Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Romania

Wolf Theiss

Introduction

Although Romania has implemented MDR and IVDR, there is still some secondary legislation that needs to be enacted.

Currently, companies in Romania must seek conformity assessments from certified bodies beyond its borders, which may result in long waiting times and higher certification costs, as there are no Romanian notified bodies. This affects small and medium-sized entrepreneurs in particular. Despite this, there are currently no reported significant shortages of medical devices and the market seems to be growing.

Reimbursements from public health funds can be performed only on the basis of agreements with health insurance houses for devices that meet specific requirements and at set prices.

Unlike the strict regulations for the advertising of medicines, which have been enacted long ago, advertising of medical devices has been regulated as part of the implementation of MDR. The methodological norms for the advertising of medical devices and in vitro medical devices are still to be enacted.

Romanian legislation is still to be adapted for technological advancement in healthcare, despite an increased demand for technology. Neither specific national regulations nor established market practices address SaMD. AI-powered medical devices do not seem to be on the agenda just yet, but this may soon change given the increased challenges the world is facing with AI.

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
X	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.
	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
	Lack of specific legislation regulating technology in the health care sector
	Other example(s)

The implementation of MDR and IVDR had a late start in Romania. The legislative acts adapting the national legal system to MDR and IVDR came into force with a delay in Q4 of 2022 and Q2 of 2021 respectively, thus creating regulatory uncertainty for companies activating on the market. Secondary legislation, including methodological norms regulating the provision of device information in English to healthcare professionals by manufacturers, norms of procedure for medical devices provided under article 5 para. 5 of MDR and IVDR and methodological norms on advertising of medical devices and in vitro medical devices, has not been enacted yet.

Romania currently does not have any notified bodies under MDR or IVDR, meaning Romanian entrepreneurs will have to seek conformity assessments from certified bodies outside Romania. This translates into 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 Romania.

Nonetheless, there are currently no reported significant shortages of medical devices in Romania and the market seems to be on an ascending path.

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

The National Agency for Medicines and Medical Devices of Romania (in Romanian: *Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale din România*, "**ANMDMR**") is the regulatory authority tasked with overseeing medical devices in Romania.

Manufacturers with offices in Romania that place custom-made medical devices on the market under their own name, are obligated to register in the national data base of medical devices maintained by the ANMDMR. These manufacturers are required to provide information on their headquarters and a description of the medical devices placed on the market. The ANMDMR also registers information on vigilance in the national database.

The ANMDMR is authorised to conduct performance and conformity checks of medical devices, which include the review of documents, physical or laboratory tests using samples and on-site inspections. The ANMDMR can inspect manufacturers, suppliers, importers, distributors and other entities involved in the medical device sector, as well as professional users of medical devices. The inspections are carried out based on an annual inspection plan drafted by the ANMDMR. Inspections can be unannounced, themed or reactive.

If a device poses an unacceptable risk or is counterfeit, the ANMDMR may seize, destroy or neutralise it to protect public health. In terms of devices that do not pose an unacceptable risk but fail to comply with medical device requirements, the ANMDMR may require the manufacturer to rectify said non-compliance. If the non-compliance persists, adequate measures may be imposed for the withdrawal, interdiction and/or restriction on market placement of medical devices that compromise the health and/or security of consumers.

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?

Reimbursement from the public health fund

Reimbursement for medical devices from the Health Insurance Houses can be performed only on the basis of an agreement concluded between the supplier of the medical devices and the Health Insurance Houses. This only applies for medical devices that meet specific requirements. Prices are set in such agreements and medical device suppliers can only amend them during the annual contracting period organised by the Health Insurance Houses. The National Insurance House publishes and periodically reviews the price lists of medical devices intended for the recovery of organic or functional deficiencies in outpatient settings. The conclusion of agreements with the Health Insurance Houses implies a highly regulated procedure, with no room for negotiation.

Patients receive a prescription for those devices, which are redeemable at pharmacies or medical retail outlets with Health Insurance Houses contracts. The reimbursement by the public payer covers the reference price.

Regulatory approvals

The legislative acts aligning the Romanian legal system with the MDR and IVDR do not include any additional local regulatory approvals. 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. Information on medical devices for patients must be in Romanian, while English can be used for professional devices, with consent from the ANMDMR.

At present, there is no notified body in Romania. As mentioned above, this creates a less favourable setting for small and medium-sized entrepreneurs.

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

Unlike the strict regulations related to the advertising of medicines, the lack of regulations in Romania for the advertising of medical devices resulted in the free promotion of the latter. This gave the medical devices market an advantage compared to the medicines market.

As part of the national implementation of MDR, implementation legislation clarified and specified **the rules under which medical devices can be advertised.** However, the methodological norms for the advertising of medical devices and in vitro medical devices have yet to be enacted.

