanning helps policymakers monitor the medicine pipeline and prioritise medicines based on their expected clinical and fiscal impact, improving the predictability of reimbursement decisions and expenditure control. Without horizon scanning, ad hoc categorisation, weak prioritisation, budget overruns, and delayed patient access to innovative therapies may occur. Horizon scanning also strengthens medicine assessment processes by enabling the early identification and selection of medicines for assessment.

In developed countries, horizon scanning is standard practice and forms the basis for innovation planning. Ireland combines national monitoring with international cooperation (Benelux, IHSI). The United Kingdom integrates horizon

scanning directly into HTA through the NICE Innovation Observatory, while Norway links early warnings to HTA and central decision-making. The Netherlands operates a public two-year Horizonscan Geneesmiddelen, and Italy uses a multi-stage model up to 36 months before a medicine launch. Sweden and Austria apply horizon scanning in regional and specialised models. These approaches demonstrate that systematic horizon scanning is a key tool for identifying innovation and managing costs.

Joint European initiatives also play an important role. The Benelux initiative (Belgium, the Netherlands, Luxembourg, Austria, and Ireland) brings countries together for joint horizon scanning, which is particularly beneficial for smaller countries lacking capacity for comprehensive national monitoring. The International Horizon Scanning Initiative (IHSI) provides participating countries (Belgium, Denmark, Ireland, Luxembourg, the Netherlands, Norway, Portugal, Sweden, and Switzerland) with a common methodology and database of medicines in late stages of development, including expected launch dates and budgetary impacts. These platforms enhance coordination, predictability, and the negotiating position of their members.

Source: IMF (2025b)

Table 22: Measure from subchapter 3.5

Measure	Description
Ensure the effective functioning of patient registries	Improve estimates of the eligible patient population by automatically collecting treatment data in patient registries.
Refine indication restrictions for selected medicines	Indication restrictions should be refined for expensive medicines where the estimated number of treated patients has been significantly exceeded or where off-label use may occur. Restrictions should be designed so that health insurance companies can easily verify compliance.
Introduce horizon scanning	Use horizon scanning to anticipate the entry of new medicines and prepare the system for their potential budgetary impact.

4 The system of patient co-payments lacks transparency, and it is unclear whether it effectively serves its purpose

The resources available for new medicines are also influenced by the share of costs borne directly by patients. The level of patient co-payment in each country is affected by the scope of categorized medicines (which medicines the country is willing to reimburse from public funds), the co-payment system (whether and how much the patient pays for a specific medicine), and exemptions from co-payments (how the country protects vulnerable population groups). In Slovakia, public resources could be freed up by de-listing low-benefit medicines that are not reimbursed even abroad, and by reassessing the co-payment system and its exemptions.

Direct payments by patients are a standard form of co-financing for healthcare. Patient co-payments for medicines are intended to discourage excessive consumption. Higher co-payments not only reduce medicine consumption, but also lead to fewer prescriptions (Guindon et al., 2022; Harris et al., 1990). Patient co-payments in each country are influenced by the scope of categorised medicines, the co-payment system, and exemptions from co-payments.

When deciding whether a medicine should be reimbursed from public funds, countries primarily consider its clinical and therapeutic benefits. If a country chooses not to reimburse a medicine, patients must pay the full price themselves. This most often applies to medicines intended for supportive or complementary treatment, such as those for the common cold. In some cases, these medicines may still require a prescription, even though the patient bears the full cost (Table 23). Differences in national approaches can result in the same medicine being reimbursed by insurance in Slovakia, while patients pay the full price in other countries.

To limit overconsumption of publicly funded medicines, countries often introduce co-payments. These are most commonly set as a percentage of the reimbursement, although some countries use a fixed fee regardless of the medicine's price. In Slovakia, the maximum co-payment is determined by the MoH SR and listed in the official list of reimbursed medicines.

Table 23: Examples of medicines by type of patient co-payment in Slovakia

Category	Description	Example
Over the counter	Patients can purchase the medicine at a pharmacy without a prescription.	Erdomed 20x225mg
Prescription only – not covered by health insurance	Medicines similar to over-the-counter medicines, but often with a higher concentration of the active ingredient. They are not reimbursed by health insurance (the patient pays 100% of the cost), but must still be prescribed by a doctor.	Erdomed 20x300mg
Prescription – covered by health insurance	Prescription medicine. Its price is partially or fully covered by health insurance.	

Source: VFM

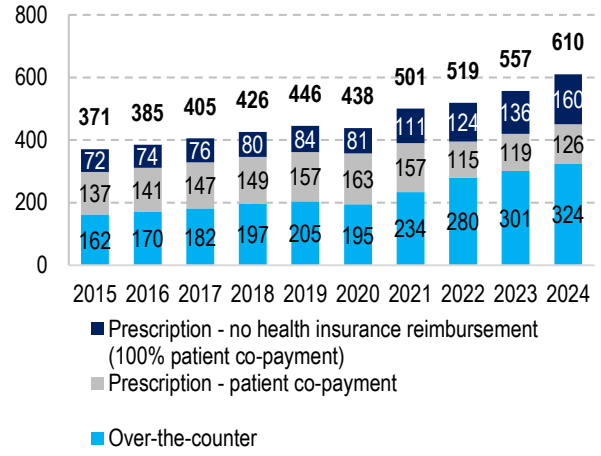
Exemptions from co-payments are intended to protect individuals who would be disproportionately burdened by healthcare expenses. While co-payments help rationalise medicine consumption, they can also limit access to treatment for certain population groups. High co-payments disproportionately affect low-income populations and, in some cases, may prevent them from accessing necessary treatment altogether (Chandra et al., 2024). Patients may try to avoid these costs by not collecting their medication, postponing it, or reducing their dosage.

Slovak households' expenditure on medicines exceeded EUR 600 million (0.5% of GDP) in 2024, with over half (EUR 324 million) spent on over the counter (OTC) medicines. Household spending on medicines has increased by 65% since 2015, broadly in line with nominal GDP growth of 62%. More than half of private spending is on OTC medicines, for which expenditure has doubled since 2015 (Figure 25). Expenditure on prescription medicines with full patient co-payments has also risen, while household spending on prescription medicines has decreased following the introduction of zero co-payments for selected population groups.

Households do not consume all purchased medicines, generating additional costs associated with disposal. Residents are expected to return unused medicines to pharmacies, where they are collected and subsequently disposed of by the State Institute for Drug Control (ŠÚKL). Compliance with this obligation is not universal, and some unused medicines likely end up in municipal waste. As a result, ŠÚKL statistics do not capture all unused medicines in Slovakia and are not

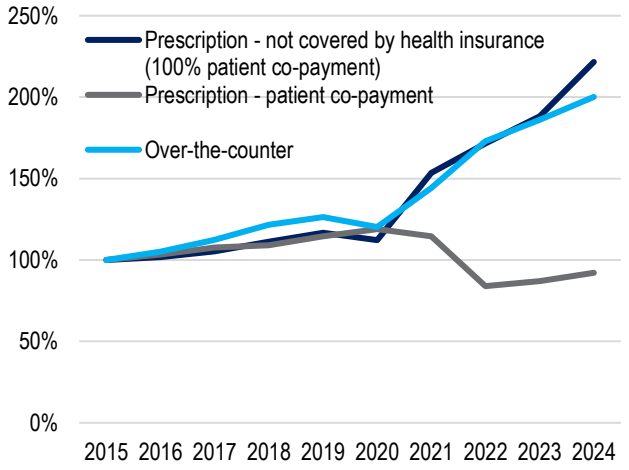
disaggregated into OTC and prescription categories. The total cost of collecting unused medicines in 2024 exceeded EUR 970,000. The volume of medicines collected has grown over time, from 146 tonnes in 2018 to 291 tonnes in 2024[26].

Figure 24: Household expenditure on medicines, in EUR million



Source: NCZI

Figure 25: Development of household expenditure on medicines, 2015=100%



Source: NCZI

4.1 Avoid reimbursing low-benefit, low-cost medicines from public funds

When deciding whether a medicine should be reimbursed, its clinical benefit should be taken into account. Approaches to public reimbursement vary across countries. In Slovakia, under the law, medicines intended for supportive or complementary treatment—those that do not directly target the cause of a disease but alleviate symptoms and improve patient comfort (e.g., vitamins, minerals, probiotics)—are not eligible for categorisation.

The same medicine that is reimbursed by insurance companies in Slovakia may be fully paid for by patients in other countries or may even be available without a prescription. In Slovakia, anti-allergy eye drops are prescription-only and partially covered by PHI, while in Poland, Germany, Italy and Sweden, patients can buy them without a prescription (the medicine has a different name in each country). In Slovakia, supplementary medicines are also reimbursed, including, for example, medicines for insomnia, liver regeneration, and prevention of frequent respiratory tract infections. Unlike in Slovakia, in neighbouring Czech Republic and Poland, medicines containing silymarin, intended for liver regeneration, are fully paid for by patients. In Slovakia, the reimbursement for liver regeneration medicines from the PHI in 2025 was EUR 5 million (Table 24).

Table 24: Examples of medicines[27] in neighbouring countries that are not reimbursed from public funds, unlike in Slovakia

Active ingredient	Czech Republic	Hungary	Potential savings (million euros)
Silymarin	Not reimbursed	Not registered, other medicines with the same active ingredient are not covered	5.0
Metamizole, sodium salt	Only the injectable form is covered	Not registered, other medicines with the active ingredient are not covered	3.1
Other immunostimulants (WHO change)	Not even registered	Not registered, other medicines with the active ingredient are reimbursed	1.6
Zolpidem	Not reimbursed	Not reimbursed	0.7

Source: NCZI, SÚKL, NEAK

A review of the medicines reimbursed from public funds could potentially free up to EUR 54 million. The MoH SR should regularly assess the justification for public reimbursement of medicines. In the summer of 2025, the ministry submitted a request to de-list 14 OTC medicines, for which health insurance companies paid almost EUR 2.4 million in 2024. These

[26] However, this figure is also partly influenced by 2023, as the autumn collection from pharmacies did not take place at that time due to the interruption of operations at two incinerators. Pharmacies are required to take back unused medicines and deliver them to incinerators twice a year.

[27] Due to current legislation and concluded MEA agreements, it is not possible to disclose the names of the medicines concerned.

include medicines that are reimbursed by public health insurance, even though they are—or should be—OTC. De-listing mainly low-cost medicines with limited clinical benefit or those intended for complementary treatment could generate savings of up to EUR 54 million (Table 25).

Table 25: Overview of medicines whose reimbursement by public health insurance could be reassessed, by ATC group, in EUR thousand

ATC	Number of packages	Patient co-payment	Reimbursement by health insurance
Analgesics	1,580	2,812	4,160
Anaesthetics	64	40	410
Anthelmintics	125	31	177
Antianaemic agents	780	1,223	4,663
Anti-inflammatory and anti-rheumatic medicines	822	1,704	2,113
Antimycotics used in dermatology	30	58	77
Antithrombotic agents	2,032	3,626	14,631
Diagnostics	1	3	29
Digestives, including enzymes	287	573	2,707
Diuretics	4	2	10
Emollients and dermatoprotectives	81	31	708
Immunomodulators - stimulants (change in WHO)	206	893	5,250
Other medicines for musculoskeletal disorders	4	43	82
Other medicines for the digestive tract and metabolism	173	248	5,946
Medicines for the biliary tract and liver	552	1,067	5,016
Mineral supplements	1,074	2,435	3,579
Blood substitutes and perfusion solutions	99	8	55
Ophthalmic products	45	91	120
Psychoanaleptics	1,110	1,072	3,157
Psycholeptics	1,340	1,534	1,581
Total	**10,414**	**17,492**	**54,473**

Source: data provided by health insurance companies

Transferring prescription medicines to over-the-counter (OTC) status can simplify access and reduce pressure on outpatient clinics. Such transfers are also being considered in other developed countries (Kuhler et al., 2023; Milonas et al., 2012). However, alongside potential economic benefits, the safety of OTC availability must be carefully evaluated. Several countries—including Australia, Canada, New Zealand, and the United Kingdom—apply a decision tree when converting medicines to OTC status, which systematically assesses the relevant benefits and risks before making a decision (Kuhler et al., 2023; Brass et al., 2011; Brass et al., 2013).

Table 26: Measure from subchapter 4.1

Measure	Description
Reconsider the reimbursement listing of low-cost medicines with limited benefits	De-listing low-cost medicines with limited clinical benefits that patients can reasonably afford to purchase themselves.

