Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Poland

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Introduction

Despite the bottlenecks related to access to notified bodies and certain types of conformity assessments, there are currently no reported significant shortages of medical devices in Poland. While the overall business outlook remains positive, the limited number of notified bodies has led to longer wait times and higher costs, particularly affecting small and medium enterprises.

Market access in Poland is heavily influenced by public financing mechanisms. Reimbursement for medical devices is complex and often involves lengthy procedures, including health technology assessments (HTAs). While the Polish Medical Devices Act aligns with the MDR and IVDR, specific national regulations exist for advertising, distribution and product liability. With fines for breaches of safety requirements as high as EUR 1.2 million, national law provides additional protective measures beyond the general liability framework set out in the MDR/IVDR.

While Poland has seen advancements in digital healthcare, specific regulations for telemedicine devices, SaMD and AI-powered medical devices are still evolving. The Ministry of Health has initiated an e-health application certification programme to clarify the regulatory landscape for SaMD. However, challenges remain in terms of reimbursement and clear regulatory pathways for AI-powered medical devices.

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
	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
	SME vulnerability
	Shortage of expertise and resources
X	Other example(s)

The implementation of MDR and IVDR was delayed in Poland. The Medical Devices Act, adapting the Polish legal system to MDR and IVDR (the **"Act"**) came into force in 2022 - a year later than it should have – creating an uncertain regulatory landscape for Polish companies. In addition, Polish entrepreneurs continue to cope with an insufficient number of notified bodies, a situation that has not improved since the Act came into force.

For IVDR certifications, only 12 notified bodies are currently available in Europe, none of which are based in Poland. Moreover, not all types of conformity assessments are available in Poland. This includes a representative sample of a medical device and certification that the device, its documentation and relevant life cycle processes comply with MDR provisions (Annex X).

The low number of notified bodies translates into very limited possibilities for certification of medical devices and causes long waiting times and higher certification costs. Small and medium-sized entrepreneurs are particularly affected, as higher prices and language barriers hinder their ability to use notified bodies outside Poland.

Nonetheless, there are currently no reported significant shortages of medical devices in Poland. Although the ongoing military conflict on the border and the persistent instability of the global supply chain pose risks for the Polish medical device industry, the overall business outlook continues to be positive.

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

The Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (Polish: *Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych,* "**URPL**") is the primary regulatory authority tasked with overseeing medical devices in Poland. To a limited extent, when sold by pharmaceutical wholesalers and pharmacies, the trade of medical devices also falls under the supervision of the Pharmaceutical Inspection (Polish: *Inspekcja Farmaceutyczna*).

While the European Commission now has the authority to classify products as medical devices under the MDR/IVDR, the URPL retains this power in certain cases. For example, customs authorities may seek URPL confirmation regarding a product's classification as a medical device, typically to determine an applicable VAT rate. Additionally, at the request of customs and tax authorities, URPL can provide an opinion on whether a device meets the necessary requirements, especially if documentation is incomplete. If the URPL finds evidence of non-compliance, it may require corrective measures before market introduction or, if corrective measures are not possible, destruction of the product. Therefore, non-EU suppliers must ensure that medical devices entering the EU are accompanied by complete documentation in English or Polish, as per MDR/IVDR requirements.

Once in Poland, the URPL is authorised to conduct performance and conformity checks of medical devices, including documentary reviews, physical or laboratory tests using samples and on-site inspections. The Act empowers the URPL to inspect clinical trial sponsors, manufacturers, suppliers, subcontractors and entities involved in device maintenance, repair, calibration and installation. Inspections must be initiated within 30 days of notifying an intention to inspect, with a minimum notice period of seven days. In addition, the URPL may

conduct unannounced inspections if there is a reasonable suspicion of non-compliance with MDR/IVDR regulations or if a device is suspected of causing an unacceptable risk. Unlike general inspection limitations, medical device inspections are exempt from restrictions on the number of inspections per year or their duration.

If a device poses an unacceptable risk or is falsified, the URPL may seize, destroy or neutralise it to protect public health. With regard to devices that do not pose an unacceptable risk but fail to comply with medical device requirements, the URPL may require the manufacturer to rectify said non-compliance. This could involve addressing issues like mislabelling, which do not affect safety. If non-compliance persists after a specified deadline, the URPL may issue an administrative decision prohibiting or restricting market availability, requesting that the device in question be withdrawn from the market or prohibiting its use.

