

# Access to innovative medicines in Lithuania

Summary of the current situation

**Authors, project managers:**

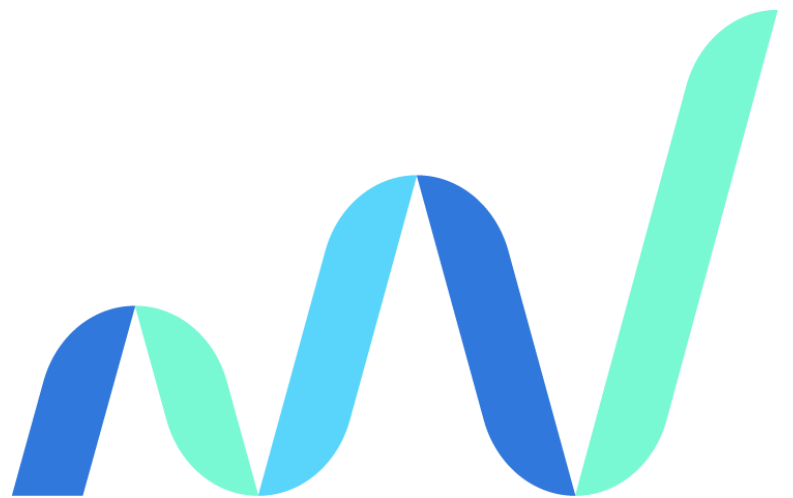
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# Introduction

Access to treatment is one of the most important indicators of the effectiveness of a healthcare system<sup>1</sup>. Over the past decade, significant pharmaceutical policy changes have been implemented in Lithuania. Nonetheless, national assessments and European Union (EU) analyses show that access to medicines remains one of the main challenges for the Lithuanian healthcare system.

Compared to other EU countries, Lithuanian patients have to wait for innovative medicines longer and have less options to choose from. According to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the average waiting time for new medicines in Europe is 578 days, while in Lithuania it is 819 days<sup>2</sup>. However, access to at least one drug in most innovative drug therapeutic groups is ensured nationally<sup>3</sup>. According to the Ministry of Health of Lithuania (MoH), more than 70% of newly authorised medicines in the EU have not been submitted for the inclusion in the reimbursement list. The reason for this has not been identified<sup>4</sup>.

Given the rapid progress in medical science and the growing needs of patients<sup>5</sup>, the role of the state is becoming particularly important in ensuring that new, effective and safe treatments are available.

This analysis identified the main areas that limit Lithuania's competitiveness in the field of medicine accessibility: regulatory processes, financial and human resources, cooperation between institutions and market participants, as well as market characteristics.

## Regulatory and policy context

### Strategic priorities in Lithuania

Health technology and biotechnology is one of the three priority areas for research, experimental development and innovation (R&D&I) in Lithuania. This area covers molecular technologies for medicine and biopharmaceuticals, advanced applied technologies for personal and public health, medical engineering for early diagnosis and treatment, as well as the development of safe food and sustainable agrobiological resources. Innovation and advanced manufacturing are encouraged in these areas<sup>6</sup>.

Lithuania's strategic political vision for 2050 is also focused on promoting innovation in all areas of public administration, especially in science, technology and innovation (STI) sector. The aim is to create a favourable environment for innovation, improve STI funding and nurture talent. **Health technology and biotechnology are highlighted as having potential for economic growth, public health and national security and the following actions are to be taken:**

- Funding and its optimisation must become a priority, integrated into national policy. Given Lithuania's international competitiveness potential in health technologies and biotechnologies, it is important to ensure

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<sup>1</sup>[https://www.researchgate.net/publication/312161419\\_Health\\_system\\_frameworks\\_and\\_performance\\_indicators\\_in\\_eight\\_countries\\_A\\_comparative\\_international\\_analysis](https://www.researchgate.net/publication/312161419_Health_system_frameworks_and_performance_indicators_in_eight_countries_A_comparative_international_analysis)

<sup>2</sup> <https://efpia.eu/media/oeganukm/efpia-patients-wait-indicator-2024-final-110425.pdf>

<sup>3</sup> <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/defining-essential-innovative-medicines-and-measuring-their-use-in-europe/iqvia-institute-defining-essential-innovative-medicines-and-measuring-their-use-in-europe-09-22.pdf>

<sup>4</sup> <https://sam.lrv.lt/lt/veiklos-sritys/farmacine-ir-kita-su-tuo-susijusi-veikla/vaistu-kainodaros-ir-prieinamumo-stebesena/wait/>

