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DIGIVITALITY

Country-level Action plan on public financing of digital Healthcare solutions

Czech Republic

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STRENGTHENING EVIDENCE, INTEGRATION AND FINANCING FOR DIGITAL MEDICAL DEVICES IN THE CZECH REPUBLIC

A practical framework for improving assessment, integration and adoption of digital health technologies within the public healthcare system

Summary

- Digital medical devices have the potential to enhance the capabilities of the Czech healthcare system, particularly with regard to caring for patients with chronic conditions and an ageing population.
- However, the existing legislative framework (comprising Act No. 48/1997 Coll., Act No. 289/2025 Coll., the new Act on the Categorisation of Medical Devices, the National eHealth Strategy, and AI methodological guidance) does not yet provide a unified, transparent, and practical pathway for the assessment, integration, and public financing of digital medical devices.
- Currently, digital solutions are channelled through general mechanisms (reimbursement of services, separately reimbursed material and prescription of medical devices), which were originally designed for other types of technology and are not well suited to software.
- Stakeholders have identified five key barriers: 1) MDR/AI governance uncertainty; 2) integration challenges within certified hospital information systems; 3) unclear reimbursement pathways; 4) an absence of standardised evidence requirements; and 5) procurement processes not adapted to software.
- These barriers are primarily procedural and organisational rather than technological, meaning they can be addressed without major legislative changes.
- The Action Plan therefore proposes four feasible steps: a practical national MDR–evidence–financing guideline; a small regulatory/testing sandbox; outcome-based pilot agreements; and a procurement metrics pack for digital solutions.
- In the medium term, it would be appropriate to open a discussion on more structured, accelerated pathways for digital medical devices, inspired by international examples such as DiGA, mHealthBelgium and PECAN.

Purpose of the Action Plan

This Action Plan sets out priority steps to improve conditions for assessing, integrating and publicly financing digital medical devices in the Czech Republic. Rather than proposing legislative reform, it aims to provide a practical and feasible operational framework. The proposed measures aim to make processes for digital solutions more predictable, transparent and efficient, enhancing the accessibility and quality of care within the public health insurance system.

The document is primarily addressed to national stakeholders responsible for regulation, reimbursement and innovation adoption in the Czech healthcare system, including the Ministry of Health, health insurance funds, healthcare providers, professional organisations and technological innovators. The Action Plan is based on expert consultations with these stakeholders and reflects their needs and expectations, as well as the constraints of the current system.

Context and current state in the Czech Republic

The Czech Republic is gradually transforming its healthcare system digitally, guided by the updated National eHealth Strategy, which sets out milestones extending to 2035. This strategic framework encompasses electronic documentation, data sharing, security, interoperability, and the development of contemporary digital services. The urgency of these goals is increasing due to demographic pressures: people aged 65 and over now represent around 20.5% of the population (approximately 2.25 million people), significantly outnumbering children under 15. This ageing trend is increasing the demand for stable, accessible and efficient healthcare, particularly for chronic and long-term conditions[1].

Although the Czech reimbursement system for healthcare and medical devices is well established, it was not originally designed with digital technologies in mind. While national regulations define the financing of traditional medical services and devices, they do not yet provide a clear or practical framework for modern digital tools, such as software-based medical devices or telemedicine solutions. Consequently, these technologies currently have to fit into older, more generic processes created for physical devices or conventional services, which often do not align with the way digital solutions operate or evolve[2].

Consequently, healthcare providers, insurers, and technology developers encounter several systemic uncertainties, including unclear software classification under the MDR, difficulties in integrating digital tools into certified hospital information systems, fragmented financing options, an absence of standardised evidence requirements, and procurement processes that are not suited to software. These factors impede the wider adoption of digital medical devices

[1] csu.gov.cz/seniori-v-datech/vekova-strukturaction

[2] Based on the current Czech regulatory framework governing reimbursement of healthcare services and medical devices, in particular Act No. 48/1997 Coll. on Public Health Insurance and its amendment Act No. 289/2025 Coll., as well as national implementation of MDR/IVDR and the Act on the Categorisation of Medical Devices. These instruments do not specify dedicated procedures for digital or software-based medical devices.

at a time when an ageing population and an increasing number of chronically ill patients are putting pressure on the healthcare system to deliver care more efficiently.

Identified barriers and proposed action steps:

Following an expert consultation a set of concrete barriers that currently hinder the wider adoption of digital medical devices within the Czech public healthcare system were identified[3]. These barriers are primarily procedural and organisational, rather than technological. The action steps outlined below can be implemented within the existing legislative framework.

