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AIPM'S PROPOSALS ON HEALTHCARE AND ACCESS TO MEDICINE

2026

AIPM'S PROPOSALS ON HEALTHCARE AND ACCESS TO MEDICINE

Special attention to the pharmaceutical industry and the broader healthcare sector (life sciences sector) is essential for the country's sustainable development. **Continuous partnership is required to ensure that Hungary can fully benefit from the outcomes of healthcare innovation.** The pharmaceutical industry enables the modernization of patient care and, by enabling Hungarian patients to benefit from scientific advances, contributes to the creation of high value-added, attractive innovative jobs and supports the scientific community, all of which also generate tangible economic benefits.

It is important that the government of the day regards **our industry as a driver of the country's competitiveness** rather than as a source of cost pressure. This means recognising the **value-creating role of innovation and considering its long-term healthcare and economic benefits**, rather than focusing exclusively on short-term cost containment.

In 2026, global developments are becoming increasingly unpredictable, and the pharmaceutical industry is no exception. We are at a critical period where, in the interest of Hungarian patients, it is essential to work together and mobilise all

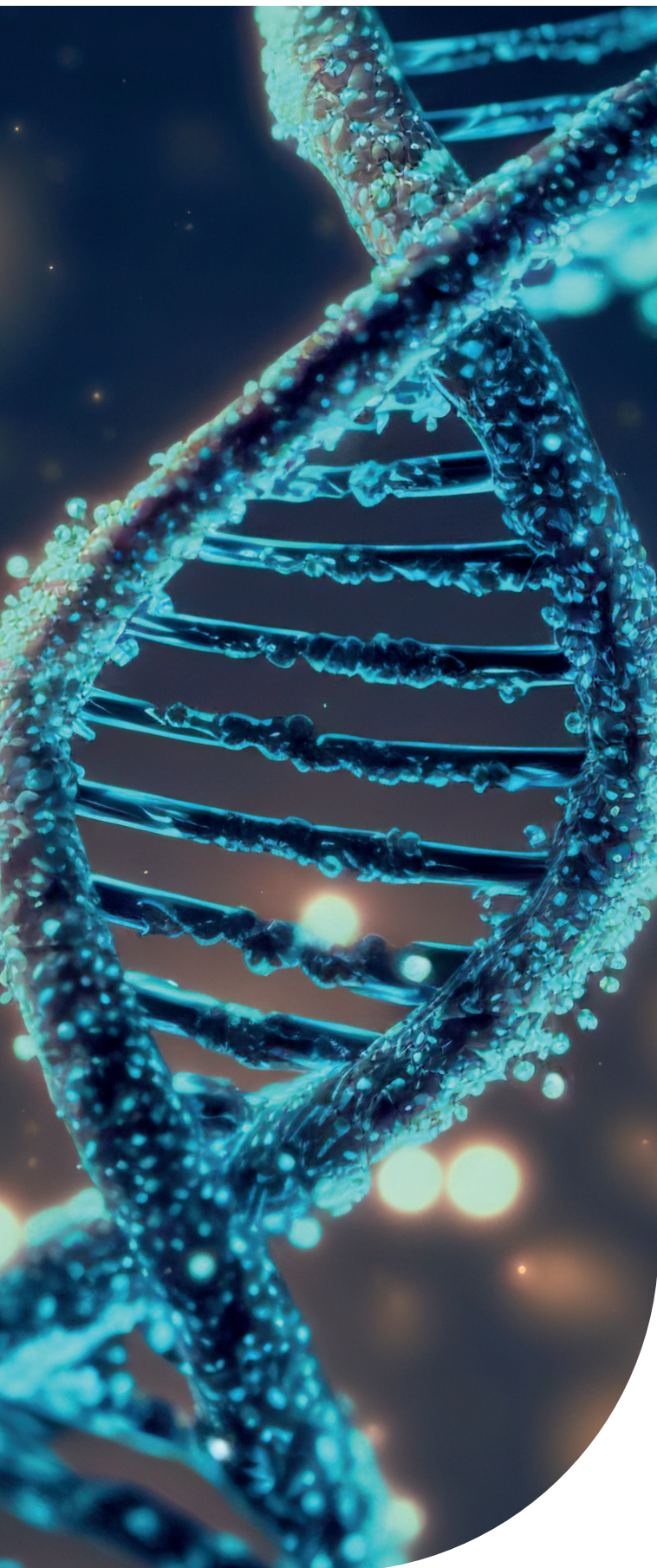
Whether an independent Ministry of Health or another institutional structure representing the healthcare sector is established, the industry stands ready to engage in regular consultation forums where supply-related risks can be addressed transparently before they escalate into political issues.



