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Drug policy in broader budgetary context (Slovakia)

Executive summary

Drug policy is a comprehensive topic that is constantly evolving. To ensure its optimal set-up, policy-makers should not think of it as isolated policy but rather as one part of the whole system of healthcare provision, considering also broader context (patient management, other forms of healthcare, cooperation with caregivers, social policy, budgetary context). At the same time, there is no single view on the issue, because each stakeholder perceives, to a greater or lesser extent, its current setting from his or her point of view.

The main goal of this study is to introduce drug policy from different perspectives. Another goal is to identify key problem areas in the current set-up of the system. To achieve both these goals, we have included the drug policy stakeholders (patients, doctors, health insurance companies, pharmaceutical companies, regulators) themselves in the preparation of the study (qualitative interviews), and with their help we have identified the most outstanding problems. Furthermore, our goal is also to highlight the need of creation a vision and a follow-up drug policy strategy that is absent in Slovak system.

This study was prepared in February and March 2022 when the amendment to Act 363/2011 on the scope and conditions of payments for medicines, medical devices and dietetic foods from public health insurance was being discussed and prepared for government approval. Proposed changes have potential to solve some identified problems and we believe this amendment could be a start of much needed reform of drug policy.

In the following executive summary, we summarize the key findings on the current state of drug policy and the problem areas identified by consensus. We also propose some changes to drug policy.

Key findings on the current state of drug policy, identified problem areas

- In the short term, Slovakia will face threats such as an increase in oncological diseases due to the lack of cancer screening during the COVID-19 pandemic.
-In the long term, the biggest challenge for Slovakia will be the aging population that contributes to the increasing prevalence of many diseases.
- Especially in connection with the aging of the population and the arrival of expensive innovative medicines, expectations for the future are associated with an increase in expenditure on medicines.
- As financial resources are limited, policy makers have to ensure sustainability of funding with help of regulatory tools. In Slovakia, we have adopted so-called categorization of medicines. This

process (assessment of the pharmaceutical) determines which cost-effective pharmaceuticals will be covered by public health insurance, thus ensuring an efficient redistribution of health resources. Thanks to categorization there is List of Categorized pharmaceuticals (fully or partially reimbursed medicines) that defines the patient's entitlement to pharmaceuticals that have been registered, categorized and meet all the indication and prescription restrictions.
- There is no strategic plan with a medium (3-5 years) and long-term (more than 5 years) horizon for drug policy. Current system relies on short-term planning which is based on the approved budget (period of max. 1 year).
- There is a general consensus among stakeholders on pharmaceutical spending being inefficient with identified potential for savings.
- Overall, the pharmaceutical market is perceived as small (given the size of the population compared to other EU countries), with over-regulation, with frequent legislative changes and a number of exceptions.
- Drug policy is becoming less transparent. Although data is collected (not systemically), the public has limited access to it.

Low availability of innovative medicines

In recent years, very expensive innovative medicines have started to appear on the global and European markets. Many of these pharmaceuticals have huge potential, but some of them have also uncertain clinical effects for the patient (it is sometimes difficult to determine whether they meet the concept of value for money). Slovak drug policy is not yet ready for this situation. Innovative medicines are not entering our market at the same pace as in other developed countries and our system is gradually developing an unmet medical need for innovative drugs (in the study, we focused on oncological drugs, where the condition is documented by analyzes). We have only about 33% of all oncology medicines registered by the European Medicines Agency available to our patients (categorized medicines). As these are often very expensive medicines, the main reason for their poor availability in our country is simply put money and also categorization conditions.

Slovakia has had a categorization process in place since 2011, where meeting cost-effectiveness is the sole criterion for classifying pharmaceuticals as a partially or fully reimbursed from health insurance. The comparison with the surrounding countries shows that Slovakia has stricter categorization conditions and therefore most of the stakeholders agree that in order to improve the availability of innovative medicines, it is necessary to adjust the threshold setting. The exact level of the threshold and the exclusivity of this criterion remain the subject of disagreement, which the MoH must resolve. One of the mentioned possibilities is, for example, the introduction of Multicriteria decision analysis, which has great potential in HTA, but is at the same time extremely demanding and currently not standardly used in other EU countries. An alternative proposal for changes in categorization is the proposal to strengthen HTA and apply the tools

developed by the European HTA Network, such as HTA Core Model, Methodical Standards for HTA. In December 2021, Regulation (EU) 2021/2282 of the European Parliament and of the Council on health technology was adopted, which forms the basis for joint assessments within the EU and it could also give us valuable inspiration for changes in our system.

