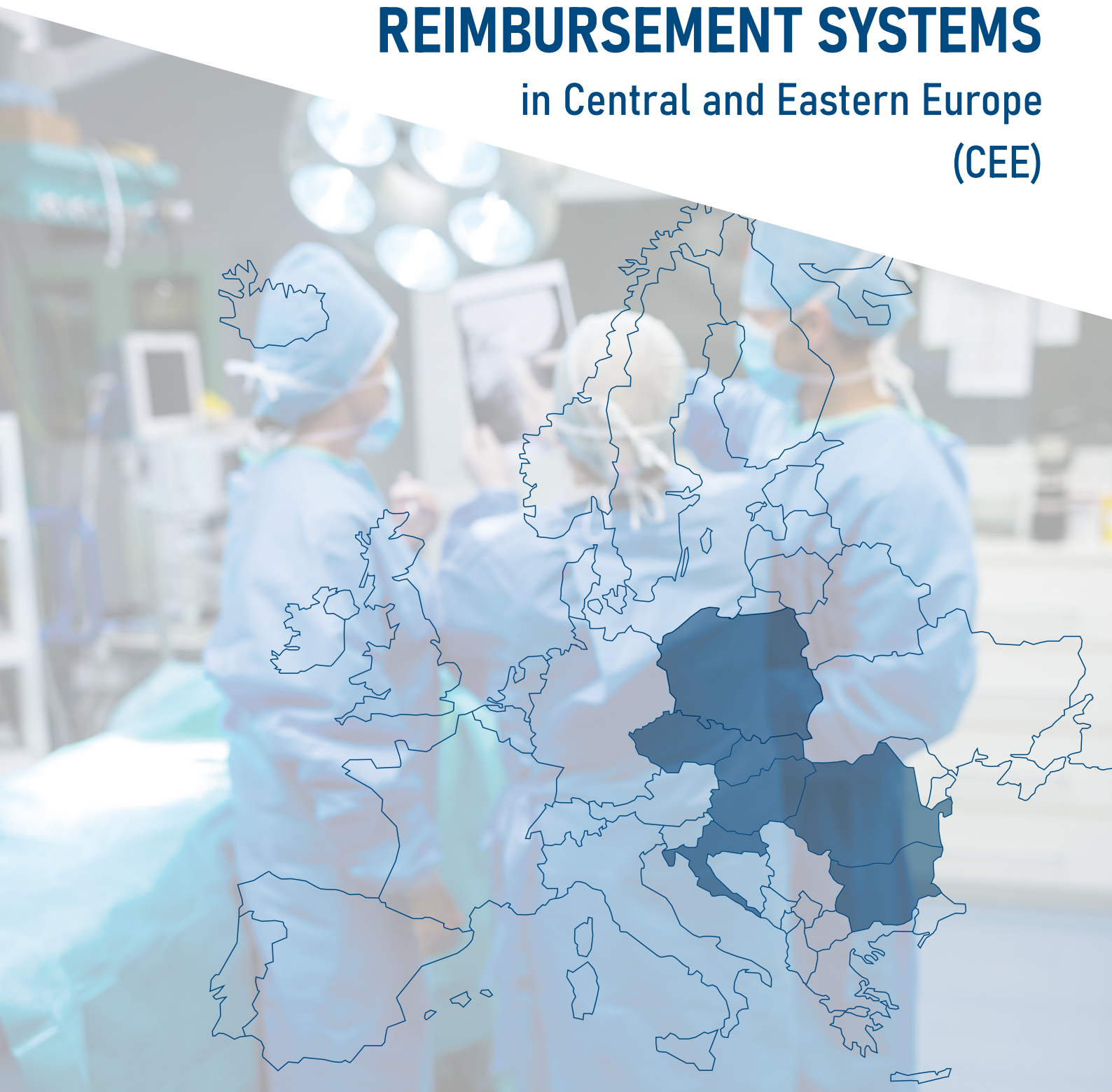
OVERVIEW OF MEDICAL DEVICE REIMBURSEMENT SYSTEMS

in Central and Eastern Europe (CEE)



Coalition of CEE Medical Device National Associations

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Warsaw, June 2026

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INTRODUCTION

Medical devices represent one of the truly fundamental pillars of modern healthcare systems. They make it possible to conduct accurate diagnostics, deliver effective treatment and support patients throughout rehabilitation. In practice, this means that medical devices accompany both patients and healthcare professionals at every stage of their interaction with the system – from the first consultation, through hospital care and medical procedures, to the recovery process. It is difficult to imagine any healthcare service being provided without the use of an appropriate medical device.

The scale and diversity of this sector are remarkable. It is estimated that within the European Union alone more than 500,000 different medical devices are registered, while globally the figure reaches approximately 2 million. By comparison, the number of approved medicines worldwide is around 16,000. These figures highlight not only the significance of medical devices, but also the breadth of the sector and its growing contribution to the safety and quality of healthcare delivery.

The medical technology industry is among the most innovative in the world. The pace of technological development – from surgical robotics and telemedicine to advanced biomaterials and clinical decision-support algorithms – is unprecedented. Every year, thousands of new solutions enter the market, supporting clinicians ever more effectively, improving the efficiency of treatments and enabling patients to return to health more quickly.

To fully harness this potential, it is essential to create a regulatory environment that ensures a high level of patient safety while not hindering technological progress. Our shared responsibility – as industry organisations, regulators and partners within healthcare systems – is to ensure that regulation remains predictable, proportionate and sufficiently flexible to keep pace with innovation.

By presenting this report, we aim to contribute meaningfully to the discussion on the future of medical device financing. A comparative view of national systems reveals both the common challenges they face and the diverse regulatory, organisational and funding approaches they adopt. We hope that this analysis will offer a valuable contribution to the ongoing discussion on the future direction of health policy and on the most effective ways to ensure that patients have access to safe, effective and innovative medical technologies. Achieving this requires a clear understanding of the specific nature of medical devices and the crucial role they play in the everyday functioning of healthcare.

WHAT WILL YOU LEARN FROM THE REPORT?

The structure outlined below served as guidance for the authors when preparing their country contributions. Although the individual chapters address broadly the same set of questions, they do so in slightly different ways. In developing this report, we intentionally allowed the authors a degree of freedom to adapt the format so that each section could best reflect the specific features and nuances of the national system it describes.

LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

An overview of the laws, regulations and policies that govern the public financing of medical devices in a healthcare system of a country.

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

How does the healthcare system work in the country?

Is it centralized or decentralized? Who acts as the payer (is it a public payer, such as a public institution funded by taxes or contributions – e.g. a national health fund or state health insurance – or a local payer(s), meaning regional or local healthcare funds or authorities managing their budgets independently)?

What are the main sources of healthcare funding (taxes, insurance contributions, other out-of-pockets mechanisms?)

Taxes: Is the healthcare system primarily funded by general taxes (e.g., in the Beveridge model)? Are there specific taxes earmarked for healthcare (e.g., alcohol or tobacco taxes dedicated to health programs)?

Insurance contributions: How does the health insurance contribution system work? Are contributions mandatory for all citizens or limited to employed individuals? Is the contribution amount income-based, and if so, how is it calculated?

Out-of-pocket payments: To what extent do patients bear healthcare costs directly? Are there caps or thresholds on out-of-pocket spending (e.g., reimbursements after reaching a certain limit)? Which services are most commonly paid out-of-pocket (e.g., dental care, outpatient services)?

Other mechanisms: Are there additional funding sources, such as donations, foundations, or NGOs? Is there a private insurance sector that complements public services? Highlight which of these sources are the main pillars of healthcare funding and which play a secondary or supplementary role.

What is the role of state, private sector and other entities in healthcare funding? What are key differences between public and private funding approaches? How do these sectors interact within the system?

Is the state the primary entity responsible for funding healthcare? Which state institutions manage healthcare funds (e.g., Ministry of Health, National Health Fund)? Does the state define the scope of guaranteed services and their standards?

What role does the private sector play in healthcare funding? Can patients use private health insurance to supplement public services? Are private providers delivering healthcare services funded by public resources (e.g., through contracts with public health funds)?

Do NGOs, foundations, or private donors play a significant role in healthcare funding? Is the system supported by collaboration with international organizations, such as the WHO or the World Bank? Are there any innovative funding mechanisms (e.g., crowdfunding, loyalty programs)?

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

What are the different types of public financing mechanisms available for medical devices in a country? How do the processes for applying for funding (decision-making process), the formal conditions required to obtain funding (formal requirements) and the extent of public reimbursement look when it comes to each type of public financing of medical devices (scope of financing)?

Decision-making process: How healthcare providers or patients apply for public financing or reimbursement for specific medical devices; is there a central body or regional authority responsible for reviewing applications; the step-by-step process (e.g., submitting evidence of medical need, cost-effectiveness evaluations, or clinical effectiveness data); whether financing is provided for all devices of a given type that meet certain requirements (based on the law or a regulation of a minister or other authority), or whether additional action by an authority is required, e.g., the issuing of an individual decision that entitles a particular device to financing.

Formal requirements: Documentation requirements, specific standards that medical devices must comply with to qualify for reimbursement, patient eligibility criteria, an importance of a place of purchase in order to obtain financing.

Scope of financing: Is the full cost of the device covered by public funds or are patients required to make co-payments; are there limits or caps on reimbursement; is financing based on a case-by-case evaluation or is a fixed sum allocated for each medical device category?

CURRENT CHALLENGES

What are the current key challenges and obstacles faced in the public financing of the medical device system in a country?

Accessibility: How easy or difficult it is for patients to access publicly financed medical devices? Are there waiting lists, regional disparities, or limitations on the availability of certain devices?

Costs: How significant is the financial burden of medical devices on public funding? Are costs of devices increasing, and how does this impact the sustainability of public financing?

Reimbursement limitations: Are there any limitations on which devices are covered or how much of the cost is reimbursed? Are there caps on reimbursement for certain categories of devices, or are only certain types of devices eligible for funding?

Equity and fairness: Does the public financing system create disparities between different groups of patients? Are certain populations (e.g., low-income individuals, rural residents, elderly patients) disproportionately affected by limitations in financing or medical device availability?

Impact of technology and innovation:

How does the pace of medical device innovation affect public financing? Are new and advanced devices quickly added to the reimbursement lists, or is there a lag in adapting the financing system to include cutting-edge technology?

Regulatory and legal challenges:

Are there challenges related to pricing negotiations, patent laws, or the inclusion of devices in reimbursement schemes?

FUTURE CHANGES

Are there plans for changes in the medical device financing system in a country that will impact the financing and reimbursement system of medical devices?

SUPPLEMENT WITH SIMPLIFIED FUNDING INFORMATION

What requirements must be met in order to sell a medical device that is funded from public sources?

COMPARISON TABLE

COUNTRY	Healthcare system	Main funding	HTA for MD	Outpatient/pharmacy reimbursement
POLAND	Centralised	Public–private	Partial	Yes
SLOVAKIA	Centralised	Public–private	Partial	Yes
CZECH REPUBLIC	Mixed	Public–private	Limited	Yes
HUNGARY	Centralised	Public–private	Partial	Yes
ROMANIA	Centralised	Public–private	No	Yes
CROATIA	Centralised	Public	Yes	Yes
BULGARIA	Centralised	Public–private	No	Very limited

MACROECONOMIC CONTEXT: HEALTHCARE EXPENDITURE IN THE COUNTRIES COVERED BY THIS REPORT

Before examining the specific legal and regulatory frameworks governing the public financing of medical devices in each of the seven countries analysed in this report, it is necessary to situate those frameworks within a broader macroeconomic and systemic context. According to Eurostat data, healthcare expenditure in the European Union reached €1,720 billion in 2023, equivalent to 10.0% of gross domestic product (GDP), or €3,835 per inhabitant. Healthcare expenditure can be analysed from three perspectives: the sources of financing, the healthcare functions that are financed, and the providers of healthcare. Each of these dimensions bears directly on the structure and scope of public financing mechanisms for medical devices.

At EU level, compulsory contributory health insurance schemes and compulsory medical savings accounts accounted for a 52.3% share of all financing in 2023, whilst government schemes accounted for 28.2%. More than half (52.7%) of healthcare expenditure in the EU in 2023 was directed towards curative and rehabilitative care, whilst nearly a fifth (17.8%) was accounted for by medical goods. Hospitals were the largest providers of healthcare in expenditure terms, accounting for more than a third (36.8%) of all expenditure in the EU in 2023, followed by providers of ambulatory health care (25.6%) and retailers and other providers of medical goods (16.2%).

The table below presents these three dimensions for the seven countries covered by this report, alongside the EU average as a reference benchmark. All figures are expressed as a percentage of current healthcare expenditure for 2023.

TABLE: *Analysis of current healthcare expenditure, 2023 – Countries covered by this report (% of current healthcare expenditure)*

	FINANCING				FUNCTIONS		PROVIDERS		
COUNTRY	Government schemes	Compulsory health insurance schemes	Other financing agents (incl. out-of-pocket)	Out-of-pocket payments	Curative & rehabilitative care	Medical goods (non-specified by function)	Hospitals	Ambulatory care providers	Retailers & other providers of medical goods
EU average	28.2	52.3	19.5	14.9	52.7	17.8	36.8	25.6	16.2
Poland	11.0	66.6	22.4	15.9	64.2	17.5	43.5	25.0	16.9
Slovakia	4.0	75.0	21.1	20.2	53.0	30.0	36.1	18.1	30.0
Czech Republic	11.9	72.7	15.5	14.6	59.6	16.2	44.9	23.8	13.6
Hungary	11.6	62.1	26.3	23.1	58.5	25.6	42.8	20.4	25.6
Romania	14.3	61.9	23.8	23.0	56.3	27.5	43.7	16.5	27.5
Croatia	7.6	77.4	15.1	9.4	56.4	21.4	50.5	16.2	21.1
Bulgaria	15.4	47.7	37.0	35.5	52.7	32.5	36.7	15.9	32.3

NOTE: *Croatia – data on out-of-pocket payments are provisional.*

SOURCE: *Eurostat (online data codes: hlth_sha11_hf, hlth_sha11_hc, hlth_sha11_hp), data for 2023*
Available at: *https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics_by_function,_provider_and_financing_scheme_*

ANALYTICAL COMMENTARY

The data presented above reveal several patterns that are directly relevant to the comparative analysis of public financing frameworks for medical devices that follows.

FINANCING MODEL

Compulsory health insurance schemes accounted for close to or in excess of three quarters of overall healthcare spending in Croatia (77.4%), Slovakia (75.0%), and the Czech Republic (72.7%). Poland (66.6%), Hungary (62.1%) and Romania (61.9%) similarly rely predominantly on compulsory insurance, though to a somewhat lesser degree. Bulgaria presents a distinct pattern – compulsory schemes registered a larger share than government schemes or other sources, but still accounted for less than half of total expenditure (47.7%). This structural difference means that the residual financing burden – falling on households and voluntary insurance – is substantially higher in Bulgaria than in the other six countries covered by this report.

MEDICAL GOODS EXPENDITURE

Medical goods (non-specified by function) were the second largest healthcare function in the EU in 2023, with an average share of 17.8% of current healthcare expenditure, though this varied substantially between countries. Among the seven countries analysed, the share of medical goods in total healthcare expenditure is notably elevated in Bulgaria (32.5%), Slovakia (30.0%), Romania (27.5%) and Hungary (25.6%) – all significantly above the EU average. Poland recorded one of the highest shares of expenditure on curative and rehabilitative care in the EU, at 64.2%, close to two thirds of current healthcare expenditure. This structural pattern, combined with a near-average share for medical goods (17.5%), suggests a comparatively contained role for medical goods expenditure within the Polish system relative to the high overall spending on direct care.

OUT-OF-POCKET PAYMENTS AND PATIENT BURDEN

The third largest source of healthcare funding in the EU was household out-of-pocket payments, with a 14.9% share in 2023. Among the seven countries in this report, Bulgaria stands out sharply: Bulgaria was one of only three EU countries where direct household payments accounted for a third or more of total healthcare expenditure, with a share of 35.5%. Croatia, by contrast, was among the small number of EU countries where out-of-pocket payments represented less than one tenth of healthcare expenditure, at 9.4%. Hungary (23.1%) and Romania (23.0%) also record out-of-pocket shares markedly above the EU average, which may reflect, at least in part, gaps in the public financing of medical devices and other non-acute healthcare needs.