How the pharmaceutical industry contributes to Hungarian society:

- A healthy and productive nation
- Safe and reliable patient care
- Value creation and sustainability
- Sustainability of the public budget
- Encouraging international investment
- Patient satisfaction

available tools to ensure that Hungary can build on current trends rather than fall behind them. The key to this is a **comprehensive, predictable and forward-looking decision-making framework that ensures transparency and enables long-term planning.**



A predictable policy environment supports innovation and strengthens investment incentives, ultimately contributing to a sustainable public budget.

Certain innovative therapies do not reach the country at all, while their generic or biosimilar follow-on products may only appear in domestic patient care 10–15 years later. As a result, the quality of healthcare in Hungary may fall behind by as much as 10–15 years and become structurally locked into a follower model. At the same time, **with an appropriate regulatory environment, Hungary can remain regionally competitive in attracting innovation-related investments**, provided that legislation is able to keep pace with the rapid development of healthcare technologies.

For the financier, the most cost-effective access to therapies is achieved when medicines are procured directly from the marketing authorisation holder rather than through distributors. However, if the market and regulatory environment is not predictable, the risk of medicine shortages increases. It is also important to recognise that pharmaceutical companies themselves finance a significant share of the medicines supply through mandatory industry contributions.

AIPM's key messages

The transformation of global supply chains and shifting economic dynamics have brought us to a crossroads. Even in a rapidly changing global environment, it is essential to ensure that the supply of medicines remains sustainable and reliably available for Hungarian citizens in the long term. Achieving this requires more efficiently allocated resources, stronger focus and adequate economic support. **A predictable environment, legal certainty, and partnership-based cooperation** are necessary both to improve the health of Hungarian citizens and to strengthen Hungary's competitiveness. **Effective healthcare and a productive population are inconceivable without a reliable, modern medicine supply.** The following ideas and proposals have been developed in this spirit.



INVESTING IN A HEALTHY SOCIETY

INNOVATION INVESTMENT GOALS

Investment in innovative medicines is not a cost, but a strategic decision that drives economic growth and a healthier society.

Background

In Hungary, the pharmaceutical industry is a strategically important sector that, in addition to supporting healthcare, generates significant exports and employment. **However, the current financing framework does not sufficiently incentivise innovation, which weakens the country's competitiveness and limits patients' access to modern therapies.** Across Europe, an increasing number of countries are committing themselves to supporting pharmaceutical innovation. If Hungary does not take an explicit stance and assume measurable responsibility in support of innovation, this will have a direct impact, already in the short term, on the presence of R&D investments in the country.

Proposal

Hungary should commit to **measurable, predictable and transparent objectives** related to innovative medicines and integrate these into the appropriate national health strategy and relevant legislation. These objectives and their timelines should be public, measurable and comparable with those of other EU Member States.



Advantage for decision makers

- Improved patient health outcomes and productivity
- Stronger national competitiveness and greater attractiveness for international R&D investments
- Predictable budget planning and long-term financial sustainability

MARKET BARRIERS AND PREDICTABLE ENVIRONMENT

A predictable pricing and regulatory environment are key to ensuring high-quality patient care and maintaining Hungary's position in innovation. Equally important is the operation of a transparent, predictable and system-level reimbursement framework within the social health insurance system.

Background

In Hungary, the unpredictability of the current market and regulatory environment represents the most significant barrier to the timely access of innovative therapies. Systemic patient access to new innovative treatments may be delayed by several hundred days compared to their first international market launch before they receive reimbursement. This creates **not only a healthcare disadvantage but also a direct competitiveness gap**. It significantly undermines the country's attractiveness for international health industry and R&D investments and has a direct negative impact on clinical trials conducted in Hungary.

