

## HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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### LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

**1. Please provide a bird's-eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).**

The Lithuanian healthcare system is funded through contributions to a compulsory health insurance (CHI) scheme mainly managed by the National Health Insurance Fund under the Ministry of Health (NHIF). Funding is derived from mandatory payroll contributions from the employed population and allocations from the general government budget to cover the non-working population, ensuring universal coverage. These contributions feed the Compulsory Health Insurance Fund (CHIF), which reimburses a variety of healthcare services, medicinal products and medical devices. At the same time, Lithuania's healthcare system relies heavily on out-of-pocket (OOP) payments. Medicinal products constitute the largest share of OOP spending, followed by dental care.

The Ministry of Health (MoH) oversees the regulation and policymaking for the health system. In addition to managing the NHIF, it supervises several subordinate agencies responsible for medicinal products control, public health functions, and the licensing of services and healthcare professionals. The MoH also owns or co-owns certain healthcare providers, including all tertiary hospitals. Primary healthcare centres and most district hospitals are owned by municipalities, which also handle some public health responsibilities.

The private sector plays a minimal role in inpatient care but has a significant presence in outpatient care, particularly in dentistry. Many general practitioners operate as private providers, and the NHIF regularly contracts private providers for primary care and some specialised outpatient services.

**2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.**

Financing and reimbursement are mainly governed by the Law on Health Insurance of the Republic of Lithuania (LHI). LHI sets the general framework for healthcare financing and reimbursement from the CHIF budget, such as types of persons insured by CHI, the principles for forming the CHIF budget, reimbursement of expenses for personal healthcare services, acquisition and reimbursement of medicinal products and medical devices, as well as reimbursement of rental costs for medical equipment necessary to ensure home healthcare (nursing) for insured persons, etc.

LHI also defines the institutions responsible for implementing the CHIF budget, the rights and obligations of persons insured by CHI and healthcare organisations in the context of CHI,

the procedures for dispute resolution, the principles for cross-border healthcare cost reimbursement, and the basics of supplementary (voluntary) health insurance.

More detailed (specific) rules regarding reimbursement are provided in separate implementing legal acts, mainly adopted by the MoH. These legal acts are categorised by the health areas such as healthcare services, nursing, medicinal products, orphan medicinal products, medical devices, high-cost tests and procedures, etc.

The prices for reimbursable healthcare services and products (such as medical devices, medicinal products, etc) are fixed by the government unilaterally. Therefore, negotiations are not that relevant in this field. However, in some cases, manufacturers of medicinal products (based on the established procedure and only to the limited extent) are allowed to negotiate the reimbursable prices of medicinal products and medical devices.

### **3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?**

The main supervisory body in the field of healthcare financing and reimbursement in Lithuania is MoH. MoH is responsible for formulating, organising, coordinating and controlling the implementation of public policy on healthcare financing and reimbursement. More specific tasks related with the implementation of the healthcare financing and reimbursement are attributed to the NHIF, Compulsory Health Insurance Council (CHIC) and five Territorial Health Insurance Funds (THIFs).

The main role of the NHIF is to implement CHI and manage the CHIF budget in accordance with the procedures laid down by law and to properly represent the interests of the insured persons. NHIF is responsible for adopting decisions regarding reimbursement of healthcare services, medicinal products, and medical devices. NHIF is subordinated to the MoH.

CHIC is a collegiate advisory body based on tripartite representation. CHIC is composed of public authorities, organisations of policy holders/employers and organisations defending the interests of the insured. CHIC provides opinion on various questions related with healthcare financing and reimbursement in Lithuania.

THIFs manage a portion of the CHIF budget allocated by the NHIF. This portion is used to cover expenses for services provided by healthcare organisations and to reimburse the costs of medicinal products and medical devices. THIFs are also responsible for the conclusion of contracts with pharmacies and payment for reimbursable medicinal products and medical devices dispensed to the insured persons. THIFs operate based on the five districts in Lithuania (one THIF for each district). THIFs are subordinated to the NHIF.