Adjustment of the categorization process will almost certainly be tied to additional funding. There should be a fair discussion about how to cover this as health insurance companies might not be able to cover it without an increase in funding. It will also be important to decide on re-evaluation of categorized innovative medicines, which will not prove their real clinical benefit over time. Non-systematic data collection from patients can be a problem here. Another topic for discussion is the use of Managed entry agreements (agreements on the terms of reimbursement between health insurance companies/MoH and pharmaceutical companies), which are standardly used broad. This is not the case in Slovakia where current legislation (concluding an agreement with all three health insurance companies before applying for categorization) and intensive use of exceptions limit their potential. Furthermore, as many innovative medicines have not entered the market in recent years, there is also problem with lacking comparators in assessing the pharmacoeconomics.

Exception regime in drug policy

As a result of social pressure and non-systemic interventions, in addition to the standard regulatory instrument (categorization), a parallel stream of exceptions has been created in recent years. It is often associated with attributes such as: non-systemic, non-transparent, unjust, unpredictable and lengthy.

The system of exceptions within the competence of health insurance companies, which, in addition to categorization, reimburse patients for pharmaceuticals in an ever-increasing volume (EUR 55 million in 2021), is a non-systemic but tolerated solution among stakeholders. It is believed that without it, the availability of pharmaceuticals in Slovakia would be way worse.

According to majority of stakeholders, system with exceptions have to change. It is demanded from regulator to introduce greater transparency to the exception approval process, shorten the waiting time for application evaluation, and introduce electronic processing of applications. At the same time, it will be crucial to eliminate a volume of exceptions

1) by strengthening the standard regulation tool – categorization process

2) introduction of new tools for the regulation of innovative medicines (MEA, both financial and performance-based agreements)

3) promoting other ways of financing innovative medicines (several options for discussion: money collections, fund for innovative medicines, annuity payments, voluntary health insurance) or even whole new concepts (value-based health care)

In connection with the issue of exceptions, we have identified peculiarities of the categorization of medicines intended for the treatment of very rare diseases (prevalence is less than 1: 50,000 patients). In this case, the categorization process goes without submitting a pharmacoeconomic analysis. In this case, too, the necessary change is being considered. It should apply

1) adaptation of the definition of a rare disease following the model of the European Medicines Agency

2) introduction of some financial limit for categorization of medicines intended for the treatment of very rare diseases

3) a thorough re-evaluation of these medicines over time, as their real clinical benefit to patients is questionable due to missing data.

Generic and biosimilar medicines

The lower cost of generic and biosimilar medicines as a result of the fractional costs of their development and research represents an opportunity for the health care system to save on costs. Slovakia still has some reserves to take advantage of this opportunity; according to INEKO's calculations, there is potential for savings of up to EUR 55 million per year. Although Slovakia ranks among the countries that have above-average consumption of these medicines in both financial and quantitative terms, the trend in recent years is not favorable at all (not many are actually entering the market).

Moreover, the importance of generic and biosimilar medicines must also be seen in terms of building a healthy competitive environment. Their presence on the market increases competition and pushes medicines prices down.

We have identified several reasons why generic and biosimilar medicines do not significantly increase in total consumption. These are

- the reluctance of manufacturers to enter the Slovak market,
- over-regulation and volatility of the legislative environment,
- market distortion,
- physicians' approach to prescribing generic substitution (problem with Interchangeability)
- patients' trust in generic substitution
- dispensing of medicines in the pharmacy.

In many cases, the state could provide a helping hand 1) by setting fair rules, 2) stabilizing the legislative environment or 3) actively reaching out to producers of generic and biosimilar medicines to help them enter the market. In cooperation with health insurance companies, the state should also participate in the education of doctors and patients, as well as in setting the right motivations.