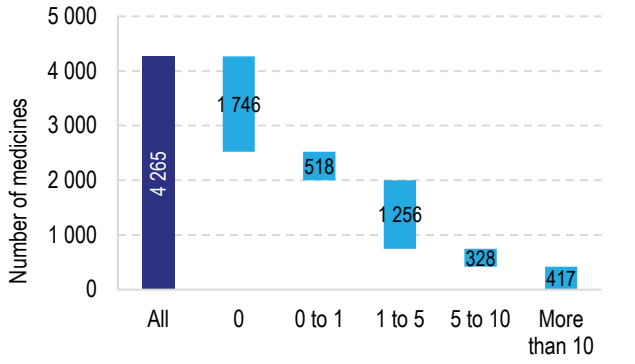
4.2 Consider implementing a flat co-payment for each prescription

The amount of the co-payment that Slovak patients pay for prescribed medicines is determined by the MoH SR. The co-payment system encourages patients to select the cheapest medicine within a reimbursement group. Typically, only the least expensive medicine with the same active substance is fully covered by public health insurance (PHI). If a patient chooses a more expensive medicine, they must pay the price difference. For example, for flu vaccines, the cheaper option is fully reimbursed by PHI (EUR 106.50), while the more expensive one costs EUR 132.40 at the pharmacy, with the patient paying the difference. To regulate consumption, a minimum co-payment is set for certain medicine groups, even for the cheapest medicine in the group (e.g., for anxiety medicines, the minimum co-payment is EUR 0.63).

The co-payment system is complex and often unclear to patients. Ordinary patients may struggle to understand how their co-payment is calculated. This lack of transparency also affects doctors, who are legally required to inform patients about potential co-payments. The MoH SR determines which medicine in a group is exempt from co-payment using a reimbursement group coefficient. Although this coefficient is published, its calculation is not explained. The Ministry also sets only the maximum co-payment at the pharmacy. Co-payments may be lower if the manufacturer reduces the price of the medicine, provided the fixed ratio between PHI reimbursement and patient co-payment is maintained, with some exceptions. The system is further complicated by exemptions designed to protect vulnerable population groups (see Chapter 4.3).

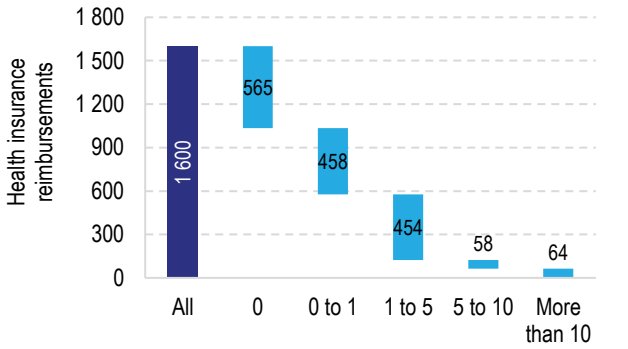
In 2024, more than 41% of medicines on the reimbursement list had a zero co-payment, accounting for 35% of PHI expenditure. Of the 4,265 medicines on the list that year, 1,746 had no co-payment set (Figure 26). PHI spent EUR 565 million (35%) on these medicines, with an additional EUR 458 million spent on medicines with a co-payment of less than EUR 1 per package (Figure 27).

Figure 26: Listed maximum co-payments for categorised medicines in pharmacies



Source: ZKL, NCZI

Figure 27: Most PHI resources in 2024 went to medicines with the lowest patient co-payments, in EUR million



Source: ZKL, NCZI

If co-payments are intended to regulate medicine consumption, they should be predictable and transparent for patients. The World Health Organization (WHO) considers it poor practice to operate multiple overlapping regulations within the system, as this creates confusion. Such uncertainty can discourage low-income households from obtaining medicines. If patients do not know in advance how much they will pay for prescribed medicines at the pharmacy, they may reduce or limit their treatment. Countries with the lowest proportion of households financially burdened by healthcare costs—i.e., those with minimal risk of limiting treatment due to low income—typically have common fixed co-payments for medicines, targeted exemptions, and the option of supplementary insurance covering medicine costs.

Internationally, co-payments are most often set as a percentage of the medicine's price, although some countries use a fixed co-payment regardless of cost. Percentage co-payments represent the share of the medicine's price paid by the patient relative to public funds, and this share may be constant or variable across medicines. Fixed co-payments aim to simplify the system and increase cost predictability for patients. This approach is used to some extent in Austria and England.

A fixed co-payment per medicine or prescription can also help reduce excessive consumption. Various mechanisms abroad simplify the system for patients and thereby improve regulation of medicine use. For example, in England, patients pay a fixed amount per prescription, whereas in Austria they pay a fixed amount per medicine. If the medicine's price is lower than the fixed co-payment, patients pay only the lower price, but if it is higher, they pay the full price.

Box 15: Determining Patient Co-Payments in Slovakia

The maximum patient co-payment is calculated as the difference between the final price of a medicine and the reimbursement provided by the public health insurance (PHI). PHI reimbursement is determined by categorising the medicine based on the maximum price per unit of the basic active ingredient (ŠDL) of a comparable medicine already reimbursed by insurance companies (see Appendix 10 for pricing details).

Typically, only the cheapest medicine within a reimbursement group is available without a co-payment. This rule is intended to encourage patients to choose the least expensive alternative when medicines share the same active ingredient. If a manufacturer sets a price above the PHI reimbursement, the patient must pay the difference.

In certain medicine groups, patients cannot avoid co-payments, as not all groups include an alternative without a co-payment. Co-payments in these groups aim to curb overconsumption of medicines, such as antimigraine or non-steroidal anti-inflammatory medicines. Patients paid the highest co-payments for medicines not intended for acute conditions—for example, reproductive medicines. The highest average co-payment for a medicine containing follitropin alfa in 2024 was EUR 165.

Whether the cheapest medicine has a co-payment is determined by the reimbursement group coefficient. PHI reimbursement is calculated based on the lowest price within the reimbursement group for a standard dose of the medicine, multiplied by the coefficient. The MoH SR publishes the reimbursement group coefficient on the first day of each month. However, publicly available materials do not explain how the Ministry calculates these coefficients. Additionally, not all medicines are included in reimbursement groups or have a set coefficient. A reimbursement group must consist of at least two reference medicines.

If a seller or distributor wishes to reduce the price below the level specified in the ZKL, they must maintain **a fixed ratio between co-payment and reimbursement**. An exception applies to medicines whose co-payment exceeds 3% of the average wage from two years prior (currently EUR 42.90). More expensive medicines may thus be cheaper for patients at the pharmacy, potentially displacing generic and biosimilar medicines.

Table 27: Measure from subchapter 4.2

Measure	Description
Consider introducing a fixed co-payment	Introduce a fixed co-payment per package to make the system more transparent for patients, for example by adopting a system similar to that used in Germany with minimum and maximum co-payment levels.

4.3 Remove the zero co-payment caps for specific population groups

The co-payment system should be designed carefully to ensure it does not restrict access to treatment for vulnerable households, while still effectively limiting overconsumption of medicines. Excessively high co-payments can impede access for low-income households, in some cases preventing treatment entirely or reducing it to the point of causing permanent health damage. Conversely, very low co-payments fail to curb medicine consumption. Quarterly co-payment caps further protect selected households from unaffordable costs.

In Slovakia, three protective quarterly caps are currently in place (EUR 30, EUR 12, and EUR 0). Under Slovak law, vulnerable groups include all pensioners (quarterly caps of EUR 30), persons with disabilities (EUR 12), and children under six years of age (EUR 0). Within these groups, co-payments per quarter cannot exceed the cap; if they do, health insurance companies cover the excess. This entitlement applies to the cheapest medicine in each reimbursement group.

The introduction of zero co-payments for selected groups has significantly reduced total co-payment levels. Zero co-payments for non-working pensioners with pensions below 60% of the average wage, and for children under six, were introduced in 2021 and 2022, respectively, substantially lowering overall co-payments. Children were only recognised as a vulnerable group in 2021; prior to this, no protective cap applied.

Table 28: Quarterly co-payment caps for vulnerable groups[28]

Quarterly caps	Old-age pensioners	Persons with disabilities	Disabled pensioners	Children	Expenditure 2024 (million euros)
EUR 30	Income higher than EUR 858 in 2025				2

[28] The data for returned co-payments include dietary foods and medical devices.

Quarterly caps	Old-age pensioners	Persons with disabilities	Disabled pensioners	Children	Expenditure 2024 (million euros)
EUR 12		Income higher than EUR 858 in 2025	Income higher than EUR 858 in 2025		4
EUR 0	Not working, pension lower than EUR 858 in 2025	Not working, pension lower than EUR 858 in 2025	Not working, pension lower than EUR 858 in 2025	Children under 6	70.6 (of which 9.1 million are children)

Source: Act No. 363/2011, Act No. 81/2021, ÚDZS (2025)

Repealing full exemptions from co-payments and returning to the pre-2022 caps could free up approximately EUR 40 million without significant social impact. Full exemption from co-payments contradicts the primary purpose of co-payments, which is to limit overconsumption. Returning to the caps in place before 2022 would mean a shift from zero co-payments to low co-payments—on average EUR 10 per month for pensioners and EUR 4 per month for persons with disabilities. Non-zero quarterly caps would still provide sufficient protection for vulnerable groups[29].

In addition to repealing full exemptions, the government should reassess which population groups are considered vulnerable in relation to medicines. Selection of groups should be more closely linked to household income. By contrast, age-based criteria appear unjustified. The Statistical Office of the Slovak Republic evaluated residents aged 65 and older as among the least at risk of poverty, with poverty risk up to 5.5 percentage points lower than the total population. Conversely, the most vulnerable groups include single-parent families, families with multiple children, residents of excluded communities, and people living in regions with low employment rates (ŠÚ SR, 2025). Other population groups should also be reconsidered—for example, working pensioners with above-average incomes or the broader category of persons with disabilities

Table 29: Measure from subchapter 4.3

Measure	Description
Repealing full exemptions from co-payments	Reintroduce quarterly caps on co-payments for vulnerable population groups instead of full exemptions from co-payments.
Redefine vulnerable groups	More precisely define the population groups eligible for protective limits on medicine co-payments, taking into account their socio-economic circumstances.

Box 16: Zero co-payments caps for medicines introduced in 2021 and 2022

The original Medicines Act already included quarterly co-payment caps. In 2021, zero co-payments were introduced for children under six years of age. From 2022, zero co-payments were also extended to selected groups of pensioners, depending on the level of their old-age pension.

Currently, most pensioners (unless their income exceeds 60% of the average monthly wage from two years prior), persons with disabilities, and children under six are fully exempt from co-payments. These are zero quarterly co-payments, meaning that under certain conditions, the health insurance company covers the co-payment instead of the patient. In 2023, more than 80% of eligible old-age pensioners met these conditions.

Table 30: Overview of quarterly caps

Group	Disabled / disability pensioner	Old-age / retirement / early retirement pensioner / 62+	Children under 6	Disabled children
2011	EUR 30	EUR 45	-	-
2016	EUR 25	EUR 25	EUR 8	EUR 0
2018	EUR	EUR 30	EUR 10	EUR 0
2021	EUR 12	EUR 30	EUR 0	EUR 0
From 2022	EUR 0 if the pension is less than 60% of the PMM	EUR 0 if the pension is less than 60% of PMM	EUR 0	EUR 0

Source: Slov-Lex

[29] The Czech Republic also has established caps, although they have never been set to zero. A general per-insured-person cap is defined – the quarterly equivalent would be around EUR 50 (maximum 5,000 CZK per year).

Bibliography

AGENCY FOR THE EVALUATION OF MEDICAL TECHNOLOGIES AND TARIFFING, 2024. *Recommendation No. 150/2023 of 10 January 2024*. Available online: https://bip.aotm.gov.pl/assets/files/zlecenia_mz/2023/122/REK/2024%2001%2010%20BP.410.150.2023.MZ_Orap_publikacja%20BIP.pdf

BRASS, E. P., LOFSTEDT, R., and RENN, O., 2011. Improving the Decision-Making Process for Nonprescription Drugs: A Framework for Benefit–Risk Assessment. *Clinical Pharmacology & Therapeutics*, vol. 90, no. 6, pp. 791–803.

BRASS, E. P., LOFSTEDT, R., and RENN, O., 2013. A Decision-Analysis Tool for Benefit–Risk Assessment of Nonprescription Drugs. *Journal of Clinical Pharmacology*, vol. 53, no. 5, pp. 475–482.

BRINKHUIS, F., GOETTSCH, W. G., MANTEL-TEEUWISSE, A. K., and BLOEM, L. T., 2024. Added benefit and revenues of oncology drugs approved by the European Medicines Agency between 1995 and 2020: retrospective cohort study. *British Medical Journal*, vol. 2024, no. 384, Open access. Available online: https://www.bmj.com/content/384/bmj-2023-077391

BüSSGEN, M. and STARGARDT, T., 2022. Changes in launch delay and availability of pharmaceuticals in 30 European markets over the past two decades. BMC Health Service Research, vol. 22, no. 1457, Open access. Available online: https://link.springer.com/article/10.1186/s12913-022-08866-7

DABBOUS, M., CHACHOUA, L., CABAN, A., TOUMI, M., 2020. Managed Entry Agreements: Policy Analysis From the European Perspective. *Value in Health*, vol. 23, no. 4, pp. 425-433.