<sup>5</sup> <https://ligoniukasa.lrv.lt/lt/naujienos/600-milijonu-euru-pacientu-sveikatai-kam-panaudotos-lesos/>

<sup>6</sup>[https://eimin.lrv.lt/uploads/eimin/documents/files/Pa%C5%BEangios%20gamybos%20\(pramon%C4%97s\)%20%20kelrodis%202023%2005%2022.pdf](https://eimin.lrv.lt/uploads/eimin/documents/files/Pa%C5%BEangios%20gamybos%20(pramon%C4%97s)%20%20kelrodis%202023%2005%2022.pdf)

consistent promotion of innovation, reducing fragmentation of activities and strengthening cooperation between business, science and the public sector.

- In order to achieve a favourable regulatory environment, administrative processes must be simplified and decision-making accelerated. Public procurement must ensure competitiveness, transparency and be adapted to innovative technologies.
- Tax incentives and the investment climate must be tailored not only towards attracting investment, but also towards retaining it, creating a long-term innovation ecosystem<sup>7</sup>.

**The programme of the 20th Government of Lithuania (office taken on 25 September 2025) foresees increased availability of innovative medicines** and improved the green corridor conditions for large-scale manufacturing projects, bringing them closer to the conditions applied to defence industry projects:

- The government plans to develop incentives for large investments, promote breakthrough technologies, with a particular focus on life sciences and R&D. The aim is to improve conditions for large-scale manufacturing projects in strategic sectors, ensure competitive business financing instruments and provide greater state support.
- It aims to ensure personalised medical services for patients with rare and genetic diseases, to further develop advanced therapy technologies and improve their accessibility to the population. There are plans to improve the availability of innovative medicines and develop a patient-oriented pharmaceutical policy. It is also planned to improve the reimbursement system for the treatment of ultra rare diseases and to strengthen the involvement of healthcare professionals and patient organisations in reimbursement decision-making<sup>8</sup>.

## Path to market access

### Reimbursement regulation in Lithuania

An application to include a medicine into the reimbursement system can be submitted by the marketing authorisation holder (MAH) or their representative, healthcare professionals' or patients' associations. The aim of the national process is to compare the efficacy, safety and costs of a new drug. The medicine, for which an application has been submitted, is compared with other drugs on the market for the treatment of the same disease. It is then determined whether the benefits to patient health justify the costs to the state.

The process is composed of few key stages (Figure 1):

1. Health technology assessment (HTA) is an evidence-based scientific process that summarises information on medical, economic, social and ethical issues related to the use of health technologies. HTA is an essential tool that helps EU Member States make decisions on the use, price and reimbursement of new health technologies<sup>9</sup>. In Lithuania, HTA is performed by the State Medicines Control Agency of Lithuania (SMCA).
2. In parallel to the assessment carried out by the SMCA, the National Health Insurance Fund under the Ministry of Health of the Republic of Lithuania (NHIF) compares whether the submitted price of a medicine corresponds to its declared price in other reference EU countries, or whether the submitted price corresponds to the average wholesale price of the three lowest reference countries. The NHIF also evaluates the medicine's five-year budgetary impact on the Compulsory Health Insurance Fund (CHIF).
3. The recommendations of the SMCA and the conclusions of the NHIF are submitted to the MoH's commission for the Reimbursement of Medicinal Products and Medical Devices (Reimbursement Commission)<sup>10</sup>. One of

<sup>7</sup> [https://www.lrs.lt/sip/getFile3?p\\_fid=83422](https://www.lrs.lt/sip/getFile3?p_fid=83422)

<sup>8</sup> <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/24290d0099f611f0bb51b0620d4bdb93>

<sup>9</sup> [https://ec.europa.eu/commission/presscorner/api/files/document/print/en/qanda\\_25\\_227/QANDA\\_25\\_227\\_EN.pdf](https://ec.europa.eu/commission/presscorner/api/files/document/print/en/qanda_25_227/QANDA_25_227_EN.pdf)

<sup>10</sup> <https://www.e-tar.lt/portal/lt/legalAct/TAR.E83CFAB10E7B/asr>

the following decisions on reimbursement must be taken within 180 days following the submission of the application<sup>11,12</sup>:

- Reimburse – if the medicine does not require additional CHIF funds, or if the projected increase in costs from the CHIF budget in the second year of reimbursement would be equal (or less) to 0.03% of the total CHIF expenditure on reimbursement of medicinal products in the previous year. In such cases the medicine is immediately included in the list of reimbursable medicines.
- Include in the reserve list – the medicine is considered eligible for reimbursement, but there are insufficient CHIF funds for its inclusion in the reimbursement system. The list is reviewed twice a year and reimbursement is allocated based on priority.
- Refer to the Negotiation commission – the Reimbursement Commission may also refer the matter to the Negotiation Commission with an aim to reduce the price of the medicine<sup>13,14</sup>.
- Do not reimburse.