Proposal

Removing market barriers and making the current reimbursement system more transparent and reformed is essential to ensure that **Hungary provides a predictable and investment-friendly environment for innovative medicines**. This may include simplifying regulatory processes and creating conditions for long-term planning. The most important tool in this regard is a **forward-looking, predictable, system-level reimbursement process within the social health insurance system, conducted at least annually, preferably more frequently**.



Advantage for decision makers

- Faster patient access to therapies, leading to improved health outcomes
- Stronger national innovation attractiveness and improved retention of international investments
- More predictable budget planning and sustainable financing

HUNGARY'S COMPETITIVENESS

Maintaining the country's competitiveness requires a productive and healthy society, where an adequate level of physical and mental well-being ensures a sustainable and productive workforce, thereby significantly contributing to the reduction of pressures on the healthcare system. The creation of a healthy workforce - one of the key drivers of economic growth - requires the everyday application of modern scientific advances. If the health status of active members of society deteriorates, it reduces their ability to work, their income and the level of tax revenues generated, while increasing healthcare and social expenditures.

The broader societal value and impact of medicines beyond their direct use are undeniable. They provide direct solutions to the social and public health challenges affecting the population, including the treatment of both chronic and acute diseases. Improvements in population health have a direct and immediate impact on economic productivity.

The pharmaceutical industry itself also strengthens competitiveness, as it is among the most productive sectors, creating high added value through activities (such as research, education and manufacturing, while also generating multiplier effects across numerous related industries that collaborate with the sector, etc.). Moreover, the industry has traditionally strong foundations in Hungary, the preservation of which requires clear policy commitment, focus and prioritisation. A solid basis for this already exists, as several member companies operate global or regional service and research centres in Hungary, employing highly skilled professionals engaged in high value-added, innovative work and leading developments in artificial intelligence and digital solutions. Many of the professionals working in these centres are Hungarian employees, and the international environment provides an attractive career alternative for talented Hungarian professionals.



Hungary operates in a highly competitive environment globally, within the EU and across the region.

Background

Practical support for access to innovation is essential. A clear example of this is clinical trials, which have significant positive impacts for the country in many aspects. On the one hand, many patients, often those who have no other treatment options, gain access to potential therapies through participation in clinical trials. In addition, clinical trials support the professional development of physicians and facilitate their participation in the international scientific community. It generates cost savings for the government, as patients receive treatment without public financing. At the same time, health industry stakeholders involved in clinical research create substantial economic added value and retain highly skilled professionals in Hungary by offering attractive, innovative jobs.

Advantage for decision makers

Competitiveness requires not only a healthy workforce but also **the preservation of Hungary's regional role in innovation.** Retaining clinical trials and R&D investments requires a predictable pricing and financing environment, as well as practical support for the clinical research ecosystem.



MAKING HEALTH A PRIORITY

POSITIONING HEALTHCARE AS A TOP PRIORITY AT THE HIGHEST LEVEL OF GOVERNMENT

To strengthen Hungary's competitiveness, healthcare must become a clear priority. The areas of health and healthcare need to receive greater emphasis in government decision-making and policy priorities. One possible instrument to achieve this is the establishment of a dedicated Ministry of Health (which would enable objective, long-term policy and financial planning).

Ensuring adequate representation of healthcare therefore requires ministerial-level representation within the government, in order to effectively advocate for healthcare considerations and policy objectives.

A healthier society is a fundamental instrument for achieving government objectives. Preserving work capacity, strengthening employability and maintaining the size of Hungary's population are therefore not only matters of national economic interest, but also contribute to increasing overall public satisfaction.

Background

In Hungary, life expectancy at birth was 77 years in 2024, compared to the EU average of 81,7 years¹. This means that, even within the Visegrád region, Hungary has the lowest life expectancy at birth.

Healthy life years and avoidable mortality are key indicators of the quality of a healthcare system and are both essential for a country's productivity. Hungary needs to make progress in closing the gap with the EU average in these indicators as well. This requires **independent government-level representation of healthcare, supported by appropriate expertise and a well-defined sectoral governance structure.**

At present, there is no adequate level of representation within the government for healthcare-related legislation, nor for other matters affecting healthcare or the health industry. Such

representation could support better understanding and decision-making, as well as ensure that healthcare priorities are appropriately reflected alongside other government policy areas.