DAVIS, C. et al., 2017. Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. *British Medical Journal*, vol. 2017, no. 359, Open access. Available online: https://www.bmj.com/content/359/bmj.j4530

EMA, 2023. *Budget 2024: Budget commentary*. Available online: https://www.ema.europa.eu/en/documents/other/european-medicines-agency-budget-2024_en.pdf

GUINDON, G. E., FATIMA, T., GARASIA, S., and KHOEE, K., 2022. A systematic umbrella review of the association of prescription drug insurance and cost-sharing with drug use, health services use, and health. *BMC Health Service Research*, vol. 22, article no. 297, Open access. Available online: https://link.springer.com/article/10.1186/s12913-022-07554-w

HARRIS, B. L., STERGACHIS, A., and RIED, L. D., 1990. The Effect of Drug Co-Payments on Utilisation and Cost of Pharmaceuticals in a Health Maintenance Organisation. *Medical Care*, vol. 28, no. 10, pp. 907-917.

CHANDRA, A., FLACK, E., and OBERMEYER, Z., 2024. The Health Costs of Cost Sharing. *Quarterly Journal of Economics*

IQVIA, 2024. *EFPIA Patients W.A.I.T. Indicator 2023 Survey*. Available online: https://efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf

IQVIA, 2025. *EFPIA Patients W.A.I.T. Indicator 2024 Survey*. Available online: https://www.iqvia.com/-/media/iqvia/pdfs/library/publications/efpia-patients-wait-indicator-2024.pdf

IMF, 2025a. Slovak Republic: Technical Assistance Report - Note on Central Fund for Exceptional Access to High-Cost Medicines. Washington, DC: IMF.

IMF, 2025b. Slovak Republic: Technical Assistance Report - Note on Horizon Scanning for New Medicines. Washington, DC: IMF.

IMF, 2025c. Slovak Republic: Technical Assistance Report - International Experience on the Negotiation Process of Single Source Pharmaceuticals and its Application to Slovakia. Washington, DC: IMF.

IZA, 2024. *Malignant breast tumours in Slovakia: epidemiological analysis and recommendations for systemic measures*. Available online: https://analyzy.gov.sk/files/archiv/74/zhubne-nadory-prsnika-SR.pdf

KUHLER, T. C., et al., 2024. Real-world Data and Evidence to support a switch in status from Prescription drug to Over the Counter drug as applied by the EMA, the US FDA, the MHRA, and the BfArM. *Clinical Therapeutics*, vol. 46, pp. 208-216.

MILONAS C. et al., 2012. PHP84 The Economic Health Value from Rx to OTC Switch in Greece. *Value in Health*, vol. 15, no. 7, Open access A303.

Ministry of Health of the Slovak Republic, 2022. Change in expenditure on medicines compared to 2021 after taking into account the impact of Amendment 363/2011. Available online: https://www.nrsr.sk/web/Dynamic/DocumentPreview.aspx?DocID=510052

Ministry of Health of the Slovak Republic, 2025. Draft law amending and supplementing Act No. 363/2011 Coll. on the scope and conditions of reimbursement for medicines, medical devices and dietary foods based on public health insurance and amending and supplementing certain acts as amended by later regulations and amending and supplementing certain acts. *Legislative process LP/2025/594*. Available online: https://www.slov-lex.sk/elegislativa/legislativne-procesy/SK/LP/2025/594

Ministry of Health of the Slovak Republic, 2025. Decree of the Ministry of Health of the Slovak Republic laying down details for calculating the relevant multiple of gross domestic product for determining the threshold value of the medicinal product under assessment. *Legislative process LP/2025/230*. Available online: https://www.slov-lex.sk/elegislativa/legislativne-procesy/SK/LP/2025/230

Ministry of Health of the Slovak Republic, 2026. *Categorisation portal*. Available online: https://kategorizacia.mzsr.sk/Lieky/Common/Requests

NACI, H. et al., 2025. Population-health impact of new drugs recommended by the National Institute for Health and Care Excellence in England during 2000–20: a retrospective analysis. *Lancet*, vol. 405, no. 10472, pp. 50-60.

NCI, 2020. *For Women with Breast Cancer, Regular Exercise May Improve Survival*. Available online: https://www.cancer.gov/news-events/cancer-currents-blog/2020/breast-cancer-survival-exercise

NCZI, 2024. *National Cancer Registry of the Slovak Republic: Report on patients with malignant tumours – clinical and epidemiological characteristics of the disease (valid from 2025)*. Available online: https://www.nczisk.sk/Documents/aktuality/PDF_Navod_pre_hlasenie_pacientov_do_NOR_SR.pdf

NCZI, 2025. *Consumption of human medicines, medical devices and dietary foods in the Slovak Republic*. Available online: https://www.nczisk.sk/Statisticke_vystupy/Tematicke_statisticke_vystupy/TOP-50-liekov/Spotreba_humannych_liekov_zdravotnickych_pomocok_dietetickych_potravin_SR/Pages/default.aspx

NICE, 2017. Interim Process and Methods of the Highly Specialised Technologies Programme Updated to reflect 2017 changes. Available online: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf

NICE, 2022. *NICE technology appraisal and highly specialised technologies guidance: the manual*. Available online: https://www.nice.org.uk/process/pmg36/chapter/economic-evaluation-2#presenting-expected-cost-effectiveness-results

NICE, 2025. *Changes to NICE's cost-effectiveness thresholds confirmed*. Available online: https://www.nice.org.uk/news/articles/changes-to-nice-s-cost-effectiveness-thresholds-confirmed

NIHO, 2025. The drug rozanolixizumab (Rystiggo) as an adjunct to standard treatment for refractory patients with generalised myasthenia gravis in stages MGFA II-IV. *Health Technology Assessment*, No. L143. Available online: https://niho.sk/wp-content/uploads/2025/01/NIHO_rozanolixizumab-Rystiggo_generalizovana-myastenia-gravis-L143.pdf

NIHO, 2026. *Published projects*. Available online: https://niho.sk/publikovane-projekty/

SAO, 2022. Audit Report 2022: National Health Registers NCZI. Available online: https://www.nku.gov.sk/documents/33855/189570/96858-0-110.pdf/1d8fec72-9508-bd03-1134-586f7dd4393e?t=1698020752175

SAO, 2023. Opinion of the Supreme Audit Office of the Slovak Republic on the draft final accounts of the Slovak Republic for 2022. Available online: https://www.nku.gov.sk/documents/d/nku/stanovisko-nku-k-navrhu-szu-za-rok-2022

SAO, 2024. Opinion of the Supreme Audit Office of the Slovak Republic on the draft final accounts of the Slovak Republic for 2023. Available online: https://www.nku.gov.sk/documents/d/nku/stanovisko-nku-sr-k-navrhu-statneho-zaverecneho-uctu-sr-za-rok-2023

NR SR, 2022. *Government bill amending and supplementing Act No. 363/2011 Coll. on the scope and conditions of reimbursement of medicines, medical devices and dietary foods based on public health insurance and amending and supplementing certain acts as amended by later regulations and amending and supplementing certain acts*. Details of the draft law. Available online: https://www.nrsr.sk/web/Default.aspx?sid=zakony/zakon&MasterID=8697

OECD, 2015. *Health Data Governance: Privacy, Monitoring and Research*. Paris: OECD Publishing. Available online: https://www.oecd.org/content/dam/oecd/en/publications/reports/2015/10/health-data-governance_g1g5a9e9/9789264244566-en.pdf

OECD, 2024. *Access to oncology medicines in EU and OECD countries*. OECD Working Paper No. 170. Available online: https://www.oecd.org/en/publications/access-to-oncology-medicines-in-eu-and-oecd-countries_c263c014-en.html

PANGARSA, et al. 2023. The effect of multidisciplinary team on survival rates of women with breast cancer: a systematic review and meta-analysis. *Annals of Medicine & Surgery*, vol. 85, no. 6, pp. 2940-2948.

PEARSON, S. D., THOKALA, P., STEVENSON, M., and RIND, D., 2019. The Effectiveness and Value of Treatments for Spinal Muscular Atrophy: A Summary from the Institute for Clinical and Economic Review's New England Comparative Effectiveness Public Advisory Council. *Journal of Managed Care & Specialty Pharmacy*, vol. 25, no. 12, Open access. Available online: https://www.jmcp.org/doi/10.18553/jmcp.2019.25.12.1300

PERSSON, U. and JöNSSON, B., 2016. The End of the International Reference Pricing System? *Applied Health Economics and Health Policy*, vol. 14, pp. 1-8.

RECKERS-DROOG, V., EXEL, J., and BROUWER, W., 2021. Willingness to Pay for Health-Related Quality of Life Gains in Relation to Disease Severity and the Age of Patients. *Value in Health*, vol. 24, no. 8, pp. 1182-1192.

REYES-TRAVÉ, A., et al., 2021. Characterisation of the Pharmaceutical Risk-Sharing Arrangement Process in Catalonia. *PharmacoEconomics*, vol. 39, pp. 973–982, Open Access. Available online: https://link.springer.com/article/10.1007/s40273-021-01046-1

SCHMIDT, M. et al., 2015. The Danish National Patient Registry: a review of content, data quality, and research potential. *Clinical Epidemiology*, vol. 7, pp. 449–490.

STROHMAIER C., ZECHMEISTER-KOSS, I. 2024. *Threshold values in health economic evaluations and decision-making*. AIHTA Project Report No.: 163. Vienna: HTA Austria. Available online: https://eprints.aihta.at/1549/1/HTA-Projektbericht_Nr.163.pdf

SÚKL, 2025. Procedure for assessing cost-effectiveness analysis. Available online: https://sukl.gov.cz/metodiky-stanoveni-cen-a-uhrad/sp-cau-028/

TOMEK, D., PŠENKOVÁ, M., and BALVAN, B., 2010. Patient registries – the need for real data in evaluating the efficacy, safety and cost-effectiveness of oncological drugs. *Oncology*, vol. 5, no. 2, pp. 85-88. Available online: https://www.solen.sk/storage/file/article/1385a3552328dc8fed52a8d32aa17dff.pdf

ÚDZS, 2024. *Report on the status of PHI implementation for 2023*. Available online: https://www.udzs-sk.sk/wp-content/uploads/2024/08/Sprava-o-stave-vykonavania-PHI-za-rok-2023.pdf

ÚDZS, 2025. *Report on the implementation of PHI for 2024*. Available online: https://www.udzs-sk.sk/wp-content/uploads/2025/09/Sprava-o-stave-PHI-za-rok-2024.pdf

VFM, 2019. *Review of healthcare expenditure II: final report*. Available online: https://www.mfsr.sk/files/archiv/44/revizia_zdravotnictvo_2.pdf

VONČINA, L. et al., 2023. *Review of Latvia's Pricing and Reimbursement System and its Lists of Reimbursed Medicines*. Available online: https://www.vm.gov.lv/lv/media/13686/download?attachment

VOP, 2025. Proposal to initiate proceedings on the conformity of legal regulations pursuant to Article 125(1)(a) of the Constitution of the Slovak Republic. Ref. no.: 4159/2025/VOP. Available online: https://vop.gov.sk/wp-content/uploads/2025/05/Navrh_VOP_na_US_SR_na_zacatie_konanania_o_sulade_pravnych_predpisov-

vynimkove_lieky.pdf?fbclid=IwZXh0bgNhZW0CMTAAYnJpZBExaUl5UnBiM3lvREJkOHB4dgEeP84jabVNp77hdzvqiL8KiouR1ckgbKj-Js7KOwv2HF6R5i3sfRwwecOeOyA_aem_h2ytzfZT2vEWPSM5LPtWIA

Decree No. 298/2022 Z. z. of the Ministry of Health of the Slovak Republic of 19 August 2022, laying down details for calculating the relevant multiple of gross domestic product for determining the threshold value of the medicinal product under assessment. Available online: https://static.slov-lex.sk/static/SK/ZZ/2022/298/20220901.html

Decree No. 74/2014 Coll. of the Ministry of Health of the Slovak Republic of 11 March 2014, establishing a list of reports to national health registers, their characteristics, details on the content of national health registers, procedures, methods, scope of reporting units and deadlines for reporting to national health registers. Available online: https://static.slov-lex.sk/static/SK/ZZ/2014/74/vyhlasene_znenie.html

WIESELER, B., MCGAURAN, N., and KAISER, T., 2019. New drugs: where did we go wrong and what can we do better? *British Medical Journal*, vol. 2019, no. 366, l4340.