PROVIDERS OF MEDICAL GOODS

The share of current healthcare expenditure accounted for by retailers and other providers of medical goods averaged 16.2% in the EU in 2023, but varied greatly

between countries, from 13.6% in the Czech Republic to 27.5% in Romania, 30.0% in Slovakia and 32.3% in Bulgaria. Croatia recorded the highest hospital expenditure share among the seven countries and among all EU Member States, at 50.5% of current healthcare expenditure.

Taken together, these figures establish a meaningful baseline for understanding why the design of public financing frameworks for medical devices differs considerably across the seven countries. Countries with high out-of-pocket burdens and high medical goods shares – most notably Bulgaria, Slovakia and Romania – face structurally different policy challenges compared to those – such as Croatia and the Czech Republic – where public financing accounts for a larger proportion of healthcare costs and medical goods expenditure remains closer to or below the EU average. The country-by-country analysis that follows should be read in light of these macro-level differences.

BULGARIA

GENERAL OVERVIEW OF BULGARIAN MARKET

POPULATION (2024)

6 437 360

HEALTHCARE EXPENDITURE (2025 FORECAST)

APPROX. BGN
14.0 BILLION
(APPROX. EUR 7.2 BILLION)

HEALTHCARE EXPENDITURE (% OF GDP)

7.9%
OF GDP (2023)

SOURCE: *NSI (National Statistical Institute), Eurostat*

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The Bulgarian section of this report presents the current situation regarding the regulation of medical technologies and public funding for medical devices in Bulgaria. Medical technologies and in vitro diagnostics play a vital role in modern healthcare systems, enabling earlier diagnosis, more personalized treatment, better clinical outcomes, and improved quality of life for patients.

MedTech Bulgaria represents the medical technology sector in Bulgaria and acts as a reliable partner to institutions, healthcare professionals, and patient organizations in developing sustainable healthcare policies. As part of the broader European MedTech community, we believe that transparent, predictable, and innovation--friendly regulatory and reimbursement frameworks are essential for ensuring timely patient access to safe and effective medical technologies.

The Bulgarian healthcare system continues to face significant challenges related to access, quality, sustainability, and the long-term predictability of public funding mechanisms. In this context, constructive dialogue between institutions, industry, and healthcare stakeholders is more important than ever. We hope that this chapter will contribute to a better understanding of the current situation regarding the reimbursement of medical devices in Bulgaria and will support future discussions on improving the system in the interest of patients and society.

Best regards

Tsveta Yotsova
Chairman of the Board of MedTech Bulgaria

LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

Comparative context: Bulgaria applies a centralized, single-payer legal framework with strong payer control over reimbursement decisions and limited formal application pathways compared to many EU jurisdictions.

Public financing of medical devices in Bulgaria is governed primarily by the Health Insurance Act and secondary legislation adopted by the National Health Insurance Fund (NHIF) and the Ministry of Health (MoH). The NHIF acts as the single public payer and is responsible for negotiating, managing, and reimbursing medical devices financed from public funds. In addition, the Ministry of Health maintains the electronic medical devices database (MEDDEV), which is mandatory for all medical devices and IVDs released on the Bulgarian market. It sets maximum prices applicable in public procurement and reimbursement procedures and which are sold on the Bulgarian market.

Prices of medical devices are not regulated at market level and may be freely determined by manufacturers and distributors. Value-added tax (VAT) for medical devices is set at the standard national rate of 20%, with no reduced rates or exemptions for specific device categories.

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

Compared to most EU Member States, Bulgaria relies more heavily on out-of-pocket payments and provides a narrower publicly guaranteed benefits package. Bulgaria also records some of the lowest health expenditure per capita in the EU, despite a rapid increase in total health spending over the last decade.

How does the healthcare system work?

The Bulgarian healthcare system is highly centralized and operates under a single public payer model. The National Health Insurance Fund is the sole institution responsible for compulsory health insurance and public reimbursement of healthcare services and medical devices. The NHIF guarantees equal access to healthcare services for insured individuals and allows free choice of healthcare providers that have contracts with the regional health insurance funds.

What are the main sources of healthcare funding?

The primary source of healthcare funding in Bulgaria is compulsory health insurance contributions. For 2024 and 2025, the contribution rate remains 8% of gross salary, of which 4.8% is paid by the employer and 3.2% by the employee. Public sources account for approximately 65% of total healthcare expenditure, which is significantly below the EU average of around 81%.

Private healthcare expenditure represents approximately 35% of total spending, largely driven by out-of-pocket payments. This share is considerably higher than the EU average (around 15%) and reflects the limited scope of publicly reimbursed services and medical devices.

The compulsory health insurance system covers a basic package of healthcare activities guaranteed by the NHIF budget. Emergency care for uninsured persons is financed by the Ministry of Health. The state covers the compulsory health contributions for 11 population groups such as children under 18 years of age, students under 26 years of age enrolled in regular education, pensioners, social aid recipients, unemployed individuals registered with the Labor Office, etc. The state contributions cover approximately one third of the total NHIF budget but cover two thirds of the total population.

Role of the private sector

Private health insurance plays a marginal role in Bulgaria, accounting for approximately 1% of total healthcare funding. In contrast, private hospitals have a strong and growing presence. Hospital care is delivered by both public and private providers, with the expansion of the hospital sector in recent years driven primarily by private investment. Both public and private hospitals may contract with the NHIF and receive public funding for covered services and medical devices.

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

Comparative context: Bulgaria's reimbursement model for medical devices is more restrictive compared to other EU systems, with a higher reliance on hospital-based financing and limited outpatient reimbursement.

The NHIF reimburses medical devices for both outpatient and inpatient use. Reimbursement mechanisms differ significantly depending on whether devices are used in outpatient care or as part of hospital treatment.

A large proportion of medical devices in Bulgaria are not reimbursed at all and are fully paid by patients. Among reimbursed devices, some are partially reimbursed, while only a relatively small group benefits from full public coverage.

Medical devices for inpatient use

Medical devices used in hospital care are generally procured by hospitals and financed through public funds. Hospitals in Bulgaria may be state-owned, municipal, university-owned, or private; however, all hospitals contracted with the NHIF receive public financing.

Bulgaria does not apply a Diagnosis-Related Group (DRG) system. Instead, a specific annual procedure exists for financing medical devices outside the standard NHIF clinical pathways. Under this procedure:

- Prices for eligible medical devices are negotiated once per year;
- Fully reimbursed devices are paid directly by the NHIF to suppliers after use;
- Partially reimbursed devices are reimbursed to hospitals after use;
- The NHIF does not commit to guaranteed purchase volumes;
- Total expenditure cannot exceed the annual NHIF budget.

Major inpatient device groups eligible for public financing include, among others:

- Heart valve prostheses and thoracic aortic vascular prostheses;
- Stents and transcatheter valve prostheses;
- Hip, knee, and shoulder joint prostheses;
- Cochlear implant systems;
- Cardiac pacing and neurostimulation systems;
- Medical devices for neurosurgical, spinal, electrophysiology, and large-volume complex surgical interventions.

Medical devices for outpatient use

For outpatient care, the NHIF reimburses selected groups of medical devices intended for individual patient use. These include:

- Blood glucose monitoring devices;
- Ostomy products;
- Non-adhesive dressings for patients with epidermolysis bullosa;
- Medical devices for oxygen therapy;
- Products for conditions requiring testing and adjustment of urine extraction devices.

Despite the existence of reimbursement mechanisms, many outpatient medical devices remain fully paid by patients. Even when reimbursement is available, patient co-payments are often substantial.

CURRENT CHALLENGES

The public financing system for medical devices in Bulgaria faces several significant challenges.

High out-of-pocket burden:

Patient co-payments for medical devices are among the highest in the EU, frequently reaching 40-50% for reimbursed therapies and up to 80% overall. This results in limited access to several life-saving therapies, particularly implantable medical devices.

Mismatch between population needs and reimbursement priorities:

Bulgaria ranks among the EU countries with the highest premature mortality from cardiovascular diseases, while access to endovascular and implant-based therapies remains restricted due to reimbursement limitations.

Inequality and imbalance:

There is a pronounced imbalance in reimbursement across different categories of medical devices, as well as a structural disparity between the financing of medicinal products and medical devices, estimated at approximately a 90% to 10% ratio in favor of medicines.

Limited reimbursement scope: A large number of socially significant medical devices, including many orthopedic and traumatology implants, remain excluded from public financing, particularly in outpatient care.

Fiscal and structural constraints: Annual budget caps, once yearly price negotiations, and the absence of long--term volume commitments restrict predictable access to innovative and high-cost devices.

Taxation: Medical devices are subject to the standard VAT rate of 20%, with no reduced rates or exemptions, further increasing costs for both public payers and patients.

FUTURE CHANGES

Comparative context: Unlike several EU countries introducing structured pathways for innovative and digital medical devices, Bulgaria currently lacks formal reform commitments in this area.

At present, no comprehensive reform of the medical device financing system is formally announced. Nevertheless, ongoing discussions focus on the need to reduce patient co-payments, expand reimbursement to socially significant device categories, and address the structural imbalance between drug and device financing.

Future policy developments may also consider differentiated VAT treatment for medical devices and improvements in reimbursement mechanisms to enhance equity, sustainability, and access to innovation.

SUMMARY

Comparative summary

Bulgaria represents a highly centralized but underfinanced model for medical device reimbursement, characterized by limited coverage and exceptionally high patient financial participation when compared with EU averages.

Bulgaria operates a centralized, single-payer healthcare system in which the National Health Insurance Fund plays a dominant role in financing medical devices. Despite existing reimbursement mechanisms for inpatient and selected outpatient devices, the system is characterized by limited coverage, high patient co-payments, and significant inequalities across device categories. Addressing these challenges remains essential to improving access, fairness, and sustainability in the public financing of medical devices.

- Compared to the EU average, Bulgaria relies substantially more on out-of-pocket payments for medical devices.
- While public sources account for around 81% of healthcare spending in the EU, in Bulgaria they represent approximately 65%.
- Patient co-payments for medical devices in Bulgaria are among the highest in the EU, reaching up to 40–50% for reimbursed therapies and up to 80% overall.

- In contrast to many EU Member States, Bulgaria lacks differentiated VAT rates or exemptions for medical devices.
- Despite ranking among the EU countries with the highest cardiovascular mortality, Bulgaria provides limited reimbursement for implantable and endovascular medical devices.
- Medical devices account for a larger share of total healthcare expenditure in Bulgaria than the EU average, yet high unmet medical needs persist.

Country summary – Bulgaria

Bulgaria operates a highly centralized healthcare system based on a single public payer model, with the National Health Insurance Fund acting as the sole institution responsible for financing healthcare services and reimbursed medical devices. Public funding relies primarily on compulsory health insurance contributions, complemented by limited state budget financing. Compared to the EU average, Bulgaria allocates a significantly lower share of public resources to healthcare, resulting in a narrower scope of publicly reimbursed services and medical devices.

Public financing of medical devices is characterized by restrictive reimbursement mechanisms, particularly in outpatient care, and strong reliance on hospital-based procurement. While selected groups of inpatient medical devices are financed through annual NHIF procedures, a large proportion of medical devices remain fully paid by patients. Even where reimbursement exists, patient co-payments are substantial and among the highest in the EU.

The system exhibits pronounced inequalities across medical device categories and a structural imbalance between the financing of medicinal products and medical devices. This is particularly problematic given Bulgaria's high burden of cardiovascular and chronic diseases, which often require implantable and technologically advanced devices. Overall, Bulgaria represents a centralized but underfinanced medical device reimbursement model, marked by limited coverage, high patient financial participation, and constrained access to innovation when compared with EU standards.

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CROATIA

GENERAL OVERVIEW OF CROATIAN MARKET

POPULATION (2025)

3 848 160

HEALTHCARE EXPENDITURE (2022-2024)

APPROX. EUR
6.5-6.7 BILLION
(based on recent expenditure levels and GDP growth)

HEALTHCARE EXPENDITURE (% OF GDP)

APPROX.
7.5%
OF GDP

SOURCE: *World Bank; WHO / European Observatory on Health Systems and Policies; International Trade Administration (U.S.)*

The Croatian section of this report presents the current situation regarding the regulation of medical technologies and public funding for medical devices in Croatia. Medical technologies and in vitro diagnostics play a vital role in modern healthcare systems, enabling earlier diagnosis, more personalized treatment, better clinical outcomes, and improved quality of life for patients.

CroMed represents the medical technology sector in Croatia and acts as a reliable partner to institutions, healthcare professionals, and patient organizations in developing sustainable healthcare policies. As part of the broader European MedTech community, we believe that transparent, predictable, and innovation-friendly regulatory and reimbursement frameworks are essential for ensuring timely patient access to safe and effective medical technologies.

The Croatian healthcare system continues to face significant challenges related to access, quality, sustainability, and the long-term predictability of public funding mechanisms. At the same time, Croatia has demonstrated important progress in several areas of healthcare modernization, digitalization, and patient access to innovative therapies and technologies. In this context, constructive dialogue between institutions, industry, healthcare professionals, and patient organizations is more important than ever.

We hope that this chapter will contribute to a better understanding of the current situation regarding the reimbursement and financing of medical devices in Croatia and will support future discussions on improving the system in the interest of patients and society.

Best regards,

Damir Detić
President, CroMed

Jurica Toth
Board Member, CroMed

LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

Comparative context:

Public financing of medical devices in Croatia is governed by several overlapping legal and regulatory frameworks. The key institutions responsible for regulating and financing medical devices are the Ministry of Health, the Croatian Health Insurance Fund (HZZO), and the Agency for Medicinal Products and Medical Devices (HALMED).

The principal pieces of legislation governing medical devices in Croatia are:

- **Act on Medicinal Products and Medical Devices (NN 76/13, 90/14, 100/18):** Act on Medicinal Products and Medical Devices (Zakon o lijekovima i medicinskim proizvodima) – the primary national statute that establishes the regulatory framework for placing medical devices on the Croatian market, sets out requirements for conformity assessment, post-market surveillance, and advertising, and designates HALMED as the competent national authority for device oversight.
- **EU Regulation 2017/745 on Medical Devices (MDR):** Directly applicable EU framework regulation that replaced the previous Directive 93/42/EEC. It governs the classification, clinical evaluation, CE marking, unique device identification (UDI), and post-market follow-up of medical devices placed on the EU market, including Croatia. HALMED acts as the national notifying authority and market surveillance body.
- **Act on Compulsory Health Insurance (Zakon o obveznom zdravstvenom osiguranju, NN 80/13 and subsequent amendments):** The foundational statute governing HZZO's operations, defining the scope of the mandatory health insurance basket, the criteria for including healthcare products (including medical devices) in reimbursement, the rules for setting reimbursement levels, and the appeals process for manufacturers and patients.
- **Public Procurement Act (Zakon o javnoj nabavi, NN 120/16, 114/22):** Establishes the framework for public procurement of healthcare products, including centralised and hospital-level tenders for medical devices. It governs transparency, equal treatment of suppliers, award criteria, and contract management for all publicly funded procurement.
- **Act on the Right of Access to Information (Zakon o pravu na pristup informacijama):** Defines HZZO's obligations to publish its reimbursement lists, procurement outcomes, and pricing agreements, contributing to accountability in public spending on medical devices.

Reimbursement decisions for medical devices are taken by HZZO, which acts as the single public payer. Devices are procured either centrally by the Ministry of Health through the Central Procurement Office (CEI) or individually by hospitals. Pricing and reimbursement are primarily based on DRG tariffs, flat rates, or per-session funding, depending on the type of service.

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

How does the healthcare system work?

Croatia has a universal, single-payer healthcare system managed by the Croatian Health Insurance Fund (HZZO). The Ministry of Health oversees policy development and implementation, while HZZO manages financial flows and reimbursement mechanisms. Local governments own and manage the majority of hospitals and primary care centers.

