Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Hungary

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Introduction

The challenges of aligning Hungarian national laws with the EU MedTech regulations are primarily related to the increased regulatory burden and administrative changes, such as stricter standards for clinical evaluations, postmarket surveillance, high compliance costs and limited access to notified bodies. Manufacturers and importers with a Hungarian presence must also fulfil a notification obliga-tion towards the pharmaceutical authority. Geopolitical factors such as the Ukraine war have also impacted product availability.

All these factors lead to a slower adoption of new technologies and devices. These affect smaller manufacturers in particular, as many of them struggle with limited resources, forcing them to exit the market.

Partly under medical devices, Hungary treats medical aids as a special product category, subject to a separate regulation. These products can only be sold to patients by pharmacies or specialised stores. Medical aids are subject to detailed rules for reimbursement, advertising and promotion.

Opportunities in digital health, including telemedicine and AI-powered devices, face regulatory gaps but show promise due to Hungary's evolving digital health infrastructure. National initiatives like the EESZT provide a great foundation for growth.

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
X	Supply chain disruptions due to COVID-19, Ukraine war, etc.
X	Enterprises consider MDR/IVDR and/or national implementing regulations as a disincentive to launching innovation in your country / the EU in general
	Delays in innovation / access to new devices / new technologies in general
X	SME vulnerability
	Shortage of expertise and resources
	Other example(s)

The challenges in aligning Hungarian national laws with the **MedTech** Regulations (the Medical Devices Regulation (**MDR**) and In Vitro Diagnostic Regulation (**IVDR**)) are primarily related to the increased regulatory burden and administrative changes. These challenges contribute to a slower adoption of new technologies and devices, limiting access to state-of-the-art treatments and diagnostics within the local market.

Key challenges include:

- The standards introduced by the MedTech Regulations are more demanding than the previous framework (e.g. they require more detailed clinical evaluations, risk management documentation and more rigorous post-market surveillance processes).
- The limited access to notified bodies poses significant delays in device certification and recertification.
- The need to comply with the MedTech Regulations discourages some companies from introducing innovative products in Hungary, slowing the pace of domestic technological advancement in healthcare.

In addition, supply chain disruptions stemming from geopolitical events such as the Ukrainian conflict, exacerbate these issues by impacting the availability and price of materials required for manufacturing medical devices.

These demands and circumstances particularly affect smaller and medium-sized companies with limited resources to comply with the new legal regime. Many smaller manufacturers who are unable to meet the requirements of the MedTech regulations are choosing to discontinue their presence in Hungary or their marketing of certain products.

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

The National Centre for Public Health and Pharmacy **(NNGYK)** is the main regulatory authority responsible for overseeing medical devices. The NNGYK's key role involves registering medical devices, ensuring compliance with EU and Hungarian regulations and enforcing legal requirements that support patient safety. The Hungarian Competition Authority enforces competition laws also within the med-tech industry. The Customs Authority is also a key player, verifying that imported medical devices meet regulatory standards before entering the local market.

Enforcement mechanisms include periodic inspections (for a specific range of medical devices) by the certified bodies and official as well as market surveillance inspections by the NNGYK, to ensure compliance with local and the MedTech regulations. Within the framework of these inspections, the NNGYK is entitled to impose penalties on non-compliant companies or healthcare providers, along with other administrative actions for devices that fail to meet safety standards.

Furthermore, in the event of non-compliance with the notification obligation prior to the commencement of the marketing of medical devices, in vitro medical devices (IVDs) and certain medical aids (see the definition of medical aids in Q3 below), the NNGYK may, among other things, order the temporary cessation of the infringing activity, impose a fine of between HUF 10,000 and HUF 140,000 (approx. EUR 25 – 345[1]), revoke the company's operating licence or initiate the company's removal from the register of operations.

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?

Medical devices and IVDs

Market entry can be particularly challenging for SMEs who find it harder to cope with the high costs, complex administrative hurdles and lack of proper public funding.

In order to access the Hungarian market, companies that manufacture or distribute medical devices or IVDs must:

i. issue a conformity assessment to verify that their products meet the regulatory standards, (for higher-risk medical devices, a notified body [NEOEMKI Kft. and CE Certiso Kft. for medical devices and NNGYK for IDVs] must certify compliance, which can be a lengthy process given the limited availability of these bodies);

ii. comply with their notification obligation, in other words they must notify the NNGYK that they plan to place their device(s) on the Hungarian market;

iii. take into account that medical devices and IVDs are not usually reimbursed from the Hungarian social security system. They are, as a rule, procured via public procurement procedures under the Hungarian Public Procurement Act (Act CXLIII of 2015), where price is the primary determinant factor. Some devices are even procured centrally by the National Health Insurance Fund (**NEAK**), whose procedure is governed by Government Decree 16/2012 (II. 16.) as well; and

iv. also be aware that general underfunding of the Hungarian healthcare system may create additional difficulties for market players in setting pricing and sales structures.