Act No. 363/2011 Coll. on the scope and conditions of reimbursement of medicines, medical devices and dietary foods based on public health insurance and on amendments to certain acts. Available online: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2011/363

Act No. 153/2013 Coll. on the National Health Information System and on amendments to certain acts. Available online: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2013/153/

Act No. 81/2021 Coll. of 5 February 2021, amending Act No. 363/2011 Coll. on the scope and conditions of reimbursement of medicines, medical devices and dietary foods based on public health insurance and amending certain Acts, as amended, and amending certain Acts. Available online: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2021/81/

Annexes

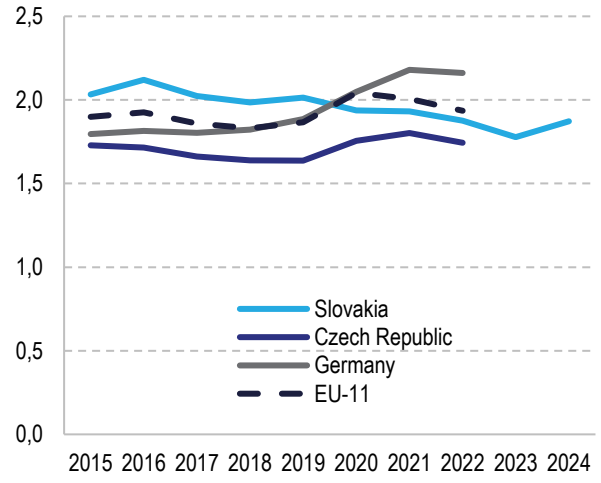
Annex 1: The informative value of international comparisons of pharmaceutical expenditure is limited

The OECD database should, in principle, allow for straightforward international comparisons of pharmaceutical expenditure and consumption. According to more detailed information in the methodological guide, however, comparability is limited. Expenditure definitions vary between countries (what is considered pharmaceutical expenditure, and whether a medicine is part of inpatient or outpatient care). The scope of data collection also differs, both for consumption and expenditure (pharmacy sales, outpatient care, inpatient care, commercial sales). In some cases, even the definition of a daily dose differs.

- **In international comparisons, the most commonly used indicator is expenditure on medicines sold in pharmacies. Slovakia is overestimated in this measure because it also reports part of expenditure in hospitals and outpatient care.** According to Healthcare Spending Review II, this amounted to EUR 200 million in 2019. According to the Statistical Office of the Slovak Republic, the practice has not changed substantially since then.
- **The main challenge in comparing volume consumption and generic uptake is the scope of data collected.** Some countries do not include hospital consumption, while others do not track over-the-counter medicines or medicines not at least partially reimbursed from public sources. Additionally, several groups of medicines cannot be included in consumption data because a defined daily dose cannot be established, such as dermatological medicines, modern oncology medicines (antineoplastics and immunomodulators), and medicines for sensory organs.
- **Therefore, the selection of countries in international comparisons differs for each analysis to ensure that only comparable data are used.**

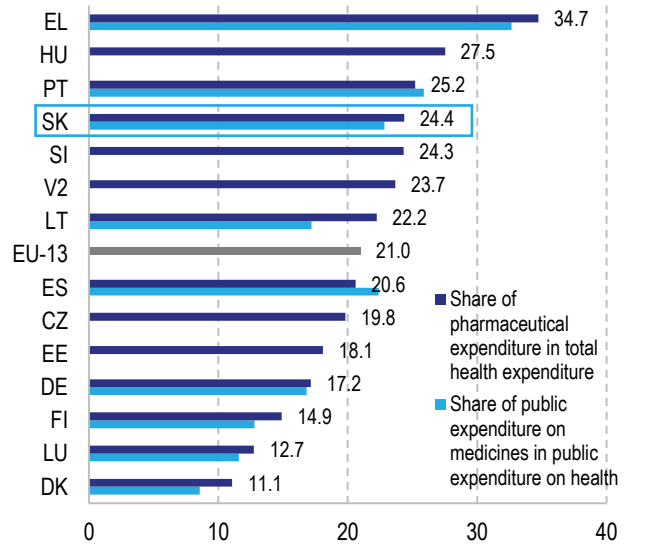
Total pharmaceutical expenditure[30] (public and household expenditure) relative to the size of the economy in Slovakia was broadly comparable with other EU countries. Between 2015 and 2024, Slovakia spent on average 2% of GDP on medicines, which is comparable to the EU11 average (1.92% of GDP) and Germany (1.94% of GDP), and slightly higher than the Czech Republic (1.7% of GDP). Slovak expenditure as a share of GDP had been gradually declining, but the trend reversed in 2022 following the pharmaceutical reform, which significantly streamlined the categorisation of medicines reimbursed from PHI.

Figure 28: Total pharmaceutical expenditure, in % of GDP



Note: EU-11 consists of 11 countries for which data was available for 2015–2022. *Source: OECD, VFM*

Figure 29: Share of pharmaceutical expenditure in total health expenditure, in %, 2022



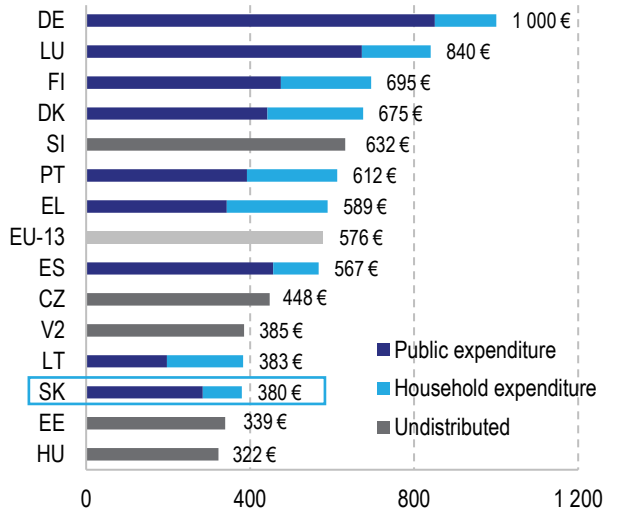
Note: EU-13 consists of 13 countries for which data was available in 2022. V2 consists of the Czech Republic and Hungary. *Source: OECD, VFM*

[30] In the SHA methodology, this is a memorandum item that EU countries are not required to report. For this reason, Slovakia does not report this data, which has been supplemented from NCZI data (2025).

However, pharmaceutical expenditure represents a larger share of total healthcare expenditure in Slovakia than in many other EU countries. This is partly because medicine prices are relatively uniform across countries due to reference pricing, unlike other healthcare costs, such as wages for healthcare personnel or prices of medical services, which vary more with national income. Being one of the lower-income EU countries, Slovakia thus spends less on price-sensitive healthcare services, which increases the relative weight of pharmaceutical expenditure.

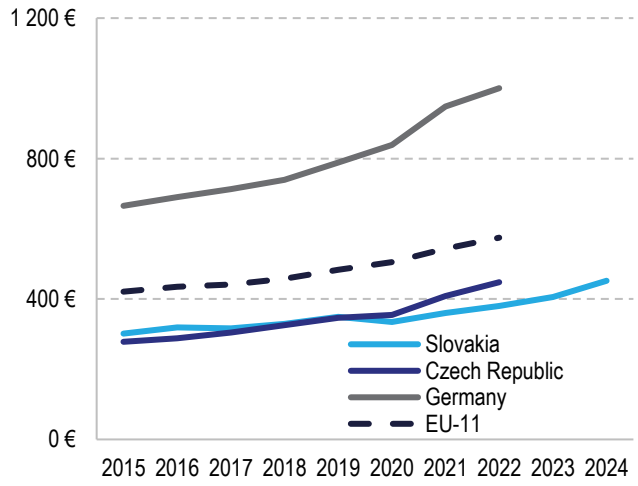
Per capita expenditure on medicines, however, remains below the European average. Lower GDP per capita in Slovakia translates into lower spending on medicines, with the average Slovak consuming medicines worth EUR 380 in 2022, significantly less than in wealthier EU countries. Future increases in per capita spending are likely to be constrained by the pace of economic growth.

Figure 30: Total expenditure on medicines per person at current prices, in EUR, 2022



Note: Same as in Figure 29. *Source: OECD, VFM*

Figure 31: Total expenditure on medicines per person at current prices between 2015 and 2022, in EUR



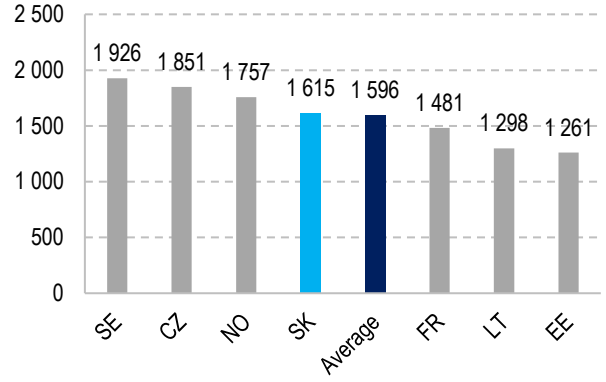
Note: Same as in Figure 28. *Source: OECD, VFM*

The quantity of medicines consumed in Slovakia is not higher than in European countries for which comparable data are available.[31] The Czech Republic consumes approximately 15% more daily doses, and Sweden 20% more. In contrast, the Baltic countries consume 21% and 22% less, respectively. Overall, Slovak consumption is around the average level. However, this only covers medicines for which a defined daily dose can be determined. Entire groups of medicines are missing from the data, namely dermatologicals (D), antineoplastics and immunomodulators (L), antiparasitics, insecticides and repellents (P), sensory organs (Z), and miscellaneous (R).

The volume of medicines consumed has remained relatively stable over time, while expenditure continues to grow. Between 2016 and 2022, consumption increased by only 0.7%. The rise in expenditure is primarily driven by the introduction of new and expensive medicines, a trend that accelerated following the legislative changes in 2022 (Chapter 1).

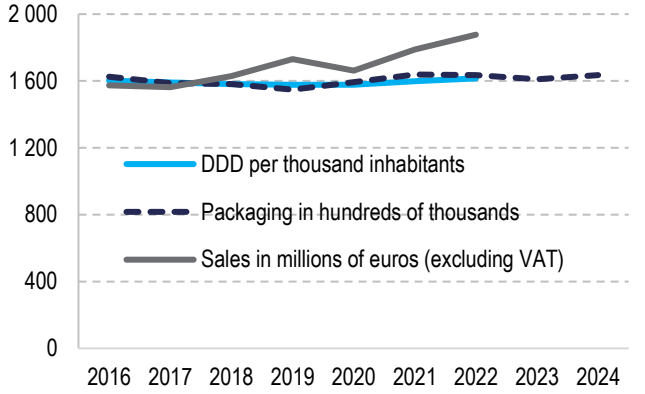
[31] In this context, only six countries are broadly comparable to Slovakia, though even among them there are minor differences in data reporting. Consequently, in the Health Expenditure Review II, consumption was compared only with the Czech Republic and Sweden, which remain the most methodologically comparable to Slovakia.

Figure 32: Pharmaceutical consumption in countries with comparable reporting, in DDD per thousand, 2022



Source: OECD, VFM

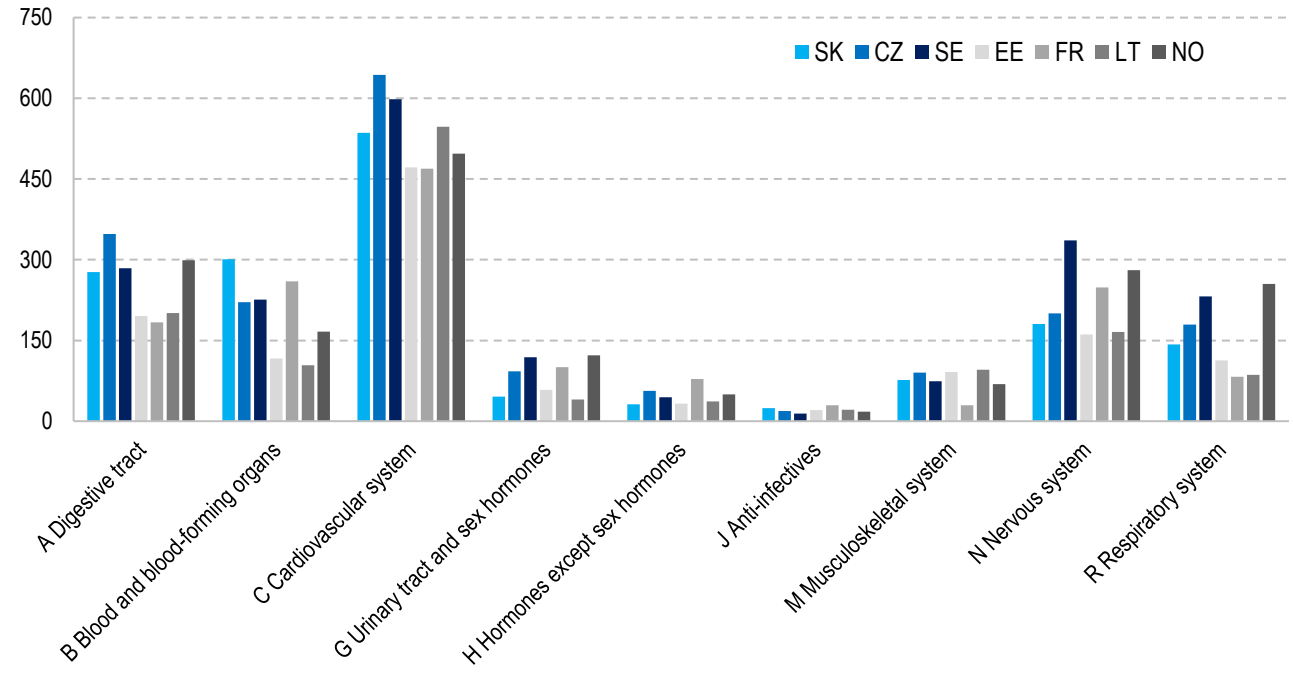
Figure 33: Development of pharmaceutical consumption in Slovakia



Source: OECD, VFM

The structure of medicine consumption by ATC[32] groups does not differ significantly across countries. Other countries show lower consumption only in the "blood and blood-forming organs" group. However, consumption is overestimated for Slovakia, the Czech Republic, and Sweden because these countries define the daily dose of folic acid differently from others (0.4 mg versus 10 mg). Folic acid represents a substantial portion of group B (over 50% in Slovakia), so this 25-fold difference in the defined daily dose markedly inflates the reported number of daily doses.