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?

According to the Polmed Trade Association report published this year (“**PTA Report**”) , public and private healthcare providers constitute the primary market for medical devices in Poland, accounting for 63.7% of total domestic demand in 2020 (approx. EUR 1.8 billion). Direct household expenditure on medical devices, estimated at around approx. EUR 620 million, contributes minimally to the overall demand.

Consequently, market access in Poland hinges on public financing mechanisms, which differ from those envisaged for medicinal products and encompass three main categories:

i. **Standard pharmacy reimbursement**

Applicants can apply for reimbursement of a specific medical device following a time-consuming and costly health technology assessment (HTA). Successful price negotiations with the Ministry of Health lead to a medical device being included on the reimbursement list. Currently, reimbursement of specific medical devices primarily includes glucose strips, dressings and pen needles.

ii. Reimbursement of generic medical devices on prescription

The Ministry of Health publishes and periodically reviews a generic list of medical device categories eligible for public reimbursement. Medical devices that correspond to the specified requirements qualify for public reimbursement. Due to the absence of a formalised procedure for adding new categories of medical devices, the Minister for Health retains discretion over list adjustments. Patients receive a prescription for those devices that are redeemable at pharmacies or medical retail outlets with National Health Fund contracts.

While this path covers a wide range of medical devices (crutches, optical products, hearing aids, wheelchairs, ostomy bags, wigs etc.), the reimbursement by the public payer does not cover the entire cost. Typically, patient co-payments exceed 40% of total device prescription.

iii. Bundled payments through medical institutions

This category includes medical devices bundled with healthcare services. Medical institutions with National Health Fund contracts receive remuneration for healthcare procedures involving the use of medical devices. While medical institutions have discretion with regard to the selection of medical devices, procurement is done through public tenders where price is the primary determinant. As a result, Poland still lags in device availability, including high-tech options, despite the increasing number of modern diagnostic medical devices. While e-health initiatives have progressed in recent years, proposing new reimbursement categories also remains time-consuming and costly due to the absence of standardised HTA guidelines for most medical devices.

In terms of regulatory approvals, Poland's Medical Devices Act, aligning the Polish legal system with the MDR and IVDR, does not include any local specific regulations. Manufacturers must ensure their devices comply with legal requirements and issue a conformity assessment, which in certain cases must be preceded by obtaining a notified body certificate. Declarations of conformity for patients must be in Polish or have a sworn Polish translation, while English suffices for professional devices.

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

A lack of precise regulations in Poland for advertising of medical devices resulted in many entities registering their products as medical devices to promote them freely (unlike strictly regulated medicinal products).

While the MDR sets out general **requirements for the advertising of medical devices**, the Act significantly clarifies and specifies the rules in this respect. Although neither the MDR nor the Act provide a precise definition of "advertising," national regulations and case law outline a broad range of activities that qualify as advertising. This includes traditional TV and radio spots, posters, internet banners, direct marketing to medical professionals, sponsoring industry events and providing samples for promotional purposes.

Influencer activities promoting medical devices on social media, are also covered by national regulations. The President of the Polish Competition Authority has issued recommendations related to the labelling of such advertising posts. In principle, advertising of a medical device can be carried out by the manufacturer, authorised representative, importer or distributor. These entities may commission the advertising of medical devices to a marketing agency or an influencer, for example. If the agency or influencer fails to obtain a written approval from the entity commissioning the advertisement, they will be responsible for the advertisement complying with the law instead of the commissioning entity.

Like medicinal product advertising, medical device advertising targeting a broad audience should be phrased in a universally understandable manner. Medical and scientific terms must be explained in a clear and accessible way. All advertisements must include essential product information, such as the device's name or trade name and intended use. The Minister of Health's regulations on medical device advertising outline detailed requirements, including the identification of the advertising entity, the manufacturer and the authorised representative (if appointed). Additionally, a warning stating "*This is a medical device. Use it in accordance with the instructions for use or the label*" is mandatory.

It is important to note that not all materials related to medical devices are considered advertising. For instance, catalogues or price lists containing only basic product information are exempt from advertising regulations.