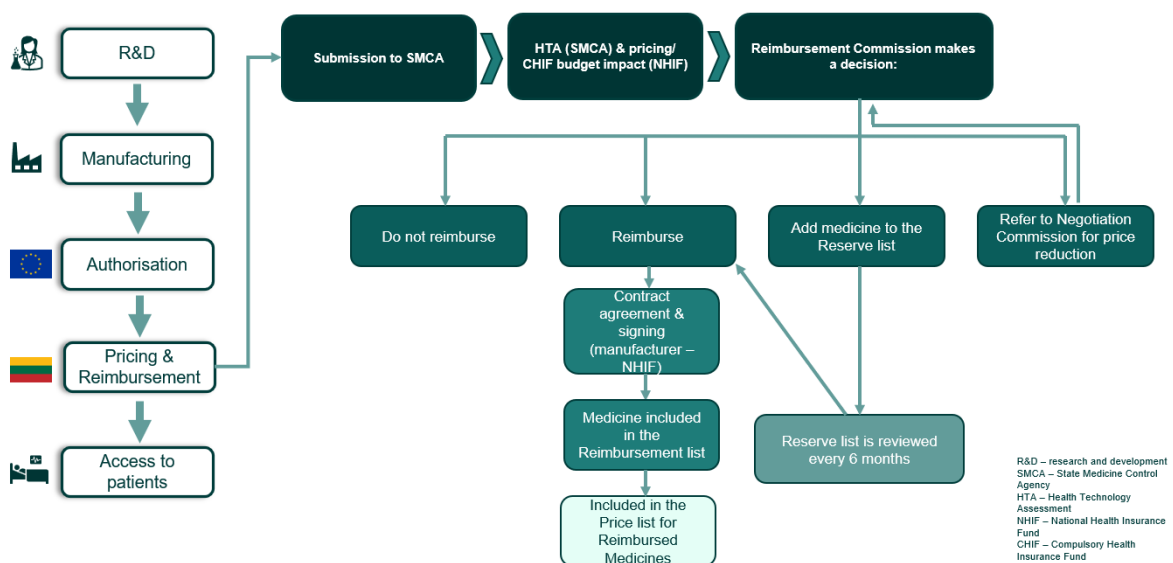


Figure 1 Reimbursement process in Lithuania.

### Reimbursement of costs for ultra rare human health conditions

In Lithuania, there is an additional process for the reimbursement of treatment of ultra rare diseases. This process is based on individual requests from university hospitals or healthcare professionals organisations.

The Commission for the reimbursement of treatment costs for very rare conditions, coordinated by the NHIF, examines the requests and makes a decision within 10 working days (or 1 working day in urgent cases where the patient's condition does not allow for a longer assessment)<sup>15</sup>.

<sup>11</sup> <https://eur-lex.europa.eu/legal-content/LT/TXT/PDF/?uri=CELEX:31989L0105>

<sup>12</sup> <https://www.valstybeskontrolė.lt/LT/Product/24211/vaistu-prieinamumas-gyventojams>

<sup>13</sup> <https://ligoniukasa.lrv.lt/lt/naujienos/nuo-paraiskos-iki-paciento-kompensuojamuju-vaistu-kelias-lietuvoje/>

<sup>14</sup> <https://www.e-tar.lt/portal/lt/legalAct/TAR.E83CFAB10E7B/asr>

<sup>15</sup> <https://www.e-tar.lt/portal/lt/legalAct/4db55820afc011e5b12fbb7dc920ee2c/asr>

The following decisions can be made:

- To reimburse or pay for the costs of services – even if ultra rare conditions are not included in the formal indications for the provision of services.
- Partial reimbursement – part of the costs must be covered by the MAH, healthcare institution or non-governmental organisation. Before deciding on partial reimbursement, the payer may – subject to the estimated costs – negotiate with the MAH or enter into outcomes-based agreements.
- Conditional reimbursement in urgent cases.
- Do not reimburse.