Figure 34: Overview of Slovak pharmaceutical consumption and EU countries with comparable reporting, by ATC groups, in defined daily doses – DDD per thousand inhabitants, 2022[33]



Source: OECD, VFM

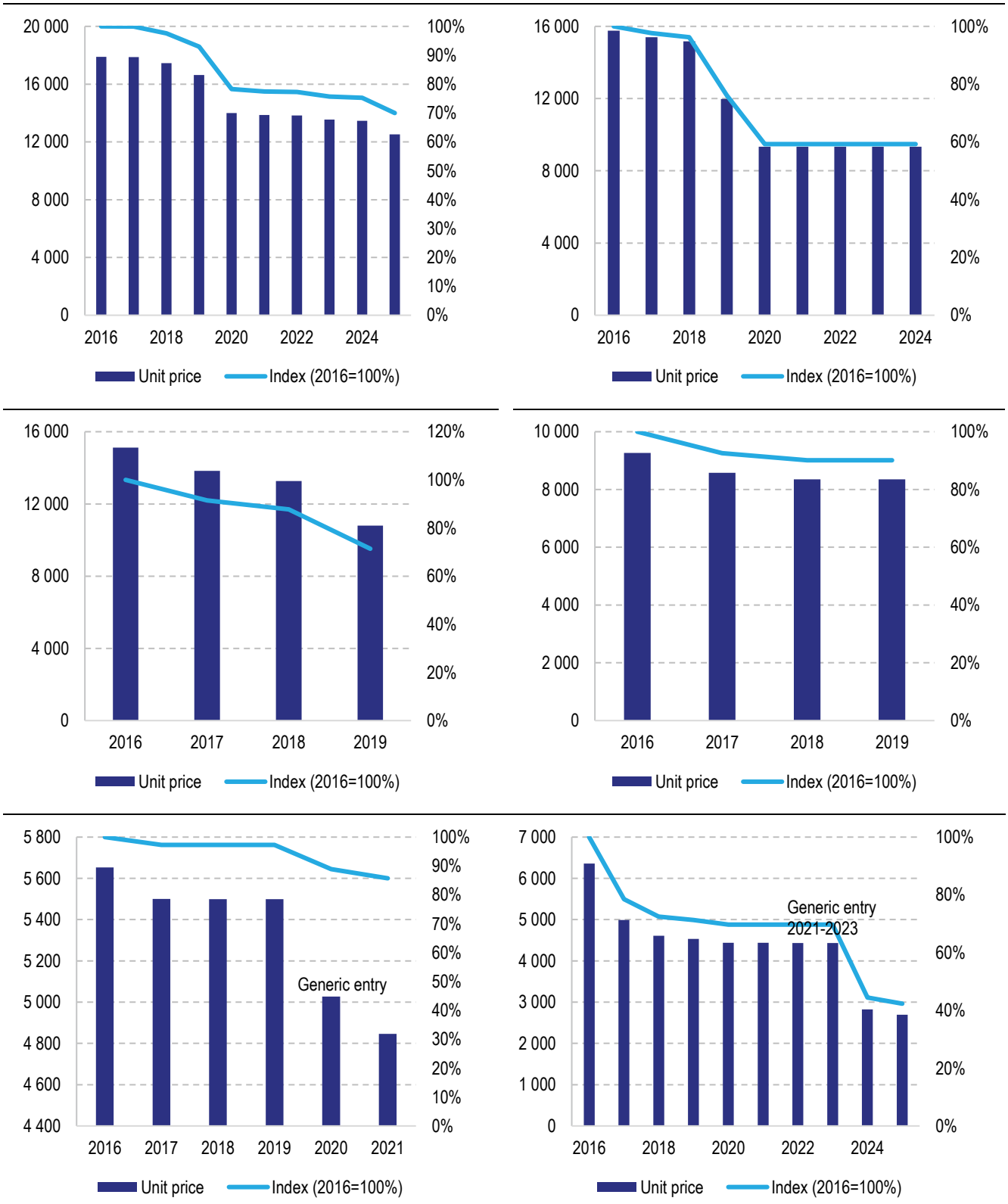
[32] Anatomical Therapeutic Chemical Classification System for medicines.

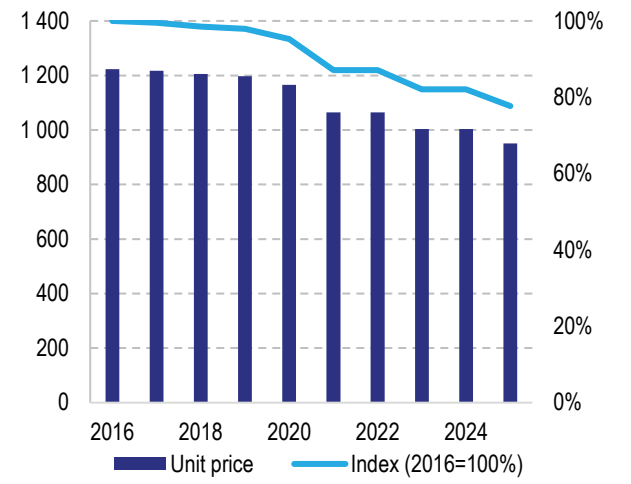
[33] Within ATC group B, total consumption in DDD is substantially overestimated because Slovakia, the Czech Republic, and Sweden report folic acid consumption differently from other OECD countries due to different definitions of a single DDD (0.4 mg versus 10 mg). Folic acid represents a large share of group B (over 50% in Slovakia), so this 25-fold difference in definition greatly inflates the reported number of daily doses.

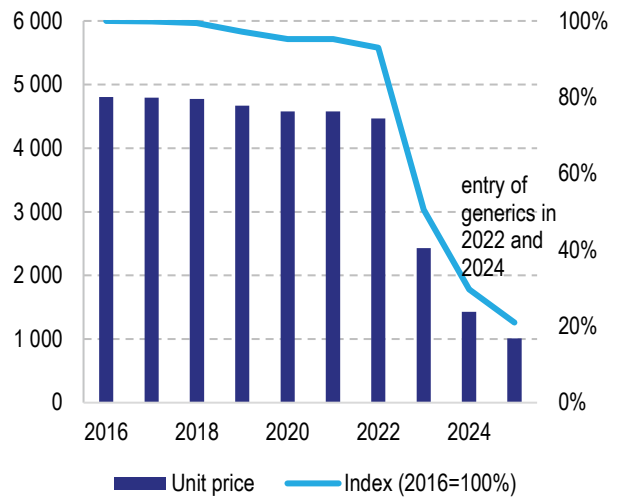
Annex 2: Development of medicine prices over time

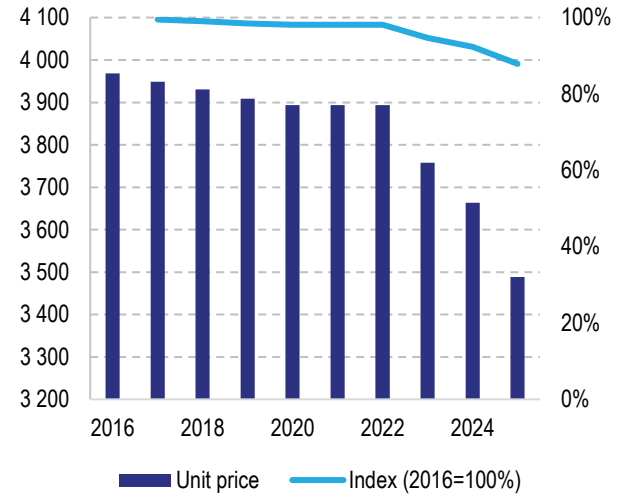
The unit price of medicines generally declines over time, primarily due to reference pricing and the entry of generics. Figure 33 presents the ten original medicines that were among the most expensive in the 2016 list of reimbursed medicines.

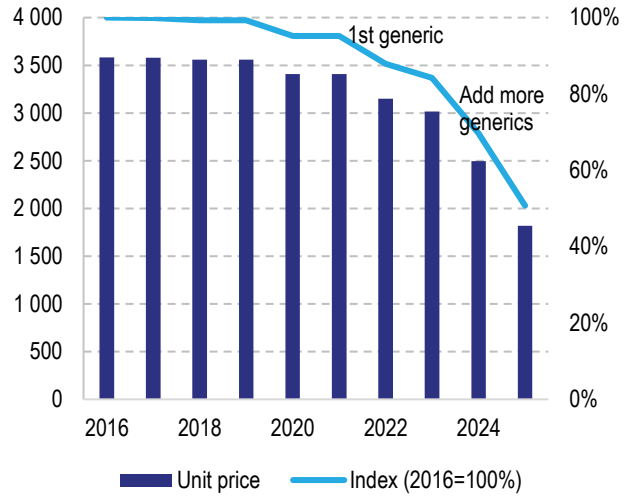
Figure 35: TOP 10 most expensive medicines in 2016 and their price development until 2025 (or until de-listing)









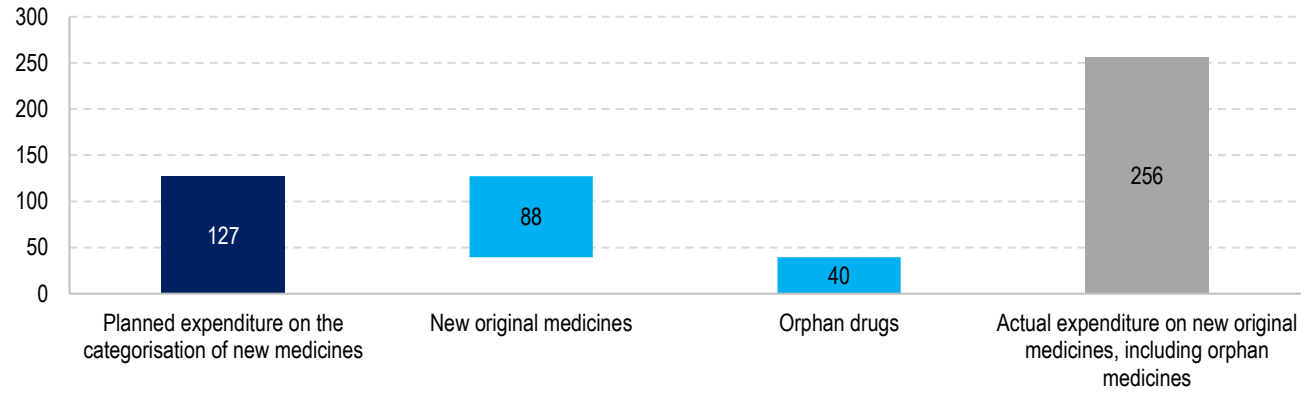


Source: MoH SR, ZKL

Annex 3: Implications of the 2022 Pharmaceutical Reform for 2024

The 2022 medicines reform aimed to increase the availability of new medicines and gradually reduce the gap with the Czech Republic. The expected expenditure from the introduction of 72 medicines that were reimbursed in the Czech Republic but not yet in Slovakia was estimated. In practice, only 25 of these medicines entered the Slovak system, while an additional 116 original medicines were categorised instead.[34]

Figure 36: Expected versus actual change in expenditure on new original medicines resulting from the 2022 reform (difference between 2021 and 2024), in EUR million



Note: The increase in actual expenditure may be slightly lower due to refunds that health insurance companies charge on the income side and may not all be captured in the NCZI data on pharmaceutical consumption.