What are the main sources of healthcare funding?

Healthcare in Croatia is financed through four main channels:

- **Mandatory payroll contributions:** The dominant source. Employers pay a 16.5% contribution on gross salaries directly to HZZO. Self-employed persons and other insured individuals pay contributions at equivalent rates based on a deemed income base. These contributions account for approximately 75-80% of total public health expenditure.
- **State budget transfers:** A supplementary transfer from the state budget covers certain population groups not in employment (e.g. children, pensioners below threshold, social-assistance recipients) and funds specific public health programmes. It represents a smaller but structurally important complement to contribution income.
- **Supplementary (voluntary) health insurance:** Enrolled on a voluntary basis, supplementary insurance covers the co-payments that arise within the mandatory scheme. Approximately two-thirds of the Croatian population holds supplementary cover — either purchased privately from HZZO or commercial insurers, or provided by the state free of charge for socially vulnerable groups. Without supplementary insurance, patients face co-payments of up to 20% on most services.
- **Out-of-pocket payments:** Direct out-of-pocket payments account for a moderate share of total health expenditure and include co-payments for those without supplementary cover, privately purchased over-the-counter medical devices and aids, and services obtained outside the publicly reimbursed basket.

What is the role of state, private sector and other entities in healthcare funding? What are key differences between public and private funding approaches? How do these sectors interact within the system?

The public sector dominates service delivery. In 2024, public healthcare institutions employed over 75,000 people and the system comprises 5 clinical hospital centres, 6 clinical hospitals, 22 general hospitals, and over 100 primary and specialised healthcare facilities. The Ministry of Health sets policy and owns the regulatory architecture, while HZZO manages purchasing and reimbursement. Local and regional governments own and fund the infrastructure of most public hospitals and primary care centres.

The private sector operates primarily in primary care (private general practitioners and specialists contracted by HZZO), dental care, laboratory diagnostics, and elective/cosmetic procedures outside the HZZO basket. Some private hospitals also hold HZZO concession contracts for specific services, reimbursed at agreed tariffs.

Interaction between sectors occurs through concession arrangements, HZZO framework contracts with private providers, and public-private procurement agreements. Medical device manufacturers engage with both HZZO (for reimbursement listing) and public hospital procurement offices (for supply contracts).

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

The Croatian Health Insurance Fund (HZZO) is responsible for defining reimbursement levels for medical devices. Public procurement is conducted through either national centralised tenders (coordinated by the Central Procurement Office, CEI) or hospital-level tenders. Reimbursement levels are tied to DRG categories, procedure codes (DTP/DTS), and annual budgets approved by HZZO.

Public financing covers devices used in hospitals and those available to patients for home use. Hospital-based devices are fully covered under DRG-based payments, while outpatient devices may be co-financed or provided under specific reimbursement schemes.

Step-by-step listing process:

The process for including a new medical device in the public reimbursement framework involves the following stages:

1. **Application and eligibility screening:** The manufacturer or authorised representative submits a formal application to HZZO. The application must demonstrate that the device holds a valid CE mark under EU MDR 2017/745 (or the transitional regime), is registered in HALMED's national device database, and satisfies the clinical and safety requirements of the applicable product category.
2. **Health Technology Assessment (HTA):** HZZO's expert commission, often supported by external clinical specialists and health economists, carries out a health technology assessment (HTA). The HTA examines clinical effectiveness (comparative evidence against standard of care), patient safety data, and cost-effectiveness expressed as incremental cost per quality-adjusted life year (QALY) or cost per clinical outcome. Manufacturers are expected to submit a full HTA dossier in the format specified by HZZO.
3. **Commission review and decision:** HZZO's Reimbursement Commission (Povjerenstvo za lijekove i medicinske proizvode) reviews the HTA findings and issues a recommendation. For devices with significant budget impact, the Ministry of Health may be consulted. HZZO's Management Board takes the final formal decision on inclusion.
4. **Coding and classification:** The device is assigned to the relevant DRG group, DTP (diagnostic-therapeutic procedure) or DTS (diagnostic-therapeutic service) code in HZZO's reimbursement nomenclature. For outpatient devices, a separate reimbursement code and tariff are established.

5. **Pricing:** Where HZZO exercises price control, reference pricing is applied. This may be based on the lowest price among a defined basket of comparable EU member states, the manufacturer's net price from a comparable market, or the outcome of a tender procedure. For high-value implants and devices, individual price negotiations between HZZO and the manufacturer may take place before final listing.
6. **Publication and periodic review:** The device is published on HZZO's official reimbursement list. Listings are subject to periodic reassessment, typically every two to three years, or upon the availability of new clinical evidence or a significant change in market price.

Formal documentation requirements

A complete listing application to HZZO must include:

- Valid CE certificate and Declaration of Conformity under EU MDR 2017/745,
- HALMED registration confirmation and EUDAMED registration number (where applicable),
- Full HTA dossier: systematic literature review, clinical data summary, economic model, and budget impact analysis,
- Summary of product characteristics and instructions for use in Croatian,
- Proposed reimbursement code, tariff, and justification,
- Evidence of pricing in comparable EU markets (reference pricing data),
- Post-market clinical follow-up plan.

Reimbursement levels and pricing rules

Reimbursement levels depend on the care setting and device category. In the inpatient setting, devices are reimbursed as part of the DRG payment, which covers the all-inclusive cost of a hospitalisation episode. No separate itemised payment for the device exists — the hospital receives a flat DRG tariff and manages internal device costs within that envelope. This structure creates pressure on hospitals to procure devices at the lowest available price.

For outpatient and home-use devices (orthopaedic aids, hearing aids, ostomy supplies, CPAP machines, etc.), HZZO maintains a positive list (Pravilnik o ortopedskim i drugim pomagalima) with individually set reimbursement prices. HZZO reimburses up to the listed price; if the retail price exceeds the listed price, the patient pays the difference. Co-payments may also apply for patients without supplementary insurance.

For centrally procured high-value devices (e.g. cardiac implants, joint prostheses), the CEI runs framework tender procedures. The awarded price becomes the binding reimbursement ceiling; HZZO pays the contracted price directly to the supplier or reimburses hospitals at that rate.

Additional financing through Indicator D (high-cost devices)

Beyond standard DRG-based and outpatient reimbursement, Croatia operates a dedicated supplementary financing mechanism for exceptionally high-cost medical technologies – known as Indicator D (Pokazatelj D). This mechanism acknowledges that certain advanced device-dependent procedures carry device costs that cannot be sustainably absorbed within the fixed DRG tariff, and it therefore provides a separate, additive payment covering the cost of the device on top of the standard DTS (diagnostic-therapeutic service) price.

Under the Indicator D model, hospitals bill HZZO for the procedure at the applicable DTS rate and simultaneously claim reimbursement for the device itself at a separately agreed or tendered price. This dual-payment structure ensures that the acquisition cost of the high-value implant or device does not fall entirely within the hospital's operating budget envelope, making it financially viable for institutions to offer these treatments within the public system.

Some of technologies currently financed through the Indicator D mechanism include:

- **TAVI (Transcatheter Aortic Valve Implantation):** minimally invasive aortic valve replacement using a transcatheter-delivered prosthetic valve; the high unit cost of the valve system is reimbursed separately from the DTS procedure tariff.
- **RAS procedures (Robot-Assisted Surgery):** surgical interventions performed using robotic platforms (e.g. da Vinci system); the per-procedure device and consumable costs are covered through the Indicator D supplement on top of the standard surgical DTS tariff.
- **Atrial fibrillation (AFib) catheter ablation:** electrophysiology-guided ablation procedures for the treatment of atrial fibrillation; the cost of single-use mapping and ablation catheters and associated disposables is financed separately via Indicator D, given that these consumables represent the dominant cost driver of the procedure.
- **DBS (Deep Brain Stimulation):** neurostimulation therapy involving surgical implantation of electrodes and an implantable pulse generator for conditions such as Parkinson's disease, essential tremor, and dystonia; the neurostimulator system is reimbursed as a device payment alongside the DTS tariff for the implantation procedure.

The Indicator D mechanism represents an important policy tool for ensuring patient access to high-cost but clinically significant technologies without placing unsustainable financial pressure on individual hospitals. Inclusion of a technology in the Indicator D framework requires a specific HZZO decision and is typically subject to volume caps or prior-authorisation requirements to manage overall budget impact.

CURRENT CHALLENGES

Croatia's healthcare financing system faces several structural and operational challenges:

High contribution rates: Croatia carries one of the highest payroll-based health contribution rates in the EU at 16.5%, limiting both employer competitiveness and the capacity to raise additional revenue through rate increases.

Hospital arrears: Persistent accumulated debts across hospital networks arise from a combination of delayed HZZO payments, underpriced DRG tariffs that do not reflect true service costs, and inefficient internal budget management. Arrears constrain hospitals' ability to procure innovative devices on commercial terms.

Outdated DRG/DTS system: The current DRG/DTS classification system is technically obsolete. Many device-intensive procedures are bundled into DRG tariffs set without adequate cost data, meaning hospitals are systematically underpaid for high-cost device procedures and have little incentive to adopt innovation.

Regional inequalities: Access to advanced diagnostic imaging, specialist consultations, and device-dependent procedures varies substantially between Zagreb and rural or island communities. Inequalities in infrastructure and specialist availability translate directly into unequal access to device-supported care.

Workforce shortages: An ageing medical workforce and sustained emigration of healthcare professionals to higher-wage EU member states create capacity constraints that affect the adoption and operation of technically complex medical devices.

Limited access to innovative devices: The combination of restrictive reimbursement lists, slow HTA procedures, and DRG underfunding creates a multi-year lag between EU market authorisation and clinical availability of innovative devices in Croatian public hospitals. This gap is among the widest recorded in European access benchmarking studies.

Despite these challenges, the Recovery and Resilience Plan (RRP) and EU Structural Funds have provided significant resources for hospital reconstruction, equipment modernisation, and digitalization, including telemedicine platforms and electronic patient records.

FUTURE CHANGES

Croatia is preparing a comprehensive reform of its healthcare financing system. A new Diagnosis-Related Group system – DRG 11 – has already been procured. Once implemented, it is expected to introduce procedure-level costing that more accurately reflects the real cost of device-intensive care, improve the transparency of hospital billing, and provide HZZO with better data for reimbursement negotiations.

Additional planned reforms include:

- Alignment of HTA processes with the EU Joint Clinical Assessment framework under Regulation (EU) 2021/2282, which will apply to Class III devices from 2030.
- Introduction of performance-based and outcomes-linked reimbursement models for selected high-value devices.
- Streamlined market access pathways for devices that have already received reimbursement in multiple EU member states.
- Digital transformation of HZZO's reimbursement management systems, enabling real-world evidence collection and adaptive pricing.
- Integration of AI-driven analytics into healthcare planning and budget forecasting.

The ongoing digital transformation, supported by the RRP, aims to modernise data management, improve cost control, and enable more evidence-based inclusion of innovative medical devices.

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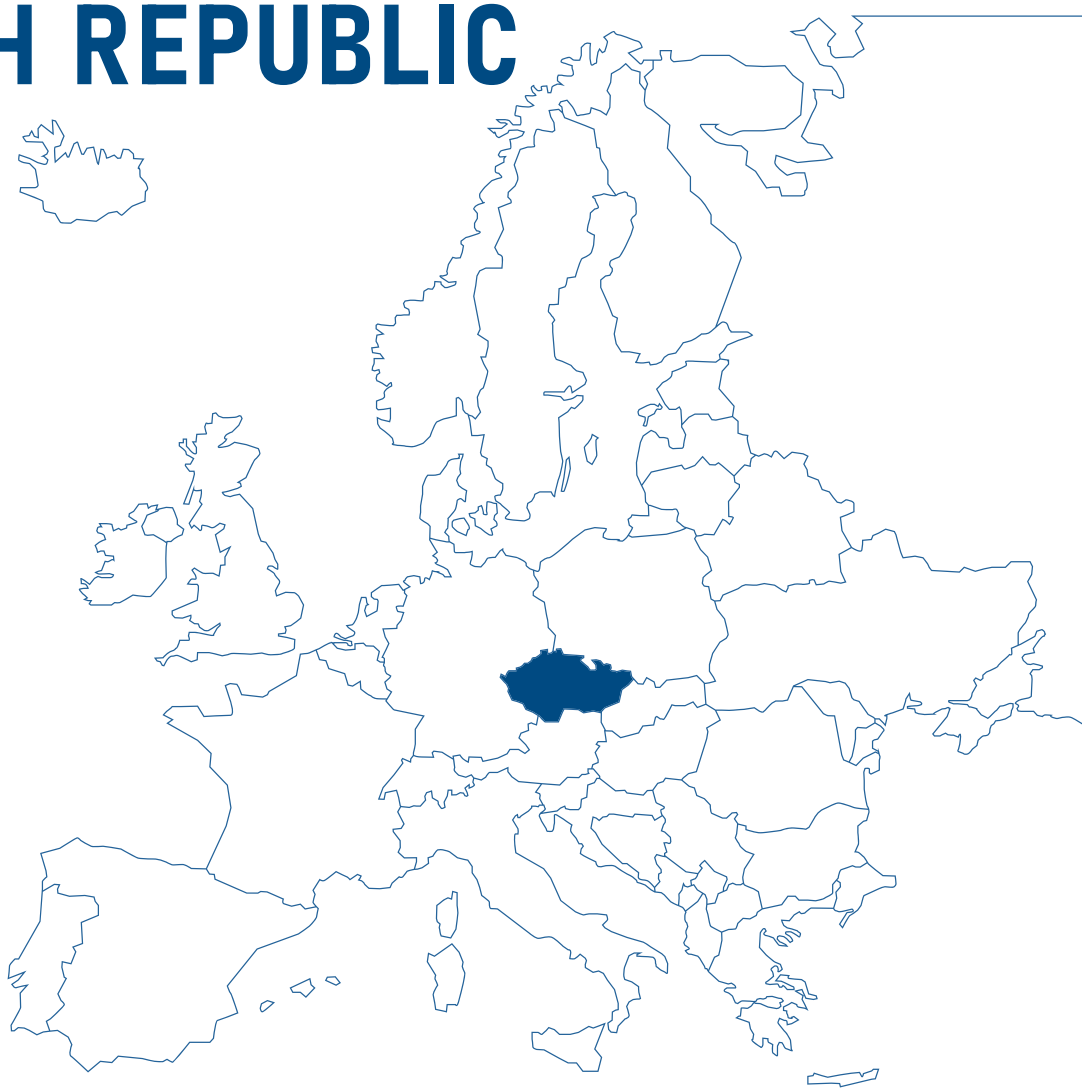
CZECH REPUBLIC



GENERAL OVERVIEW OF CZECH MARKET

POPULATION (2025)

10 915 839

HEALTHCARE EXPENDITURE (2022-2024)

CZK 642 BILLION

(2023) total current health expenditure

HEALTHCARE EXPENDITURE (% OF GDP)

8.4%

OF GDP (2023)

SOURCE: *Czech Statistical Office (CZSO); WHO / World Bank; Eurostat (SHA)*

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Česká asociace dodavatelů
zdravotnických prostředků

The Czech Republic operates a compulsory public health insurance system providing universal coverage to nearly the entire population. Health care financing is based primarily on mandatory insurance contributions administered through multiple health insurance funds, under the regulatory oversight of the Ministry of Health. The system combines solidarity-based financing with a mixed provider structure involving both public and private entities. Health outcomes are generally comparable to those of other Central European countries, while overall expenditure remains below the level of many Western European systems.

The Czech health care system is characterized by broad accessibility, a dense provider network, and good availability of advanced medical technologies. Although inpatient care remains important, policy discussions increasingly focus on efficiency, outpatient care, prevention, digitalization, and value-based health care. Governance of the system involves close interaction between the Ministry of Health, health insurers, regulatory authorities, providers, and professional societies.