### Expanding pharmaceutical industry locally

Three national institutions play a key role in promoting the development of an innovative pharmaceutical industry in Lithuania: Invest Lithuania (IL), the Ministry of Economy and Innovation (MoEI) and the Innovation Agency (IA):

- IL's role includes attracting foreign investment, financial incentives, production, consulting and cooperating with institutions. MoEI coordinates the green corridor initiative for large investment projects. Both institutions provide incentives not only to the pharmaceutical sector, but to all eligible investments. The role of the IA focuses on supporting and developing businesses established in Lithuania.
- The role of MoH or subordinate institutions covers further stages of the pharmaceutical value chain, such as coordination and regulation of administrative services (e.g. GMP, GDP, authorisation, reimbursement).

## Access to medicines in Lithuania – current situation

**An increasing number of Lithuanians are using reimbursed medicines; CHIF expenditure and budget for medicines is also increasing each year.** However, Lithuania is among the third of EU countries that allocate the lowest share of their GDP to healthcare – 7.2% (the EU average is 10.4%)<sup>16</sup>:

- Almost half (45%) of Lithuanian residents are using reimbursable medicines and medical aids. Since 2020, this number has increased by 6.3%.
- CHIF expenditure for reimbursable medicines and medical aids is growing – between 2021 and 2024, it increased from €406 million to €628 million<sup>17</sup>. So is the CHIF budget – one of the fastest growing areas is medicines and medical aids. In 2025, the CHIF budget consisted of €3.9 billion. Of this, 14.8% was allocated to the financing of reimbursable medicines and medical aids<sup>18</sup>. In 2026, in order to improve access to medicines, an additional €106 million is planned to be allocated to medicines and medical aids reimbursement<sup>19</sup>.
- Lithuania has established the maximum amount it can pay for patient's additional quality-adjusted life years gained as a result of a medicine. Currently, it amounts to 1, 3 or 5 times the GDP per capita. The existing reference cost-effectiveness values for 2025 came into force in 2020. They must be reviewed and approved by the MoH every three years<sup>12,14</sup>. The values applied in Lithuania are among the highest in the EU - Latvia applies a limit of 3, Poland 2.6 GDP per capita<sup>12</sup>.

<sup>16</sup> [https://www.oecd.org/content/dam/oecd/en/publications/reports/2024/11/health-at-a-glance-europe-2024\\_bb301b77/b3704e14-en.pdf](https://www.oecd.org/content/dam/oecd/en/publications/reports/2024/11/health-at-a-glance-europe-2024_bb301b77/b3704e14-en.pdf)

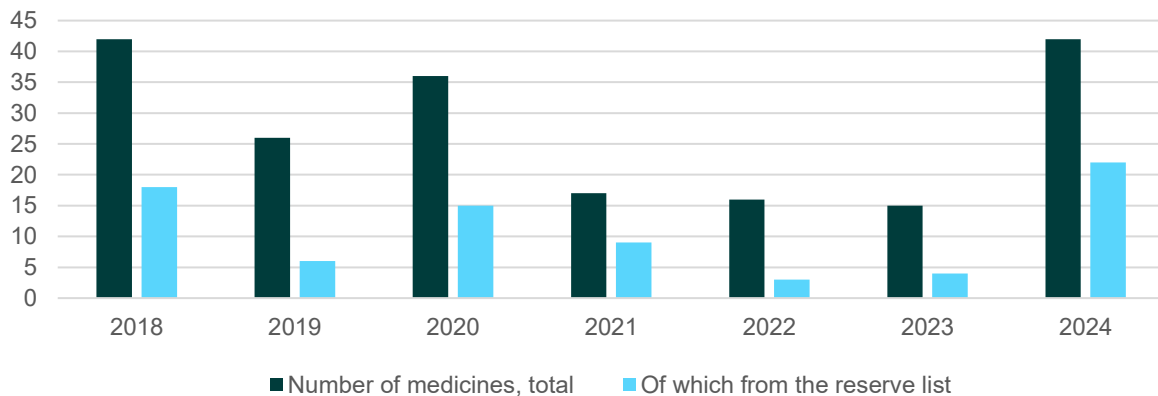
<sup>17</sup> [https://ligoniukasa.lrv.lt/public/canonical/1746524455/12933/Metin%C4%97%20analiz%C4%97%20004.25%20\(3](https://ligoniukasa.lrv.lt/public/canonical/1746524455/12933/Metin%C4%97%20analiz%C4%97%20004.25%20(3)

<sup>18</sup> [https://ligoniukasa.lrv.lt/public/canonical/1744268687/12826/Apie-NHIF-biudzet-trumpai-2025%20\(10 April 2024\).pdf](https://ligoniukasa.lrv.lt/public/canonical/1744268687/12826/Apie-NHIF-biudzet-trumpai-2025%20(10%20April%202024).pdf)

