Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Life Sciences & Healthcare

Wolf Theiss

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This 2024 Wolf Theiss Guide is intended as a practical guide to the general principles and features of the basic legislation and procedures in countries included in the publication.

While every effort has been made to ensure that the content is accurate when finalised, it should be used only as a general reference guide and should not be relied upon as definitive for planning or making definitive legal decisions. In these rapidly changing legal markets, the laws and regulations are frequently revised, either by amended legislation or by administrative interpretation.

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Introduction

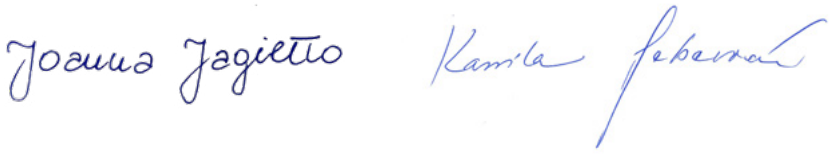
The Wolf Theiss Guide to Medical Devices in CEE & SEE offers an in-depth examination of the medical device industry in Central, Eastern and Southeastern Europe, focusing on the regulatory landscape, as well as key developments and opportunities shaping the sector.

While the implementation of MDR/IVDR has been largely completed, with some exceptions, secondary legislation still needs to be enacted in certain countries. However, reporting obligations in some jurisdictions exceed those set at the EU level. Additional provisions at the national level continue to exist, such as those related to advertising, promotion and product liability.

Limited access to notified bodies leads to frequent delays and increased certification costs. Often complex and cumbersome reimbursement frameworks create further challenges. Moreover, delays in innovation and access to new devices and technologies are attributed to underdeveloped practices, a shortage of expertise and resources, as well as regulatory uncertainty.

However, the use of telemedicine and SaMD is gaining traction; with AI-powered devices expected to follow. While regulation continues to lag behind practice, some countries, have made attempts to define and regulate these areas to varying degrees of detail.

The journey to modernising healthcare through medical devices in Central, Eastern and Southeastern Europe is marked by both complexity and opportunity. This guide delves into the regulatory challenges that shape the medical device industry in the region and offers insights into the existing hurdles, areas of progress and anticipated regulatory updates.



Joanna Jagiello and Kamila Seberova

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Austria

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Introduction

The list of entities subject to monitoring and certain reporting obligations in Austria extends beyond the provisions of the MDR and the IVDR. It includes persons and entities that use medical devices, such as beauty salons and fitness centres.

The reimbursement of medical devices is not standardised. Reimbursements within hospitals are regulated differently depending on the type of hospital operator. Reimbursement of medical devices outside of hospitals depends on the social insurance institution involved. In addition, patients generally contribute a certain co-payment towards the cost of the device.

The catalogue of offences that trigger sanctions is extensive and deliberate attempts to commit offences are also considered to be sanctionable.

Neither telemedicine devices nor SaMD or AI-powered medical devices have been regulated in a comprehensive way in Austria to date. Specific regulations on the use of telemedicine devices still need to be developed. Telemedicine services and devices already exist on the market, however, providing these services involves a high degree of legal uncertainty.

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)
	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.
	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)

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

i. Regulatory authorities

Pursuant to the Austrian *Medizinproduktegesetz 2021* (Medical Device Act 2021, **MPG 2021**[1]), which adapts the national law to the provisions of the MDR and of the IVDR, the regulatory authority for medical devices in Austria is the Bundesamt für Sicherheit im Gesundheitswesen (**BASG**). The BASG is also, as in the past, the authority in charge of market surveillance with respect to medical devices. The Austrian Agency for Health and Food Safety GmbH (**AGES**) is the BASG's auxiliary body that effectively interacts with market participants.

ii. Enforcement mechanisms

The MPG 2021 covers a wide range of market players, ranging from companies and healthcare facilities to persons who use, operate, manufacture and test medical devices on a professional or commercial basis. These entities' activities are subject to monitoring by BASG/AGES.

Monitoring now also extends to persons/entities whose commercial activity does not primarily involve the operation of medical devices, but who nevertheless use them, (e.g. beauty salons and fitness centres). Furthermore, persons who merely use medical devices from time to time are now also subject to reporting obligations in the event of serious incidents under the MPG 2021. The legislator again explicitly had beauty salons in mind, since they use devices that fall under the scope of the MDR, such as instruments used for liposuction, lipolysis and lipoplasty.

In addition, the MPG 2021 still contains very detailed provisions on the admissibility of advertising activities in relation to medical devices, with the exception of misleading advertising, which is now dealt with in the MDR.

Apart from these aspects, the provisions on market surveillance in the MPG 2021 still only apply to companies, institutions or persons that do not sterilise or place devices bearing a CE marking on the market, which are combined with other devices/products in the form of a system or procedure pack.