According to stakeholders, the justification for the use of generic and biosimilar medicines is clear, but opinions differ on the interchangeability of the original. Although, in the case of a generic medicine, the original is equally effective from the medical point of view, nocebo effect (deterioration of health due to expectations of its harmfulness), patient compliance (drug use process, adherence to schedule and dosing schedules) and adherence to treatment (phenomenon or condition in which the patient adapts to the doctor's treatment procedure and requirements, accepts prescription requirements and follows the doctor's instructions, as well as adapts his lifestyle) can significantly negatively affect the treatment process. For patients who do not understand or are concerned about the principle of generic prescription, treatment with generic medicines may be inappropriate. Therefore, one should not forget to help elderly patients, who often have difficulty navigating medicines. It was confirmed by doctors that constant changes in medicines are more to their detriment, while it is not only the patient's discomfort but also the problem of adherence to medication, which affects the outcome of treatment.

Financial resources in drug policy

Slovakia is on its way to become one of the oldest countries in Europe, which we consider to be one of the biggest challenges for healthcare in the medium and long term. Some forecasts speak of reaching the limit of one million seniors as early as 2025. Assuming that health insurance companies will be able to pay for a larger volume of consumed drugs without increasing the budget and at the same time finance incoming innovative drugs only from the achieved austerity measures is far too optimistic. The remaining expenditure may therefore need to be financed in other ways.

The patients themselves co-participate on medicine funding to the great extent. Their share already accounts for approximately 24% of the total volume of expenditure on medicines. For the most vulnerable patients, a protective limit on co-payments has been introduced. It protects patients from catastrophic medicine spending and the associated social unavailability of medicines.

By far the most important source of funds today is the collection of insurance premiums. Revenues from premium collection for economically active people (approximately 77% in 2020) are crucial in terms of volume. Though system is not perfect (funds depend on the economic activity which is risky in times of economic recession, pandemics), we consider these resources

to be a stable part of the system and we do not expect a change in the system in the near future due to the fact that this is a very politically sensitive matter.

Another source of funds comes from state itself. It has a form of payment for state insured (children, students, pensioners, the unemployed, on a disability pension, on a maternity leave, etc.). Major changes have taken place here recently. Until the end of 2019, an arbitrary percentage was used for state policyholders with the function of the insurance rate, assessment base and number of state policyholders. Since 2020, the system has changed, from now on the state payment is determined technocratically at the Ministry of Finance of the Slovak Republic and subsequently approved in the state budget law as a fixed amount. The criticism of the new setting is that the fixed amount does not have an anti-cyclical attribute (much needed in the event of a recession). Moreover, much worried are stakeholders over the decline in payments for state policyholders below the level of 4% in recent years.

With regard to financial resources addressed to medicines, it is also necessary to look at the Draft Budgetary Plan for 2022-2024, in which the Ministry of Finance expects an increase in expenditure on medicines due to the aging population (EUR 10 million per year). The proposal also envisages the introduction of changes in drug policy, for which the ministry has allocated additional funding for innovative treatment (EUR 119 million in 3 years). This amount does not fully cover the stakeholders' estimated gap in innovative treatment which is EUR 100-200 million.

Proposal of the concept of changes in drug policy

These are not specific recommendations, rather a suggestion of new way of thinking about drug policy (broader context, planning ahead, looking at new ways of financing) so that, as a society, we have effective, safe and reasonably expensive medicines available at the end of the day.

- It is necessary to prepare a strategic plan for the medium to long term horizon in dialogue with stakeholders, including the Ministry of Finance of the Slovak Republic (due to financial coverage) and patient organizations (patients' interests). The plan should be based on a comprehensive vision of healthcare (also lacking), where drug policy is not viewed in isolation. The preparation of the plan should also include the implementation of a horizon scanning (in cooperation with pharmaceutical companies) and the preparation of scenarios in relation to the aging population. Last but not least, the strategic plan needs to be linked to funding.

- As inefficiencies in spending cannot be easily eliminated, in order to ensure the availability of medicines (including innovative ones with good clinical benefits), it will be necessary to increase resources for medicines by increasing the payment for the state insured (at least 4%).