Medical devices reimbursement represents a distinct and technically complex area of the Czech reimbursement framework. Depending on the care setting, devices may be reimbursed through hospital payment systems, separate reimbursement mechanisms, or prescription-based outpatient pathways. Reimbursement decisions are influenced by regulatory classification, clinical evidence, budget impact, and categorization processes. In recent years, the Czech Republic has seen increasing debate regarding innovation uptake, transparency, health technology assessment methodologies, and the sustainability of medical device financing.

Yours sincerely,

Miroslav Palat, M.D., M.B.A.
President, CzechMed

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

How does the healthcare system work?

The Czech healthcare system is intended to consist of independent public institutions and sickness funds established under a special law. However, the state plays a significant role annually by establishing the health care financing decree. (A document addressing the funding and growth of all segments of Cz H.Care – hospitals, outpatients, laboratories etc.) This makes the system a hybrid between health insurance or sickness funds driven and a national health service with central government intervention.

What are the main sources of healthcare funding?

There is a general health coverage in the Czech Republic. 40% of the population are employees. Their healthcare contributions are derived from their gross income. (*For further details, see below*) 55% of the population are defined as having no taxable income, thus, they do not contribute to health care funding. Their health coverage is provided by the state from the state budget. The remaining around 4% are self-employed persons who care for their health contributions themselves.

Taxes: For individuals without taxable income, the healthcare contribution is sourced from the general state budget and is allocated at approximately €86 per month per person, which is equivalent to roughly €1,000 annually. Funds raised from the taxation of alcohol or tobacco are not dedicated to health contributions or health programmes. Persons without taxable income, although constituting a majority at around 55% of the population, "contribute" (the state budget pays this amount) only about 25% to the general health insurance funds.

Insurance contributions: The largest contribution is made by employed persons. Their contribution is 13.5% of their gross salary, which is paid for by the employee at 4.5% and 9% by the employer.

Out-of-pocket payments: Out-of-pocket payments are relatively low compared to other European countries. They are in the range of 12% to 15% of the overall health spending. Most of these come in the form of co-payments for medicines or prescription medical devices. Health care per se is provided free of charge. An exception to this is dental care, where we can see a large number of dental surgeons not having a contract with the sickness funds at all. There are, however, not well-documented grey co-payments for health services collected by various healthcare institutions, predominantly outpatient. These co-payments cover additional services such as appointment scheduling and admission to specific health facilities. They represent a grey area of monetary transactions between the consumer (patient) and the provider of health services.

Other mechanisms: Private donations and collections may occur in situations of particularly severe conditions, particularly in children whose cases have gained media attention. Private co-insurance does not exist in the Czech Republic. There have been attempts to develop a framework for an additional source of income for the healthcare system. These have largely failed on the grounds that there was no authoritative list of

fully reimbursed services to which additional services could potentially be covered by a private co-insurance.

What is the role of state, private sector and other entities in healthcare funding? What are key differences between public and private funding approaches? How these sectors interact within the system?

As indicated before, the responsibilities are dual:

The health insurance companies or sickness funds are responsible for collecting the contributions (from the employees and the employers).

There is a redistribution mechanism where 100% of the funds collected are re-distributed to the sickness funds based on the spectrum of their insured, their age, comorbidities, and pharmaceutical consumption.

The Ministry of Health moderates a yearly discussion between sickness funds and healthcare providers on annual growth rates. If the provider sectors and health sickness funds agree on growth rates, this is accepted as consensus. If no agreement is reached, the Ministry of Health defines a growth rate for the upcoming year. Consequently, the state exerts significant influence over the growth of health funding and its utilisation.

The hospital sector is predominantly in public hands, with the exception of certain hospital chains, some foreign-owned, some locally owned. These present a minority in the hospital landscape. On the other side, the ambulatory sector is dominantly run by private entities, be it small or joint doctors' practices, or chains, or polyclinics which are in private hands. The income of these institutions is nonetheless dominantly from the public healthcare insurance scheme.

The healthcare system's income is primarily derived from health insurance funding. Occasionally, crowdfunding or collections are raised for particularly severe cases that receive media attention. This may include children with inborn defects requiring expensive and often experimental treatment or individuals requiring chronic care with highest level of dependency. Such cases are highly intensive and typically require a prolonged period of support.

LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

Reimbursement Legislation (Public Health Insurance)

Act No. 48/1997 Coll. on Public Health Insurance

[■] **Scope:** Fundamental reimbursement framework.

[■] **Regulates:**

- Conditions under which medical devices are reimbursed
- Categorization and reimbursement groups
- Patient eligibility and prescription rules
- Role of SÚKL in reimbursement decisions

Act No. 349/2025 Coll.
(amending Act No. 48/1997 Coll. on Public Health Insurance)

What it regulates:

- Introduces a **new reimbursement framework for prescribed (voucher-based) medical devices.**
- Establishes a **categorisation tree directly in the legislation** (typically in annexes to the Act).
- Replaces the previous system based primarily on implementing decrees with a more **structured and legally anchored classification.**

Key regulatory elements:

- Definition of **reimbursement groups and subgroups.**
- **Indication criteria** for each category.
- **Prescription rules** (who can prescribe, under what conditions).
- **Reimbursement limits and coverage levels.**
- Greater standardisation of decision-making for payers and authorities

Act No. 526/1990 Coll. on Prices

[■] **Scope:** General price regulation law.

[■] **Regulates:**

- Legal basis for price control mechanisms
- Enables issuance of price decisions (including for medical devices indirectly)

Ministry of Health Price Decision
(Cenový předpis MZ ČR – e.g. current Price Regulation for Medical Devices)

[■] **Scope:** Issued periodically (typically annually or ad hoc).

[■] **Regulates:**

- Maximum prices and reimbursement caps for selected medical devices
- Trade margin regulation (if applicable)

Hospital Reimbursement Context (Indirect but Relevant)

Decree on (General Health Care) Reimbursement
(Úhradová vyhláška, issued annually by Ministry of Health)

Scope: Annual regulation of healthcare provider payments.

Regulates:

- Hospital reimbursement via DRG (CZ-DRG system)
- Indirect inclusion of medical device costs within DRG payments
- No explicit device-level reimbursement (except specific cases)

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

There are two separate reimbursement pathways for medical devices: one for prescription devices dispensed in outpatient care and the other for hospital-based devices included in health procedures. The reimbursement of prescription devices is regulated by a classification tree. When a new supplier introduces a new product it can assign it to an existing branch of the tree. This allocation is then subject to scrutiny for a limited number of weeks. If no issues are raised by the relevant authorities or competitors the product is reimbursed according to the rules applicable to that category.

Hospital devices intended for use within medical procedures in hospital settings must undergo a different process. A new product must be included in the general sickness funds' reimbursement catalogue. This process is characterised by volatility and vague rules for several years. It is usually an undefined criterion that makes the negotiation between the supplier and the sickness fund complex. Unfortunately, due to the fact that many officials within the sickness funds are more educated in pharmaceutical matters than in devices, various requirements resembling the pharmaceutical process are gradually being introduced to new devices seeking a place in the reimbursement catalogue. The process is currently under revision.

Additionally – price regulation: The two separate processes required for entering reimbursement for prescription and hospital devices have been described. It is also important to note that devices that have overcome the hurdles outlined are subject to price regulation. This regulation is not applied at the point of entry; the supplier is free to determine the price. However, annual price changes are limited to a maximum set out in the pricing decree issued by the Ministry of Health. This may typically be 2-3% or higher (5-8%) as negotiated by medical technology associations during periods of significant inflation (2022-2024).

Formal requirements: Reimbursement rules are applied generally and therefore this is independent of the type and role of the provider that dispenses prescribes or applies the medical device. Co-payment may be eligible for prescription devices if the product has been introduced to the market with a price exceeding the reimbursement level. However, co-payment is not possible for medical devices used in hospital procedures. In such cases the patient has limited opportunities to negotiate the type or cost of devices to be used or implanted with medical personnel.

Scope of financing: The cost of prescription devices is covered up to the limit of reimbursement. The cost of hospital devices is fully covered by the hospital budget. As hospitals receive reimbursement for their medical procedures, the procurement of medical devices is largely determined by the reimbursement of their care, not reimbursement of individual devices. This raises a valid concern whether the reimbursement level for devices listed in the Sickness Fund catalogue is accurately reflected in the reimbursement of medical procedures to hospitals. The paradox is that hospital-use devices must undergo a complex process to enter the reimbursement catalogue. However, this catalogue has a marginal impact on procurement and usage within the hospital as hospitalisation is reimbursed in bulk according to the DRG system where the exact reimbursement level of a particular device consumed in patient care is largely irrelevant.

CURRENT CHALLENGES

What are the current key challenges and obstacles faced in the public financing of a medical devices system in a country?

Accessibility: Both the strength and the weakness of the Czech health care system lie in a rather liberal access to care and technologies, resulting in a non-negligible level of misuse.

Costs: The expenditure for medical technologies is in the region of 5% of overall health care expenditure, in that sense there is no impact on the sustainability of health care financing.

Reimbursement limitations: There is an unwillingness on the side of sickness funds to cover large numbers of innovative devices. On one hand, there is good access to innovative technologies. On the other hand, they are trying to exercise restrictive measures for new or existing health technologies.

Equity and fairness: The Czech society is quite egalitarian and so is the access to care and technologies.

Impact of Technology and Innovation: Even now, health technologies can provide a competitive advantage and value by reducing other medical expenditures such as hospital stays and recovery periods. They also impact the economic activities of patients treated quickly and efficiently with cutting-edge technologies. As a general rule, sickness funds do not readily adopt modern technologies.

Regulatory and legal challenges: Regulatory challenges are limited. The challenges in pricing regulations and obtaining reimbursement have been described above.

FUTURE CHANGES

The establishment of a legal framework to include hospital devices in a reimbursement catalogue is underway. This catalogue, currently managed by the largest sickness fund, will come into the competence of the Czech competent authority. While this move will enhance transparency, there is a legitimate concern that the process may resemble pharmaceutical reimbursement processes utilising categories and the concept of interchangeable devices.

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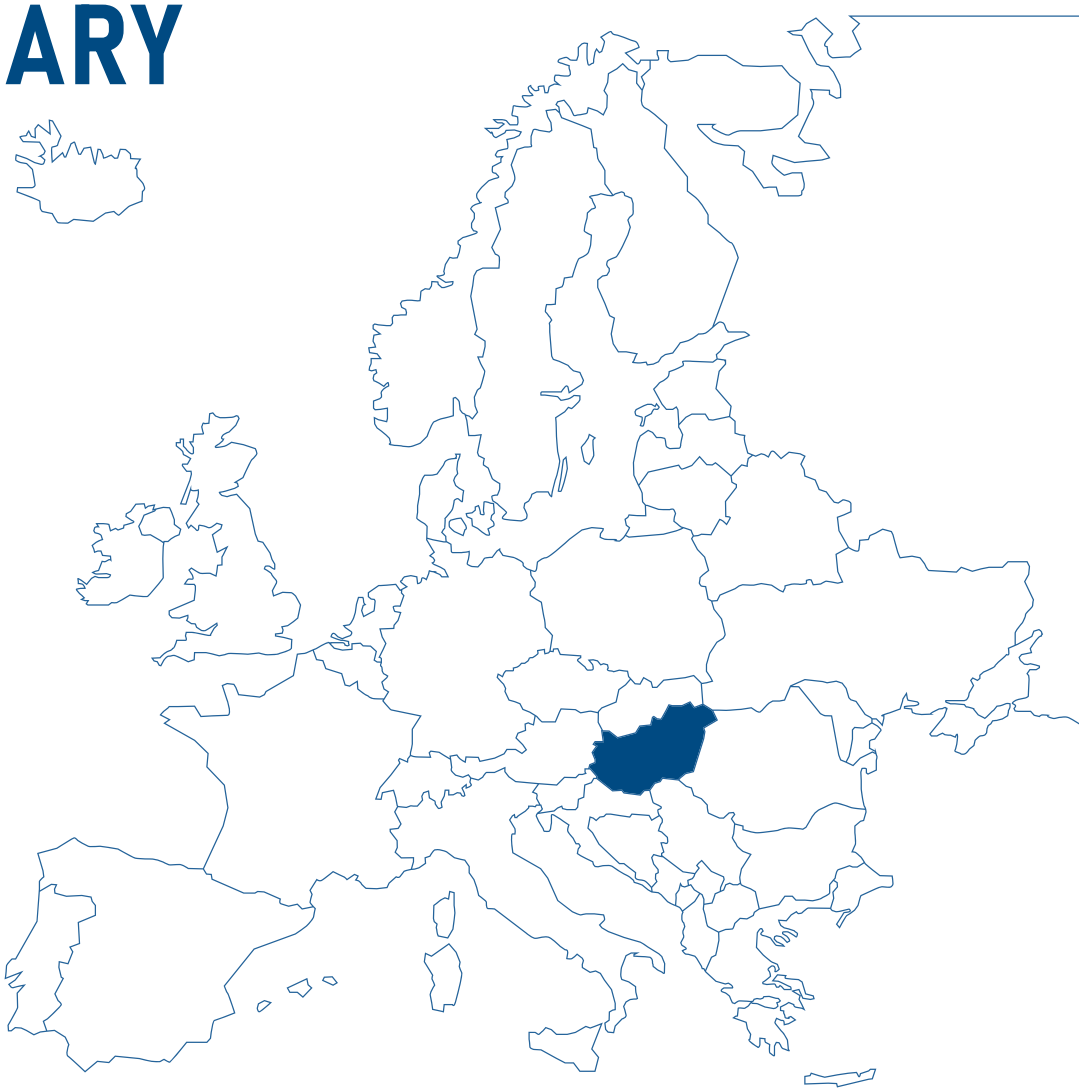
HUNGARY



GENERAL OVERVIEW OF HUNGARIAN MARKET

POPULATION (2025)

9 632 287

HEALTHCARE EXPENDITURE (2022-2024)

APPROX. HUF
6.0 TRILLION
(2023)

HEALTHCARE EXPENDITURE (% OF GDP)

6,4%
OF GDP (2023)

SOURCE: *Hungarian Central Statistical Office (KSH); Eurostat (SHA); WHO*

Orvostechnikai Szövetség
AMDM Hungary

ETOSZ
ASSOCIATION OF HEALTH TECHNOLOGY SUPPLIERS AND MEDICAL DEVICE MANUFACTURERS

The nearly four decades that have passed in Hungarian healthcare since the political transition of 1990 have been a period of unfinished reforms and missed opportunities.

While Hungary has opted for a public healthcare system, demand-side needs have also forced the emergence of private healthcare services.

However, the dominance of the public healthcare system also means that funding and access are far from stable. As a result, public funding as a percentage of GDP now stands at less than 5%.

The picture is mixed regarding healthcare technologies. While advanced technologies are present in the healthcare system, regulatory frameworks for adoption, financing, and public procurement are typically rigid and hinder innovation.

From the sector's perspective, the volume of hospital debt has been one of the biggest challenges in recent years: actual average payment terms exceeded 270 days, and receivables outstanding for over a year were not uncommon.

Another problem was that the (low) price was often the primary, and in many cases exclusive, evaluation criterion in public procurement, which also hindered the introduction of modern equipment and technologies.

In this situation, the two professional associations, ETOSZ and AMDM Hungary play a major role, acting together to address the challenges facing the medical technology sector.

In the chapter on Hungary, we provide an overview of the current state of the Hungarian healthcare system, including specific regulations concerning medical devices.

As professional associations, our mission is to draw the attention of current decision-makers to the fact that the use of modern and effective healthcare technologies benefits the entire country and society by improving prevention, patient care, and rehabilitation.

Yours sincerely,

Tamás Rádai
ETOSZ

László Rásky
AMDM Hungary

LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

The basic laws covering the healthcare system in Hungary are Act CLIV of 1997 on Healthcare and Act LXXXIII of 1997 on Mandatory (Public) Health Insurance.

Patients in Hungary can use medical devices reimbursed by the public payer either in the course of public healthcare services or they can purchase home use medical devices (so-called medical aids) upon a doctor's prescription in pharmacies or medical aids shops.