<sup>19</sup> <https://ligoniukasa.lrv.lt/lt/naujienos/2026-m-NHIF-biudzetas-leis-uztikrinti-svarbiausiu-sveikatos-paslaugu-testinuma-63A/>

**In Lithuania, few new medicines are available and they enter the reimbursement system slowly.** According to data published by EFPIA in 2025, an average of 46% of newly approved medicines were included in reimbursement systems in EU countries<sup>2</sup>:

- Lithuania ranks second to last in the EU with 16% of new medicines available, lagging behind other Baltic countries and countries with similar GDP per capita. Nonetheless, Lithuania ensures access to at least one innovative medicine in most major therapeutic groups for the treatment of cancer, cardiovascular diseases, diabetes, immunological and neurological diseases, hepatitis and cystic fibrosis<sup>3</sup>.
- For the treatment of rare diseases, Lithuania does rank higher – 23% of new drugs are available to patients (the EU average is 42%)<sup>2</sup>.
- According to data from the Organisation for Economic Co-operation and Development (OECD), approximately 40% of selected new oncology drugs are reimbursed in Lithuania. However, this indicator also lags behind the EU average (around 60%)<sup>20</sup>.
- The number of newly reimbursed medicines decreased steadily between 2020 and 2023 (Figure 2). In 2024, there was an increase in the total number of medicines and in the number of medicines transferred from the reserve list to the general reimbursement system<sup>17</sup>. In order to assess the long-term positive trend, it is necessary to monitor the data for the years to come.



*Figure 2 Number of medicines included in the list of reimbursable medicines („List A“). Figure 4 Number of medicines included in the list of reimbursable medicines („List A“). Source: NHIF*

- It is important to recognise that the number of medicines available in a country depends on whether applications for their reimbursement have been submitted by pharmaceutical companies. In Lithuania, applications for 70% of newly approved medicines were not submitted and their inclusion in the reimbursement system therefore could not be assessed<sup>4</sup>.

In the EU, it takes an average of 578 days from the central authorisation of a medicine to its inclusion into national reimbursement systems. In Lithuania, this period takes an average of 819 days and is one of the slowest in the EU<sup>2</sup>; 92% of decisions on drug reimbursement were delayed by more than six months<sup>12</sup>.

\* Does not exclude clock stops set by the MoH order.

<sup>20</sup> [https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/02/eu-country-cancer-profile-lithuania-2025\\_9a52818d/b260e7d1-en.pdf](https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/02/eu-country-cancer-profile-lithuania-2025_9a52818d/b260e7d1-en.pdf)

- Nonetheless, processes have been speeding up in recent years. Between 2022 and 2024, the average time taken to assess HTA applications in Lithuania reduced by 48% (Figure 3).

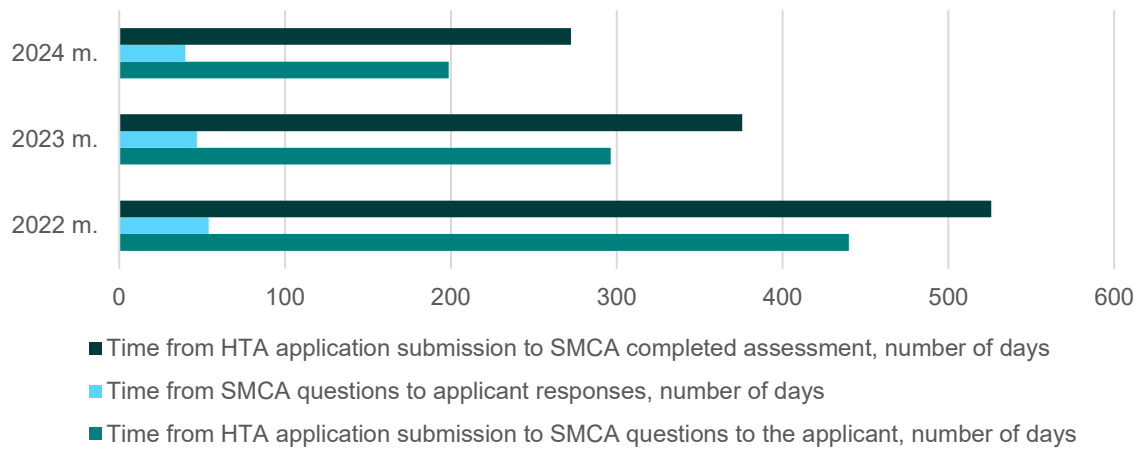
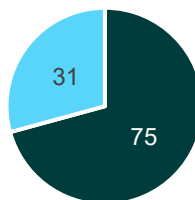