1 The MPD 2021 entered into force on 1 July 2021 in relation to medical devices and on 26 May 2022 in relation to in-vitro diagnostics.

2. 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. Regulatory approvals

Manufacturers of custom-made devices, as well as distributors, must register with a notified body before commencing their activities.[2] Given that the EUDAMED (European Database on Medical Devices) is not fully functional yet, registration is still carried out by the Gesundheit Österreich GmbH (**GÖG**), Austria's research and planning institute for the healthcare sector.

The GÖG is also responsible for setting up and maintaining registers for pacemakers, implantable defibrillators and loop recorders. It also maintains implant registers for active implantable medical devices, soft tissue implants, cardiovascular, neurological and orthopaedic implants.

ii. Reimbursement

The reimbursement of medical devices is not standardised in Austria, as there is no overall agreement for reimbursement (cost coverage by the National Health Fund). It is important to note the distinction between two types of reimbursement: intramural (within the hospital) and extramural (outside the hospital).

Intramural reimbursement is regulated differently depending on the type of hospital operator (i.e. state-owned, community-owned or private institution).

Extramural reimbursement depends on the social insurance institution involved, which regulates the coverage of costs for individual products. Patients generally contribute a defined co-payment towards the cost of a product. In some cases, prior authorisation must be obtained from the social insurance provider. For products that are not regulated by a tariff, a cost estimate from the contractual partner is often also required.

2 The registration obligation for manufacturers, authorised representatives and importers is (only) regulated in the EU regulations.

iii. Language requirements

Another barrier to market entry for foreign manufacturers may be the language requirement, as most of the documents addressed to the users and authorities must be in German.

Medical devices may only be supplied to users or patients if the accompanying information is in German. However, if the medical device is intended exclusively for professional users, information in English is sufficient. Moreover, users and patients must be presented with the EU declaration of conformity in German at their request. The BASG can request documents in connection with the proof of conformity in German.

Manufacturers must provide the field safety notice in German, without exception. Only certain documents can be provided either in German or English to conformity assessment bodies or notified bodies; there is also a choice between German and English for audit, assessment and inspection reports from a notified body.

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

i. Applications for determination

Domestic manufacturers can submit an application for determination to the BASG if they intend to place a product on the market. The BAGS determines whether the product is a medical device, accessory, custom-made device or an active, implantable or invasive device. An application can also be submitted to determine the categorisation and classification of a product.

ii. Exemptions from conformity assessment procedures

Authorisations for exemptions from conformity assessment procedures under the MDR can be applied for in the interest of health protection. The information required for the application includes the following:

- The justification of the extent to which the use of a medical device is necessary in the interest of health protection.
- Evidence of the lack of availability of equivalent medical devices for which the conformity assessment procedures have already been carried out.

- Confirmation of compliance with essential safety and performance requirements applicable to the medical device, taking into account its intended purpose. If certain essential safety and performance requirements are not fully met, a benefit/risk assessment will be required.

An authorisation for such an exemption is not required if a doctor or a dentist confirms that a medical device is necessary for a specific patient, in order to avert a danger to life or serious impairment of health.

iii. Clinical trials

For clinical trials that are not conducted to demonstrate the conformity of a device,[3] authorisation must be obtained from the BASG in cases where the clinical trials may have an impact on the diagnostics and/or therapy of a trial subject according to the MPG. Other clinical trials must be reported to the BASG.

Sponsors of clinical trials are obligated to take out personal injury insurance for damages caused to trial participants in the context of clinical trials, regardless of fault.

In addition, sponsors have to provide the trial subject with a contact point from which the trial subject can obtain information.

When conducting clinical trials in hospitals, the sponsor must notify the medical director of the hospital before the start and after the end of the trial. Trial subjects must not incur any costs.

Some noteworthy regulations concern the involvement of ethics committees:

A special regulation provides that the "lead ethics committees" for multi-centre clinical trials that were initially introduced in relation to medicinal products under the Medicinal Products Act (*Arzneimittelgesetz*, AMG) also act as ethics committees under the MPG 2021.

Ethics committees assess compliance with data protection regulations and with the provisions on the collection, storage and future use of biological samples. The opinion of the ethics committees must contain a clear statement of approval or rejection of the clinical trial.

Reports of adverse events that occur in Austria during clinical trials must now also be submitted by the sponsor to the assessing ethics committee.

3 With regard to clinical trials conducted to demonstrate the conformity of devices, the requirements of the MDR generally apply, cf. Art. 82 MDR.

