Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Slovak Republic

Wolf Theiss

Introduction

A number of factors cause delays in market entries and restrict access to the supply chain in the Slovak Republic. The complexity of the regulatory pathway and the need to submit extensive documentation can be challenging, particularly for smaller companies or new products. The intricacies of regulatory requirements, including the language requirements for documentation, create administrative burdens. Additionally, meeting conformity assessment and compliance requirements before marketing a device may pose challenges, especially if these steps are not completed promptly or correctly.

Reimbursement schemes exist for various types of distribution, from hospitals and pharmacies to tailor-made devices. Reimbursement costs, however, are often limited to the cost of cheaper products or are set by the authorities. Advertising of medical devices is subject to fewer restrictions compared to medicinal products and is governed by the general provisions for all products.

The regulation for the provision of healthcare services via electronic communication technologies was adopted back in 2020 and electronic prescription systems have been regulated since 2018. However, despite their growing use in practice, telemedicine devices and software are not fully regulated.

1. What are the biggest challenges your country is facing in terms of ensuring the smooth implementation of Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), as well as fostering the growth of the medical devices market?

	Stricter standards compared to previous regulations
	Increased costs (such as re-certifying existing products, conducting additional clinical evaluations and updating technical documentation)
X	Lack of sufficient number / limited access to notified bodies / notified body bottlenecks
	Partial / incomplete implementation of MDR/IVDR
	Stricter /Additional requirements at national level
X	Slower approval process
	Supply chain disruptions due to delays in certifying certain devices
X	Supply chain disruptions due to COVID-19, Ukraine war, etc.
	Enterprises consider MDR/IVDR and/or national implementing regulations as a disincentive to launching innovation in your country / the EU in general
X	Delays in innovation / access to new devices / new technologies in general
	SME vulnerability
	Shortage of expertise and resources
	Other example(s)

Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on Amendments and Supplements to Certain Acts, has been amended several times to implement the Medical Devices Regulation (MDR) and in vitro diagnostic medical devices regulation (IVDR) of the European Union. These regulations were implemented gradually through three amendments, which came into effect in 2020, 2021 and 2023. The amendments aimed to harmonise requirements for compliance, risk management and conformity assessment of medical devices, in order to enhance patient protection and ensure the safety and transparency of these devices.

Currently, there is only one notified body in the Slovak Republic that is designated for both MDR and IVDR compliance – 3EC International. This organisation is responsible for the conformity assessment of medical devices under MDR and IVDR regulations. Its role is to verify that medical devices meet stringent requirements for safety, quality and performance, thereby ensuring that they can be marketed and used in the Slovak Republic and across the European Union (EU). The organisation's work supports vigilance processes and helps maintain supply chain stability for medical devices.

2. What are the regulatory authorities and enforcement mechanisms for the medical device market in your jurisdiction?

The State Institute for Drug Control (**ŠÚKL**) plays a significant role in ensuring compliance, vigilance and the safety of medical devices and in vitro diagnostic medical devices. Its primary activities include maintaining the national register of medical devices. Distributors responsible for making devices available on the market are registered for a period of five years. The ŠÚKL also verifies the accuracy and compliance of data that is submitted to the electronic registration system by manufacturers, authorised representatives and importers.

Furthermore, the ŠÚKL fulfils the role of regulatory authority of a Member State. This includes overseeing clinical evaluations, conducting health technology assessments (HTA) and ensuring risk management during market surveillance of medical devices. The institute is also responsible for the conformity assessment of diagnostic in vitro medical devices through performance studies and for vigilance to monitor adverse events.

In addition to its national activities, the ŠÚKL actively cooperates with EU Member States to address supply chain disruptions, ensure proper risk classification and promote the safe and effective use of medical devices, thereby protecting public health.

Responsibility for notified bodies lies with the Slovak Office of Standards, Metrology and Testing, which oversees their authorisation, notification and regulatory pathways to meet EU obligations. This ensures alignment with Medical Devices Regulation (MDR) and compliance with the Product Liability Directive for safe market entry.

3. What are the key market access challenges and requirements for medical devices in your jurisdiction, including reimbursement, regulatory approvals and potential barriers to entry?

Placing medical devices on the market

In order to market a medical device or an in vitro diagnostic medical device in the Slovak Republic, several legal and safety requirements must be met. According to Act No. 362/2011 Coll. on Medicinal Products and Medical Devices, manufacturers must ensure that devices are correctly installed, maintained and used in compliance with their intended purpose, thus ensuring safety and avoiding adverse events for patients or users. During exhibitions and trade fairs, in vitro diagnostic medical devices that do not yet meet regulatory compliance may be displayed, provided there is a visible notice stating that their use will be allowed only after meeting the regulatory requirements. Marketing mercury thermometers for measuring body temperature and sphygmomanometers for the general public, for instance, is prohibited.

Before placing a device on the market, a manufacturer, authorised representative, importer or distributor must notify the ŠÚKL within 14 days of the device becoming available on the market. This process involves submitting the necessary documentation, such as the EU Declaration of Conformity, conformity assessment certificate and instructions for use. The obligation to provide documentation does not apply to Class I medical devices or Class A in vitro diagnostic medical devices, unless requested by the ŠÚKL.

The ŠÚKL oversees the national register of medical devices and conducts vigilance activities, including the notification and registration of medical devices. After a device is placed on the market, the ŠÚKL assigns a unique code to the device and updates the database.

Reimbursement of medical devices

Medical devices provided in hospitals are fully reimbursed, except for those listed in special schedules. If interchangeable devices are available, reimbursement is limited to the cost of the least expensive device.