Courts do not play a major role in shaping healthcare financing and reimbursement policies in Lithuania. However, occasionally, decisions are made in this area that establish certain rules, such as those concerning the obligation to conclude clawback agreements or to reimburse orphan medicinal products.

### **4. Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?**

Public health spending in Lithuania saw a significant boost due to funds allocated for the Covid-19 response. In 2021, total health expenditure accounted for 7.8 per cent of GDP. A marked increase in spending began in 2019 and continued through the first two years of the

pandemic. Public spending represented 69 per cent of the total in 2021, amounting to 5.4 per cent of GDP, highlighting the prioritisation of public financial resources during the crisis. Significant investments were made in vaccine procurement, Covid-19 testing, personal protective equipment, and initiatives such as hotlines and mental health support measures.

However, the pandemic has not changed the general system of healthcare financing.

**5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?**

All Lithuanian citizens and permanent residents who contribute to the CHIF budget are entitled to publicly funded healthcare services (including reimbursement of medicinal products and medical devices). Nearly all legal residents of Lithuania (over 99 per cent) are covered by the CHI scheme. Ukrainian refugees employed in Lithuania receive health coverage equivalent to that of residents, whereas others are entitled to emergency care and a limited range of additional healthcare services. Undocumented migrants, except for particularly vulnerable groups such as unaccompanied minors, are only eligible for essential medical aid, although larger migrant accommodation centres may provide some primary healthcare services. Uninsured individuals, regardless of their status, retain the right to access emergency healthcare services.

Healthcare organisations participate in the reimbursement scheme by concluding contracts with the THIFs for the provision and reimbursement of healthcare services from the CHIF budget ('reimbursement contract'). A reimbursement contract specifies the list of services that will be reimbursed from the CHIF budget, the conditions for the provision of the services and the amount of the CHIF budget earmarked to cover the costs of such services. All healthcare organisations in Lithuania (both public and private) can participate in this reimbursement scheme on an equal basis and conclude reimbursement contracts with THIFs. However, the tendency is that access to these contracts is more limited for private healthcare organisations. Insured patients can receive free healthcare services (reimbursed from the CHIF budget) only from those healthcare organisations, that have reimbursement contracts in place.

As regards the medicinal products, marketing authorisation holders or their representatives (MAHs) have equal access to the reimbursement system of medicinal products if their medicinal products meet clinical effectiveness, economic and price criteria. The same mechanism and principles apply for the medical devices. For more information, please see Q12.

**HEALTH INSURANCE FINANCING AND COVERAGE**

**6. How are health insurance carriers financed? How are premiums determined?**

CHIF budget is financed from the three main sources: (1) mandatory CHI payments; (2) contributions from the state budget and (3) other legal sources.

Approximately half of the population contributes mandatory CHI payments, while the other half – comprising pensioners, recipients of social or disability benefits, income support beneficiaries, children under 18, one parent or legal guardian of a child under eight or two or more children under 18, registered unemployed individuals, asylum seekers, and certain other groups – qualifies for state-sponsored coverage.

The amount of CHI contributions is income-based and calculated according to tariffs unilaterally set by the government.

Meanwhile, private insurance companies, providing additional healthcare insurance, are financed from natural and legal persons contributions based on the terms and conditions of the private insurance contract. This type of the insurance is optional and not mandatory in Lithuania.

Since the funding sources for the CHIF budget and CHI tariffs fall under the scope of state health policy, the courts have a limited role in this process. However, critical questions regarding the compliance of certain CHIF budget financing rules with the Constitution of the Republic of Lithuania ('Constitution') may be referred to the Constitutional Court. The Constitutional Court then issues binding decisions on such matters. In this limited scope and only on a case-by-case basis, the Constitutional Court can influence the determination of CHIF budget financing sources and the establishment of CHI tariffs.

**7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?**

In Lithuania, only healthcare services and goods pre-approved by the government are eligible for reimbursement from the CHIF budget. Healthcare services and goods that are not pre-approved, are not reimbursed from the CHIF budget, requiring patients to cover these costs as OOP expenses.