Another area of local implementation is the **registration system for medical device distributors**. Under the Act, distributors who introduce devices into the Polish market for the first time must register to be listed in the database. Distributors that are exclusively purchasing devices within Poland are exempt from registration. The register primarily collects information on available devices, not on all entities trading in medical devices. Entities must submit device data within seven days of importation.

Finally, the MDR/IVDR leaves laying down proportionate penalties for infringement of its provisions to member states and their competent authorities. The Act empowers authorities to impose financial penalties of up to approximately 1.2 million euro for breaches of safety requirements, such as placing a non-compliant medical device on the market.

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

Polish national law provides for additional protective measures, which go beyond the general framework for product liability set out in the MDR/IVDR.

Persons who purchase or use dangerous products enjoy broad protection. This stems primarily from Directive 85/374/EEC on liability for defective products (“**Product Liability Directive**”) and its implementation into Polish law. A medical device is considered a dangerous product if it poses a potential hazard, even hypothetically, in typical or foreseeable usage conditions. The hazard may arise from design flaws, inaccurate labelling or incorrect instructions. Liability for dangerous products is based on strict liability, meaning the trader is responsible regardless of fault. Despite the general principle that manufacturers are liable for damages caused by dangerous products, both importers and distributors, even those falsely presenting themselves as manufacturers, can also be held liable. Moreover, the entity marked on the product as the manufacturer is responsible, even if they are not the actual manufacturer. This is to protect injured parties who may struggle to identify the true manufacturer. Injured parties have flexibility in choosing whom to sue, potentially targeting multiple entities involved in the production or distribution chain.

Only natural persons can assert claims under these provisions and the entity to which the injured party will be able to address its claims can only be a legal entity. Contractual relationships between the injured party and the manufacturer or other involved entities are not required for filing a claim.

Within the framework of dangerous product liability, we distinguish between liability for death and bodily injury (personal injury) and liability for damage to property (property damage). There is no minimum or maximum claim amount required for personal injury, as it should be compensated in full, regardless of the severity. For property damage, liability is limited to damage or destruction of personal (non-professional) property, including both movable and immovable property. Property damage below EUR 500 is not covered under this type of liability.

Finally, companies placing medical devices on the market as consumer products will be additionally subject to the EU General Product Safety Regulation (GPSR) 2023/988. The GPSR which comes into effect on 13 December 2024, introduces significant changes to product safety regulation and enforcement. Its provisions will apply to medical devices unless more specific provisions exist in the MDR/IVDR. The local implementation of the GPSR in Polish law is ongoing.

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 ongoing digitalisation of the Polish healthcare system, including e-prescriptions, electronic medical records, as well as the increasing use of technology in diagnosis and treatment, require the adjustment of national regulatory frameworks to reflect these technological advancements.

While the Polish Medical Activity Act permits the provision of healthcare services via IT or communication systems (e.g., remote patient consultations), there is no separate legal definition of "**telemedicine**" in Poland. From a legal standpoint, telemedicine equipment like digital stethoscopes or monitoring wearables must be classified as a medical device under the MDR/IVDR general rules.

Software marketed on its own (i.e., independent of any medical device) can also be regarded as a medical device under the MDR/IVDR. However, no specific national regulations nor established market practices address **SaMD** in Poland. Despite the lack of a clear reimbursement path for digital health solutions and standardised HTA guidelines for most medical devices, many Polish startups are actively developing digital health solutions and mobile health applications.

In order to clarify which e-health applications qualify as SaMD, the Ministry of Health launched an e-health application certification programme in 2023, which initially did not provide for funding for implementation of applications in public healthcare. As of 2024, with the new Innovation Director, the project envisages financing from EU funds and currently the goal is to expand the health applications portfolio (PAZ) from its current two applications to at least a dozen.

The Innovation Team established by the Ministry of Health reviews and recommends implementing new digital solutions, including medical devices or systems that optimise healthcare provider workflow. An interactive innovation register with around 200 entries, including AI-powered solutions, has been created for this purpose. Despite the widespread discussion of AI in Poland and the fact that many software producers utilise AI algorithms, no national regulations have been adopted in this area. The uncertainties surrounding AI in the medical device domain mirror those faced by other EU countries.

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