Source: quarterly reports on pharmaceutical consumption from the NCZI, ZKL, MoH SR, processed by VFM

Most of the expected medicines were antineoplastics and immunomodulators, primarily oncology medicines. In reality, 54 medicines in this ATC group entered the system, but only 20 were among the originally anticipated 72. Overall, up to 71% of the increase in reimbursements for new original medicines was allocated to this group.

Table 31: New original medicines in the ZKL at the end of 2024 compared to 2021

ATC group	Expected	Share (%)	Arrived	Share (%)	Extra	Health insurance costs (EUR)	Share (%)
Antineoplastics and immunomodulators	34	47	54	38	34	180,602,049	71
Anti-infectives for systemic use	7	10	13	9	13	19,059,978	7
Musculoskeletal system	0	0	5	4	5	13,196,946	5
Cardiovascular system	1	1	9	6	9	12,364,366	5
Blood and blood-forming organs	5	7	16	11	14	9,584,288	4
Nervous system	5	7	18	13	18	9,214,907	4
Sensory organs	1	1	1	1	1	2,511,247	1
Dermatologicals	0	0	3	2	3	2,470,433	1
Digestive tract and metabolism	10	14	10	7	8	2,323,472	1%
Systemic hormonal preparations other than sex hormones	4	6	5	4	5	2,277,356	1
Respiratory system	3	4	4	3	3	1,344,057	1
Various	1	1	2	1	2	783,005	0
Urogenital system and sex hormones	1	1	1	1	1	8,022	0

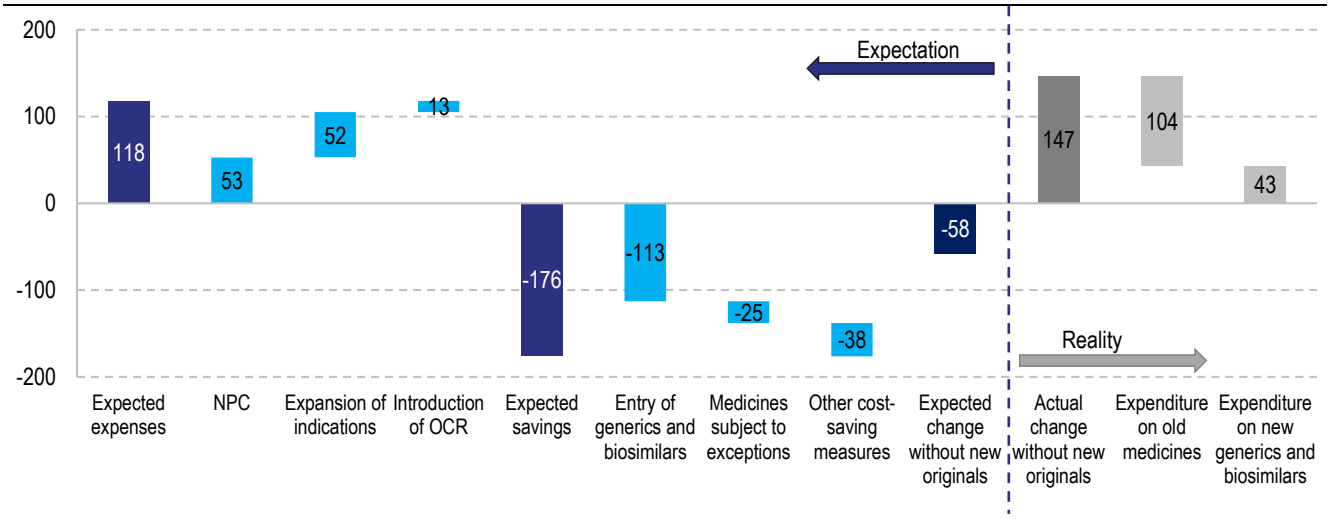
Source: quarterly reports on pharmaceutical consumption by NCZI, ZKL, MoH SR, processed by VFM

The expected increase in expenditure was to be offset primarily by savings from the entry of generics and biosimilars (EUR 113 million). However, the planned cost reductions proved overly ambitious, and higher spending occurred on

[34] Examples of medicines that were categorised in Slovakia but not in the Czech Republic at the end of 2024 include Soliris, Vyvgart, and Ultomiris. Ultomiris was subsequently categorised in the Czech Republic, but for a different indication than the one reimbursed in Slovakia.

medicines already included in the system in 2021. Expenditure on medicines (excluding the categorisation of new original medicines) was projected to decrease by EUR 58 million by 2024 due to these savings, but it actually increased by EUR 147 million, according to NCZI quarterly reports on medicine consumption. The increase in spending on existing medicines (EUR 104 million) was driven roughly equally by the expected NPC (EUR 53 million) and the expansion of indications (EUR 52 million), while EUR 43 million was allocated to new generics and biosimilars in the ZKL.

Figure 37: Expected versus actual change in expenditure from the 2022 reform, excluding new original medicines (2021–2024), in EUR million

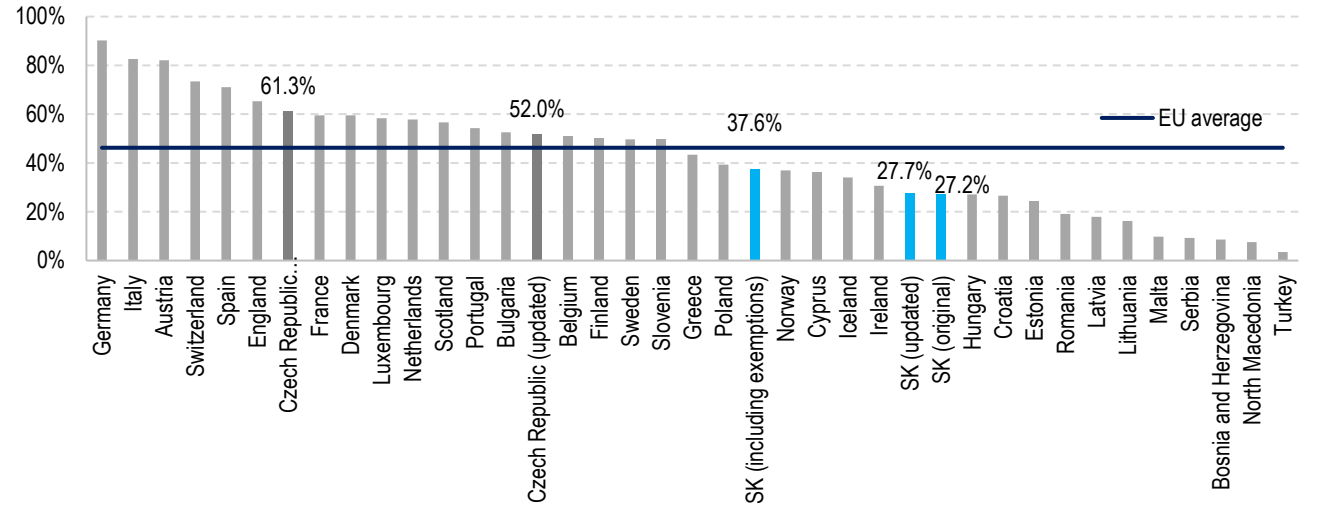


Note: The increase in actual expenditure may be slightly lower due to refunds that health insurance companies charge on the income side and may not all be captured in the NCZI's pharmaceutical consumption data.

Source: quarterly reports on pharmaceutical consumption from NCZI, ZKL, MoH SR, processed by VFM

Annex 4: Availability of new medicines in 2025

Figure 38: Share of new medicines approved by the EMA in 2020–2023 that were available at the beginning of 2025



Note: original – original availability in IQVIA, updated – availability in ZKL in May 2025, including exceptions – including medicines submitted for exemption. *Source: IQVIA, NCZI, MoH SR, VFM*

Annex 5: Cost-effectiveness threshold values in Slovakia and selected European countries

Table 32: Conditions for determining the cost-effectiveness threshold of a new medicine in Slovakia in 2025[1]

Country	QALY value (determined)	QALY value (in euros)	Multiple of GDP per capita
Slovakia (before 2022)	28 to 41 times the average wage	40,040 – 58,630	1.76–2.57
Slovakia (from 2022)	**2 to 10 times the GDP per capita[2]**	**45,621 – 228,105**	**2 to 10**
Hungary	1 to 10 times GDP per capita[3]	21,515 – 215,145	1 to 10
Poland	3 times GDP per capita[4]	61,376	3
Czech	1.2 million CZK[5]	47,770	1.63
Latvia	3 times, EUR 300,000[6]	62,728 – 300,000	3 to 14.35
Netherlands	EUR 20,000 and EUR 80,000[7]	20,000 – 80,000	0.33 to 1.33
Norway	NOK 275,000 to 825,000	23,648 – 70,943	0.30 to 0.91
United Kingdom	GBP 20,000 to 300,000[8]	23,623 – 354,350	0.52 to 7.77

Source: NIHO, VFM

[1] The ECB's average exchange rates for 2024 were used for conversions from national currencies. Except for Hungary, GDP figures from Eurostat for 2023 were used (UK figures calculated according to OECD).

[2] Act 363/2011 and Decree No. 298/2022 Z. z. MZ SR.

[3] Hungary uses several thresholds similar to Slovakia, but does not track absolute QALY increases, only percentage increases. As in Slovakia, common medicines are limited to three times the GDP.

[4] Source: Agencja Oceny Technologii Medycznych i Taryfikacji (2024).

[5] The Czech SUKL considers the value of CZK 1.2 million/1 QALY to be a generally acceptable cost-effectiveness threshold, taking into account the possible risks of the analysis when deciding on values between EUR 0.9 million and EUR 1.2 million. Source: SUKL.

[6] The threshold price of EUR 300,000 is used for medicines for rare diseases, source: Vončina et al. (2023)

[7] Source: Reckers-Droog, V., et al. (2021)

[8] Source: the baseline is 20,000 to 30,000 NICE (2022) and for highly specialised technologies it increases to 300,000 GBP NICE (2017).

Annex 6: Patient registries

Patient registries are databases designed to collect information on the health status and treatment of patients with serious diseases or groups of diseases. In addition to supporting clinical research, they serve as an important tool for identifying epidemiological trends and for planning preventive and screening programmes. They also provide reliable data for pharmacoeconomic analyses, which can directly influence negotiations with pharmaceutical manufacturers and the setting of budget limits. However, patient registries in Slovakia do not function effectively or are not accessible to relevant organisations. The data in the registries are often not updated and, compared with other countries, they also lag behind in covering a wider range of diagnoses and socio-demographic aspects of morbidity. Effective management of patient registries could positively influence the pricing of new medicines on the Slovak market, as well as the prevention and treatment of patients.

The purpose of national health registries (NHR) is to monitor newly diagnosed patients and the treatment of specific diseases, particularly oncological and other serious chronic conditions. Patient registries may also include socio-economic information on patients. The data are primarily used in clinical research to improve the diagnosis and treatment of serious diseases. They also have the potential to support pharmacoeconomic research on the effectiveness and consumption of medicines, although this potential has long been underutilised.

Slovak national registries are largely dysfunctional. Thirteen patient registries are supposed to operate in Slovakia, but three of them were completely non-functional in 2022. The SAO (2022) criticised the National Health Information Centre (NCZI) for failing to update the oncology registries, with the most recent available data dating back to 2012. Even the registries that are formally operational do not meet the required standards. Their credibility is undermined by insufficient administrative oversight by the NCZI and by healthcare providers failing to comply with their legal reporting obligations. The shortcomings of the national health registries are also evident in their limited use in international databases, such as the European directory of patient registries maintained by the European Commission, where Slovakia is currently not represented.

Box 17: The importance of NZR for epidemiological analysis in Slovakia

High-quality data can help in the prevention and treatment of serious diseases. National registries should monitor the development of disease at the patient level. Microdata at the patient level can help to effectively localise the occurrence of diseases and identify areas for increased attention by preventive programmes. Prevention and screening help detect disease in its early stages, which facilitates treatment when necessary and reduces the cost of disease across the entire population.

