Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Croatia

Wolf Theiss

Introduction

In recent years, procurement prices for medical devices have significantly increased due to rising fuel, transportation and labour costs. Delays in adapting the reimbursement policies and regulations of the Croatian Health Insurance Fund (HZZO) have further impacted product availability, given that a substantial portion of medical devices is covered by insurance.

However, market entry is expected to become faster with the full implementation of the MDR and IVDR, as administrative burdens and processing times will be reduced. Additionally, the HZZO has upgraded the standards for categories of medical devices, allowing more advanced versions to be covered by insurance.

Croatian regulations include additional protective measures for product liability beyond those outlined in the MDR/IVDR. While the Act on the Implementation of the MDR and IVDR, the Medical Devices Act and its associated ordinances establish an enforcement framework, the Civil Obligations Act provides comprehensive rules on liability for defective products.

Although there is a push to digitalise healthcare and introduce AI-based innovations, Croatia struggles with a shortage of experts in biomedical and health informatics, which is crucial for further progress in this area.

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
	Other example(s)

Croatia was opportune in its efforts to implement the MDR and the IVDR regulations through the Act on the Implementation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (the "**Act**"), which came into force in November 2018. Despite this early adoption, the Croatian medical device market has recently faced significant challenges in achieving smooth implementation and market growth.

Croatia imports over 90% of its medical devices, making the market highly sensitive to global economic shifts. In recent years, procurement prices for medical devices have significantly increased due to rising fuel, transportation and labour costs driven by the COVID-19 pandemic and the ongoing war in Ukraine. Delays in adapting the reimbursement policies and regulations of the Croatian Health Insurance Fund (**HZZO**) had further impact on market

participants and product availability, particularly for devices covered by insurance, which constitute a substantial part of the market.

Currently, there is only one notified body designated under the MDR in Croatia and none under the IVDR. Additionally, MDR and IVDR regulations, along with the Croatian implementing Act, are not the only regulations governing medical devices. The older Medical Devices Act (the "**MDA**") and its subordinate regulations remain in force, imposing additional national obligations on market participants.

Finally, while there is a push to digitalise healthcare and introduce AI-based innovations, Croatia struggles with a shortage of experts in biomedical and health informatics, which is crucial for further progress in these areas.

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

The responsibilities for enforcement of medical devices regulations are divided between the Croatian Agency for Medicinal Products and Medical Devices (Croatian: *Agencija za lijekove i medicinske proizvode*, "**HALMED**") and the Croatian Ministry of Health.

HALMED plays a central role in the enforcement of the MDR and the IVDR; it is responsible for verifying data entered into EUDAMED, the EU's electronic registration system for medical devices, as well as assigning a unique registration number to each operator. HALMED also resolves disputes between manufacturers and notified bodies regarding medical device classification, issues certificates of free sale for the export of medical devices and conducts vigilance activities. This entity also grants authorisation for the marketing or use of specific products within Croatia for which the prescribed conformity assessment procedures have not been completed, provided that their use is in the public interest regarding health and patient safety.

Additionally, HALMED maintains the medical device distributor registry established under the MDR and the IVDR. Under the MDA, HALMED also continues to maintain the registry of Class I medical devices, the registry of medical device manufacturers and the registry of wholesale distributors of medical devices. HALMED oversees procedures for granting, suspending, amending and revoking licenses for the retail sale of medical devices under the MDA and receives notifications regarding the placing of Class IIa, IIb and III medical devices on the market. This also applies to in vitro diagnostic medical devices and active implantable medical devices in Croatia. The collected data is used to monitor and oversee the vigilance system for medical devices.

The Ministry of Health decides on the appointment of conformity assessment bodies, notifies the European Commission and oversees and conducts evaluations; it also allows HALMED to approve the marketing or use of products for which the prescribed conformity assessment procedures have not been completed. Lastly, the Ministry of Health, through its pharmaceutical inspection, oversees the implementation of regulations relevant to medical devices with the authority to order specific measures as detailed in the answer to Q5.

Another significant body is the Croatian Health Insurance Fund (Croatian: *Hrvatski zavod za zdravstveno osiguranje*, "**HZZO**"), which influences the medical device market through its management of the Basic and Additional Lists of medical devices. These lists include medical devices that are partly or fully covered under the compulsory health insurance system. Manufacturers or authorised representatives must submit proposals for the inclusion of medical devices on these lists. The HZZO evaluates these proposals, sets pricing regulations and determines reimbursement conditions.

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?