Healthcare services are reimbursed from the CHIF budget only if they are included in the official reimbursement lists. These lists specify the reimbursable base prices for each service, which are presumed to fully cover the cost of the respective service. Therefore, healthcare organisations that have entered into reimbursement contracts with THIFs are prohibited from charging patients' additional co-payments for services covered by the reimbursement list and funded from the CHIF budget. However, patients (if properly informed) may opt for additional healthcare services or more expensive treatment alternatives, for which healthcare providers can legally charge patients with OOP payments.

Healthcare services reimbursement lists are administered by the MoH, which includes/excludes healthcare services from these lists and unilaterally determines the base prices of these services. When evaluating whether a healthcare service should be included in the reimbursement list, two main criteria are considered: (1) the effectiveness of the personal health care service; and (2) the need for personal health care service (more than one case of health disorder per 200,000 inhabitants of the Lithuania during a calendar year).

There are no differences in coverage for in-person medical appointments and telemedicine appointments. However, according to the healthcare services reimbursement lists, the base price (reimbursed from the CHIF budget to insured persons) of telemedicine appointments tends to be lower compared to in person medical appointments.

**HOSPITAL SECTOR**

**8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?**

As mentioned in Q7, in Lithuania, only healthcare services listed in the reimbursement lists are eligible for reimbursement. To access a free-of-charge healthcare service covered from the CHIF budget, a patient must visit a healthcare organisation that has a reimbursement contract with the THIF for the specific service. Once the insured patient receives the service, its base price is reimbursed to the healthcare organisation from the CHIF budget, following the procedures established by law.

Indicated reimbursement procedure and principles equally applies to stationary (inpatient) and ambulatory (outpatient) healthcare services.

The reimbursement system in Lithuania faces criticism for its fixed base prices, which, while intended to fully cover healthcare service costs, are often considered too low and unreflective of market conditions. As a result, healthcare organisations are compelled to offer patients additional or alternative services to offset actual operating expenses, rather than charging co-payments for services reimbursed from the CHIF budget (which is not allowed). This practice creates confusion among insured patients and may even lead to violations of the reimbursement contracts.

#### **9. How are the prices of such services determined? How is economic efficiency controlled?**

As mentioned in Q7, healthcare services are reimbursed from the CHIF budget in accordance with the base prices that are unilaterally determined by the MoH. MoH calculates and determines base prices based on the special calculation methodology ('methodology'). According to the methodology, the base prices are determined in accordance with three key principles: objectivity (ensuring that costs are allocated to services fairly and without distortion of cost data or financial results); transparency (requiring a clear and straightforward system for calculating costs across healthcare organisations); and public accessibility (mandating that information on the pricing system's principles and results be available and understandable to those entitled to access it). Further, the methodology provides detailed criteria and formulas for base prices calculation.

Economic efficiency is controlled by allowing (and requiring) the MoH to review base prices of healthcare services if certain criteria, established in the methodology, are triggered. For example, the base prices are reviewed to reflect inflation, increased or decreased CHIF budget for healthcare services, etc.

The prices for paid healthcare services (not reimbursed from the CHIF budget) provided by healthcare organisations owned by the state or municipality, are also unilaterally determined by the MoH. Prices for paid services are indexed according to the criteria set out by the MoH.

### **HEALTHCARE PROVIDERS IN PRIVATE PRACTICE**

#### **10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?**

In case private healthcare organisations have concluded reimbursement contracts with THIFs, the services covered by such agreements are financed and reimbursed as explained in responses to Q7 and Q8.

**11. How are the prices of such services determined? How is economic efficiency controlled?**

In case private healthcare organisations have concluded reimbursement contracts with THIFs, the prices for services covered by such contracts are determined as explained in Q7 and Q9. Private healthcare providers that do not have a reimbursement contract in place, or in case the reimbursement contract does not cover certain healthcare services, are free to independently determine the prices for the healthcare services they offer.