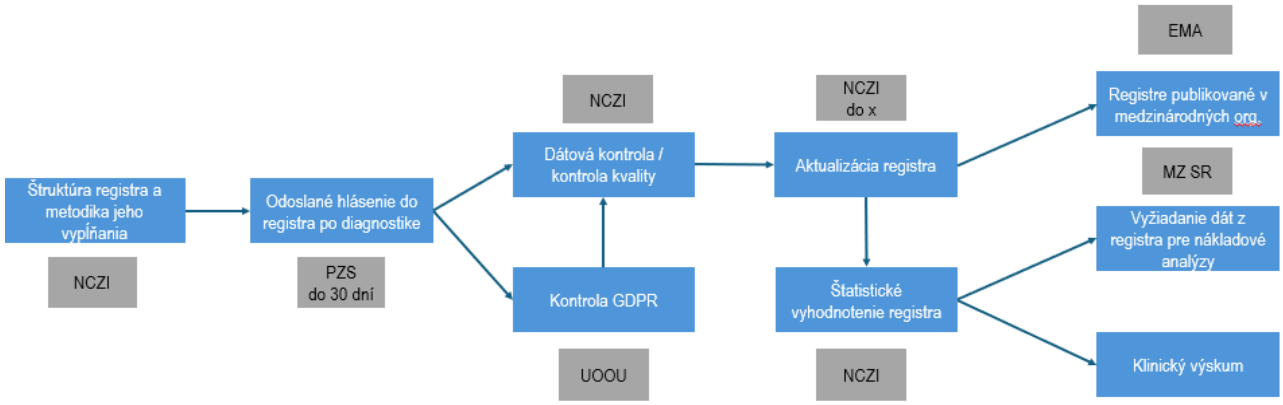
Short-term analyses demonstrate the need for long-term collection of patient data. The Institute for Health Analyses (IZA, 2024) published an epidemiological analysis of malignant breast tumours in Slovakia. Despite limited data collection capabilities, the analysis provided useful information on the incidence, survival and treatment of malignant breast tumours in the population. The output notes an increased incidence of breast cancer in younger age groups of women and poorer treatment outcomes in some regions. It also highlights large differences in incidence between regions, which, however, could not be monitored in the last decade due to a lack of patient data. The IZA analysis used data from health insurance companies, which is also used by the NCZI.

The NZR should regularly provide patient-level data. The IZA emphasises the need for up-to-date and local data in the prevention of serious diseases. This does not only apply to the cancer registry, but the same principle also applies to the other seven registries monitoring the development of disease in individual patients. Long-term epidemiological analysis of oncological or congenital diseases based on the NZR would help in the strategic placement of screening centres and better localisation of specialised healthcare. It would also detect the occurrence of diseases more reliably and earlier, which would have a positive impact on both the average life expectancy after diagnosis and the duration and cost of treatment.

Reporting to patient registries is not automated in Slovakia. Doctors must manually report data for each patient to the National Cancer Registry, in addition to reporting to the eHealth system. The NCZI portal is used for this purpose, but the process of filling it out is complicated. Since the mandatory reporting obligation of doctors to the NZR is not enforceable, systemic barriers reduce doctors' motivation to register patient data. The content of patient registries is regulated by Decree

No. 74/2014, which specifies the monitored health parameters[35] as well as the reporting obligation for healthcare providers (PZS). This is set for all NZRs at 30 calendar days from diagnosis. However, data reported within this period is not automatically added to the NZR, and the frequency of data updates by the NCZI is unknown (visualisation in Diagram 3).

Diagram 3: Visualisation of data collection in the NZR



Sources: VFM, Tomek et al. (2010), NCZI

NCZI's expenditure on the operation and control of registers in 2019–2021 amounted to EUR 2.1 million[36] **.** However, data in many registers remain inaccessible or unverifiable. The shortcomings of the NZR are thus partly covered by third parties cooperating with specialists across Slovakia. The National Atroplastic Register is administered by the University Hospital in Martin, while the register monitoring HIV treatment is managed by a private IT company (CNN Solutions) and UNB.

Existing data from the NZR are not fully utilised due to limited access. Patient data are made available for analysis only to a minimal extent. The MoH SR, which is the founder of the NCZI, can request data from the registers only on an exceptional basis and does not have standard access to them. The situation is similar for NIHO, which would use this data to assess the budgetary impact of new medicines, particularly when analysing populations with specific diagnoses. Their request for access has been rejected in the past. The situation is different abroad – in most OECD countries (2015), government officials can access approximately 85% of the data from patient registries. This access allows them to obtain more accurate information for decision-making processes and to prepare legislative changes based on reliable data.

Up-to-date data on patient numbers by diagnosis could lead to savings when setting reimbursement limits for new medicines. NZRs provide the most accurate data on populations suffering from specific diseases. Data on the number of patients who would benefit from the introduction of a new medicine on the Slovak market are important when setting reimbursement limits under MEA contracts. When concluding a contract, the MoH SR and the private entity must agree on the maximum amount of reimbursement that health insurance companies must pay. If the limit is exceeded due to higher consumption, the manufacturer is obliged to pay the difference. When launching a medicine with underestimated consumption on the market, manufacturers have an incentive to request an increase in reimbursement limits after the medicine has been categorised. Accurate consumption data could therefore be reflected in a realistic consumption ceiling for the medicine, thereby preventing a possible increase in public expenditure on these medicines in the future.

The collection of data for patient registries is not based on a uniform methodology, even abroad. Despite the creation of the EMA working group[37] , whose task is to develop a uniform methodology for patient registries, no organisation is obliged to follow its recommendations. The Agency also coordinates European patient registries on its platform, but due to the lack of a methodology for data verification, the registries shared with the EMA do not meet the conditions for qualification processes (including EMA certification).

[35] For each NZR, the scope of patient parameters is regulated by Act No. 153/2013 Z. z., pp. 37-45. For example, the National Cancer Registry should process basic socio-economic data (permanent residence, economic activity, employer) and surgical procedures, findings, patient progress in cancer classification with ongoing treatment evaluation.

[36] Of this, wage costs amounted to EUR 1,401,050.46, expenditure on software work and consultations amounted to EUR 15,175.20, expenditure on intermediary services amounted to EUR 234,000.00 and expenditure on the operation of the information system amounted to EUR 412,387.89.

[37] The European Medicines Agency brings together the health authorities of EU Member States and stakeholders in the pharmaceutical industry. With an annual budget of EUR 478.4 million (EMA, 2023), the EMA has a mandate to supervise and evaluate pharmaceutical products.

Box 18: Foreign practice

The Scandinavian countries are the EU leaders in patient registry management. Sweden, Denmark and Norway collect data in centralised patient registries administered by the state. These registries monitor parameters such as hospitalisations, the diagnostic process and the entire duration of treatment. Oncology registries, which are often kept separately, specifically by type of cancer, are a separate chapter. Scandinavia is also cited as a practical example in data updating. For example, Danish doctors are required to report changes to the patient registry on a monthly basis. However, data from doctors is typically updated on a weekly basis, and in some healthcare facilities on a daily basis (Schmidt et al., 2015).

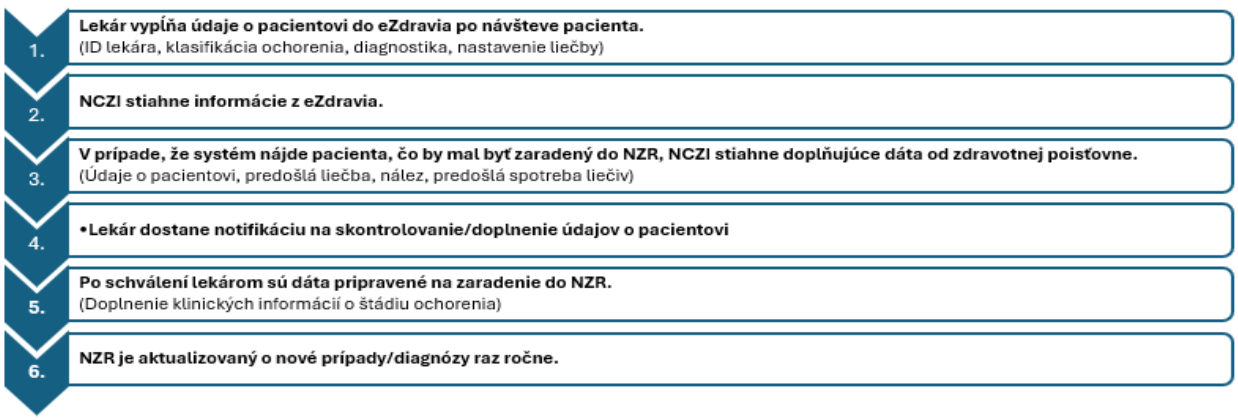
The Czech Republic performs better than Slovakia in terms of data updates and the range of diagnoses covered. The frequency of data updates varies between individual registers, but most are updated annually. In addition, there are special patient registers focused on high-cost treatment of certain diseases, such as ovarian cancer. In total, there are 34 patient registries in the Czech Republic, but two-thirds of these registries are managed by the private sector. The Czech equivalent of the NCZI (ÚZIS) manages 12 patient registries.

The Benelux countries use patient registries in negotiations on medicine prices in MEA contracts. Belgium, the Netherlands and Luxembourg have an average of 15 registries for specific diagnoses, which are mainly managed by the local ministries of health. Unlike in Slovakia, however, data from the registers is also directly used to supplement analyses for MEA contracts. In the Netherlands, for example, output from patient registers is linked to limiting expenditure during treatment, with the Dutch equivalent of the NCZI (RIVM) collecting data for its own register directly to inform health policy.

A temporary solution is to extract data from health insurance companies, from the so-called Insured Person's Account. Adding a decade of non-digitised data to patient registries involves a lengthy administrative process based on incomplete data. However, in order to set the correct reimbursement limits for new medicines, it is necessary to know the long-term development of disease incidence in the Slovak population now. Incidence and prevalence can be estimated with high accuracy using an algorithm that works with reimbursement data from health insurance companies and can be verified by comparison with foreign statistics, historical trends and registry data for the last few years.

The latest output on the incidence of malignant tumours in Slovakia, with data up to 2022 (NCZI, 2024), could not be based solely on data from patient registries. For the missing years, these were replaced by an innovative algorithm for expected cases of malignant tumours from the NCZI, which supplemented the missing years with data provided in reimbursement payments from health insurance companies. However, data from health insurance companies do not contain full clinical information and the stage of the disease, which is crucial for the statistics needed for the entry of innovative medicines. The number of patients with a specific stage can currently only be estimated based on the proportions of target disease subtypes abroad or based on data from 2015. Some clinical characteristics, particularly genomic subtypes and mutations in tumour tissue, which are crucial for innovative medicines, are also missing from the registry. It is therefore necessary to continue to innovate the data collection of registries and to extract data from pathological and genetic medical reports.

Diagram 4: Visualisation of data collection in the National Cancer Registry after automation



Sources: VFM, NCZI

Slovakia should automate reporting to the NZR via eZdravie. The eZdravie system has been operating in Slovakia since 2018, and currently more than 19,000 healthcare providers report information to it. However, eZdravie is not connected to the NZR, which creates an additional burden on healthcare providers, who would have to enter duplicate data into multiple systems at once. Automatic updating of data from eHealth in the NZR would eliminate a significant portion of the otherwise manually entered data on patient visits and diagnoses at the doctor's office. Diagram 2 shows the reduction in workload for healthcare providers, who, with the automation of the system, would only need to enter qualitative data into eHealth during the examination, in addition to standard patient data, if the patient is included in the patient register on the basis of their diagnosis. Currently, healthcare providers enter patient information (last 3 columns) into the systems twice. The use of available software for the effective collection of patient data, as in other countries, would increase the reliability of health data for pharmacoeconomic analyses and research (for more information on Danish automation, see Box 19).

Box 19: Automation of healthcare administration in Denmark

Patient registries can be made more efficient through automatic data reporting. One of the main problems with Slovak patient registries is the insufficient reporting of new cases to the system. These must be reported manually by healthcare providers, often duplicated. Barriers to reporting could be overcome by a system of automatic reporting from multiple sources outside the PZS, similar to the healthcare system in Denmark.

Danish NZRs are updated on a daily basis. The primary source of data in Danish NZRs is the eHealth system, which is filled in by the doctor during the patient's visit. Once the relevant diagnoses have been entered, the patient data appears in the appropriate register. Thanks to automatic downloads from eHealth, Denmark has the most up-to-date health data in the world. This data is divided into a general population patient register (the closest equivalent in Slovakia is the benefits reported by health insurance companies, which, however, do not track the course of the disease) and further redistributed into registers according to diagnoses.

The data sources need to be interconnected. The eHealth system captures the current status of the patient. However, this does not provide a sufficiently comprehensive picture of the incidence of individual diseases in the Danish population, so this data is supplemented with sources from the death register, laboratory tests and the register of medicines sold. All registers are linked via patients' birth numbers, making it possible to track the entire journey and treatment of a patient in each register. Compatible data facilitates the linking of existing registers and streamlines the reporting obligations of local healthcare providers and the frequency of register updates.