Human capital is the most important foundation of a country's economy, and it can be fully utilised when **the workforce is healthy and able to work**. Every day an employee spends on sick leave due to the lack of appropriate treatment represents a tangible loss to GDP.

It is desirable that healthcare has dedicated representation at government meetings, focused exclusively on this sector. Such representation could significantly strengthen **cooperation between the healthcare and economic sectors**, while making the positive economic impacts of healthcare more visible at the highest levels of government. For healthcare to become a genuine priority, this representation is essential (serving as the 'face

¹ OECD data, 2024

and advocate' of the sector) so that decision-makers clearly understand that **the quality of healthcare influences the performance and outcomes of the entire economy**. This would help ensure that well-considered healthcare decisions are made in support of both the government's human sector policies and its economic policy objectives. Such representation is necessary not only for effective decision-making, but also for the efficient, measurable and transparent use of public resources.

- *A top priority for voters*
- *Human capital as a driver of GDP*
- *Timely and appropriate care helps prevent higher costs in the future*

The prioritisation of healthcare is also justified by the fact that, according to consistent public surveys, healthcare is the most important policy area for Hungarian citizens^{2,3}. In addition, it is economically well justified, as timely and appropriate early intervention can significantly reduce future costs.

Proposal

A predictable, long-term healthcare sector strategy is required, one that is implemented in a coherent manner, considers the health status of the population, and ensures the conditions necessary to achieve its objectives. **From both a national economic and human capital perspective, healthcare is a central component in the achievement of government objectives.** This requires independent, expert-level representation of healthcare within the government, enabling healthcare-related considerations and policy perspectives are effectively integrated into high-level government decision-making.

Advantage for decision makers

- Better understanding at the government level of the role and importance of healthcare, and its contribution to the country's productivity and long-term development
- A clear signal to society that citizens' priorities are being recognised
- Decision-making aligned with long-term social and economic objectives, supporting the development of a more productive and sustainable society
- Improvement in overall health indicators and progress towards the EU average
- More efficient use of budgetary resources
- A more satisfied society

² <https://www.ipsos.com/en/what-worries-world>

³ https://www.ipsos.com/sites/default/files/ct/news/documents/2025-10/ipsos_health_service_report_2025-final_0.pdf

STRENGTHENING DIALOGUE-BASED, TRANSPARENT PHARMACEUTICAL REGULATION AND REIMBURSEMENT PROCESSES

A sustainable healthcare system, one that takes into account both the population's health status and economic productivity, requires a dialogue-based and transparent regulatory framework, for both its development and maintenance. Its key components include reducing information asymmetry, ensuring the prior communication of legislative changes, and actively engaging industry stakeholders. Such a system enhances the safety of patient care, enables faster access to therapies, improves patient satisfaction, supports a healthy and productive society, and contributes to the predictability of public expenditure.

Medicines are not consumer goods but rather "maintenance costs for the machinery that generates GDP," meaning an investment in the sustainable productivity of the population.

Background

Pharmaceutical and health policy operate within a multi-stakeholder environment, where individual decisions affect all actors. **Sudden, uncoordinated measures can lead to uncertainty and planning challenges, thereby creating broader business uncertainty and an increasing risk to supply continuity.**

Proposal

In order to strengthen dialogue-based and transparent pharmaceutical regulation and reimbursement frameworks, it is essential that **government and industry cooperate through continuous dialogue.**

Any legislative change affecting the healthcare system is inconceivable without the active involvement of industry stakeholders, timely prior communication, jointly agreed impact assessments, and the sharing of the expected content and timing of decisions are all indispensable.

We propose the establishment of a **consultation platform that brings together all stakeholders in the healthcare system** (medical professional organizations, professional colleges, government decision-makers, authorities, patient organizations, industry representatives, medical universities, pharmaceutical wholesalers, and pharmacists) through which the prior consultation of healthcare strategies and the support of their operational implementation (including through legislative changes) can be ensured.

Beyond ensuring transparent processes and stakeholder dialogue, it is important to emphasize that predictable regulation and a forward-looking pricing policy are key drivers of industry investment. Ongoing reforms and developments within the EU demonstrate that Hungary must also take action in order to prevent future supply shortages.