- Part of the funds must also be directed to generic and biosimilar prescriptions, where it is necessary to make the market more attractive for companies.

- At the same time, it is absolutely essential to prepare for the arrival of medicines for innovative treatments, which will be very expensive many times and therefore their entry will also depend on whether the regulator implements appropriate regulatory tools in time to make the system sustainable. There are various tools (MEAs, risk and cost sharing) that are already here, but also completely new ways of financing (e.g. the Fund for Innovative Treatment) or new concepts (Value-based health care).

- Our recommendation is to take a comprehensive look at all the regulatory measures in place and to reconsider them judiciously on the basis of the set priority objectives. Subsequently, it is necessary to change the legislation and control or even sanction compliance with the law.

- Our recommendation is also to adhere to a clear definition of the patient's legal claim for medicines (List of categorized medicines is a good toll), exceptions may exist, but only for exceptional cases, not to circumvent the system. The patient must be able to find out what treatment he is legally entitled to and, on the basis of this finding, be able to decide in advance after considering his or her own health risks whether preventive measures are needed on his part (additional health insurance, lifestyle adjustment or prevention). At the same time, we recommend facilitating patients' access to other forms of treatment financing beyond the statutory entitlement (e.g. annuity payments, co-insurance).

- Realization of expectations in healthcare must occur sooner or later because even in the case of 100% elimination of inefficiencies, there will not be enough money in the system to cover increasing medicines consumption and innovative pharmacotherapy if funding does not change. We have identified various financing scenarios that we should consider for the future:

Patient 's financial contribution →

Financial resources for medicines ↓

Scenario I – status quo	Scenario II
Scenario III	Scenario IV

1) Scenario I - is the scenario we are currently pursuing (status quo). This is a scenario in which the system will remain strong in solidarity (almost everything will be paid from SHI except for co-payments for medicines at the level as today; the protective limit for the most vulnerable patients will remain in place). At the same time, the system will not receive significantly more funds that would reflect the aging of the population and cover the reimbursement of innovative medicines (not only oncology but all innovative medicines that will enter the EU market within 5-10 years and have a demonstrable clinical benefit, not necessary cost-effectiveness). In such a case, it is likely that Slovakia will lag even further behind the other EU countries such as Germany, Austria or the Netherlands in pharmacotherapy, and treatment with innovative medicines will be almost non-existent in our market. At the same time, if the identified savings are achieved in the system, these will be used to cover the growing consumption of pharmaceuticals due to the aging population and to support the position of generic and biosimilar medicines in our market. In this scenario, we should prepare patients for the fact that there will be no reimbursed innovative treatment from SHI and to get the needed medicine patient would have to A) fundraise money through collections, charity, crowdfunding, etc. B) take a loan C) contract voluntary health insurance if available.
2) Scenario II - In such a scenario, we expect the patient's co-participation (with some annual ceiling). The patient will pay for medicines for general consumption such as antibiotics, pharmaceuticals for indigestion, antihistamines. In this scenario, the budget for pharmaceuticals would not increase rapidly. Increased consumption of medicines due to the aging population would be covered from savings (higher patient's co-participation and elimination of inefficiency in the system). Part of the savings will also be used to support the use of generic and biosimilar medicines and to fund innovative treatments, but it will be necessary to regulate very strictly what innovative medicines will be reimbursed. As in the case of previous scenario, patients will have to reach for loans, crowdfunding or additional health insurance to finance their innovative treatment.
3) Scenario III – the strong solidarity of the system stays; the regulator will not introduce any other form of patient participation in pharmacotherapy but will increase each year (probably through the payment for the state insured) either the entire drug budget (covering increase drug comsumption and some innovative treatment) or alternatively create an Innovative Medicines Fund. Calculations on the budget increase will be based on the National Plan for Health Protection and Prevention, predicted developments in the aging population and also the results of horizon scanning. We do not assume that in this scenario it will be possible to cover all innovative medicines.

4) Scenario IV - is a combination of increased patients´ participation (the setting of the annual ceiling must be taken into account), savings from inefficiencies in the system and especially a significant increase in funds from the state budget.