Table 33: International Overview of Patient Registry Management

Country	How is data entered into the registry?	Number of registry administrators	Managed by	Frequency	Reporting obligation
Slovakia	NCZI form	2	State	annually*	Yes
Czech Republic	NHIS system	1	State / Private	per year	X
Austria	X	7	State / Private	X	Yes
Luxembourg	X	3	State	X	No
Belgium	eHealth	7	Country	per year	no
Netherlands	eHealth + insurance companies	7	State / Private	per year	X
Norway	eHealth	7	State	per year	Yes
Sweden	eHealth + insurance companies	3–4	State	monthly	X
Finland	X	3	State / Private	5 days from diagnosis*	Yes
Denmark	Health Data Authority / eHealth	3–4	State	monthly	Yes

*Note: Frequency indicated as the period during which the doctor is required to report patient data to the registry is marked with an *. Missing data is marked with an X.*

Source: OECD, National health information administrators in the given country

Annex 7: Dealing with budget compliance is insufficient in the decision on medicine categorisation

Figure 39: Budget information in the decision on the categorisation of the medicine Litfulo

Ministerstvo pre účely predikcie nákladov pripravilo odhad výdavkov VZP na lieky na rok 2025, ktorý je vyčíslený vo výške **1.786,54** mil. €. Ministerstvo uskutočnilo odhad výdavkov započítaním odhadom vývoja nákladov na kategorizované lieky a novo zaradené lieky do ZKL od 01/2024
do 06/2025 a dopadom úsporných opatrení vyčíslených v dopade zákona č. 266/2022 Z. z., ktorým sa mení a dopĺňa zákon č. 363/2011 Z. z. o rozsahu a podmienkach úhrady liekov, zdravotníckych pomôcok a dietetických potravín na základe verejného zdravotného poistenia a o zmene a doplnení niektorých zákonov v znení neskorších predpisov a ktorým sa menia a dopĺňajú niektoré zákony.

Odhad výdavkov na lieky z rozpočtu VZP / mil. €	2024	2025
Očakávaná skutočnosť - všetky lieky	1 661,280 €	1 786,541 €
Dietetické potraviny	39,000 €	40,000 €
Vplyv liekov zaradených do ZKL (Y)	36,931 €	99,953 €
Vplyv osobitnej cenovej regulácie	3,639 €	4,683 €
Úspora generiká a biosim., úsporné politiky	- 47,486 €	- 47,486 €
SPOLU OS Lieky + DP	**32,084 €**	**97,150 €**
SPOLU OS Lieky	**- 6,916 €**	**57,150 €**

Na základe odhadu dopadu liekov zaradených do zoznamu kategorizovaných liekov a odhadovaného vývoja výdavkov na lieky z VZP ministerstvo zastáva názor, že nemôže nastať situácia, že prostriedky zdravotných poisťovní v súčasnosti určené nebudú postačovať na úhradu týchto liekov v roku 2025. Ministerstvo pri prognózovaní vychádza z Vyhlášky MZ SR č. 55/2024 Z. z. a jej prílohy, ktorá určuje celkovú sumu výdavkov určenú na zdravotnú starostlivosť v rozpočte v roku 2024, a z rozpočtu VZP bez zmien politík na lieky na rok 2025.

Annex 8: Entire pages of documents are redacted

Figure 40: Statement on NIHO assessment No. 66 for Tirzepatide (Mounjaro) in the treatment of type 2 diabetes mellitus

Annex 9: Overview of protective co-payments regulations for medicines in EU countries

Table 34: Overview of protective regulations on co-payments for medicines

Country	Type of co-payment	Ceiling	Exceptions	Valid as of
Slovakia	Percentage surcharge		Cap on additional payments for pensioners, children and persons with disabilities	2025
Germany	Fixed and percentage co-payment Min. EUR 5 per medicine and 10% co-payment of the medicine price	Max.: EUR 10 per prescription Annually: 2% of annual income (total for healthcare)		2020
England	Fixed co-payment £9.15 per prescription	Annually: £105.9	Children, seniors, unemployed persons, persons with chronic illnesses, low-income households (approx. 90% of prescribed medicines are free of charge)	2022
Norway	Percentage co-payment Full price of medicines is paid up to EUR 117, then the co-payment decreases.	Annually: EUR 234	Residents under 21 years of age (except for contraception)	2020
Slovenia	Percentage co-payment positive list (0-30%), intermediate list (90%)			2021
Poland	Fixed and percentage co-payment 77 cents/pack with 30 DDL/co-payment (30-50% of the reference price if it is the cheapest medicine)		People over 75 and selected vulnerable groups	2019
Portugal	fee based on the therapeutic benefit of the medicine			2017
Netherlands	full amount paid up to the ceiling	Annual ceiling for all healthcare (in 2025 – EUR 385)		2016
Latvia	Fixed and percentage co-payment 71 cents per prescription (if the medicine is fully reimbursed), otherwise 25-50% of the price of the medicine.		Children, all medicines priced below EUR 4.27 and selected low-income households	2019
Spain	Percentage co-payment – by category medicines for chronic diseases: 10% with a ceiling of EUR 4.24 per medicine pensioners according to income (income up to EUR 100,000 per year 10%, if they have more, then 60%) others with an income of up to EUR 18,000 per year – 40% others EUR 18,000-100,000 per year: 50% others over EUR 100,000 per year: 60%	Various ceilings based on annual income (EUR 8-62 per month)	Exceptions – pensioners according to income, orphans, disabled minors, people on minimum wage, unemployed people without benefits, medication prescribed due to work-related injuries	2024

Source: Health Systems in Transition publications

Annex 10: Important terms used in pharmaceutical policy

Innovative medicine – Slovak legislation does not recognise the term innovative medicine. It is mostly used to refer to medicines that have been approved by the EMA and have not yet been available outside of clinical trials. It says nothing about the benefits of the medicine. A more appropriate term is therefore new medicine.

The Medicines Act and the MoH SR decree, which determines the multiples of GDP for the threshold price, use the terms medicine for common diseases, medicine for rare diseases and medicine for innovative treatment.

A medicine for rare diseases is intended for the diagnosis, prevention or treatment of a rare, serious or chronically debilitating disease that affects no more than 5 people in 10,000 in the EU. This status may also be granted to a medicine for a disease with a very low incidence, where its development would not be economically viable without support. However, there must be no satisfactory treatment available, or the new medicine must offer significant added value.

Advanced therapy medicinal products (ATMPs) include:

- **Gene medicines** – contain gene(s) that are inserted into the patient's cells (or delivered in another way) to treat, diagnose or prevent disease. E.g. replacing a damaged gene with a healthy one.
- **Somatic cell therapies** – contain living cells that have been modified and are used to treat, prevent or diagnose diseases. E.g. a patient's cells modified in the laboratory and returned for treatment.
- **Tissue engineering medicines** – contain modified tissues or cells that are used to repair human tissue. E.g. tissues created in a laboratory to replace skin, cartilage or heart muscle.
- **Combination medicines for innovative treatments** – ATMPs that combine cells or genes with a medical device (e.g. biomaterials, support structures). E.g. genetically modified cells applied using a special carrier implanted in the body.

A generic medicine is a medicine that contains the same active substance or combination of active substances as the original medicine. The officially determined price of the first generic medicine to enter the market cannot exceed 51% of the price of the original medicine (Act No. 363/2011 Z. z. § 16(4)(j)).

A biologically similar medicine (biosimilar) is a biotechnological copy of a biological medicine that has been proven by comparative clinical trials to be similar in its physical and chemical properties, efficacy and safety to the original medicine. The officially determined price of the first biosimilar to enter the market may not exceed 75% of the price of the original medicine (Act No. 363/2011, Section 16(4)(k)).

The officially determined price is the price of the medicinal product set by the Ministry, which cannot be exceeded (either for the first or subsequent sales) when selling the medicinal product to the holder of a wholesale distribution authorisation in Slovakia (sale by the manufacturer/marketing authorisation holder to the national distributor). **The official price** is based on the European reference price, unless there is special price regulation.

The European reference price of a medicine is the arithmetic mean of the three lowest prices among the officially determined prices of the medicine in other Member States. If a medicine has an officially determined price in only one EU country, the arithmetic mean of that country and the two lowest unit prices of the medicine in other Member States is calculated (if there are only two countries, the lowest unit price of another Member State is added). If the medicine does not have an officially set price in other countries, the arithmetic mean of the three lowest unit prices in EU countries is calculated.

The final price is the maximum price of the medicine in a public pharmacy (including VAT, distributor's margin and pharmacist's margin).

Health insurance reimbursement - the maximum amount of health insurance reimbursement for a medicine included in the ZKL is determined as a multiple of the number of standard doses of the active ingredient contained in the medicine and the maximum amount of health insurance reimbursement per standard dose of the active ingredient, but not exceeding the maximum price of the medicine in a public pharmacy. It therefore depends on the coefficient (multiple) and the reference price (group reimbursement) within the reimbursement group.

A reimbursement group consists of two or more reference groups according to the division specified in the list of reimbursement groups. The same maximum reimbursement by the health insurance company – group reimbursement – is

determined for all reference groups that make up the reimbursement group. This applies to all indications (the reimbursement may only be changed in special cases).

The group reimbursement for a reimbursement group is determined as a multiple of the reference price of the reimbursement group and the coefficient specified in the list of reimbursement groups.

The reference medicine for a reimbursement group is the medicine with the lowest maximum price per unit in the reimbursement group.

The reference medicine is the medicine with the lowest maximum price in the reference group in a public pharmacy, converted to the ŠDL.

The reference group is determined for each medicine included in the ZKL. It contains medicines that contain the same active ingredient, have the same route of administration, have the same or comparable dosage form, and contain the same amount of active ingredient in a single dose, the same concentration, or the same amount of active ingredient in a package.

The reference group is divided into **reference subgroups** so that the difference in the number of standard doses of the active substance in one package between the smallest and largest package of the medicine in one subgroup is not greater than 20% (relative to the smallest).

The reimbursement group for the reference group shall be **determined** and the reimbursement group determined for the reference group shall be changed and cancelled in such a way that the reimbursement group contains reference groups in which medicinal products representing alternative pharmacotherapeutic interventions are included and that the reimbursement group is not formed by only one reference group.

The method of determining the maximum reimbursement in the reference group (Section 6) is specified in Act 363 for mandatory vaccines, extended-release medicines, and combinations of medicines, unless specified by law or regulation (decree). A special method also applies to medicines that are in the ZKL and are "centre" medicines (must be administered by a doctor, toxic medicines, medicines with special storage requirements, threat of deterioration of the medicine, administered in the ÚZZ).

Patient co-payment – the maximum amount is the difference between the maximum price of medicines in a public pharmacy and the maximum reimbursement by the health insurance company.

Fixed ratio of co-payment and reimbursement – when sold, medicines must comply with the ratio between the health insurance reimbursement and the insurance co-payment. If they want to reduce their price below the maximum, both components must decrease at the same rate. According to Section 89(1), unless otherwise specified, the ratio between the health insurance company's reimbursement and the insured person's co-payment for a medicine, medical device or dietary food must remain unchanged when the selling price changes.

Exception to the fixed ratio of co-payment and reimbursement – the requirement to maintain a fixed ratio of co-payment and reimbursement by the health insurance company does not apply (among other things) if the patient's co-payment exceeds 3% of the average wage from two years ago (the fixed ratio then does not apply to the entire reference group) and for medicines subject to special price regulation.

Special price regulation (§ 14b) allows the price to be increased above the reference price if the manufacturer of the medicine declares an increase in production costs (raw materials, energy, wages). The application must include the arithmetic mean of the 10 cheapest EU countries, or all of them if there are fewer. The price may not exceed the average of the 10 cheapest countries, or all countries if there are fewer than 10 (Section 21). The MoH SR decides whether a medicine is subject to special price regulation on the basis of an application under Section 14 or on its own initiative.

Box 20: How the exception to the fixed ratio of co-payment and reimbursement works

Selling price of the medicine with an exception to the fixed ratio – the maximum price of Invokana in a pharmacy is EUR 159.77, the insurance company reimbursement is EUR 150.3, and the co-payment is EUR 9.47. The co-payment is less than 3% of the average wage from two years ago (EUR 42.9). The seller must maintain a fixed ratio of co-payment and reimbursement, so if they wanted to reduce the price of the medicine by EUR 9.47, the reimbursement would fall to

EUR 141.39 and the co-payment to EUR 8.91. However, if the medicine were exempt from the fixed co-payment, the seller could reflect the entire reduction in the co-payment, so that the medicine would cost EUR 150.3 and the patient would not have to pay anything extra.

Price reduction in pharmacies (hypothetical example) – Medicine A and medicine B have the same co-payment, but medicine A has a higher maximum final price than medicine B, which is reflected in a higher co-payment. If both medicines decided to compete on price, medicine A has the option of reducing its price at the pharmacy so that the patient does not pay any additional charge. Medicine B does not meet the exception to the fixed co-payment and reimbursement ratio, so if it matches the price of medicine A, the patient will pay an additional 31.58 euros with the insurance company reimbursing 118.42 euros. It is very likely that they would choose the medicine with a zero co-payment, which is actually more expensive for the public budget. The example only applies if both medicines are not in the same reference group. If the medicines were in the same reference group, the exception to the fixed ratio of co-payment and reimbursement would also apply to medicine B.

Table 35: Consequences of the exception to the fixed co-payment, in EUR

	Maximum price	Reimbursement	Co-payment	Price after discount	Reimbursement	Additional payment
Medicine A	200	150	50	150	150	0
Medicine B	190	150	40	150	118.42	31.58

Diagram 1: Determination of the official and final price of a medicinal product outside special price regulation