Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Czech Republic

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Introduction

The current regulatory framework based on the MDR/IVDR in the Czech Republic imposes stricter standards compared to previous regulations. Increased costs, bottlenecks due to a shortage of notified bodies and a slower approval process create significant challenges for manufacturers and distributors of medical devices.

Due to delays in the EUDAMED's launch, there are three information systems that are currently operating in the Czech Republic simultaneously, which makes the registration and notification procedure burdensome and time consuming. The national reimbursement system for medical devices lacks flexibility and clarity. A new law on the reimbursement of voucher-based medical devices is set to take effect in 2025; however, no changes are anticipated for the reimbursement of hospital-based devices.

While manufacturers bear primary responsibility for defects, distributors and healthcare providers can also be held liable if they fail to meet their specific obligations. Consumers generally have two years to claim a defect.

The digitalisation of the healthcare system in the Czech Republic has been given a new opportunity with a recent amendment to the Healthcare Services Act. The Act also defines telemedicine services and outlines the basic conditions for offering such services.

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?

X	Stricter standards compared to previous regulations
X	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
	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
X	Shortage of expertise and resources
	Other example(s)

Act No. 375/2022 Coll. on Medical Devices and In Vitro Diagnostic Medical Devices (**"Medical Devices Act"**) replaces the earlier national framework (Act No. 89/2021 Coll., on Medical Devices and Act No. 268/2014 Coll., on In Vitro Diagnostic Medical Devices). This consolidated law seeks to unify and streamline national legislation in the medical devices sector as a whole.

In the Czech Republic there are currently only two notified bodies designated under the MDR: CMI and ITC and none under the IVDR. The notified bodies issue guidelines for medical device manufacturers regarding conformity assessment procedures.

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

The primary regulator of the medical device market in the Czech Republic is the State Institute for Drug Control (SUKL). The SUKL ensures that medical devices comply with EU regulations, including MDR and IVDR. Its key responsibilities include monitoring the safety, efficacy and quality of devices by overseeing registration and managing post-market surveillance to protect public health. The SUKL also collaborates with other regulatory bodies from the bloc to ensure adherence to EU-wide standards.

In order to enforce compliance, the SUKL conducts regular inspections, audits and market surveillance of manufacturers, distributors, importers and healthcare institutions. If violations are found, the SUKL can impose penalties, issue warnings or revoke certifications. In cases of serious non-compliance or safety concerns, the SUKL has the authority to take corrective actions, such as recalling devices, restricting their distribution or prohibiting their sale.

The SUKL maintains a system for healthcare professionals and manufactures to report adverse events related to medical devices and potential risks; it reviews trend reports and, if necessary, notifies manufacturers to take action while informing relevant authorities, including the European Commission. It keeps records of serious adverse events and corrective actions for 15 to 30 years, depending on the severity. If initial safety measures are insufficient, the SUKL can enforce further action and also publicly share safety alerts via the Medical Devices Information System.

The SUKL also handles the adjudication of regulatory offenses, including the collection of fines.

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?

i. Information System for Medical Devices

Due to delays in the EUDAMED's launch, the Czech Republic is currently operating three systems simultaneously. In 2024, the SUKL introduced a new Information System for Medical Devices (**ISZP**) to replace the existing RZPRO system in the future and complement EUDAMED.

The tasks under the Medical Devices Act are managed through the ISZP, including notifications of activities by distributors, service providers, manufacturers of custom-made devices and reporting on the repackaging/relabelling of medical devices. It also includes new modules, such as one for ethical committees, which currently lacks a tracking tool.

Tasks that should be handled through the EUDAMED interface under the MDR and IVDR will remain in the RZPRO system for now, until EUDAMED is fully functional. These processes in RZPRO cover the activities of manufacturers and authorised representatives based in the Czech Republic, importers, clinical evaluation sponsors and the issuance of Free Sale Certificates (FSC).

ii. Reimbursement of Medical Devices in the Czech Republic

Reimbursement for medical devices lacks flexibility and clarity when it comes to two particular device categories:

1. **Voucher-Based Medical Devices:** These devices are prescribed via a medical voucher and covered by public health insurance. A proposed legislative change aims to create a separate law for the categorisation of these devices, allowing for more flexible and timely updates in response to societal and technological developments. The law will include a "categorisation tree", which lists devices eligible for reimbursement based on their indications and technical specifications. This change is expected to take effect on 1 January 2025, although the timeline is uncertain as the proposal is still under review.
2. **Hospital-Based Medical Devices:** This category includes devices used in hospital settings, such as implants, pacemakers and catheters, which are billed directly when healthcare services are provided. Currently, reimbursement for these devices is based on a "catalogue number" system set by health insurers. The Constitutional Court declared this system unconstitutional due to its lack of transparency and procedural clarity. However, no new legislative changes have addressed this issue, leaving a significant gap in the regulation of hospital device reimbursement.