Barrier 1: uncertainty in MDR classification and AI governance

Problem description: Manufacturers, providers and payers face persistent uncertainty regarding the classification of software as a medical device, how to define its intended purpose, how to validate updates and version changes, and how to ensure compliance with AI governance requirements such as transparency, human oversight and risk management. The absence of a practical interpretative guide slows down the adoption process and increases the risk of incorrect classification.

Proposed action: Develop a concise, practical MDR–AI–evidence guideline for digital medical devices. This would provide a clear, user-friendly overview of MDR obligations, evidence requirements and financing options within the Czech reimbursement system.

Potential roles of stakeholders:

- The Ministry of Health: methodological leadership.
- Institute of Health Information and Statistics of the Czech Republic (ÚZIS): alignment with national data standards and data governance frameworks; methodological input for evidence requirements.
- State Institute for Drug Control: regulatory interpretation and MDR compliance.
- Health Insurance Funds: alignment of evidence expectations.
- Professional societies/academia: expert input and validation.

Barrier 2: Integration hurdles in certified hospital information systems (HIS).

Problem description: Hospitals must protect the integrity of their certified HIS environments. Therefore, integrating new digital tools is often perceived as risky, technically demanding and

[3] The working group was established within the Interreg Central Europe project, DIGIVITALITY, which aims to improve the availability and uptake of digital health solutions within public healthcare systems across Central Europe. The Czech working group comprised representatives from the Ministry of Health, the State Institute for Drug Control, health insurance funds, hospitals, and other healthcare providers, as well as academic and university experts.

costly. Currently, there is no standardised set of minimum interoperability requirements, no testing environment, and no clear process for safely connecting digital tools.

Proposed action: Establish a safe testing/regulatory sandbox that allows digital solutions to be tested outside production HIS environments (2–3 priority use cases per year).

Potential roles of stakeholders:

- The Ministry of Health: coordination and regulatory oversight.
- Institute of Health Information and Statistics (ÚZIS): development and maintenance of interoperability standards; coordination with the national eHealth architecture.
- Selected pilot hospitals/healthcare providers: operational implementation.
- HIS vendors: technical cooperation and interoperability support.
- National eHealth Centre: integration standards.

Barrier 3: unclear and fragmented financing pathways

Problem description: Digital solutions currently fall under traditional reimbursement mechanisms (healthcare services, separately reimbursed material, and prescription-based medical devices), none of which were designed for software. Clear entry requirements, evidence standards, timelines and predictability are lacking.

Proposed action: Introduce structured, outcome-based pilot agreements between payers and providers using predefined metrics and transparent evaluation protocols.

Potential roles of stakeholders:

- Health Insurance Funds: design and execution of pilots.
- Healthcare providers: implementation and data collection.
- The Ministry of Health will ensure methodological consistency.
- Institute of Health Information and Statistics of the Czech Republic (ÚZIS): analytical support, monitoring frameworks and methodologies using national health data.

Barrier 4: lack of standardised evidence requirements and metrics.

Problem description: There is no standardised set of endpoints, proof of concept (PoC) protocols or acceptability criteria to guide decisions on digital medical devices. This results in inconsistent requirements for developers, as well as uncertainty for providers and payers.

Proposed action: Create an Evidence & Metrics Pack containing baseline clinical, process and technical indicators; minimum real-world evidence and patient-reported outcomes requirements; and guidance for short PoC studies.

Potential roles of stakeholders:

- Health insurance funds: definition of decision-making criteria.
- Professional medical societies: clinical endpoints.
- Academia/research institutions: methodology and real-world evidence guidance.
- The Ministry of Health is responsible for validation and publication.
- Institute of Health Information and Statistics of the Czech Republic (ÚZIS): data standards, technical specifications for real-world evidence collections, validation of indicators within national datasets.

Barrier 5: Procurement processes not adapted to software.

Problem description: Historically, public procurement templates and contractual standards have been geared towards hardware. However, software requires different lifecycle management, contractual structures and operational guarantees, including continuous updates, cybersecurity and audit trails.

Proposed action: Develop a software-specific procurement metrics pack for hospitals, including interoperability, cybersecurity, release management, SLA parameters and governance requirements.

Potential roles of stakeholders:

- Ministry of Health: creation of a methodological template.
- Hospitals/healthcare providers: adoption into procurement practice.
- The Ministry of Regional Development's Public Procurement Department will ensure procedural compliance.
- Cybersecurity authorities: cybersecurity standards.
- HIS vendors and industry associations: technical feasibility review.
- Institute of Health Information and Statistics of the Czech Republic (ÚZIS): ensuring alignment with national data, interoperability and semantic standards; technical input into procurement criteria where relevant.