Figure 3 SMCA HTA application evaluation time. Scope - applications whose evaluation has been completed. Source: SMCA. Data accessed in October 2025

- While final decisions for the inclusion of a medicine into the reimbursable medicines list are made quickly, applications have to wait in line until they are discussed at MoH's Reimbursement Commission meetings.
  - After the SMCA HTA, it takes the Reimbursement Commission an average of 106 days\* to make a decision whether to include a medicine into the reimbursed medicines list or not (Figure 4).
  - The longest (75 days\*) is the time until the application is discussed for the first time at the commission meeting. This, however, includes the time it takes pharmaceutical companies to submit and SMCA to evaluate additional data (e.g. access improvement schemes) or the NHIF to perform a repeat cost assessment – without it, the discussion on a possible inclusion into reimbursable medicines' list cannot begin.



- Time until the application is discussed at the committee meeting for the first time, number of days
- Time from the first discussion at the committee meeting until the final decision, number of days

Figure 4 Duration of Reimbursement Commission decision-making in 2024–2025. Source: MoH. Data accessed in October 2025

While the reimbursement process for the treatment of ultra rare human health conditions is designed as an individual, application-based assessment for very rare conditions only, in practice, a large number of applications is examined, and applications for certain medicines are often re-evaluated:

- Between 2024 and October 2025, the Commission for the reimbursement of treatment costs for very rare conditions considered over 440 applications for medicinal products (medical aids and personal healthcare services were excluded from this analysis). Different applications for cannabidiol, tafamidis, pembrolizumab,

\* Does not exclude clock stops set by the MoH order.

budesonide and human normal immunoglobulin were evaluated more than 18 times<sup>21</sup> .

- The majority of assessments are positive. Between 2020 and 2022, the commission adopted 81% positive and 19% negative decisions on treatment reimbursement<sup>12</sup> .

Finally, the conclusions of the State Audit Office's audit conducted in 2023 state the main problems with the availability of medicines in Lithuania. These are: slow inclusion of medicines into the reimbursement system, the reimbursement of new medicines and medicines for ultra-rare diseases is an area of unmet need, insufficiently developed alternative channels for purchasing medicines, a lack of alternatives in the event of medicine shortages, and irrational use of medicines<sup>12</sup>.

## Stakeholder insights: factors shaping medicine access and competitiveness

- As part of this analysis stakeholders interviews were held in order to identify the factors limiting Lithuania's competitiveness in the area of medicine access. Additionally, data from Invest Lithuania on lost pharmaceutical investments was analysed.
- The interviews covered the key challenges faced in terms of access, changes in the ecosystem that could improve it, and ways to increase Lithuania's competitiveness in the field.
- Stakeholders interviewed: representatives of the MoH, SMCA, NHIF, IL, Vilnius University and Lithuanian University of Health Sciences, healthcare professionals, pharmaceutical companies and associations (total of 23 individuals). Interviews were held from 25 September 2025 to 22 October 2025.

The main problems, measures taken to address them and key conclusions are outlined below.

### Regulatory system

All stakeholders identified the regulatory system as a factor influencing competitiveness, with the regulation of drug reimbursement being the most widely cited. Several pharmaceutical companies indicated that they did not enter the Lithuanian market due to unfavourable regulation, but did not provide further details.

Stakeholders note that a clearer legal framework, predictable processes and a more flexible pricing policy could contribute to improving patient access to innovative treatments and strengthening Lithuania's competitiveness:

#### 1. **Problem identified by stakeholders: regulatory system**

Differences in terminology between EU and national legislation hinder effective cooperation. The HTA process, based on scientific methods and objectivity, is lengthy, unpredictable and more stringent in practice than in most EU countries. This limits the strategic planning of both institutions and pharmaceutical companies.

→ **Measures taken by institutions:** In order to ensure uniform quality of assessments and compliance with the HTA Regulation, an HTA methodology is being developed, a "four-eyes" principle is applied to ensure the objectivity of assessments, the HTA questions and answers stage is being optimised, and legislative changes are being implemented to speed up processes and ensure evidence-based process management.

#### 2. **Problem identified by stakeholders: reserve list and orphan drugs**

Although there is a reserve list of medicines, medicines may remain on it for a long time due to budget constraints. Furthermore, there is no separate reimbursement procedure for orphan medicines.