The legal framework for promoting reimbursed medical aids involves Act XCVIII of 2006 and Decree No. 3/2009 (II. 25.) EüM of the Minister of Health. These laws cover aspects like the provision of free samples (which must be clearly marked and follow strict rules), the costs of promotional events for healthcare professionals, and reporting obligations to the competent authority (NNGYK). Decree No 14/2007 (III. 14.) EüM of the Minister of Health outlines the rules for accepting medical devices for reimbursement, including their ordering, distribution, and repair.

Currently, there are no specific reimbursement methods in Hungary dedicated to high-tech medical technologies or mobile health applications.

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

How does the Hungarian healthcare system work?

Hungary has a centralized system based on mandatory health insurance, with NEAK (National Health Insurance Fund Manager) as the central public payer.

The National Health Insurance Fund covers, among other things, expenditures on a great number of health services provided to people having health insurance. The National Health Insurance Fund also covers certain health services provided to persons without insurance such as emergency services.

Hungary's healthcare system is funded through a combination of mandatory social security contributions, general tax revenues, and specific earmarked taxes. There are some earmarked taxes („sin" taxes) on certain unhealthy products like tobacco and alcohol.

Overall, Hungary has a mixed funding system, with the predominance of direct budgetary funding coming from taxes.

What are the main sources of healthcare funding?

The main pillars of Hungarian healthcare funding are mandatory health insurance contributions (from employees and employers) and state budgetary assistance, with the dominance of the latter.

The total amount of contributions payable by employees in 2025 is 33.5% (without allowances), meaning that regular Hungarian workers pay this amount from their gross salary in order to receive their net salary.

The system is also significantly supplemented by patient co-payments for services like pharmaceuticals, dental care, and rehabilitation, which makes out-of-pocket spending relatively high.

Taxes: In 2025, the following taxes and contributions are deducted from an employee's salary:

- 15% personal income tax,
- 18.5% social security contributions, of which:
  - 10% is pension contribution,
  - 7% is health insurance contribution, and
  - 1.5% is labour market contribution.

The employer pays the following taxes and contributions on gross wages:

- 13% social contribution tax.

Out-of-pocket mechanisms: In case of publicly reimbursed pharmaceuticals and medical aids, a co-payment mechanism applies. This means that the National Health Insurance Fund provides a financial contribution to (i.e. pays a part of) the purchase price. The same co-payment mechanism applies to the rental/repair fee of certain reimbursed medical aids. After the deduction of the National Health Insurance Fund's financial contribution, the rest of the price is paid by the patient.

Private health spending also plays a prominent role in Hungary, accounting for more than a quarter of total health spending. This mainly comes from out-of-pocket payments, the rate of which is well above the EU average.[1] Patients and households in Hungary bear healthcare costs through out-of-pocket payments especially for pharmaceuticals, outpatient care, dental care, and medical aids.

Other mechanisms: **Private health insurance**

There is a private health insurance sector in Hungary that complements the public system. The public system is primarily funded by mandatory contributions, while private insurance offers a way to access private clinics for faster service, higher comfort, and potentially more modern equipment.

In 2024, contribution revenues paid into health and mutual aid funds by private health insurers in Hungary increased, reaching HUF 104.8 billion, which represents a 20.4% increase compared to the previous year. [2]

What is the role of state, private sector and other entities in healthcare funding? What are key differences between public and private funding approaches? How do these sectors interact within the system?

The state is the primary entity responsible for funding healthcare in Hungary, which is managed by NEAK[3], a government entity. The state also defines the scope of the healthcare services available within public health insurance, as well as their standards through legislation and decrees.

The private sector plays a significant role in funding Hungarian healthcare, primarily

[1] State of Health in the EU. Hungary Country Health Profile 2025
[2] Data source: MNB (National Bank of Hungary)
[3] National Health Insurance Fund Manager

through **out-of-pocket payments** and, to a lesser part, **private insurance**. Patients in Hungary can use private health insurance to supplement public services, which is a common practice due to limitations in the public system.

Some private providers in Hungary may deliver healthcare services funded by public resources through contracts with NEAK. While the system is a mix of public and private services, and many private clinics operate on private funding, NEAK can enter into contract with both public and private providers to offer services to those entitled under the national insurance system.

Private and non-governmental resources have become increasingly important due to high out-of-pocket spending and the limited public resources of the National Health Insurance Fund. Innovative models have started to emerge in the private sector, driven by technology and patient-centric approach.

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

In Hungary, there are two ways in which medical devices can be publicly funded:

- medical devices used in clinical care,
- home use medical devices (medical aids) available in pharmacies/special shops on prescription.

In both cases, the public funding comes from **NEAK**.

Devices used in clinical care

Public health insurance covers outpatient and inpatient health services with zero co-payment for the patients. This applies also to the medical devices that are used by healthcare professionals in the course of the care. Such medical devices are procured by hospitals and outpatient service providers, and the provided health services are reimbursed by the National Health Insurance Fund.

In the case of a minority of hospital procedures involving highly expensive medical devices (such as pacemakers, cardiac ablation catheters and surgical staplers), the hospital can get not only the normal reimbursement fee for the given procedure but also an additional payment covering the costs of the devices used.

In principle, innovative new medical technologies can get public reimbursement after a health technology assessment, based on evidence of the clinical and economic value of the technology. In practice, however, only a few technologies undergo health technology assessment due to unclear regulatory environment.

Home use devices (medical aids)

NEAK is the central body handling applications for public reimbursement of medical aids. Distributors may apply to NEAK, which then distributes applications to the relevant bodies. The process involves submitting evidence of medical need and clinical effectiveness, which are then evaluated, including cost-effectiveness assessments, to determine if reimbursement is approved.

In Hungary, a medical aid can be reimbursed for defined patient groups meeting specific criteria, pre-defined by law, rather than needing an individual decision for each patient.

The content of the application for reimbursement is prescribed by law. The application may only be submitted to the health insurance authority by a qualified marketer registered at the health insurance authority.

Documentation and standards: MDR, CE marking. Hungary demands supplier pre-qualification, quality management verification, and service background documentation. Eligibility is determined by professional medical need, rather than where a purchase is made.

Scope of financing: Public insurance partially reimburses the costs of certain medical aids, with reimbursement rates varying by item. There are caps or limits on reimbursement, which can be based on fixed sums for specific categories.

CURRENT CHALLENGES

What are the current key challenges and obstacles faced in the public financing of a medical devices system in a country?

The Hungarian medical device reimbursement landscape presents several challenges that manufacturers, distributors and other stakeholders must navigate strategically.

Inadequate financial resources: The most fundamental challenge facing the Hungarian healthcare system is chronic underfunding. Regular budgetary underplanning at the national level results in constant and massive hospital debts. This financial strain affects all aspects of the healthcare system, including the adoption and utilization of medical technologies. Hospitals operating under severe budget constraints often prioritize immediate financial considerations over long-term clinical benefits or cost-effectiveness. This can lead to reluctance to adopt new technologies, even when reimbursed, if they require any upfront investment or disrupt established clinical pathways.

Additionally, budget constraints at the national level create intense competition for limited resources among different healthcare priorities. Medical devices must compete not only against other devices but also against pharmaceuticals, infrastructure investments, and workforce costs for their share of the healthcare budget.

Accessibility: Access to publicly financed medical devices in Hungary is challenging due to a combination of factors, including underfunding, shortages of medical staff and equipment, and a lack of clear reimbursement pathways.

Hungary's healthcare system faces significant accessibility challenges due to long waiting lists for many procedures, particularly certain specialist and elective surgeries, and regional disparities in the availability of services.

There are significant disparities in the availability of medical technologies throughout Hungary. Applied medical technologies, waiting times, and overall quality of care in inpatient settings can vary dramatically nationwide. This geographic inequality means that even after securing reimbursement, manufacturers may face challenges

in ensuring equitable access to their technologies across different regions and healthcare facilities. This is particularly problematic for technologies that are reimbursed but not prioritized by healthcare authorities.

Slow uptake of innovation:

The rapid pace of medical innovation in Hungary poses a challenge for public financing, as there is a delay in adapting the reimbursement system to include new, advanced technologies. Therefore, cutting-edge technology is not added quickly; the current system faces delays because it must balance innovation with cost containment.

Problems with transparency:

A particularly challenging aspect of the Hungarian system is the lack of transparency in decision-making processes. In many cases, reimbursement requires legislative changes that necessitate political support beyond purely technical or clinical considerations. This political dimension introduces an element of unpredictability into the process.

FUTURE CHANGES

Hungary held parliamentary elections in April 2026 with a landslide victory of a new political party TISZA. The new parliament and government were formed in May 2026.

Based on TISZA's commitments made during the election campaign, healthcare is expected to get a higher political priority with significant changes in the health system, including the creation of an independent Ministry of Health and raising public healthcare spending to 7% of GDP by 2030 so that public funding will cover the true costs of healthcare.

Another important policy element is the promised creation of a Health Quality Control Authority that would make quality indicators of healthcare providers publicly available, establishing feedback mechanisms to health policy decisions regarding financing and management evaluation.

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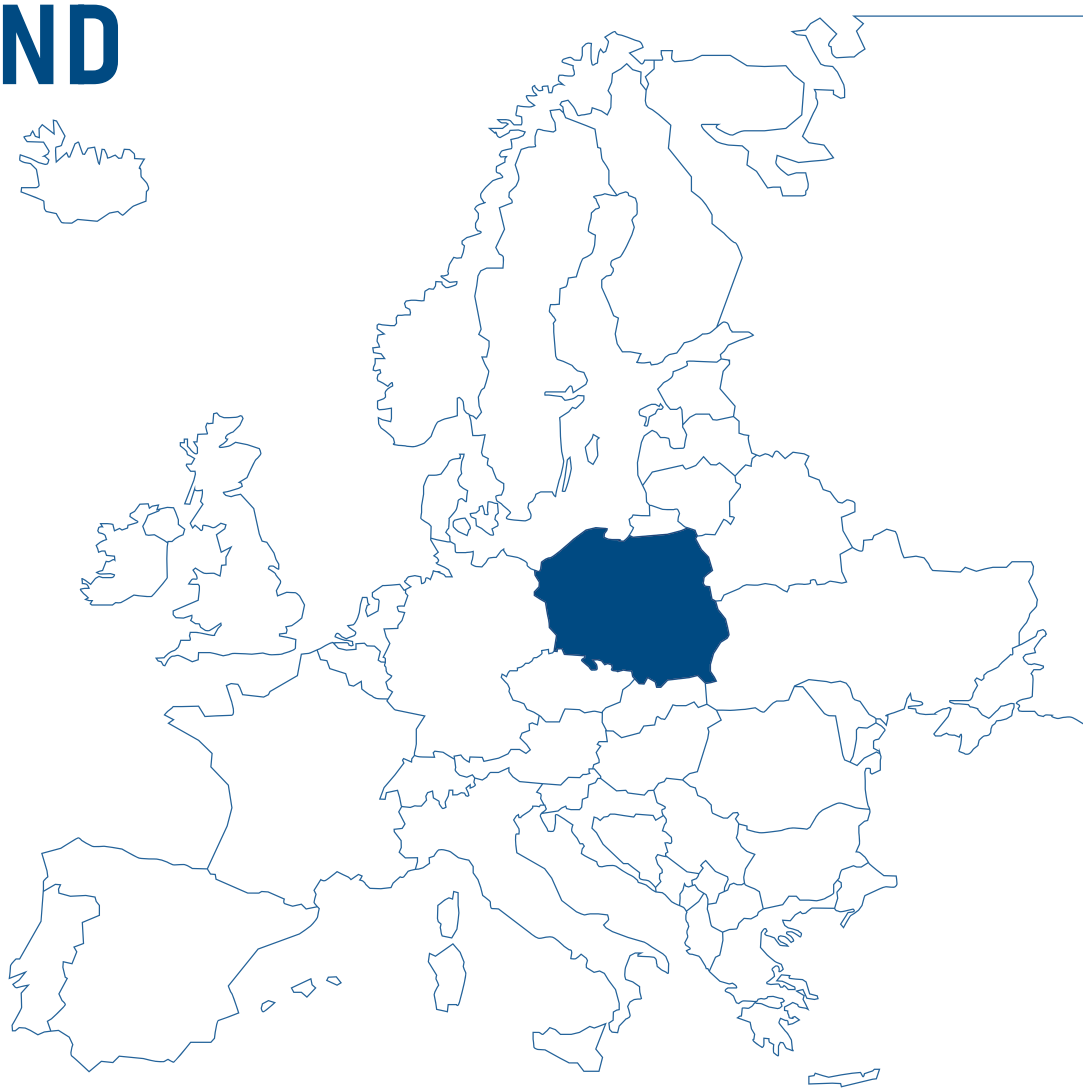
POLAND



GENERAL OVERVIEW OF POLISH MARKET

POPULATION (2024)

37 489 000

HEALTHCARE EXPENDITURE (2022-2024)

PLN 293.6 BILLION
(approx. 68.2 billion EUR)

HEALTHCARE EXPENDITURE (% OF GDP)

8.1%
OF GDP (2024)

SOURCE: *GUS, NFZ*

POLMED
THE POLISH CHAMBER OF COMMERCE OF MEDICAL DEVICES

It is my pleasure to introduce the Poland chapter of this report on the rules of public financing for medical devices in selected European countries. Medical technologies are an indispensable part of today's healthcare: they enable faster and more accurate diagnosis, support effective treatment, and improve patients' quality of life. Ensuring timely and fair access to these technologies is therefore not only a matter of system efficiency, but above all a matter of patient needs.

Poland's healthcare system is largely centralised, with the National Health Fund playing a key role as the main public payer. At the same time, the system combines different mechanisms of financing and reimbursement for medical devices – ranging from devices provided within hospital procedures, to devices available in pharmacies on prescription, and products supplied to patients on request. Understanding how these pathways work in practice – and where the main challenges lie – is essential for decision-makers, healthcare professionals, patient organisations and the medtech sector.

I hope that this chapter will serve as a useful reference point and contribute to a constructive discussion on how to strengthen transparency, predictability and sustainability in the public funding of medical devices, while maintaining a clear focus on outcomes for patients.

Yours sincerely,

Arkadiusz Grądkowski
President, POLMED Chamber of Commerce

LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

The system of financing medical devices in Poland is based on the provisions of the Act of May 12, 2011 on Reimbursement of Medicines, Foodstuffs for Special Nutritional Purposes and Medical Devices and the Act of August 27, 2004 on Publicly Financed Healthcare Services.

Polish patients can use medical devices reimbursed by the public payer in several different ways, such as by using healthcare services that are guaranteed services, participating in pilot/ health programs or health policies, or during hospitalization in a public hospital. In addition, they can purchase prescription or request-based medical devices (so-called medical device supplies) from a pharmacy.

Currently, Polish regulations do not include a reimbursement mode dedicated to modern technologies and do not allow medical devices that are mobile applications to be covered by reimbursement.

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

How does the healthcare system work?

The Polish healthcare system is based on the activities of the National Health Fund, whose revenues are the proceeds of health insurance contributions. Sources of funding also include the state budget and local government budgets.

The state budget funds cover, among other things, expenditures on certain healthcare services, the creation and transformation and debt reduction of medical entities, the financing of certain types of tasks of entities conducting medical activities, or the financing of air sanitary transport teams. The state budget also pays for health care services provided to persons other than insured persons.

In turn, **local government units** may, in order to meet the needs of the local government community in the field of healthcare, taking into account, in particular, the regional map of health needs, priorities for regional health policy and the state of availability of healthcare services in the provincial area, finance guaranteed healthcare services for the residents of this community. Local government units may also establish their own medical entities.

The nature of the Polish healthcare system can thus be described as **mainly centralized**.

What are the main sources of healthcare funding?