Advantage for decision makers

Transparent, dialogue-based processes simultaneously improve the quality and safety of patient care and enable faster access to therapies, enhance patient satisfaction, contribute to a healthier and more productive society, strengthen the sustainability of public finances, and encourage international investment in a stable and predictable environment.

REGULAR INCLUSION OF NEW ACTIVE SUBSTANCES AND INDICATIONS INTO THE PUBLIC REIMBURSEMENT SYSTEM

A stable, transparent, and predictable pharmaceutical reimbursement system would provide security for patients, healthcare professionals, and decision-makers alike, while sustainably supporting the improvement of the Hungarian population's health. Predictable and regularly scheduled reimbursement decisions would not only enhance equity in access to care but also increase the societal acceptance of government decisions, without generating significant additional costs.

Background

Of the 173 new medicines authorized in the EU between 2020 and 2023, only 13 have been incorporated into the publicly funded reimbursement system in Hungary⁴, leaving Hungarian patients at a significant disadvantage in terms of treatment outcomes compared not only to those in Western Europe, but also to patients in Poland, Slovenia, and the Czech Republic. **The regular, transparent, and predictable inclusion of new, innovative medicines is essential to ensure that Hungarian patients do not miss out on therapies that can extend their life or improve recovery prospects.** The advanced pharmaceutical evaluation process applied in Hungary makes it possible to take decisions aligned with health policy objectives based on comprehensive analyses, including the assessment of clinical needs and available financing options.

Proposal

Following a positive decision by the quarterly ministerial reimbursement committee, approvals should be granted at ministerial level and formally published at least once a year. The process preceding publication should also become transparent to applicants, including which new active substances and indications the government intends to include, as well as which submissions are rejected and for what reasons.

Advantage for decision makers

- More advanced and a broader range of therapeutic options available to patients and treating physicians
- As a result of regulated and regular reimbursement decisions, healthcare expenditures would become more predictable.
- A continuous and predictable reimbursement system could significantly reduce the emergence of political criticism and help ensure that pharmaceutical reimbursement issues are addressed at a purely professional policy level. Regularity also enhances transparency, which is conducive to investment willingness. In addition, a predictable process has a strong trust-building effect
- Reducing administrative burdens for physicians, the NEAK, and the Batthyány-Strattmann László Foundation, while ensuring that, for as many medicines as possible, cost control mechanisms implemented by NEAK are applied, thereby supporting the most efficient use of public funds. In the context of a regular reimbursement system, and provided sufficient administrative capacity at NEAK, effective price and volume control can be achieved through price-volume agreements and the payment of applicable taxes
- Regular reimbursement supports the reduction of administrative burdens for both NEAK and the BSLA by ensuring that individual equity-based reimbursement (named patient program) is reserved for therapies that are not widely used

⁴ Hungarian Gazette, issue 177, year 2023

THE IMPORTANCE OF ESTABLISHING AN EARLY ACCESS REIMBURSEMENT SYSTEM

The establishment and operation of a conditional reimbursement system would be beneficial for patients, the healthcare system, the NEAK, and the Hungarian economy.

Background

The level of innovation and complexity of new therapeutic solutions and technologies is continuously increasing. As a result, established routines and the traditional “this is how we have always done it” approach are no longer sufficient. Instead, new patient monitoring methodologies need to be developed and integrated into routine care to ensure that these therapies can deliver their full clinical benefit. For this reason, early access schemes have been introduced in several European countries. In most cases, a **structured, transparent, and predictable framework for early access** has either already been established or is currently under development.

Proposal

Early access to medicines through a conditional reimbursement system **can best ensure the maximum expected health gain from new therapies**, as well as its measurability under local conditions.



Advantage for decision makers

- Creates an opportunity to establish the routine use of new, complex technologies and to develop best practices
- At the same time, a system for the collection and evaluation of therapeutic data can be established
- A therapy-specific financing approach can be developed
- A conditional reimbursement system would attract clinical trials to Hungary

BATTHYÁNY-STRATTMANN LÁSZLÓ FOUNDATION FOR HEALING

The Foundation plays a gap-filling role in financing rare and high-cost therapies. Building on its experience to date, further developments are needed to ensure that equity-based reimbursement effectively contributes to improving the nation's productivity.