In outpatient care, medical devices included in the categorised medical devices list may be fully or partially reimbursed, provided they are prescribed and used in accordance with prescription guidelines, indication limits, quantity restrictions and their cost does not exceed financial limits set by health insurance providers.

In pharmacy care, medical devices listed in the categorised devices list are reimbursed fully or partially under public health insurance if prescribed and used according to restrictions set by health insurance companies, including prior authorisation when necessary.

Custom-made medical devices and special materials are eligible for reimbursement only if they meet certain requirements and are approved by health insurance providers or equivalent bodies.

Barriers to market entry

The complexity of the regulatory pathway and the need to submit extensive documentation can be challenging, particularly for smaller companies or new products. The intricacies of regulatory requirements, including the obligation to provide documentation in Slovak, Czech or English, creates administrative burdens. Additionally, meeting conformity assessment and compliance requirements before marketing a device may pose challenges, especially if these steps are not completed promptly or correctly. Such obstacles can delay market entry and restrict access to the supply chain, impacting the overall distribution of medical devices.

4. What are the specific national regulations related to MDR/IVDR implementation in your jurisdiction?

Language accessibility

In the Slovak Republic, manufacturers, authorised representatives, importers and distributors must ensure that all information accompanying medical devices and in vitro diagnostic medical devices for users and patients is in Slovak. An exception applies to devices intended exclusively for professionals, where labelling may be in English, provided instructions for use are in Slovak.

Availability of categorised medical devices

Manufacturers, authorised representatives and importers of medical devices listed in the national register of medical devices must ensure delivery within 72 hours of receiving an order from a pharmacy. This obligation is essential to ensuring the timely availability of medical devices in critical situations.

Advertising of medical devices

The advertising of medical devices is subject to fewer restrictions compared to medicinal products. While advertisements for medicines are heavily regulated, advertising of medical devices is governed by the general provisions of the Advertising Act. Advertisements must adhere to compliance standards, be truthful, non-misleading and not endanger the health of users, while respecting ethical principles.

Voluntary registration of distributors

The voluntary registration of distributors of medical devices with the ŠÚKL offers the benefit of them being included in the official register, thus enhancing their credibility in the market. Registration, which is valid for five years, ensures adherence to compliance and transparency.

5. What are the specific product liability regulations and potential sanctions for noncompliance with MedTech regulations in your jurisdiction?

In the Slovak Republic, product liability for medical devices primarily rests with manufacturers, who must ensure that their products meet all safety and performance requirements throughout their lifecycle. Additionally, distributors are responsible for ensuring that the medical devices they place on the market comply with regulations, are properly labelled and meet all required standards. If these obligations are not met, distributors may also face civil liability for damages. Furthermore, healthcare providers are responsible for reporting any adverse events involving medical devices or in vitro diagnostic medical devices to the ŠÚKL.

Non-compliance with regulations may lead to administrative fines. The ŠÚKL, as the regulatory authority, has the power to impose fines on manufacturers and distributors who fail to comply with requirements for registration, conformity assessments or product safety. Penalties for non-compliance can reach up to €50,000, depending on the severity of the violation.

If a medical device poses a risk to public health or fails to meet compliance standards, the ŠÚKL can issue an administrative decision to withdraw the product from the market. Manufacturers may also be required to initiate recalls of defective products to protect the public.

Under the Product Liability Directive, manufacturers and distributors are obligated to compensate injured parties for harm caused by defective medical devices. Affected individuals may seek damages for injuries, illnesses or death resulting from product defects.

Severe negligence or fraud, such as falsifying medical devices or endangering users with unsafe products, can lead to criminal liability under the Slovak Criminal Code. These offenses may result in criminal penalties, demonstrating the critical importance of risk management and vigilance throughout the lifecycle of a medical device.

6. What are the regulatory frameworks and market opportunities for telemedicine devices, SaMD (software as medical device) and AI-powered medical devices in your jurisdiction?

Telemedicine in the Slovak Republic is currently not fully regulated. According to the Act on Medicinal Products, a medical device is defined as a tool, instrument, device or software intended for diagnostic, preventive or therapeutic purposes. This framework may include telemedicine devices, but national legislation does not explicitly define the term "telemedicine".

In practice, telemedicine in the Slovak Republic saw significant development during the COVID-19 pandemic. Legislation passed in 2020 allowed the provision of healthcare services via electronic communication technologies, such as telephone or email consultations, eliminating the need for in-person visits to healthcare providers. This form of healthcare delivery requires the verification of the patient's identity and their relationship with a health insurance provider. A notable example of telemedicine implementation was the e-quarantine application, which monitored individuals under quarantine.

Despite its growing implementation, telemedicine remains a widely debated topic in the Slovak Republic. For example, the Slovak Society for Telemedicine and Digital Health, a group of healthcare professionals and physicians, aims to promote the concept of digital health in the country. However, there is still no comprehensive regulatory framework for telemedicine in place, presenting challenges for its further development.

The integration of telemedicine into the Slovak healthcare system has the potential to enhance healthcare delivery, but establishing a clear regulatory pathway and ensuring compliance with national and EU regulations will be crucial for its sustained growth.

AI is a frequently discussed topic. For instance, the hospital in Košice has become the first to utilise AI in emergency departments to identify fractures. The University Hospital in Bratislava also uses advanced, AI-powered robotic technology for complex spinal surgeries. However, the use of AI remains without specific legislative regulation, with oversight currently limited to the EU level.

Author:

Zuzana Hodoňová
Counsel
E zuzana.hodonova@wolftheiss.com
T +421 2 591 012 36