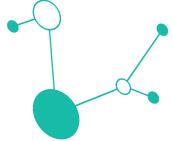


DIGIVITALITY

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

Slovakia





# ACCELERATION OF DIGITAL SOLUTIONS IN SLOVAKIA

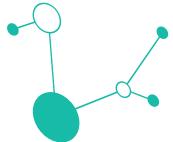
*Proposal for Fundamental Changes for Gradual Development of Systematic Financing of Digital Solutions from Public Health Insurance Resources*

## Summary

- Digital health apps brings effective solutions to key challenges in Slovak healthcare.
- It enables existing healthcare personnel to serve a larger number of patients. Remote monitoring and prevention reduce the need for doctor visits and the number of (re)hospitalizations.
- Current barriers to the expansion of digital solutions include **the absence of legal certainty in the process of categorizing medical devices** due to missing interpretations in legislation and **a lack of information about the requirements of the categorization process in a user-accessible format**.
- The first step aims to eliminate barriers that can be considered "low-hanging fruit" through **the proposed changes** - these are not politically costly structural reforms. Their removal will simplify the entry of additional digital solutions into Slovak healthcare.
- In the second step, we recommend to establish working group and develop feasibility study at the Ministry of Health to evaluate and recommended suitable concept for financing digital solutions based on the best practices from abroad.

## Why are we bringing up the topic of acceleration of digital solutions?:

Telemedicine solutions and digital therapeutics represent an effective tool for alleviating the burden of patients on healthcare personnel capacity and improving healthcare accessibility for



patients. Current challenges in the form of growth in patients from high-risk groups, including elderly people and people with chronic diseases, will continue to increase with population aging.

Despite demonstrable benefits for patients and reduced care costs and the growing use of telemedicine worldwide, Slovakia lags in creating conditions for successful implementation of digital solutions that would be reimbursed to patients from public health insurance.

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## Current State:

Currently, only basic forms of telemedicine are financed from public resources (telephone consultations, prescription issuance, and some telemedicine outpatient procedures for evaluating continuous monitoring of diabetics). **More sophisticated forms (remote monitoring of vital functions, mobile applications) have no systematic financing either from the perspective of healthcare provider services or from the technology itself as a medical device, which is the fundamental barrier to their wider availability for patients and bringing savings for healthcare personnel.** If some sophisticated solutions function in practice, they are usually individual "pilot" projects that patients finance in full, and their development is typically financed by insurance companies from their own resources.

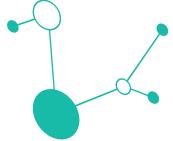
For a patient to receive reimbursement from a health insurance company for using a digital therapeutic, this digital solution must be included in the list of categorized medical devices, and the health service performed by this digital solution must be included in the NCZI registry.

**The success of telemedicine solutions is also influenced by the digital skills of the population.** 55% of Slovaks have basic digital skills, which is only slightly below the EU average. A greater challenge appears to be the use of telemedicine by seniors, where an estimated 11% of seniors are digitally skilled, while the EU average is 24%. This challenge can be easily addressed through support staff in social service facilities, which are currently used by approximately 34,000 seniors.

**The working group<sup>1</sup> identified the following procedural barriers and solutions to increase the availability of telemedicine for patients, which can be considered low-hanging fruit and whose implementation does not require structural and politically demanding reforms. In the second step,**

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<sup>1</sup>The working group is the result of the Interreg project [DIGIVITALITY](#) whose goal is to increase the availability of digital therapeutics from public health insurance in Central European countries. The working group includes the Ministry of Health of the Slovak Republic, the Association of Health Insurance Companies of the Slovak Republic, General Health Insurance Company (Všeobecná zdravotná poistovňa), Dôvera Health Insurance Company, Union Health Insurance Company, an expert on value and technologies in healthcare, and representatives from the companies Goldmann Systems and Line4health.



the working group recommends opening a discussion at the Ministry of Health about creating an accelerated regime for telemedicine solutions based on best practices from abroad.

## Barriers and Proposed Action Steps:

- **Barrier:** The definition of a medical device in legislation today does not contain the term "remote monitoring" or "digital application". Legislation contains the term software. There is a need for additional explanation by Ministry of health providing the sufficient legislative certainty that software includes also digital applications and remote monitoring solution.
  - Action:** Provide additional explanation to Act No. 363/2011 that will provide sufficient legal certainty that term software includes also medical devices including remote monitoring solutions or digital applications.
  - Responsibility:** Pharmacy and Drug Policy Section at the Ministry of Health of the Slovak republic.
- **Barrier:** Every medical device today is dispensed through pharmacies or medical device dispensaries.
  - Action:** For remote monitoring solutions or digital applications, it is necessary to introduce the possibility of electronic dispensing, i.e., something like a virtual dispensary, or alternatively, dispensing directly by healthcare providers (outpatient or during hospitalization), similar to how certain medications like vaccines are provided today.
  - Responsibility:** Pharmacy and Drug Policy Section at the Ministry of Health of the Slovak republic.
- **Barrier:** Absence of basic information about the categorization process in a user-accessible format. Digital applications and remote monitoring solutions today also emerge outside the healthcare system. The categorization process is very complex and current practice shows that digital app developers outside the healthcare can only navigate complex categorization process with help by obtaining contacts directly from healthcare experts.
  - Action:** Provide a process map on the Ministry of Health of the Slovak Republic website in a user-accessible format that will contain the necessary administrative steps, regulatory requirements, and a list of institutions involved in the categorization process. Inspiration for the process map could look as follows, ideally it should be interactive and by clicking on each step, the specific process would be described, including the institution and its role in the process.
  - Responsibility:** Pharmacy and Drug Policy Section at the Ministry of Health of the Slovak republic.