Background

The BSL Foundation was established in February 2025⁵ to provide case-by-case, equity-based financial support for medicines and medical devices that are professionally accepted in Hungary but not covered by public reimbursement, taking into account social and ethical considerations.

Proposal

- Accelerating the **decision-making process** of the Foundation
- Ensuring the **conditions for the Foundation's continuous operation**, considering all types of resources
- **Improving the transparency** of the Foundation's operations and maintaining continuous dialogue

Advantage for decision makers

Providing equity-based support, improving patient satisfaction, and enhancing population health, thereby contributing to a more productive society.

⁵ Hungarian Gazette, issue 114, year 2024

RETHINKING THE REIMBURSEMENT SYSTEM

The system-level inclusion of innovative therapies is delayed by several years compared to European and Central European averages under the current reimbursement and evaluation processes. A new, simpler and more transparent reimbursement system could reduce administrative burdens and enable faster access, while also supporting more efficient budget planning and control.

Background

AIPM has conducted a comprehensive review of the pharmaceutical reimbursement system on several occasions. In 2021, as a result of an outstanding trilateral consultation (NEAK, State Secretariat for Health, and AIPM), several important elements of the regulatory framework were amended. However, the **reimbursement system remains highly complex and lacks transparency due to the multitude of reimbursement categories, levels of support, and procedural rules.** This significantly hinders planning, predictability, and sustainability for all stakeholders. Moreover, the changing demographic, economic, and social environment further underscores the need for a reimbursement system capable of adapting to new challenges.

Proposal

A **comprehensive simplification of the pharmaceutical reimbursement system** that appropriately reflects changing demographic, economic, and social challenges.

- A pre-defined budget allocation within the **annual budget framework** dedicated to the inclusion of new innovative therapies
- A regular and predictable reimbursement system for new active substances and new indications
- Currently, approximately one in four outpatient reimbursed medicines is effectively financed by pharmaceutical companies, alongside one of the lowest transparent price levels in Europe and continuous inflationary pressure. This burden needs to be reduced, as the **scale of industry payments** is already jeopardizing the sustainability and security of supply, which may also negatively impact patient satisfaction
- **A review of the possibility of rational price increases.** The previously mentioned inflationary environment and exchange rate fluctuations have, over time, created economically unsustainable situations for certain products
- The current **structure of pharmaceutical reimbursement** does not fully support budget transparency, and consequently, neither patient interests nor market mechanisms are adequately reflected
- It is important that budget planning is not based solely on historical baselines, but also on patient needs, taking into account long-term **sustainable financing**

Advantage for decision makers

Rethinking the pharmaceutical reimbursement system would improve planning and budgetary control for all stakeholders. This would contribute to greater predictability, faster access to innovative therapies, and, consequently, to an increase in healthy life years and overall productivity.



SUSTAINABLE HEALTHCARE FINANCING

POTENTIAL FUNDING SOURCES FOR THE FINANCING OF INNOVATIVE PHARMACEUTICAL THERAPIES

Expanding taxes on unhealthy food products and channelling the resulting revenues into the pharmaceutical budget would create a sustainable additional funding source for the inclusion of innovative medicines in the long term.

Additional resources and positive incentives lead to a healthier and therefore more productive society, increasing the return on pharmaceutical expenditure.

Background

All resources allocated to healthcare represent an investment in human capital and economic growth. Healthcare spending reflects the extent to which a government values health. **The relatively poor health status of the Hungarian population, even in a European comparison, requires higher levels of investment.** There is also a need to mobilize additional funding sources to ensure that innovative therapies, that are capable of meaningfully improving health outcomes, recovery prospects, and, consequently, economic productivity, are continuously available in Hungary.