As a member of the EU's single market, Croatia adheres to the principle of free movement of goods, which includes medical devices marked with the CE mark. The CE mark is the principal requirement for placing medical devices on the Croatian market, indicating that EU conformity assessment procedures have been completed and that the medical device meets all essential requirements prescribed by EU regulations. Conformity assessment procedures usually require the involvement of a notified body, an entity registered with the European Commission to carry out conformity assessments. Currently, there is only one notified body in Croatia that is designated under the MDR and none under the IVDR.

As previously noted, HALMED streamlines the market access process. Under the MDA, Croatian-based manufacturers are required to apply for registration in the Registry of Medical Device Manufacturers, while registration in the Registry of Wholesale Distributors is a prerequisite for engaging in wholesale activities. HALMED has up to 60 days from receiving a complete application to finalise the registration. In parallel, Croatian-based distributors are required to register in the Medical Device Distributor Registry established under the Act.

However, with the full implementation of the MDR and IVDR, the situation is expected to improve. The distributor register is expected to replace the wholesale register, potentially reducing administrative burdens. According to the Act, HALMED is required to issue a decision on registration within 30 days from the submission of a complete application to the distributor register, which should expedite the process.

Various services provided by HALMED, such as registration procedures, device classification and dispute resolution, incur fees ranging from a few hundred to over a thousand euros per service.

A significant portion of the trade in medical devices involves devices listed on the HZZO lists that are covered under the compulsory health insurance system. It can take up to 90 days for the HZZO expert committee to review a submitted proposal for the inclusion of a medical device on their lists. This is followed by the proposal being forwarded to the HZZO Management Board for a decision. Applicants are required to propose a price for the devices. Said price must align with regulatory pricing criteria, which may not always reflect current market prices.

In recent years, the Croatian medical device market has faced the risk of shortages of certain medical devices. This issue emerged in late 2022 and early 2023 due to multiple factors, including the COVID-19 pandemic, the ongoing war in Ukraine, significant rises in energy prices and major supply chain disruptions, all of which increased procurement costs. At the same time, HZZO reimbursement prices did not keep pace with these increases. Mechanisms were introduced, albeit with significant delays, that allow manufacturers and distributors of medical devices already included on the HZZO lists to request price increases when they are attributable to higher procurement costs beyond the manufacturer's control.

Additionally, over the past two years, the HZZO has upgraded the standards for various categories of medical devices, particularly orthopaedic devices, making more advanced versions available to insured persons. This initiative has motivated market participants to introduce new technologies, thus enhancing patient access to modern medical devices.

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

A distinct element of the MDR/IVDR framework in Croatia is that the enforcement of these regulations is not covered by the existing MDA. Instead, a separate law has been enacted, the Act, which sets out the rules regarding the competent authorities; their powers and responsibilities; the sale of medical devices and in vitro diagnostic medical devices; clinical trials; vigilance; supervision and sanctions for non-compliance. In contrast, the MDA sets out general requirements that medical devices must meet, including rules related to manufacturing, conformity assessment, sales and advertising.

The existing regulatory framework poses significant challenges for manufacturers, representatives and importers in terms of both compliance efforts and practical implementation of the rules. There is no single, comprehensive regulation that governs medical devices and in vitro diagnostic medical devices. Instead, requirements are divided across multiple legal instruments, including the MDA, a series of ordinances that are based on the MDA and the Act, which all apply parallelly. While the national regulations generally align with MDR/IVDR provisions, each Croatian regulation introduces specific additional requirements that must be adhered to.

This fragmentation makes compliance particularly challenging, as medical devices must adhere to various standards and guidelines outlined across multiple regulatory texts with non-compliance penalties scattered throughout.

Croatia has incorporated several provisions into the Act, which go beyond the minimal requirements of MDR/IVDR, including the following:

- Distributors are required to register in the distributor registry before commencing wholesale or retail distribution of medical devices. However, legal and natural persons authorised to perform pharmacy activities under specific legislation are exempt from this obligation.
- Conducting clinical investigations of medical devices and performing studies of in vitro diagnostic medical devices on individuals in prison or for whom coercion could affect the consent process is prohibited.
- Healthcare institutions must provide a list of all relevant supplementary information regarding devices manufactured and used within healthcare institutions to the competent authorities upon request.

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

The Act prescribes fines for non-compliance ranging from approx. EUR 13,270 to EUR 92,900 for legal entities and from approx. EUR 930 to EUR 1,330 for the responsible person within a legal entity. Lower fines are prescribed for violations concerning labelling and documentation. These fines range from approx. EUR 6,640 to EUR 26,540 for legal entities and approx. EUR 660 to EUR 1,060 for the responsible person within a legal entity.

The MDA also prescribes monetary fines, although at a lower amount.

The Ministry of Health's pharmaceutical inspection division oversees enforcement of the MDA. If inspectors discover offenses or criminal acts during inspections, they are required to report them to the relevant authorities.