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<sup>21</sup> <https://sam.lrv.lt/lt/struktura-ir-kontaktine-informacija/komisijos-ir-darbo-grupes/labai-retu-zmogaus-sveikatos-bukliu-gydymo-islaidu-kompensavimo-komisija/posedziu-protokolai-2/>

→ **Measures taken by institutions:** A review of the criteria for the reserve list of medicines is planned, and the current legislation for medicines intended and approved for the treatment of very rare conditions are planned to be reviewed.

### 3. Problem identified by stakeholders: pricing and reimbursement

Reimbursement decision-making processes carry administrative burden and offer limited flexibility in negotiations. Furthermore, pricing policies are based on the lowest EU average prices and reference cost-effectiveness values (GDP thresholds) are not suitable for certain medicines. Lastly, long-term price freezing can make it difficult to respond to changes in production costs or the economic environment.

→ **Measures taken by institutions:** Pricing policy seeks to balance budget constraints with the efficient use of funds. There are plans to review the current legislation on the reimbursement of medicines for the treatment of ultra rare conditions and to increase the GDP thresholds for orphan medicines. Proposals submitted by pharmaceutical companies to the MoH regarding contract procedures are being reviewed, and the need for price freezing is assessed annually.

### 4. Problem identified by stakeholders: information clarity

Publicly available HTA monitoring system in Lithuania is considered to be functioning properly and was not identified as a problem area. Meetings of the Reimbursement Commission are documented and publicly available. Measures are in place to ensure transparency; however, due to the limited structure and clarity of the information, practical application is difficult and hinders the development of market access strategies and outcome forecasting.

→ **Measures taken by institutions:** A review of the legislation for medicines for the treatment of ultra rare conditions should reduce the level of uncertainty.

**Authors' conclusion:** The authorities recognise key issues identified by stakeholders in drug reimbursement regulatory system and are taking steps to address them. A clearer legal framework, predictable processes and more flexible pricing are needed to improve competitiveness and access to medicines. The planned changes may reduce barriers, but clarity of processes remains key for long-term market attractiveness.

## Resources

Lithuania's competitiveness is also defined by the management of the CHIF budget and human resources:

### 1. Problem identified by stakeholders: budget management

The CHIF contribution system is not proportional, and the budget for medicine reimbursement does not meet the growing demand. It was noted that a long-term planning strategy using horizon scanning mechanisms, specifically monitoring new drug approvals and patent expiries would allow early identification of potential budget shortfalls and costs could be optimised through timely reimbursement of generic medicines.

→ **Measures taken by institutions:** Initiatives are being implemented to increase CHIF budget contributions for persons insured by the state.

### 2. Problem identified by stakeholders: lack of human resources

The public sector lacks specialists to perform the HTA, particularly in the field of pharmacoeconomics, and there are no study programmes in this field in Lithuania. Furthermore, some pharmaceutical companies indicate that they have not invested in the Lithuanian market due to a lack of talent in the life sciences sector.

→ **Measures taken by institutions:** In November 2025, the SMCA signed a cooperation agreement with Mykolas Riomeris University, focusing on scientific development and strengthening competencies in the fields of health technology, pharmacy, health economics and management.

**Authors' conclusion:** The need for CHIF growth is identified and efforts are being made to ensure its sustainability and address the unequal contributions. The public sector faces not only a shortage of qualified specialists, but its attractiveness is also limited for highly skilled specialists. A systematic approach to resource planning would allow to anticipate future needs and ensure the necessary resources in a timely manner or to take additional measures to implement them.

## Communication

The microclimate of the ecosystem directly depends on multistakeholder cooperation, the implementation of a long-term strategic direction, and determines the attractiveness of the market:

### 1. Problem identified by stakeholders: cross-sectoral partnership

There is a need for consistent and open dialogue between institutions and market players at the practical and procedural level. Existing mechanisms offer limited opportunities to seek and discuss out-of-the-box solutions. Some communication is stringent, based on legislation, and appeal mechanisms allow only partial review of decisions. The lack of a common strategic direction and trust hinders the effective functioning and development of the sector.

→ **Measures taken by institutions:** In 2025, a series of multistakeholder meetings were held. The MoH, together with market players, participates in meetings, round-table discussions and events. In 2022-2025, the SMCA also organised meetings on the principles of HTA, the results achieved and outlook for the future. Finally, a broader dialogue on the necessary changes and possible directions is being held. The proposals submitted by market players will be included when forming MoH's pharmaceutical policy directions.

### 2. Problem identified by stakeholders: public communication

In the area of public communication, there is a need to increase public awareness of the processes that determine the availability of medicines nationally (e.g. HTA).