Proposal

- **Allocating pharmaceutical industry payments for the healthcare budget**, including their dedicated use for strategic prevention purposes
- Increasing the rate or expanding the scope of the public health product tax and excise duties on heated tobacco products to cover product categories proven to be harmful to health (e.g. energy drinks), as well as currently exempt products (e.g. certain alcoholic beverages), could provide a **stable and continuous additional source of funding for innovative**

medicines. In addition, allocating a portion of excise tax revenues (from tobacco and alcoholic products) to the healthcare budget would further strengthen available resources

- **Developing a system of positive incentives** based on international best practices
- Promoting **better health literacy, healthier lifestyles, and individual responsibility** reduces pharmaceutical expenditures
- A transparently measurable share of innovative medicines within overall pharmaceutical spending

Advantage for decision makers

- Public health awareness increases and population health outcomes improve (through preventive effects), while the pharmaceutical budget gains a stable and predictable additional funding source
- This involves the fine-tuning of a socially accepted tax instrument, introduced in Hungary in 2011 and recognized by international organizations, therefore the administrative burden of the measure is limited



PRACTICAL ISSUES OF PHARMACEUTICAL FINANCING

IN ADDITION TO THE BACKGROUND, PROPOSALS, AND BENEFITS FOR DECISION-MAKERS OUTLINED ABOVE, THE AIPM COMMUNITY ALSO FORMULATES FURTHER RECOMMENDATIONS SPECIFICALLY RELATED TO PHARMACEUTICAL SUPPLY

STRENGTHENING DIALOGUE-BASED, TRANSPARENT PHARMACEUTICAL REGULATION AND REIMBURSEMENT PROCESSES

Full transparency of the pharmaceutical reimbursement and legislative processes for industry stakeholders including the ministerial phase (covering the status of decisions, as well as their criteria and rationale) and the meaningful consideration of all stakeholder inputs would reduce uncertainty, support the effective professional work of decision-making bodies (HTA Committee and ministerial committee), promote well-founded decision-making, and enable the optimal use of limited human resources, ultimately ensuring that patients gain access to the most appropriate therapies.



Background

Transparent elements are already present in Hungarian pharmaceutical policy decision-making, providing a foundation for predictable and efficient operation, however, **further increasing the transparency of processes would strengthen trust and cooperation among stakeholders.**

Proposal

In order to ensure full transparency of pharmaceutical reimbursement and related legislative processes, regular communication with industry stakeholders must be maintained, and throughout the entire public reimbursement procedure (from submission of the application to the announcement of the decision or rejection) **the status of the process, the decision criteria, and the underlying rationale should be made transparently available to the applicant, whose views should also be meaningfully taken into account, thereby supporting the more effective functioning of decision-making committees and more well-founded decisions.**

Our member companies face the following barriers:

- Currently, the applicant (typically the marketing authorization holder) does not always have the opportunity, or does not receive it in a timely manner to respond to the findings included in the HTA Department (TÉF) assessment or in the opinion of the relevant professional college section
- Applicants may formally attend the meetings of the HTA Committee (TÉB), but they are not always given the opportunity to provide substantive responses to questions raised during the assessment. Furthermore, applicants' responses and positions are not consistently reflected in the minutes, which may result in a loss of important information during subsequent ministerial evaluation
- The HTA Department's (TÉF) assessment is often provided to the applicant only 1–2 days before the HTA Committee (TÉB) meeting, which significantly limits the opportunity for a substantive response. Moreover, the official timeline of the reimbursement procedure does not account for the time required for the assessment to reach the applicant and for the preparation of a response
- The applicant does not have access to the content of the documentation package submitted by NEAK to the Ministry, and therefore cannot track how their submitted professional materials are reflected in the decision proposal
- The composition and operation of the committee supporting the final decision are not publicly available
- The rationale for ministerial decisions is not available, meaning that neither the applicant nor the professional community can understand or trace the arguments and considerations underlying a rejection or approval

- The current decision-making mechanism does not provide an opportunity for patient organizations to participate, not even in the form of written input. As a result, important patient perspectives and interests are excluded from the evaluation, even though the direct experiences and needs of affected individuals would often justify a different weighting



Advantage for decision makers

Full transparency and the meaningful consideration of the applicant's views reduce uncertainty and the need for subsequent corrections, enabling more efficient use of limited human resources and improving operational efficiency. Dialogue-based legislation contributes to a predictable economic environment, helping to sustain continuous, high-quality patient care.

REGULAR INCLUSION OF NEW ACTIVE SUBSTANCES AND INDICATIONS INTO THE PUBLIC REIMBURSEMENT SYSTEM

The regular inclusion of innovative medicines not only ensures faster access for patients, but also provides a more predictable, plannable, and efficient operation of the pharmaceutical budget for the financier.