Pharmaceutical inspectors are authorised to enforce various measures in cases of non-compliance including market withdrawal of a medical device, temporary or permanent bans on market placement and restrictions on advertising.

Furthermore, if a medical device that meets essential requirements and is legally on the market still poses a health or safety risk in its intended use, HALMED can mandate its withdrawal and restrict its use either independently or upon request from a pharmaceutical inspector.

Regarding product liability, Croatian regulations include additional protective measures beyond those outlined in the MDR/IVDR. While the MDA and related ordinances do not specifically address product liability, they provide an enforcement framework for these issues.

Under the Croatian Civil Obligations Act, a product is considered defective if it fails to provide the safety that can be reasonably expected. Manufacturers are liable for damages caused by defective products, regardless of fault. This liability covers pecuniary damages resulting from death or bodily injury, as well as damage to personal property (excluding the defective product itself), provided the property was primarily used for personal purposes. In such cases, the injured party is entitled to compensation only for the portion of the damage that exceeds EUR 500.

Compensation for non-material damage may also be claimed under the general rules of liability for damages.

In addition to manufacturers, sellers can also be liable for material defects in products. Sellers are responsible for any material defects existing at the time of the transfer of risk to the buyer, whether or not they were aware of them, as well as for later defects if the cause for said defects existed prior to the transfer. However, sellers are not liable for defects that the buyer knew about, unless they explicitly assured the buyer that the goods were defect-free.

A material defect is present if a product fails to meet the expected description, quantity or quality; is unsuitable for the buyer's specific purpose; lacks the necessary functionality or interoperability or is missing essential components, instructions or updates. In cases of defective products, consumer rights such as repair, replacement, return or price reduction must be respected.

Finally, companies placing medical devices on the market as consumer products are also subject to the EU General Product Safety Regulation (**GPSR**) 2023/988. Its provisions will apply to medical devices unless more specific provisions exist in the MDR/IVDR. The implementation of the GPSR in Croatian 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 Croatian healthcare system, including e-prescriptions, electronic medical records and the increasing use of technology in diagnosis and treatment, requires the adjustment of national regulatory frameworks to keep pace with these technological advancements.

The Croatian legal framework provides a definition of telemedicine. According to the Croatian Health Protection Act (the "**HPA**"), telemedicine is a branch of healthcare involving the remote delivery of health services through information and communication technologies when a healthcare professional and patient or two healthcare professionals, are not in the same location.

Telemedicine activities are carried out through a network of telemedicine centres, which are established by the Minister of Health upon the proposal of the Croatian Institute for Emergency Medicine (Croatian: *Hrvatski zavod za hitnu medicinu*, "**HZHM**"). Approval for the operation of telemedicine centres is granted by the HZHM, based on an application and after verifying that the proposed telemedicine centre meets the technical capability requirements. These requirements include information system accuracy and security; software support; medical diagnostic equipment; computing and communication equipment and infrastructure; along with other equipment and premises requirements. Approval is renewed every four years. The HZHM conducts oversight of telemedicine centre operations and of healthcare professionals engaged in telemedicine.

A separate ordinance specifies that the medical devices used in telemedicine must meet essential requirements in accordance with specific regulations such as the MDA and the Act, although no further details are specified.

There are no specific regulations for software as a medical device (SaMD) in Croatia. However, according to the definition of a medical device in the MDR/IVDR and the Medical Devices Act, software ("*programska podrška*") can be considered a medical device if it is intended for diagnostic or treatment purposes, among other criteria.

Croatia is actively fostering the integration of artificial intelligence (AI) into healthcare, as evidenced by the ongoing "Artificial Intelligence for Smart Health" project. This initiative aims to provide access to essential tools and support for researching, developing and launching AI-based technologies in healthcare through the AI4Health. Cro Centre. Coordinated by the Ruđer Bošković Institute, which leads the AI4Health.Cro consortium, the project issued a public call in September 2023 inviting entrepreneurs, startups and innovators to apply. The call will remain open until 31 March 2026 or until available funds are fully allocated.

While these initiatives represent significant progress, Croatia's success in the digital transformation of its healthcare sector will depend heavily on the availability of skilled professionals to develop and manage advanced information systems. Notably, Croatia is the only EU country without a formal education programme in biomedical and health informatics. Establishing these types of specialised education programmes could significantly enhance the effectiveness of healthcare digitalisation, foster the development of high-quality IT solutions and improve the allocation of resources.

Authors:

Ira Perić Ostojić
Consultant
E ira.peric@wolftheiss.com

Berislav Drašković
Senior Associate
E berislav.draskovic@wolftheiss.com