**PHARMACEUTICALS AND MEDICAL DEVICES**

**12. How are pharmaceuticals and medical devices financed and reimbursed?**

For a medicinal product to be reimbursed from the CHIF budget, a common (INN) name of the specific medicinal product must first be included in the List of Diseases and Reimbursable Medicinal Products for the Treatment of Diseases ('List A'), and afterwards – in the Pricelist of Reimbursable Medicinal Products ('Pricelist').

For a medicinal product to be included into the A List, such medicinal product must go through the health technology assessment (HTA) procedure, during which an assessment of its therapeutic value, its price, and the projected costs to the CHIF budget are evaluated. HTA is carried out jointly by the MoH, State Medicines Control Agency under the MoH and NHIF. The HTA process takes approximately up to two years.

After a medicinal product is included in the A List, reimbursement application (with indicated declared price and price applied for Lithuania of the medicinal product) can be submitted to the NHIF. If reimbursement application meets the price criteria, medicinal product is included into the Pricelist by the NHIF and becomes reimbursed for insured patients.

NHIF covers the base price of medicinal products from the CHIF budget, while patients are responsible for paying co-payments as OOP expenses. Certain categories of patients are also entitled for co-payment coverage (for example, elderly people). The base price and patient co-payment amounts are determined according to strict regulations outlined in legal acts. If the base price and (or) patient co-payment do not meet the established pricing criteria, the medicinal product is not eligible for reimbursement from the CHIF budget.

The same mechanism and principles apply for the financing and reimbursement of the medical devices.

Unlike the regular medicinal products, orphan medicinal products are reimbursed on a case-by-case basis. Each patient requiring such a medicinal product must undergo a separate reimbursement application process. If approved, reimbursement is granted only to the specific patient for whom the application was made. Other patients with the same condition must undergo their own individual reimbursement process.

To receive reimbursement for orphan medicinal products, an application for reimbursement of treatment costs for a specific patient must be submitted to the Commission for Reimbursement of Costs for the Treatment of Ultrarare Diseases ('Reimbursement Commission'). Such application must be submitted by a healthcare organisation providing tertiary personal healthcare services in the relevant area treating the patient. If the orphan medicinal product meets criteria established in the law, the Reimbursement Commission adopts a decision to reimburse orphan medicinal product for the specific patient.

### **13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?**

For medicinal products, the base price and patient co-payment amounts are determined according to strict regulations outlined in legal acts.

Specifically, base price of non-generic (original) medicinal product is determined in accordance with the price applied for Lithuania. However, if this price is higher than either (1) the average declared price for the same common (INN) name medicinal product in other European Union countries, or (2) the average of the three lowest wholesale prices listed in EURIPID (if no declared prices exist), then the lower price will be used as the base price.

Base price for generic medicinal products is determined in accordance with the lowest price applied for Lithuania of the same reimbursement group medicinal product (usually containing the same INN names). However, if this price is higher than either (1) the average declared price for the same common (INN) name medicinal product in other EU countries, or (2) the average of the five lowest wholesale prices listed in EURIPID (if no declared prices exist), then the lower price will be used as the base price.

As regards the patient co-payment, medicinal product is included in the Pricelist if patient co-payment does not exceed 25 per cent of the base price of the medicinal product and 15 per cent of the average prescription price of reimbursable medicinal products in the preceding year, and is not higher than the maximum patient co-payment per pack of the medicinal product set by the government (€5.87). These rules for calculating the patient co-payment apply equally to generic and non-generic medicinal products. Some exceptions apply when patient co-payment can exceed indicated requirements and still can be reimbursed (for example, if medicinal product is irreplaceable, it is agreed to provide a discount, etc.).

To the limited extent, some reimbursement conditions (including prices) are negotiable with the NHIF, especially if the MAHs have concluded the clawback agreements.