Taxes: The healthcare system in Poland is financed by the National Health Fund. The National Health Fund's financial resources consist primarily of revenue from the mandatory insurance contribution for healthcare, subsidies from the state budget (subsidies for financing statutorily defined tasks, subject subsidies), as well as funds from earmarked funds (e.g. Medical Fund, Solidarity Fund). On top of this, the National Health Fund receives revenue from the so-called **sugar fee** (i.e., a fee on beverages with added sweeteners and caffeine or taurine in the ready-to-drink product) and **a fee on the**

sale of alcohol in packages of up to 300 ml.

Insurance contributions:

In Poland, there is an obligation to pay a health contribution. The regulations specify which people and in what situations are exempt from this obligation, but still retain the right to health insurance (these are, for example, women on maternity leave).

Currently, the amount of health contribution paid depends on the form of taxation and the amount of income. Those who settle their income tax on a general basis (i.e., according to the tax scale) pay a health insurance contribution in the amount of 9% of the contribution assessment base (income from business activity). On the other hand, those who settle their personal income tax in the form of a flat tax (19%) pay a health contribution of 4.9% of the contribution base (business income). Those who settle income tax with a lump sum on registered income pay a monthly health contribution of 9% of the lump sum base. For those paying a tax card, the basis for health insurance contributions is the minimum wage in effect for the year.

Starting in 2022, the business owners in Poland are also required to pay an annual health contribution. The annual basis for calculating the health contribution is the business income for a given calendar year, understood as the difference between income and the costs of obtaining such income, reduced by contributions for pension, disability, sickness and accident insurance, if they were not included in the costs of obtaining income. If, after the annual settlement, it turns out that:

- a person has paid more in health insurance contributions than the annual health insurance contribution determined on the annual health contribution base – he or she can claim a refund of the overpayment;
- the amount of health insurance contributions paid by the person is less than the annual contribution – he or she must pay the difference.

In the case of entrepreneurs settling on the general basis (according to the tax scale) or the flat tax, if the annual contribution base is less than the ratio of the number of months in the year when the person was subject to health insurance and the minimum salary, he or she will be subject to the minimum annual contribution base.

Out-of-pocket mechanisms:

The public healthcare system finances the provision of health services included in the so-called **basket of guaranteed healthcare services**. The level of public financing of a given healthcare service is determined by law. Healthcare services outside the basket of guaranteed services are subject to full payment by the patient. As a rule, patients cannot pay extra for reimbursable hospital treatment. If a medical procedure involving a specific medical device is covered by public funding, the patient does not have the option of choosing another, more modern version of the device for a copayment.

Polish people pay for visits to specialists and dentists on their own or with the help of private health insurance. Information from the Central Statistical Office shows that almost 75% of Polish patients in 2023 used private dental care[4]. Hospital treatment is

[4] *https://www.rp.pl/ubezpieczenia/art41376391-polacy-wiecej-wydaja-na-prywatne-leczenie-i-czesciej-z-niego-korzystaja.*

Other mechanisms:

still mostly received by Polish residents in public hospitals.

Private health insurance

In recent years, it has become standard among employers in Poland to cover their employees with private health insurance. As part of the package, the cost of which is mostly/completely covered by the employer, the employee has access to a primary care physician and specialists, including diagnostic tests. Dental care or aesthetic medicine, meanwhile, are often covered at an additional discount. Many Polish cities have a large number of private health entities (e.g., Luxmed, Medicover, PZU Zdrowie), and patients point to the ability to register and manage their appointments via a mobile app and the high availability of appointments as advantages of private health insurance over public healthcare. Private employee health insurance thus relieves the public healthcare system of the burden of outpatient treatment. **At the end of Q2 2024, 5.11 million people in Poland had private health insurance.**

NGO activity and 1.5% of income tax

Non-governmental organizations and charitable initiatives are also active in Poland. The most well-known, the Great Orchestra of Christmas Charity Foundation, has been organizing the finals of the Great Orchestra of Christmas Charity every year throughout Poland for the past 31 years, the main component of which are street and online fundraising events. Each year, the foundation donates the funds raised to purchase medical equipment and supplies for public medical entities.

In addition, patients independently organize fundraising to cover the cost of treatment for rare or chronic diseases, which is not reimbursed by the National Health Fund. Moreover, every individual or legal entity in Poland can donate 1.5% of their income tax each year as part of their tax return to a public benefit organization of their choice (and thus a non-governmental organization working for the benefit of patients and health care).

What is the role of state, private sector and other entities in healthcare funding? What are key differences between public and private funding approaches? How these sectors interact within the system?

The National Health Fund and the Ministry of Health are primarily responsible for financing healthcare in Poland. The baskets of guaranteed benefits, i.e., health services partially or fully financed by public funds, are established by decree by the Minister of Health. The Minister of Health also decides which health services, medicinal products or medical devices will be reimbursed. At this point, Polish regulations do not provide any formal pathway for submitting applications for a product or procedure to be covered by reimbursement. In practice, patient organizations and other stakeholders can send letters of appeal to the Ministry of Health regarding the inclusion of a specific drug/ medical device or health service in reimbursement based on Article 241 of the Code of Administrative Procedure. However, the Minister of Health is not legally obligated to take such requests into account when deciding on reimbursement coverage.

The private healthcare sector is developing rapidly in Poland and, as mentioned earlier, is an important part of the Polish healthcare system, currently providing faster appointments for medical consultations and access to modern medical tech-

nologies. At the same time, the National Health Fund allows private entities to participate in the creation of the public healthcare system by allowing them to participate in competitions for the provision of specific categories of healthcare services.

NGOs and private donors play an important role as gap-fillers in the healthcare system – through funds from private fundraising, 1.5% of income tax or initiatives such as the Great Orchestra of Christmas Charity, patients are financing expensive modern therapies or treatments for rare diseases and new equipment for public hospitals. Poland cooperates with the WHO and the World Bank, signing agreements and participating in programs that make it possible to obtain funding for selected areas of healthcare. Poland is currently implementing the National Recovery and Resilience Plan (KPO), under which it receives funding from the European Union to implement digital transformation in healthcare, among other things.

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

In Poland, there are three main ways in which medical devices can be publicly funded:

- devices available on request;
- devices available in pharmacies on prescription;
- devices used in hospital procedures.

Devices available on request

This is the most common form of supply for patients. The devices covered are indicated by type in the regulation of the Minister of Health, together with the definition of:

- the persons authorized to issue instructions (doctors with a specific specialization, physiotherapists, nurses and midwives);
- the financing limit;
- the recipient's own share in the financing limit (from 0 to 30%);
- criteria for granting;
- useful life;
- repair price limit.

The Minister of Health has the exclusive competence to create the list. The list includes prostheses, orthoses, corsets, orthopaedic footwear, compression devices, optical devices, hearing aids, glycaemic control devices, mobility disability devices, tracheostomy devices, respiratory aids, stoma devices, urinary incontinence devices, breast prostheses, post-operative or breast prosthesis bras, wigs, fabric stump stockings, PT/INR measuring device and straps for this device.

Request for supplies or repairs are issued electronically and can be fulfilled at any entity with a contract with the National Health Fund (mainly pharmacies and medical shops). These entities can sell any of the devices that fall within the general categories on the list, which they indicate in the inventory of the product range that is annexed to the contract. The annex can be amended at any time by adding or

removing selected devices, but at least one device in the category must have a price within the financing limit. The patient can choose a device at any price, but public funding is limited to a certain amount, above which the patient must cover all the excess with their own funds.

Devices available in pharmacies on prescription

Devices available on prescription are individually covered by funding on the basis of a reimbursement decision issued by the Minister of Health (separate for each GTIN code). This is a system specific to medicines, but also covers diabetic products (injector needles, blood glucose meter strips) and wound dressings.

The decision is preceded by an administrative procedure initiated at the request of the manufacturer, authorised representative, importer or distributor. As part of the proceedings, price negotiations are conducted, and if the product does not have a reimbursed equivalent (i.e. a product with the same intended use and properties), it is additionally required to attach HTA analyses and to have an analysis conducted by the Agency for Health Technology Assessment and Tarification. The criteria for reimbursement include both clinical and financial aspects. The decision can be issued for 2 or 3 years. Increasing or decreasing the price and shortening the period of validity of the decision requires the initiation of another procedure and a corresponding decision.

Products covered by reimbursement are indicated in the announcement of the Minister of Health, which includes:

- identifying data of the device;
- the reimbursement category:
    - a device available in a pharmacy on prescription for all registered indications and purposes;
    - a device available in a pharmacy on prescription for indication determined by a clinical condition.
- the payment level (free up to the funding limit, fixed payment level of PLN 3.20, 30%);
- net selling price, gross wholesale price, official selling price;
- the financing limit;
- the patient's co-payment;
- the limit group;
- the effective date of the decision and its term of validity.

Electronic prescriptions can only be filled in pharmacies and patients purchase the devices at the fixed price set in the decision plus the statutory margins, taking into account the funding limit. Devices with the same or similar indications or intended uses and similar efficacy are combined in limit groups for which a common limit is set on the basis of one of the devices for which the highest of the lowest net sales prices per unit completes 25% of the sales volume generated in that limit group in

the month falling 3 months before the announcement.

Devices used in hospital procedures

Under hospital treatment, patients are entitled to free use of services, which means that the cost of medical devices used in hospital procedures is fully financed for public funds.

Depending on the procedure, the cost of the device necessary to provide the service may or may not be included in the valuation of the service. In both cases, the provider may purchase a device of any brand corresponding to the description of the service, taking into account the general principles of spending public funds (e.g. expediency, economy, obtaining the best effect from given inputs, ensuring the optimal choice of methods and means).

If the device is included in the valuation of the service, the provider does not receive additional funds to compensate for the purchase of the device, but only the amount due for the performance of the service – the valuation should include the necessity to purchase the devices and its estimated cost.

If the device is not included in the valuation of the service, the provider settles the cost of the device on the basis of the purchase invoice.

The regulations do not indicate maximum or preferred prices, however, the National Health Fund may conduct an inspection regarding the reasonableness of the choice of medical devices.

CURRENT CHALLENGES

What are the current key challenges and obstacles faced in the public financing of a medical devices system in a country?

Accessibility:

For hospital procedures, the patient cannot choose a device (e.g. of better quality) and pay extra for it – all services are free of charge and devices are purchased by providers.

Costs:

Financing limits for devices on request are relatively low and, despite the theoretical zero co-payment, the patient often has to pay the excess over the limit in order to purchase a better quality device.

Reimbursement limitations:

Some devices on request (e.g. advanced glucose monitoring systems) are only publicly funded for the paediatric population.

In addition devices on request have a defined useful life, which is not always adequate to the actual use.

Impact of technology and innovation:

High-tech medical devices are relatively slow to be included in funding, mainly for fiscal reasons.

Regulatory and legal challenges:

The list of medical devices on request is rarely updated and the introduction of new devices is the exclusive competence of the Minister of Health – there are no legal possibilities for other entities to apply for the inclusion of specific devices.

FUTURE CHANGES

Are there plans for changes in medical device financing system in Poland that will impact the financing and reimbursement system of medical devices?

THE (FAINT) PERSPECTIVE OF SYSTEMIC CHANGE

At this point in Poland, there is formally no pathway to apply for funding for medical devices that are mobile health applications. This is impossible due to the blockage resulting from the literal wording of the Reimbursement Act (which, in the context of medical devices, speaks explicitly about packaging). Another obstacle is the lack of commitment on the part of the Ministry of Health to formalize the reimbursement process for such devices.

The medical device industry in Poland has long called for an amendment to the law and the creation of a transparent application procedure for qualifying healthcare services as guaranteed.

IMPACT OF THE AMENDMENT TO THE REIMBURSEMENT LAW ON THE FINANCING OF MEDICAL DEVICES

In mid-2025, the Minister of Health conducted public consultations on the draft law amending the Reimbursement Law (dubbed by the industry as the "Quick/ Broad Amendment to the Reimbursement Law", or "SZNUR" for short). However, the proposed solutions do little to address the issue of medical device reimbursement. As part of the SZNUR, the Ministry of Health proposes to make it mandatory to review the regulation of medical devices on request at least once every two years. This change should be viewed positively, as it creates an opportunity to expand the category of medical devices available on request. Until now, this has not happened very often, which meant that the catalog of medical devices available on request was not always in line with patients' current health needs.

However, the introduction of an overview of the list of requested devices should only be the beginning of changes in the field of requested medical devices. The Minister of Health has the exclusive authority to determine the list, and no procedure has been provided for submitting suggestions for changes in this regard. Consideration should be given to the possibility of proposing the inclusion of new categories of devices by specific entities, such as national or provincial medical consultants or patient organizations.

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ROMANIA

GENERAL OVERVIEW OF ROMANIAN MARKET

POPULATION (2023)

18 518 000

HEALTHCARE EXPENDITURE (2022-2024)

EURO
18 BILLION
(2023, current health expenditure)

HEALTHCARE EXPENDITURE (% OF GDP)

5.7%
OF GDP (2023)

SOURCE: *Eurostat database 2025, OECD / European Commission – State of Health in the EU: Romania Country Health Profile 2025*

The Medical Device industry is one of the main providers of solutions for patients within the Romanian health care system, being visible from diagnosis to treatment and rehabilitation of the patients. Over 80% of the medical devices market (manufacturers, importers, distributors, representatives of large international companies, but also Romanian companies specialized in medical technologies, equipment, and consumables) is supplied by companies which are members of AFPM (Asociația Furnizorilor de Produse Medicale) – the local industry association related to European Medtech association. The strategic priorities in the area of medical devices promoted by AFPM covers: (1) sustainability and adequate financing in the health system, (2) increasing patient access to innovative medical technologies sustainable financing, (3) development of a National Strategy for Diagnostics, and (4) ensuring a predictable and fair legislative framework.

Medical technologies bring benefits in multiple ways. They enable people to live longer and better lives, thus giving them the opportunity to contribute to society. At the same time, medical technologies improve the quality of healthcare as well as the efficiency and sustainability of healthcare systems. Thus, the understanding of the financial framework, local rules and incentives or barriers for the utilization of medical devices could be of interest not only for international researchers but also for companies, consultants, and decision-makers around the world.

Yours sincerely,

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LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

The Romanian health care system is a mainly a public financed system and the medical devices (MD) are one of the dimensions reimbursed (completely or partially). The functioning of the system is regulated generally by the Law # 95/2006 on the Health Care Reform with its consecutive government decisions and ministerial orders. Medical Devices regulations at EU level (#2017/745 & #2017/746) are transposed in the Romanian legislation through the Government Ordinance #46/2022 (for EU #2017/745 regulation on MD) and through the Government Ordinance #137/2022 (for EU #2017/746 regulation on IVD MD).

The access of Romanian patients to medical devices reimbursed by the public payer is done in several ways, such as benefiting from different healthcare services that are part of the basic package of reimbursed services, participating in pilot/ health clinical research programs, benefiting from an MD during a hospitalization episode (in-patient or day care) or based on a prescription that allows patients to obtain an MD (for free or via a co-payment) from a pharmacy.

In Romania, there is not a dedicated Health Technology Assessment (HTA) process for MD to get reimbursement, most of the market for MD being constructed around public acquisitions (tenders). Currently, local regulations do not allow medical devices that are mobile applications to be covered by public reimbursement.

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

How does the Romanian healthcare system work?

The Romanian health care system is based on a Bismarckian model of compulsory social health insurance (SHI), where the main public payer is the National Health Insurance House (NHIH) who covers around 77% of public funding. NHIH is a single payer to cover the SHI, contracting with health care providers via its 43 branches (Local Health Insurance House – LHIH), 42 of them based on districts/geographical criteria and 1 covering the Defense/Security institutions of Romania. The funds from insured people are collected centralized into a single fund and then distributed by NHIH towards LHIH. Another important payer is the Ministry of Health (MoH) which is financing the health care system using several mechanisms: direct reimbursement of several expenditures in areas like Public Health, Forensic Medicine, Emergencies System etc., National Health Programs (NHP) and Priority Actions (AP).

Consequently, the financing of the Romanian health care system is centralized, even some health funds could be disbursed by the Local Authorities (City Halls, District Councils), especially to local public hospitals or ambulatory offices.

What are the main sources of healthcare funding?