1 Using the exchange rate calculated at the time of preparing this guide (November 2024).

Medical aids

In Hungary, there is a special product category which is called "medical aids" (in Hungarian: *„gyógyászati segédeszköz"*). This category includes two types of products: (a) devices made available for personal use to patients suffering from a temporary or persistent health impairment or disability (including IVD devices for self-testing purposes) and (b) technical devices for nursing and caring purposes, which are not treated as medical devices and are designed for use without the continued presence of a healthcare professional.

Medical aids can only be sold to patients by pharmacies or specialised stores that hold a license issued by the public health administration.

To access the Hungarian market, companies that manufacture or distribute medical aids must:

i. comply with strict advertising and promotional rules;

ii. take into consideration that special reimbursement rules apply to medical aids and that the Hungarian social security system is particularly underfunded in this segment; and

iii. notify the NNGYK that they intend to place their product on the market, if said product is subject to the notification obligation detailed below.

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

In addition to the provisions of the MDR and the IVDR, further requirements are primarily laid down in Decree 4/2009 (III. 17.) of the Ministry of Health for medical devices (**Medical Device Decree**) and Decree 8/2003 (III. 13.) of the Ministry of Health, Social and Family Affairs for in vitro medical devices.

Notification obligation with respect to medical devices, in vitro medical devices and certain medical aids

Manufacturers and importers with a registered office in Hungary are subject to a notification obligation. They are required to report their own data as economic operators, along with data of the devices (medical devices, IVDs or certain medical aids) they distribute to the National Medical Device Register ("Nemzeti Orvostechnikai Regiszter" or "NOR"), maintained by the NNGYK, prior to the commencement of the marketing of the device. Failure to comply with

the notification obligation may result in the sanctions mentioned in the answer to Q2.

Promotion and advertising of medical aids

If a medical device qualifies as a medical aid, Hungarian legislation establishes the following rules for its advertising and promotion:

- Medical aids may not be advertised to the public if they can be dispensed from the pharmacy with a prescription or are approved for social security subsidies. Advertising is permitted for other medical aids. The advertisement must, however, inter alia, draw the attention of the user/patient to read the instructions for use and to consult a doctor (or healthcare professional) in case of questions.
- Similar to the promotion of medicinal products, the promotion of medical aids to healthcare professionals is also strictly regulated by Hungarian law. Promotion can only be carried out by the registered medical sales representatives of the promoter company. The promoter company is subject to a notification obligation towards the NNGYK and shall pay a monthly fee for each person who acts as a medical sales representative.. Hungarian laws lay down the definition of promotional activity and include detailed rules for different promotional activities (e.g. events, gifts, product sample, donations and so on); compliance with such rules is monitored and supervised by the NNGYK. Failing to comply with these rules may result in fines both for the promoter company and the medical sales representative.

Additional national provisions

Hungary unified its national regulations related to the adverse events reporting system to ensure compliance with the MedTech Regulations. In cases where manufacturers fail to report adverse events, significant penalties in line with the EU regulations apply.

Medical devices defined as high-risk devices under the Medical Device Decree must undergo inspections (by certified notified bodies) at certain intervals (every 1-3 years) following their entry into service. This obligation primarily concerns healthcare providers that use said devices. However, should healthcare providers fail to conduct these periodic inspections, the NNGYK may warn the healthcare provider or even impose a fine.

Furthermore, labels and instructions for the use of medical devices and IVDs must be provided to the end user in Hungarian.

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

Hungarian product liability regulations

Product liability regulations for medical devices are primarily governed by the Hungarian Civil Code (Act V of 2013 of the Civil Code), which establishes the framework for liability arising from defects in products. Under these regulations, manufacturers, importers or distributors (if the manufacturer cannot be identified) of devices can be held liable for damages caused by defective products. A product can be defective if it fails to provide a level of safety that is generally expected, with special regard to the purpose of the product and the way in which it can be reasonably expected to be used, the information provided in connection with the product, the date of the marketing of the product and the current state of scientific and technological achievements.

The burden of proof lies with the claimant (injured party). Damage caused by defective products means any damage that is: (a) incurred by the death, bodily injury or any impairment to the health of a person, caused by a defective product and (b) caused by a defective product to other objects valued in excess of EUR 500, if such an object is intended for private use or private consumption and generally used for said purposes by the claimant as well.

The Hungarian Civil Code lists reasons under which a manufacturer can be relived of liability, such as if the product was in perfect condition at the time it was placed on the market and the cause of the defect developed subsequently to that. However, in this case the burden of proof lies with the manufacturer. The manufacturer is not exempt from liability alleging that a third party contributed to the occurrence of the damage.