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

The Medical Devices Act and related regulations in the Czech Republic address several key areas:

Borderline Products

The Medical Devices Act incorporates rules regarding decisions on "borderline products", which determine whether a product falls under the MDR or IVDR regulations. The European Commission can also make these determinations through implementing acts.

If a decision by the SUKL conflicts with a European Commission ruling, the new law now requires the SUKL to annul its previous decision automatically (ex officio). Affected parties cannot request this process directly, they can only suggest that the SUKL initiate the proceedings.

Registration of Medical Devices

While the MDR and IVDR require medical device registration at the EU level through the EUDAMED database, distributors in the Czech Republic still have reporting obligations under the Medical Devices Act via the Czech Medical Devices Information System (ISZP). Distributors must report the device's unique device identifier (UDI-DI) and intended purpose. If this information is not available in EUDAMED, they must provide the trade name and generic group.

Specific Advertising Restrictions

The Act introduces strict advertising rules for medical devices, similar to those for pharmaceuticals. Advertising includes any activity that encourages the prescription, sale or use of medical devices, such as sales visits, providing samples and sponsoring events.

Advertising to the General Public: Medical devices that are prescription-only or intended for healthcare professionals cannot be advertised to the public. Public ads must offer simplified, essential information about the device's use and safety, including the trade name, purpose and a safety message. Ads must not target children under 15, exaggerate claims, invoke fear or suggest unnecessary medical care. Celebrity or expert endorsements are also prohibited.

Advertising to Professionals: Ads aimed at healthcare professionals must be distributed only through channels reserved for experts and provide accurate, objective information. While full details from the device manual are no longer required due to practical limitations, ads must still include enough information for professionals to assess a device's safety and clinical benefits. This type of advertising can also target non-medical staff, such as lab technicians and biomedical engineers.

Gifts and Benefits: The law restricts gifts, travel, hospitality and other benefits offered in relation to advertising. Samples may be provided but must be clearly labelled and limited to the quantities necessary for testing.

Catalogues and Price Lists: Necessary communications like sales catalogues and price lists are not considered advertising. Sales catalogues and price lists may now include basic descriptions of medical devices, which were previously restricted. These descriptions are limited to essential details for identification and are not considered advertising.

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

In the Czech Republic, primary responsibility for defects in medical devices lies with the manufacturer. Manufacturers must ensure that their devices meet all safety and performance standards throughout their entire lifecycle. If a defect arises that poses a risk to patient safety, the manufacturer is obligated to notify the relevant parties and, if necessary, arrange for the device's withdrawal or replacement.

While manufacturers bear the primary responsibility for defects, distributors and healthcare providers can also be held liable if they fail to meet their specific obligations. Specific responsibilities and entitlements:

- **Manufacturer:** Under EU regulations, manufacturers are required to market only safe and effective medical devices. If a defect occurs, they must take corrective action such as informing stakeholders, recalling or replacing the defective product.
- **Distributor:** Distributors are responsible for ensuring that the devices they market meet safety and performance standards, are properly labelled and comply with regulations. If they fail in these duties, they can be held liable for defects.

- **Healthcare Providers:** Hospitals or clinics are responsible for the proper use of medical devices according to the manufacturer's instructions. If a defect arises due to misuse by the healthcare provider, they may be liable, but only if the defect was not caused by the device itself.
- **Legal Protection for Patients:** Patients who experience a defective medical device are entitled to repair, replacement or compensation under consumer protection laws and medical device regulations. Consumers have two years to claim a defect. If a defective device causes injury or loss, patients can seek compensation from the responsible party.

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?

The recently adopted amendment to the Healthcare Services Act (Act No. 372/2011 Coll.) introduces substantial measures aimed at digitalising the Czech healthcare system, including the official regulation of telemedicine. Telemedicine, the practice of providing healthcare remotely via digital technologies, previously lacked a clear legal framework, which created uncertainty for healthcare providers.

The amendment defines telemedicine services as those delivered remotely using telecommunication and information technologies. It is now legal for these services, now categorised as "consultation services," to be provided remotely. Examples include telemonitoring, where a patient's health data is monitored and sent to healthcare providers.

The amendment outlines basic conditions for offering telemedicine, emphasising safety and the quality of communication. Only licensed healthcare providers will be permitted to offer telemedicine services. Most importantly, the amendment does not change the current requirements for obtaining healthcare licenses, including technical and staffing standards. It also clarifies which telemedicine services can be offered outside traditional healthcare facilities.

Further details, such as methods for verifying a patient's identity remotely, technical standards for communication and guidelines for obtaining patient consent for recording interactions, will be specified in regulations currently being drafted by the Ministry of Health.

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