The Romanian health care system is based on a mixture of public and private funding, with public funding accounting for around 77% of total expenditures and private funding accounting for around 23% of total health expenditures. Health care expenditures represent around 5,8% of GDP and account for 858 Euro per inhabitant (Eurostat data, 2022). In terms of health care providers, the Romanian

health care system is a mixture of public and private providers with hospitals mainly public owned and ambulatory and ancillary services mainly private owned.

Insurance contributions: Insurance contributions are the main sources of financing for the public SHI scheme managed by the payer – NHIH. All citizens have the obligation to pay the health contribution and to become insured people, but in practice around 85% of Romanian population is insured. The health contribution accounts for 10% of the individual income and is paid by each person (for the employees, the employer keeps the 10% health contribution and directs it towards NHIH). There are a lot of exemptions from this obligation but still retain the right to health insurance (children, women on maternity leave, retirees, pensioners).

Other sources of funds for the SHI scheme are represented by the claw-back taxation (a fixed tax of 15% for generic drugs or 25% for innovative drugs) and the State Budget subsidies, because the NHIH runs out of budget every year.

The SHI scheme provides to insured people the basic package of health care services that includes all types of health care provisions, including drugs and MD on prescription. The uninsured people benefit only from the minimum package of health care services that includes only some prevention and emergency care, but no medicines or MD on prescription.

Taxes: The general taxation model (based on the Beveridge model) applies to the funds managed by the Ministry of Health. Alongside the funds collected at the State Budget from general taxation, there are also some earmarked taxes (alcohol, tobacco and sugar) that contribute towards the budget of Ministry of Health.

Ministry of Health financed health care services are dedicated to all Romanian citizens (insured or not with NHIH) and covers specific areas like public health, forensic medicine, emergency rooms and ambulances etc.

MoH manages the National Health Programs (NHP), which are (1) Public Health Programs and (2) Curatives Programs. The Curatives Programs are financed by SHI scheme and run by NHIH, even if they are addressed to all Romanian citizens. NHP reflect some health specific priorities and cover some specifics MD or drugs in different areas: Oncology, Diabetes, Orthopedy, Cardio-vascular Diseases, Rare disease etc. The funds from NHP could be accessed by both public and private providers.

MoH also manages the Priority Actions (AP), which represent a financing mechanism to cover specific priorities only in public hospitals (e.g. Trauma, Stroke, Intensive Care, Heart Attack etc.) and are addressed to all Romanian citizens.

Local Administration (City Halls, District Councils) could add supplementary funds for their own providers of health care, from the taxes collected locally.

Out-of-pocket payments: As previously mentioned, the SHI provides a basic package of health care services for insured people and a minimum package of health care services for uninsured people. All other services outside of these packages must be paid totally directly out-of-pocket or using a subscription towards voluntary health insurance (private insurance). The typical services not covered are most of the dental services, esthetic surgery, and special accommodation in hospitals.
Other out-of-pocket funds are spent on: (1) Co-payments for the insured people (e.g. % of the price of a covered drug), (2) Contributions of the insured people

(e.g. a certain amount in a private hospital or certain amount for an external prothesis). In some public health care facilities, there are also "under-the-table" payments for the physicians or nurses.

In public hospitals there is a compulsory contribution of 10 RON (local currency, around 2 Euro) for each hospitalization episode, but the hospital could not charge any other out-of-pocket contribution from the patients. The private hospitals are allowed to charge the patients with different amounts, representing the difference from the total expenditures for the patient and the amount reimbursed by the NHIH.

Other mechanisms:

Voluntary (Private) Health Insurance (VHI)

The provisions on VHI are presented in the same Law # 95/2006 on the Health Care Reform which stipulates that only Supplementary and Complementary voluntary health insurance schemes could be developed (it is not allowed to have Substitution voluntary health insurance). Only private companies can sell VHI and there are several local or international companies on the market. Most of the people with VHI receive an insurance plan from the employer as part of employee benefits, because there is a tax deductibility for 400 Euro/year for the employer on this destination (VHI). The same deductibility applies for individual people buying a VHI, and both deductibility could sum up for one individual. The services covered by VHI are usually the ones where the patients need an out-of-pocket payment. The VHI market value increased in the last years to overcome 100 mil. Euro, but is very small compared with SHI (over 14 billion Euro).

Health Subscriptions (Pre-paid health care services)

The pre-paid services cover different preventive services and are sold by different networks of health care providers directly to employers, who provide them towards employees as benefits. There is the same 400 Euro/year deductibility on the employer accounts for these pre-paid services. This financing mechanism is very popular among employers, has existed for more than 25 years and the total market value exceeds 500 mil. Euro.

NGO activity and 3.5% of income tax

Non-governmental organizations and charitable initiatives are present in Romania. Some are local foundations; others are local branches of international NGOs. Some of these NGOs could provide health care services financed via their own sources or using a contract with SHI. Other NGOs could support patients and facilitate access of patients to different type of health care services (like Patient Group Organizations).

In addition, patients independently organize fundraising to cover the cost of treatment for rare or chronic diseases, which are not reimbursed by the SHI or MoH.

Moreover, every individual in Romania can donate up to 3.5% of their income tax each year as part of their tax return to a public benefit organization of their choice (and thus a non-governmental organization working for the benefit of patients and health care).

What is the role of state, private sector and other entities in healthcare funding? What are key differences between public and private funding approaches? How do these sectors interact within the system?

As mentioned, NHIH and MoH are the main responsible for public health care financing. The regulation of the health care system is driven by the MoH who is in charge with health care policies, including the area of SHI (managed by NHIH). The basic and the minimum package of services provided by SHI scheme, the content of the National Health Programs and Priority Actions as well as the Reimbursement List for drugs are established by the Ministry of health through Government Decisions. The budget of the NHIH is approved every year in the Romanian Parliament as an annex of the State Budget, including the breakdown of NHIH per type of health care providers (primary care, ambulatory specialty care, hospital care, dialysis, home care etc.).

The funds collected from the private sector are small compared with the public funding, accounting for 23 % of total health care expenditure. Most private funds are flowing in the health care system for out-of-pocket services or devices, voluntary health insurance and pre-paid services (health subscriptions) being around 3% of total health care expenditure.

The private sector is the main provider of ambulatory health care services, but there are also over 100 private hospitals (most of them with less than 100 beds). The private health care providers could contract with LHIH for the services under the SHI (public funds) and National Health Programs but could not access public funds from Priority Actions managed by MoH.

NGOs, foundations, or private donors do not play a significant role in healthcare funding in Romania. Their funds cover different gaps in health care delivery (like access to innovative treatment) or in coverage for different uninsured people (homeless, poor people, people from remote areas etc.).

In the last years, supplementary funds are available through PNRR (National Recovery and Resilience Plan) and EU Funds 2021-2027 where health care system has a dedicated earmarked line. These funds are eligible for investments or training in health care services and could be used for acquisition of medical devices to be used in hospitals and ambulatory settings.

Romania has a good cooperation with the WHO and has an extensive partnership of health care financing with the World Bank. The last signed loan with World Bank started in 2014, was restructured several times and the original Project development objective (PDO) was to improve access to, and quality and efficiency of public health services in Romania.

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

In Romania there is no Health Technology Assessment (HTA) process in place for medical devices, the Competent Authority (National Agency for Drugs and Medical Devices – ANMDMR) preparing the local legislation for the application in the near future of the EU Regulation #2021/2282 on HTA.

There are several ways of financing medical devices in Romania:

a. Medical devices which represent capital expenditures. This category covers all expensive pieces of equipment that are considered capital expenditure and the responsibility for this expenditure belongs to the owner of the medical facility (Ministry of Health, Local Administration, other public entities, private owners, NGOs etc.). If the respective health care facility has a contract with the public payer (NHIH), the funds reimbursed for services by the NHIH could not be used to purchase these medical devices which represent capital expenditure.

As capital investment from public payer, the MDs with different technologies are acquired based on a public acquisition process (e.g tender), guided by the Romanian Public Acquisitions Law. The usual criterion for the tender is the minimum price, but the law offers the possibility to have also some other technical criteria as part of the acquisition process (like a Value Based Procurement – VBP). There are some examples of hospitals or other contracting authorities using VBP, but this is seldom used. No expected outcome requirements are permitted/used in the instance of VBP.

b. Medical devices which are not considered capital expenditure and are used by health care facilities (ambulatory or hospital settings) to provide different types of care/services towards patients. These MD have no direct reimbursement from the public payer, their costs are considered in the tariff for the reimbursement of the medical care/services as: consultations, procedures, imagistic, lab. tests, dialysis etc. For the lab or imagistic services provided in ambulatory settings, the payer (NHIH) establishes List with the services reimbursed and their tariff, and the health care provider decide on the medical devices to use in performing the respective services. This List is updated by NHIH together with the Specialty Commissions of the Ministry of Health.

c. Medical devices which are dispensed in open pharmacies, with or without a medical prescription and with or without reimbursed directly by the public payer (NHIH). There are no Pricing mechanisms for these MD (like for drugs, e.g using International Reference Pricing), and the public payer (NHIH) establish the Reference Price (reimbursement price) for the ones which are on a specific List for rehabilitation, prothesis etc. This list covers several therapeutical areas and a lot of medical devices (auditive prothesis, stomas, wheelchairs, external prothesis etc.).

CURRENT CHALLENGES

What are the current key challenges and obstacles faced in the public financing of a medical devices system in a country?

Accessibility:

The accessibility of patients to medical devices in open pharmacies is limited for the MDs with prescription to the List of reimbursed MDs established by the payer (NHIH). There are no regional disparities because the basic package of services reimbursed by NHIH is established at national level. The limitation could arise in some districts or in some periods if the monthly budget allocated for the MDs is consumed prior to the end of the month and then a waiting list starts to function.

TYPE OF PROVIDER	Examples of MD	Reimbursement mechanism of MD
Ancillary ambulatory care	Devices for Labs, Medical Imagistic, Nuclear Medicine etc.	- NHIH List of tariffs with covered ancillary services - Capital investment
Primary / Ambulatory care	Equipment/medical devices in the provider office	- Part of the reimbursement per medical services - Capital investment
Hospitals	Materials, medical devices, implants, equipment etc.	- Part of the reimbursement per DRG - Part of the reimbursement per day-care - National Health Programs (NHP) for Orthopedy, Radiotherapy, Diabetes, Hearing Prothesis etc. - Priority Actions (AP) for ICU, trauma, stroke - Own hospital revenues (Out of Pocket, local administration, Voluntary Insurance etc.) - Possible patient co-payment in private hospitals - Capital investment
Dialysis	Specific materials, devices and equipment	- Part of the reimbursement per dialysis episode - Capital investment
Rehabilitation	Prothesis/Orthesis and other devices	- NHIH List with Reference (Prices for each type of device) - Possible patient co-payment - Capital investment
Emergency Care	Medical devices for ambulances/ER, stretchers, cots	- Running expenditures - Priority Actions (AP) for trauma, heart attack, stroke etc. - Capital investment

Costs: The medical devices dispensed in open pharmacies are not one of the main drivers of financial burden for the NHIH. For the medical devices which are capital equipment the burden could be high for the Ministry of health or local authorities, and this is why some of the Resilience Funds and EU Funds are used for re-equipping some of the Romanian hospitals.

Reimbursement limitations:

The limitations are the consequence of the limited List of reimbursed MDs in open pharmacies established by the payer (NHIH). Also, the patients could pay a certain fee (co-payment) if the actual price of the MD is higher than the Reference price established by the NHIH.

For some high-end technologies like robotic surgery, the patients in private hospitals must pay a fee. In public hospitals there is no patient fee, but the respective services are very limited in terms of availability.

Equity and fairness:

The fairness in terms of disparities between different groups of patients is reduced if we consider the co-payment required by certain specific MDs (with price over the Reference Price) or high-end technologies in private hospitals.

Impact of technology and innovation:

In terms of the adoption of new technologies at provider level, the payer (NHIH) provides some incentives (possibility to contract a higher budget) to ambulatory providers that start utilizing new and innovative technologies in the areas of labs, radiology, Computer Tomograph, Magnetic Resonance Imaging etc.

For hospital new technologies that require additional funding like robotic surgery the Ministry of Health introduced in April 2026 a specific program ("AP-Robotica"), to facilitate the uptake of this technology in public hospitals, with dedicated funds from the Ministry of Health budget that covers the specific consumables for robotic surgery and the maintenance/service for the robotic equipment (no coverage of the capital costs).

Regulatory and legal challenges:

At this moment there are no managed-entry agreements (MEA) for medical devices in Romania, these MEAs are functioning only for certain drugs.

FUTURE CHANGES

The forecasted health authorities' plans for changes in medical devices financing and reimbursement system are the following:

- Implementation of EU HTA Regulation, including Managed Entry Agreements for MD (after the "localization" of the EU HTA Regulation for drugs).
- Increased emphasis on Value Based Procurement and better/clearer market consultation regarding MD acquisitions.
- Development of a Public Registry with all MD in use in Romania.
- Introduction of specific reimbursement mechanism for high-value medical devices and technologies.
- More regional & national tenders for MDs (National System for Emergency etc.).
- Development of specific training for the staff of hospitals about public acquisitions.
- Development of a system of operational/financial leasing for high value equipment in public hospitals.

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SLOVAKIA

GENERAL OVERVIEW OF SLOVAK MARKET

POPULATION (2024)

5 422 194

HEALTHCARE EXPENDITURE (2022-2024)

EURO
8.6 BILLION

HEALTHCARE EXPENDITURE (% OF GDP)

7.8%
OF GDP (2022)

SOURCE: *SUSR, MF SR, NCZI*

SK+MED
SLOVENSKÁ ASOCIÁCIA DODÁVATEĽOV ZDRAVOTNÍCKYCH POMÔCOK

The Slovak healthcare system is based on a compulsory public health insurance model that provides universal healthcare coverage to citizens and residents. Healthcare financing is primarily managed through three public health insurance companies, comprising one state-owned and two privately owned insurers, while the Ministry of Health of the Slovak Republic serves as the main regulatory authority. The system combines public and private healthcare providers and is strongly influenced by European Union legislation and regulatory standards. Medical devices represent an increasingly important component of the Slovak healthcare sector due to technological innovation, population ageing, and the growing demand for effective diagnostic and therapeutic solutions.

Medical devices in Slovakia include a broad range of products such as implants, diagnostic equipment, monitoring systems, assistive technologies, and digital health solutions. Their regulation is largely harmonized with the European Union Medical Device Regulation (MDR 2017/745), which establishes strict requirements for safety, quality, clinical evaluation, and post-market surveillance. The reimbursement and market access pathway for medical devices in Slovakia is closely linked to health technology assessment (HTA) and public health insurance reimbursement mechanisms.

Despite ongoing modernization efforts, the Slovak healthcare system faces several challenges related to medical devices, including limited healthcare funding, regional inequalities in access to innovative technologies, lengthy reimbursement procedures, and administrative burdens associated with MDR implementation. Nevertheless, the increasing emphasis on digitalization, patient safety, and valuebased healthcare creates opportunities for innovation and wider adoption of advanced medical technologies within the Slovak healthcare.

Yours sincerely,

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LEGAL FRAMEWORK FOR PUBLIC FUNDING OF MEDICAL DEVICES

Public financing of medical devices is primarily regulated by:

- [■] **Act No. 363/2011 Coll.** – on reimbursement of medicines, **medical devices**, and dietetic foods.
- [■] **Act No. 577/2004 Coll.** – defines what healthcare is covered by public insurance.
- [■] **Act No. 580/2004 Coll.** – health insurance system.

GENERAL INFORMATION ABOUT THE HEALTHCARE SYSTEM

How does the healthcare system work?

Slovakia's healthcare system is based on **universal coverage through mandatory health insurance**, offering access to most medical services for all residents who contribute to the system. It combines **public social health insurance** with a **mix of public and private providers**, and while coverage is broad, patients often face co-payments or waiting times.

Structure and Administration:

The system is built on **social health insurance**, managed primarily by three insurance companies:

- **Všeobecná zdravotná poisťovňa (VšZP)** – state-run, largest insurer,
- **Dôvera zdravotná poisťovňa (Dôvera)** – private,
- **Union zdravotná poisťovňa (Union)** – private.