Background

In line with health policy objectives, the regular inclusion of new, innovative medicines and indications is essential to ensure that Hungarian patients do not fall behind in accessing the most advanced therapies. The **continuous expansion of access would provide a more predictable environment** not only for patients, but also for treating physicians, as well as for manufacturers and distributors operating in Hungary.

Proposal

Following a positive decision by the quarterly ministerial reimbursement committee, where a legislative amendment is required (32/2004 or 9/1993), proposals should be submitted to the Minister to ensure that **reimbursement decisions requiring legislative changes are implemented at least once a year**, in line with the budgetary framework defined during the planning process.

If further consultation is required, the case should be referred to NEAK's competence to allow for additional discussions with the applicant and subsequently be resubmitted for consideration at a subsequent ministerial committee meeting.

In the event of a negative decision by the ministerial committee, substantive feedback should also be provided to enable the necessary modifications to be made as soon as possible.

Advantage for decision makers

A more manageable system with reduced administrative burden resulting from the continuous suspension, resubmission, and reassessment of applications. Questions related to the eligible patient population, pricing, and/or thresholds would be clarified in a timely manner, thereby avoiding subsequent financier uncertainty.

With continuous reimbursement, the financier can effectively control prices, budget impact, and patient numbers.



RETHINKING THE REIMBURSEMENT SYSTEM

A simpler, more transparent, and more predictable reimbursement system would facilitate earlier access to innovative therapies. Earlier access to such therapies can improve treatment outcomes and enable patients to return to work sooner. Shorter decision-making cycles would allow for the faster implementation of budgetary and policy priorities.

Background

The Hungarian pharmaceutical reimbursement system is highly complex, only partially transparent, and difficult to navigate. As a result, both the planning and sustainability of the pharmaceutical budget are challenging, and new innovative therapies become available in Hungary with significant delays compared to the European average. AIPM, in cooperation with the State Secretariat for Health and NEAK, has conducted comprehensive reviews of the reimbursement system on several occasions. In 2021, this outstanding trilateral collaboration led to the modification of several key elements. However, this **cooperation needs to continue, as the system remains overly complex and insufficiently transparent** due to the multitude of reimbursement categories, varying levels of support, and procedural rules. In addition, pharmaceutical reimbursement systems globally are facing new challenges. All of this significantly hinders predictability, planning, and sustainability for all stakeholders. Examples include irregular and ad hoc reimbursement decisions; the integration into the system of varying, originally temporary, tax-like industry payments (such as the 20% and 10% manufacturer paybacks and the promotional tax), persistent payment obligations linked to price-volume agreements that have not been phased out over time.



Proposal

- A **comprehensive simplification** of the pharmaceutical reimbursement system that appropriately reflects changing demographic, economic, and social challenges.
- A pre-defined budget allocation within the **annual budget framework** dedicated to the inclusion of new innovative therapies,
- A regular and **predictable reimbursement system** for new active substances and new indications
- **Eliminating the legislative requirement associated with the inclusion of new active substances and indications**, while retaining the decision-making authority of the competent minister
- **Simpler** reimbursement categories
- **New procedural frameworks** (e.g. conditional reimbursement, price adjustments, etc.)
- **Reforming the price–volume agreement system** and ensuring the phase-out of existing contracts
- **Industry payments** (e.g. price–volume agreements) **should** not serve to compensate for the underfunding of the pharmaceutical budget, but rather **support access to new, innovative therapies** (financing of diagnostics – particularly within conditional reimbursement schemes – e.g. structured data collection and the establishment of patient registries, etc.)



Advantage for decision makers

- The operation of the system becomes more efficient and transparent for the authority
- The role of the financier in pharmaceutical reimbursement decisions can be strengthened
- Faster and more flexible decision-making becomes possible, as decisions do not require legislative amendments in all cases
- Decision-making responsibility and control remain with the competent ministry, while the system becomes simpler and faster to operate
- Rethinking the pharmaceutical reimbursement system enables improved planning and effective budgetary control for all stakeholders
- Supporting earlier access to innovative therapies, thereby contributing to additional health gains