The liability period for the manufacturer is 10 years effective from the date of placing the product on the market. However, the limitation period for compensation claims is only 3 years.

At the EU level, product liability is currently regulated in the Product Liability Directive (85/374/EEC), with which Hungarian regulations align fully[2]. The EU framework allows patients to seek compensation directly from the manufacturer if a device causes harm

2 The new Product Liability Directive was signed on 23 October 2024 and will enter into force 20 days after its publication in the Official Journal of the European Union. After that, there is a 24-month transition period before the new rules start to apply in early 2026.

due to a defect (which should be proven by the claimant). Consequently, manufacturers are required to maintain strict quality controls and adhere to safety standards, in order to minimise product risks.

Companies placing devices on the market as consumer products will also be subject to the EU General Product Safety Regulation (GPSR) 2023/988.

Potential sanctions for non-compliance with MedTech Regulations

The NNGYK has the authority to impose fines and penalties for violations of the MedTech Regulations. These sanctions (see the response to Q2 above) can include significant monetary fines or withdrawal of market authorisation. In severe cases (e.g. the falsification of medical devices or IVDs), the investigating authorities may even apply criminal charges against responsible individuals

Moreover, if during a market surveillance inspection, the NNGYK finds that a product does not comply with EU or national requirements, it is entitled to:

- order the provision of extensive information to the public;
- restrict or prohibit the placement of the product on the market, along with its advertising or promotion;
- order the product's withdrawal from the market;
- order the recall of the product;
- request that the economic operator remedy defects or deficiencies and set a time limit within which the economic operator must notify the market surveillance authority of any and all remedy actions taken;
- impose conditions on or prohibit, the marketing or sale of a product until the lawful situation has been remedied;
- impose a fine (the amount of which can vary from HUF 100,000 to HUF 3,000,000,000, approx. from EUR 240 to EUR 7,310,000[3]); and
- impose additional sanctions, as provided for in other legislation.

These consequences may also be imposed jointly.

3 Using the exchange rate calculated at the time of preparing this guide (November 2024).

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?

In Hungary, telemedicine devices, Software as a Medical Device (**SaMD**) and AI-powered medical devices are primarily regulated by the MedTech Regulation, with oversight from the NNGYK.

SaMD and AI-powered devices must undergo similar regulatory scrutiny as traditional medical devices, including clinical evaluations and conformity assessments based on their classification.

The regulatory framework in Hungary also enforces GDPR standards and includes sector-specific obligations for healthcare data protection.

Telemedicine and telemedicine devices

Currently, there are two pieces of legislation that regulate the provision of telemedicine services and their financial aspects at a very high level:

- Decree 60/2003 (X. 20.) of the Ministry of Healthcare, Family and Social Affairs on the minimum professional conditions for the provision of health services. The decree lists the main technical and personnel conditions for the provision of telemedicine services, including the ICT equipment and medical devices necessary for the provision of said services by the provider, the telemedicine care procedures and the patient information leaflet;
- Decree 9/2012 (II. 28.) of the Ministry of National Resources on the definition of specialised outpatient care activities eligible for financing from the NEAK and on the conditions and rules of eligibility, as well as on the accounting of services provided. This decree sets out the main rules for the reimbursement of telemedicine services and lists those procedures and activities that can be reimbursed.

The legislator has already indicated that detailed legislation on this subject is expected to be adopted, but there is no precise information on when.

The 'Electronic Health Services Space' (**EESZT**), which came into force in 2017, offers several features which support the provision of telemedicine services, including:

- A cloud-based access to prescribed medications (e-prescriptions), allowing patients to retrieve prescriptions conveniently.
- The consolidation of nearly all medical documents in one location (e-health records), providing immediate access to said information to healthcare providers and patients.
- A recently launched appointment booking system for certain outpatient services, intended to enhance efficiency and convenience in patient care.

In addition, there are ongoing projects in the public health administration, such as the Telemedicine Framework (**TMKR**) and the "Life Path Analysis Data Platform", in collaboration with Semmelweis University. The aim of these projects is to facilitate the development of telemedicine in Hungary.

SaMD and AI-powered devices

No specific national regulations address SaMD or AI-powered devices at this moment. The Medical Device Coordination Group (**MDCG**) has issued detailed guidance on the classification and grading of software (MDCG Guideline 2019-11), which is also used by the NNGYK for the classification of devices.

However, the regulatory environment that addresses these devices in Hungary is evolving, with a focus on guidance for the Internet of Behaviours (IoB) and AI. The Data Act and AI Liability Directive are expected to enhance transparency, safety and accountability, creating market opportunities as Hungary aligns with EU digital health initiatives. Despite regulatory challenges, Hungary's healthcare system demonstrates an openness to digital health, supported by EU grants and its digital health strategy.

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