Advertising of medical devices is defined as any form of information through direct contact, as well as any form of promotion intended to stimulate the distribution, sale and use of medical devices. Separate advertising rules exist for the general public and for healthcare professionals.

Only medical devices intended for use without the intervention of qualified medical personnel in terms of diagnosis, recommendation of the device, monitoring, treatment and where advice from a pharmacist is sufficient, can be advertised to the general public. Moreover, the proposed advertising material for this type of medical device requires prior consent from the ANMDMR. This consent should be issued within 30 days of the submission of all necessary documents, except for complex advertising campaigns. In such cases, the consideration period may be prolonged at the discretion of the ANMDMR for up to a maximum of 60 days. Medical devices that serve a special purpose and are used based on a medical recommendation cannot be advertised to the general public.

Visits by medical representatives, samples, sponsorships of promotional gatherings and sponsorship of scientific congresses (especially through the payment of related transportation and accommodation expenses) are all considered advertising that targets healthcare professionals qualified to recommend or distribute medical devices. The ANMDMR must be notified in advance regarding advertising material for high-risk medical devices.

The ANMDMR is entitled to analyse the distribution of advertising materials intended for healthcare professionals as well as other forms of advertising of medical devices through self-reporting or based on reports by natural or legal persons. The ANNMDMR can also apply sanctions in cases of breach of the advertising rules for medical devices, including cessation of advertising after the material has been published and forbidding advertising material that has not been published yet.

It is important to note that not all materials related to medical devices are considered advertising. For instance, the label, the instructions/user manual or the correspondence that is accompanied by non-promotional materials and is necessary to answer specific questions concerning a medical device, are exempt from advertising regulations.

Another area of local implementation is the **registration system for medical device manufacturers** based in Romania that place custom-made medical devices on the market under their own name. Said manufacturers must register in the national database maintained by the ANMDMR and provide the address of their registered office and descriptions of the medical devices in question. The same data base will also contain information on vigilance.

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

Romanian national law does not provide for additional protective measures beyond those set forth in the MDR/IVDR.

Under the MDR/IVDR, persons who purchase or use dangerous products enjoy protection under Directive 85/374/EEC on liability for defective products ("Product Liability Directive") and its implementation into Romanian law.

According to Romanian law, a faulty product is a product that does not provide the safety that the end user is entitled to expect, taking into account circumstances such as: the way the product is presented, all foreseeable uses of the product and the date on which the product was put into circulation. Liability for a faulty product lies with the manufacturer, which includes the manufacturer itself, any person that presents themselves as a manufacturer by inscribing their own name, brand or distinctive mark on the product and the importer. If the manufacturer cannot be identified, each supplier of the product in question will be treated as the manufacturer if they do not communicate to the injured person, within a reasonable time-period, the identification data of the manufacturer or the importer. This serves to protect injured parties who may struggle to identify the true manufacturer. If there is more than one entity liable for the damage, all such entities will be jointly held liable. Injured parties must prove the damage, the fault and the link between the damage and the fault.

Within the framework of defective 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 a certain level (EUR 500 or EUR 40 depending on the type of property) is not covered under this type of liability.

Suppliers of medical devices must present proof of civil liability insurance when concluding agreements with the Health Insurance Houses for reimbursement.

Finally, companies placing medical devices on the market as consumer products will additionally be 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 Romanian law is pending enactment; the legislative process began in May 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?

Romanian legislation is still to be adapted for technological advancement in the healthcare sector, as there is an increased demand for technology, including AI-powered and hi-tech medical devices. This need has been understood by the Romanian Government, which has allocated over EUR 400 million from Romania's National Recovery and Resilience Plan (Romanian: Planul Naţional de Redresare și Reziliență, "PNRR") and from EU funds for investments in the digitalisation of the medical health sector. Nevertheless, given the lack of investment in technology within the public health system over the last decade, current priorities are the development of digital infrastructure in hospitals, e-prescription and electronic health records, as well as the interoperability of national digital systems with those from other EU Members States.

As a result of the COVID-19 pandemic, Romania took a major step in regulating telemedicine and the provision of remote medical services through electronic means. However, this new legislation still needs to evolve, in order to better serve the provision of medical services through technology. For example, there are no regulations on telemedicine equipment or their use. 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. Nonetheless, neither specific national regulations nor established market practices address SaMD in Romania, despite the fact that Romanian startups are actively developing digital health solutions and mobile health applications.

AI-powered medical devices do not seem to be on the agenda in Romania just yet, but this may soon change given the increased challenges the world is facing with AI.

Authors:

Ileana Glodeanu
Partner
E ileana.glodeanu@wolftheiss.com
T +40 21 308 81 00

Luciana Tache
Counsel
E luciana.tache@wolftheiss.com
T +40 21 308 81 00