**Authors' conclusion:** Market participants' insights are taken into account when forming pharmaceutical policy in Lithuania. However, in order to strengthen the microclimate of the sector, it is important to ensure cooperation and open dialogue not only at the strategic level but also in day-to-day administrative processes. Particular attention should be paid to strengthening trust and ensuring continuity of the strategic direction across all levels.

## Market characteristics

The market characteristics that have a direct impact on Lithuania's competitiveness consist of market size, the ability to attract investment, and geopolitical risk:

### 1. Problem identified by stakeholders: the market is small and demanding

The number of pharmaceutical companies supplying generic drugs in Lithuania is declining. The attraction of small and medium-sized enterprises is also limited – such companies are selective and can operate only in markets that can ensure clear and predictable processes. Additionally, due to the low number of patients, Lithuania usually enters the later stages market entry, with pharmaceutical companies primarily seeking reimbursement in the major EU markets. The external reference pricing and additional discount requirements applied in Lithuania further reduce the attractiveness of the market.

→ **Measures taken by institutions:** There are planned legislative changes to improve conditions for generic medicines. Additionally, proposals submitted by pharmaceutical companies to the MoH regarding contract procedures are reviewed, and the need for price fixing is assessed annually.

### 2. Problem identified by stakeholders: promising fields are underutilised

There are promising areas in Lithuania that could increase competitiveness: advanced therapy medicinal products (ATMPs), clinical trials, sandboxes and manufacturing. The manufacturing of ATMPs is already being carried out at Santaros Clinics under regulatory exemptions. In the field of clinical trials, activities are hindered by regulatory restrictions and lack of support. The current environment could be attractive for trials of generic and biosimilar medicines rather than innovative ones due to differences in standard treatment practices in Lithuania versus other EU markets. Once reimbursement processes are optimised, regulatory sandboxes could be introduced to help attract small and medium-sized pharmaceutical companies.

→ **Measures taken by institutions:** There are plans to introduce legislation for ATMPs and clinical trials. The SMCA provides scientific and regulatory advice to drug developers, researchers as well as marketing authorisation holders or their representatives.

### 3. Problem identified by stakeholders: geopolitics

Several pharmaceutical companies indicated that the geopolitical situation and the lack of financial incentives were the main reasons for not choosing Lithuania for investment.

→ **Measures taken by institutions:** State financial incentives and the geopolitical situation do not fall within the remit of the MoH or its subordinate institutions. MoH and IL are cooperating with an aim to support the growth of pharmaceutical industry in Lithuania: sharing information, considering possible regulatory measures within the scope of the MoH's responsibilities and competences.

**Authors' conclusion:** Given Lithuania's small market size, targeted adjustments to the regulatory framework are being considered to improve attractiveness in selected priority areas. They aim to create a more favourable ecosystem for both existing market participants and new companies that will create added value. In the area of drug reimbursement, it is important for Lithuania to ensure clear, predictable and more flexible processes that would compensate for its small market size and create suitable conditions for the establishment of small and medium-sized pharmaceutical companies.

## Other

1. Other reasons cited by pharmaceutical companies for not choosing Lithuania for investment included internal company strategies, logistics and infrastructure, and an insufficiently mature ecosystem. No further explanations were provided on these issues.

→ **Measures taken by institutions:** The reasons mentioned do not fall within the remit of the MoH or subordinate institutions.

## Conclusions

- Lithuanian and EU policy aims to achieve a competitive, innovative and patient-oriented pharmaceutical system. It focuses on improving the ecosystem, increasing the availability of innovative medicines and the resilience of supply chains. This is expected to be achieved by simplifying regulation, strengthening public-private cooperation and applying incentives to increase competitiveness.
- The pharmaceutical market is growing across the EU. In Lithuania, the life sciences sector is demonstrating rapid growth, and its development is prioritised. Despite the presence of major pharmaceutical companies – operating through local affiliates or third parties – patient access to medicines remains limited in Lithuania.
- Lithuania's competitiveness in the area of market access is determined by regulation, resource management, cross-sectoral communication and market characteristics. It is also influenced by long-term political vision and ecosystem maturity.
- The Lithuanian public sector is keen to strengthen the pharmaceutical sector. However, due to limited resources, actions are often reactive and fragmented, and changes are being implemented while balancing limited financial resources. Institutions recognise fundamental regulatory issues and are planning changes that could make processes more efficient and clear. The planned pharmaceutical policy strategy could help Lithuania develop a long-term direction that will ensure a more cooperative and favourable ecosystem.