Economic efficiency in the field of medicinal products reimbursement is mainly ensured through price competition in the same reimbursement groups of medicinal products (containing the same INN names) and external price reference principle (as explained above). Also, the Pricelist is prepared by the NHIF and is adopted for the period of six months by the order of the MoH. After this period, a new Pricelist is drafted with updated prices/medicinal products list for the following period of six months and the process repeats. This allows NHIF to control and gradually reflect decreasing prices of medicinal products. The stability of the CHIF budget is also ensured through conclusion of clawback agreements with MAHs.

As regards the medical devices, the base price of a medical device is determined by the price of the medical device in the same group of medical devices with the lowest price applicable in Lithuania. The patient co-payment for a medical device cannot exceed 50 per cent of the base price of the particular medical device and 50 per cent of the average prescription price of reimbursable medical devices in the preceding year, and in any case shall not be higher than the maximum patient co-payment per medical device package set by the government (€20.33).

### **LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT**

**14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.**

As already indicated in this questionnaire, courts do not play a major role in shaping healthcare financing and reimbursement policies in Lithuania. Only few cases regarding healthcare reimbursement have reached the courts. The most significant cases are discussed below.

**Civil case No. e3K-3-247-684/2023 of the Supreme Court of Lithuania**

In this case, the issue was analysed whether the manufacturer of medicinal products is obligated to enter into a clawback agreement when such an agreement is a prerequisite for the reimbursement of the medicinal product. The Supreme Court of Lithuania highlighted that, under local law, a clawback agreement must be concluded if the medicinal product is included in the A List for the first time and its inclusion results in an increased CHIF budget expense. Since the medicinal product in question met these criteria and was reimbursed from the CHIF budget, the court determined that the obligation to conclude a clawback agreement applies to the manufacturer of medicinal products.

**Administrative case No. eA-1083-463/2023 of the Supreme Administrative Court of Lithuania.**

In this case, the issue was analysed, whether the healthcare organisation can charge the patient for additional and more expensive healthcare services, when the main healthcare service is reimbursed from the CHIF budget. The Supreme Administrative Court of Lithuania concluded that even though it is allowed to charge the patient for additional and more expensive healthcare services (when the main healthcare service is reimbursed from the CHIF budget), the patient in the current case was not clearly informed in writing about the differences between a specific free (reimbursed from the CHIF budget) service and a more expensive service, as required by legal acts.

**Administrative case No. eA-599-556/2023 of the Supreme Administrative Court of Lithuania and other related administrative cases**

In these cases, the patient brought a claim against the Reimbursement Commission for failing to provide justification for its decision to deny reimbursement for orphan medicinal product and for not making a timely decision on the patient's reimbursement request. The courts ruled in favour of the patient, concluding that the Reimbursement Commission had significantly breached its duty to justify its decisions and failed to adhere to the legally established deadlines for adoption of the reimbursement decision. Consequently, the patient secured a favourable reimbursement decision and also was awarded material and non-material damages by the court.

**Constitutional case No. 14/2020 of the Constitutional Court**

In 2021, the Constitutional Court determined that the procedure for calculating the base prices of reimbursable medicinal products and medical devices, as outlined in the implementing legal acts passed by the government/MoH, is unconstitutional. The Court ruled that the methodology for calculating the base prices must first be established by law (adopted by the Parliament) and only then can be further detailed by the government/MoH in the implementing regulations. In response to this decision, Parliament has adopted the key principles of the calculation methodology of the base prices in the law.

## RECENT DEVELOPMENTS AND TRENDS

**15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.**

In early 2022, the MoH launched a major healthcare system restructuring, marking the fifth reform since 2004. Scheduled for implementation between 2022 and 2024, the reforms aim to centralise ambulance services, introduce municipal health centres as a new type of provider, develop a model for long-term care, modernise hospital services, and strengthen the health system's resilience.

Also, the reorganisation of THIFs is expected to take place starting from 1 July 2025. After this reorganisation, THIFs will be merged with NHIF, losing their independent legal status and will operate as NHIF's divisions. The primary objective of this reorganisation is to enhance the efficiency of state fund management.