These insurers collect contributions, contract healthcare providers, and reimburse costs for covered services. Oversight and policy-making fall under the Ministry of Health, while the Health Care Surveillance Authority monitors the insurance market and service quality.

Financing and Contributions:

Healthcare is funded mainly by **mandatory contributions** from employers and employees:

- **Employer:** 10% of gross salary,
- **Employee:** 4% of gross salary,
- This totals 14%, automatically deducted from payroll.

Public spending on health equals roughly **8.3% of GDP** (2024), while **out-of-pocket payments (OOP)** – like co-pays for medication, dental care, or private services – account for about **18.7% of total health expenditure, disproportionately affecting low-income residents**.

Coverage and Access:

All insured individuals are entitled to a "basic benefit package" covering:

- General practitioner (GP) and specialist visits,
- Hospital and emergency care,
- Surgeries, rehabilitation, and maternity care,
- Prescribed medications (partially or fully covered),
- Preventive services and vaccinations.

Patients can choose their GP and specialist, as long as the provider has a contract with their insurance company. For non-contracted or fully private clinics, patients pay full costs themselves.
Slovakia's model ensures broad coverage and legally mandated access but depends on balancing rising healthcare demands with financial sustainability – a challenge shared by many.

What are the main sources of healthcare funding?

The healthcare system in Slovakia is primarily funded through a mix of public and private sources, with a strong emphasis on mandatory health insurance. Here are the main funding streams:

Mandatory Health Insurance Contributions (Primary Source): This is the **largest and most important funding source**. Contributions are compulsory for most residents. Paid by: employees (a percentage of salary), Employers (a larger percentage on top of wages), Self-employed individuals, The state (on behalf of certain groups like children, students, pensioners, unemployed). These contributions go to health insurance companies such as Všeobecná zdravotná poisťovňa, Dôvera zdravotná poisťovňa, and Union zdravotná poisťovňa.

State Budget Transfers: The government contributes directly from the national budget. Mainly covers: people who do not pay contributions themselves (e.g. children, pensioners), Public health programs (vaccination, disease prevention, etc.).

Out-of-Pocket Payments: Patients pay directly for certain services, such as: some medications (co-payments), dental services, optional or non-covered treatments. These payments are relatively moderate but still significant.

Private Voluntary Insurance (Supplementary): Less common than in some other countries. Used to: access faster care, cover services not fully reimbursed by public insurance.

EU and Other External Funding: European Union funds contribute to: healthcare infrastructure, digitalization projects, modernization of hospitals.

What is the role of state, private sector and other entities in healthcare funding? What are key differences between public and private funding approaches? How these sectors interact within the system?

Roles in healthcare funding:

State (government) – the state plays a central coordinating and financing role: regulator & policymaker.

Sets rules (coverage, pricing, reimbursement, standards) through the Ministry of Health.

Financier (indirect + direct) – pays health insurance contributions for non-working groups, funds public hospitals, infrastructure, salaries, investments, occasionally covers hospital debt or injects extra funding. Ensures equity – guarantees universal access regardless of income (solidarity principle).

Private sector – Includes private insurers, providers, and investors:
Health insurance companies – collect contributions and pay providers, in Slovakia: mix of state-owned + private insurers.

Healthcare providers (clinics, hospitals) – deliver services (often under contracts with insurers), offer faster or specialized services (e.g., dental, elective procedures).

Investors & companies – expand capacity where public system is limited, respond to demand for higher quality/shorter waits. Private sector brings efficiency, innovation, and additional capacity, but is often profit-driven.

Other entities (households, NGOs, employers) – households (patients), pay out-of--pocket costs (co-payments, uncovered services). Can purchase additional voluntary services

Employers – pay a large share of insurance contributions (e.g., ~10% of wages).

Key differences: public vs private funding

ASPECT	Public funding	Private funding
Source	Taxes + mandatory insurance contributions	Out-of-pocket payments, voluntary insurance
Goal	Equity, universal access	Profit, responsiveness, choice
Access	Based on need (universal coverage)	Based on ability/willingness to pay
Cost to patient	Low or free at point of use	Higher direct payments
Efficiency	Can be bureaucratic, slower	Often faster, more flexible
Service quality perception	Standardized, sometimes long waits	Often higher comfort, shorter waits

Core distinction:

- Public = **solidarity + risk pooling**
- Private = **market-based + individual choice**

Interaction of sectors in Slovakia
Slovakia is a **hybrid (mixed) system** combining elements of Bismarck (insurance-based) and public systems.

Core mechanism: mandatory health insurance

- Everyone must be insured
- Contributions come from:
  - employees + employers,
  - state (for non-workers).

Funds are pooled in **health insurance companies** (public + private).

RULES OF PUBLIC FINANCING FOR MEDICAL DEVICES

Basic principle: reimbursement only after "categorization".
A medical device is publicly funded **only if it is officially approved for reimbursement**.

Step-by-step listing process:

1. **Registration:**
   - Device must be: CE-marked (EU rules), Notified to the Slovak authority (ŠÚKL)
   - Ensures **safety, quality, and compliance**

   Registration ≠ reimbursement
2. **Categorization (KEY step):**
   - Managed by the **Ministry of Health** – determines whether the device: is reimbursed, is not reimbursed, is partially reimbursed

Only **categorized devices** are paid (fully or partly) from public health insurance. Public financing is part of the **mandatory health insurance system**, governed by Slovak law and aligned with EU regulations. The system is supervised mainly by Ministry of Health and State institute for drug control.

Basic Principle: Medical devices are **covered from public health insurance** if they are medically necessary, prescribed by a doctor, included in the official reimbursement list. If these conditions are not met → the patient must pay fully.

Categorization and Reimbursement List: Devices are listed in the **"Kategorizačný zoznam zdravotníckych pomôcok"** (Categorisation List). **This list defines:**

- which devices are reimbursed,
- maximum reimbursement price,
- indications (diagnoses) for coverage,
- prescription restrictions (who can prescribe).

Levels of Reimbursement: There are three main financing levels:
Fully covered devices: Insurance pays 100% – patient pays nothing.

Devices available *on request*:

Process: patient decides to purchase, no doctor visit is required. The person identifies a need (e.g., checking temperature or blood pressure).

1. Visit to pharmacy or medical supply store ,devices are sold in:
   - pharmacies (lekáreň)
   - specialized shops (výdajne zdravotníckych pomôcok)
2. Basic consultation (optional) a pharmacist may:
   - recommend a suitable product
   - explain correct usage
3. Direct purchase and payment
   - patient pays full price
   - no insurance reimbursement
4. Home use – device is used independently (self-monitoring or minor care).

Devices available in pharmacies *on prescription* (na poukaz):

Process:

1. Medical examination:
   - patient visits a general practitioner or specialist
   - doctor diagnoses a condition (e.g., diabetes, mobility issue)
   - issuing of prescription (poukaz) – doctor prescribes a specific device

   The prescription includes: device type, quantity, insurance category (full/partial reimbursement).
2. Insurance approval (if required):
   - some devices (e.g., wheelchairs, CPAP machines) need prior approval from the insurance company
   - others are automatically approved

   Visit to dispensing provider – patient goes to: pharmacy OR, specialized medical device provider, device dispensing – staff verifies prescription, provides the device, explains usage and maintenance.
   Payment Insurance covers all or part of the cost, patient pays any co-payment.

Devices used in hospital procedures:

These involve a multi-step clinical and regulatory **process:**

A. **Before the procedure:**

1. Referral and diagnosis
   - patient is referred to a hospital or specialist clinic
   - diagnostic devices (e.g., imaging) confirm the condition
2. Indication for device use

   Doctor decides that a device is needed (e.g., implant, ventilator support).
   Approval and planning – for expensive devices (implants), approval may involve: hospital administration, health insurance provider.

B. During the procedure – Preparation – Device is selected and checked, must meet EU safety standards (CE marking under MDR), use by trained professionals – only qualified staff handle devices: surgeons, anesthesiologists, nurses.

C. After the procedure – Post-operative care – Monitoring with devices (ECG, vital signs monitors), device performance is checked. Documentation – device use is recorded in patient records, traceability is required (especially for implants).

D. Payment and regulation – Costs are covered by public health insurance. Hospitals are reimbursed through national healthcare system. Oversight is provided by: National Institute for drug control, EU Medical Device Regulation (MDR).

Key Differences in Process

STEP	ON REQUEST	ON PRESCRIPTION	HOSPITAL USE
Doctor involved	☒	☑	☑
Insurance involvement	☒	☑	☑
Professional supervision	☒	Partial	Full
Setting	Home	Home	Hospital
Approval process	None	Sometimes	Complex

CURRENT CHALLENGES

What are the current key challenges and obstacles faced in the public financing of a medical devices system in a country?

Lack of transparency and inefficient allocation of funds. Audits by the Supreme Audit Office show that Slovakia struggles to track how public healthcare funds translate into actual patient outcomes. Reimbursement systems are complex, fragmented, and non-transparent, with insurers using different payment models and contract amendments that are difficult to compare.

Impact on medical devices:

- difficult to assess whether expensive devices deliver value for money.
- weak incentives for cost-effectiveness or outcome-based procurement.
- risk of overpaying or misallocating budgets.

Fragmented and complex reimbursement processes: Medical devices must go through registration and categorization processes, which are less standardized and less rigorous than for pharmaceuticals. Reimbursement decisions are not always frequent or predictable. The impacts include delays in access to innovative devices, administrative burden for manufacturers and providers, and uncertainty in long-term planning and budgeting.

Rising costs vs. limited fiscal space: Medical devices are often imported at global prices, which places disproportionate pressure on lower-GDP countries like Slovakia. Hospitals already operate under financial strain and recurring debt cycles. The impact is that budget constraints limit adoption of advanced technologies, creating pressure to choose cheaper (possibly lower-quality or outdated) devices and generating tension between innovation and affordability.

Hospital debt and weak capital investment planning: Slovak hospitals regularly accumulate debt, and funding often focuses on short--term fixes rather than systemic reform. There is a need for continuous renewal of medical equipment, but financing is inconsistent. The impacts include outdated or insufficient medical equipment, delayed replacement cycles for devices, and inefficient procurement practices.

Demographic pressure and financing sustainability: Around 70% of healthcare funding comes from wage-based contributions, making the system vulnerable to population ageing. Impact: future funding shortages, Reduced ability to invest in expensive technologies, Growing tension between demand and available resources.

Weak data, evaluation, and health technology assessment (HTA) capacity: Although institutions like NIHO exist, system-wide evaluation of cost-effectiveness and outcomes is still evolving. Impact: Limited evidence-based prioritization of devices, Slower adoption of innovative but cost-effective technologies, risk of funding low-value interventions.

FUTURE CHANGES

Are there plans for changes in medical device financing system in Slovakia that will impact the financing and reimbursement system of medical devices?

In Slovakia, there are several ongoing and planned reforms that will directly or indirectly impact the financing and reimbursement of medical devices. However, it is important to understand that most changes are systemic (health financing, HTA, procurement, hospital funding) rather than device-specific. Together, they will still significantly reshape how medical devices are funded and reimbursed.

Below is a clear breakdown of the most relevant current and upcoming changes (2024–2026):

Amendment to reimbursement legislation (Act No. 363/2011)
Slovakia is actively working on amendments to the core law governing reimbursement of medicines and medical devices. Stakeholders (e.g., industry, Ministry of Health) have been negotiating changes throughout 2025. Expected impact:

- Greater transparency and predictability in reimbursement decisions
- Possible tightening of cost-effectiveness and evidence requirements
- More structured processes for including devices in reimbursement lists

This is one of the most important reforms directly affecting medical devices.

Strengthening Health Technology Assessment (HTA) via NIHO
Since 2024, new mandatory methodological guidelines for reimbursement submissions have been introduced. These aim to standardize dossiers and improve evaluation quality.

Expected impact: More evidence-based reimbursement decisions, Increased importance of cost-effectiveness and clinical value, Likely longer but more predictable approval processes. For medical devices, this means harder entry for low-evidence products and better positioning for innovative, high-value technologies.

Hospital financing reform (DRG and payment rates – 2026)
Slovakia is introducing new hospital payment structures and DRG-based financing reforms supported by the EU. New hospital base rates and funding models are being rolled out for 2026. Expected impact on devices: hospitals will face stronger cost controls, Increased pressure to use cost-effective devices and optimize procurement decisions. Potential shift toward bundled payments, where devices are included in procedure reimbursement.

Tax reform: Reduced VAT on medical devices (since 2025)
VAT on selected medical devices dropped to 5%, but others remain on 23% VAT and some on 19% VAT.

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SUPPLEMENT WITH SIMPLIFIED FUNDING INFORMATION

What requirements must be met in order to sell a medical device that is funded from public sources?

CZECH REPUBLIC

- Products to out-patients – reimbursed:
    - Inclusion in the Competent Authority reimbursement catalogue.
    - Compliance with price regulation.
- Products to out-patients – sales:
    - Patients can obtain these products also if they were not prescribed any, and pay in full.
    - Patients can buy additional amounts of medical devices, if their need exceeds the prescription limits.
    - Even in case of direct purchase of the patient, price regulation applies.
- Sale to hospitals:
    - Hospitals are free to buy any (regulatory approved) medical devices as they wish.
    - The hospitals prefer products that are listed in the reimbursement catalogue as they can declare the use of such to the sickness fund.

POLAND

- Sale to patients:
    - Medical devices available on request: inclusion of the relevant device category in the Regulation of the Minister of Health.
      This applies to prostheses, orthoses, corsets, orthopaedic footwear, compression devices, optical devices, hearing aids, glycaemic control devices, mobility disability devices, tracheostomy devices, respiratory aids, stoma devices, urinary incontinence devices, breast prostheses, post-operative or breast prosthesis bras, wigs, fabric stump stockings, PT/INR measuring device and straps for this device.
    - Medical devices available in pharmacies on prescription: an individual decision of the Minister of Health.

      This applies to injector needles, blood glucose meter strips and wound dressings.
- Sale to hospitals:
    - As a rule, participation in a tender procedure and compliance with the tender requirements.

      This applies to all medical devices, including medical equipment.

ROMANIA

- Sale to patients:
  - Medical devices with prescriptions are totally or partially covered by the National Health Insurance Fund for some categories of patients and diseases (e.g. diabetes) with inclusion of the device on a List based on a decision from the Minister of Health and National Health Insurance Fund. This applies to several therapeutical areas and a lot of medical devices (auditive prothesis, orthoses, stomas, wheelchairs, glycemic control devices, mobility disability devices, tracheostomy devices, respiratory aids, etc.
  - Medical devices are paid out of pocket if not included in the list of National Health Insurance Fund or the patient has not a valid prescription.
- Sale to hospitals (applies to all medical devices, including medical equipment):
  - In public hospitals, participation in a public tender procedure and compliance with the tender requirements for public acquisitions.
  - For private hospitals there are no compulsory requirements regarding acquisition procedures.

SLOVAKIA

To sell a medical device with public funding (i.e. reimbursement from public health insurance) in Slovakia, the company need to meet two layers of requirements:

- **Basic market access (placing the device on the market)**

  Before even thinking about funding, the device must be legally sold in Slovakia.

  Key requirements: CE marking + EU compliance (under MDR / EU rules), Technical documentation proving safety, performance, quality, EU Declaration of Conformity, Registration / notification with ŠÚKL (State Institute for Drug Control).

  Notification to ŠÚKL must include: Notification form (in Slovak), Declaration of conformity + certificates, Instructions for use (in Slovak), Labeling in Slovak, Technical documentation (if required).

- **Additional requirement for PUBLIC FUNDING (reimbursement)**

  To be paid from public health insurance, registration alone is NOT enough.

  Company must go through the "categorization / reimbursement system."

  included in the reimbursement system ("categorized"). This is governed mainly by: Act No. 363/2011 Coll. (pricing & reimbursement), Public health insurance legislation. Only categorized devices are reimbursed (fully or partially).

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