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

i. Product liability

According to the Austrian Product Liability Act (*Produkthaftungsgesetz*, PHG), manufacturers can be held liable for damages caused by defective products, including medical devices. A product within the meaning of the PHG is any movable, physical object, including "energy". The legislative restriction to physical objects (things that "can be grasped by means of the senses") makes it clear that rights and services are not products. This means that, as far as SaMD is concerned, software that is "embodied" in a physical data carrier (USB stick, CD-ROM, etc.) and causes consequential damage is subject to the Product Liability Act.

A product is considered defective if it does not provide the safety that the user may expect. The injured party must prove that the defect caused the claimed damage. In some cases, the burden of proof may shift to the manufacturer if a product is deemed unsafe.

In the case of SaMD, product liability is established when software is a damage-causing programme sequence that leads directly to damages (i.e. without the intervening behaviour of the user following the instructions). It is therefore essential, for the purpose of establishing liability with regard to a defective product, that no human behaviour be involved.

ii. Sanctions for non-compliance with MedTech regulations

In the event that a clinical trial is conducted without authorisation or notification, in accordance with the MDR or IVDR or in accordance with the provisions of the MPG, the data obtained may not be published, passed on to third parties or used for either a conformity assessment procedure or authorisation procedure. In addition, publications that have already been made must be withdrawn.

Further, the MPG contains administrative penal provisions relating to infringements of the MDR, the IVDR and of the MPG. The catalogue of offences that trigger sanctions comprises 44 items. Penalties can reach up to EUR 25,000 and, in the event of a repeat offence, up to EUR 50,000. An attempt to deliberately commit an offence is now also a sanctionable act, which means it is punishable in and of itself.

5. What are the regulatory frameworks and market opportunities for telemedicine devices, SaMD (software as medical device) and AI-powered medical devices in your jurisdiction?

Neither telemedicine devices, SaMD nor AI-powered medical devices have been regulated in a comprehensive way in Austria to date. The only law that focuses specifically on at least a limited aspect of telehealth is the Health Telematics Act 2012 (*Gesundheitstelematikgesetz 2012*). This Act contains provisions on data protection in the context of patients' electronic health records (*Elektronische Gesundheitsakte*, ELGA).

Otherwise, telemedicine devices, SaMD and AI-powered medical devices are, at most, touched upon briefly in some of the existing laws. Specific regulations on the use of telemedicine devices in general (e.g. glucose measuring devices for diabetes patients) need to be developed.

As a consequence of the Covid-19 pandemic, the need for telemedical services and devices, such as testing systems, has increased. Several manufacturers are already offering such devices in Austria. However, as the request for a preliminary ruling by the CJEU, lodged by the Austrian Supreme Court (OGH) on 13 February 2024 (UJ v Österreichische Zahnärztekammer, case C-115/24) regarding telemedical and trans-border services of dentists shows, there is still significant legal uncertainty in the field of telehealth. This is due to the fact that the laws have, for the most part, not yet been adapted to the application of telemedicine applications.

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Bulgaria

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Introduction

Bulgaria is one of the few EU countries that still has not adopted local legislation to facilitate MDR/IVDR, meaning the former medical devices regime (aligned with the MDD and IVDD) continues to apply. This results in a high degree of uncertainty for manufacturers, wholesalers and other participants in the Bulgarian medical devices market. This also precludes the establishment of local notifying bodies to facilitate local conformity assessments, ease market access and support innovation.

The local Draft Bill, which has languished in Parliament since 2023, provides for some insight into the intended scope and country specifics of implementation. The envisaged changes could improve the functioning of the local market. However, it remains to be seen whether that approach will be kept in the final version.

Limited access to public reimbursement and the often high remaining cost to be borne by patients continue to be important hurdles. In addition, the market lacks traceability and information on produced/supplied and re-sold medical devices, allowing for unfair trade practices and non-compliance with European quality and safety standards for medical devices.

Recent amendments to various existing acts introduce general provisions on telemedicine, digitisation of healthcare services and medical records. It is a welcome step towards the modernisation of healthcare in Bulgaria, but further and more detailed regulation is still necessary.

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
x	Partial / incomplete implementation of MDR/IVDR
	Stricter /Additional requirements at national level
x	Slower approval process
x	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
	Shortage of expertise and resources
	Other example(s)

<u>Delay in national implementation</u>

Bulgaria is one of the few EU countries that still has not adapted local legislation to the MDR/IVDR. Such local provisions are necessary to facilitate the direct implementation of the MDR/IVDR provisions and ensure their full application across the value chain in Bulgaria, as well as to reflect on the areas left by the MD/IVDR for local consideration and country specific rules. The delay is mainly as a result of the ongoing political instability in the country. This has led to a high degree of uncertainty for manufacturers, wholesalers and other participants within the Bulgarian medical devices market.

A Draft Bill amending the local Medical Devices Act (**Draft Bill**)[1] was introduced by the previous Parliament for public discussions in 2023. The Parliament, however, did not have enough time to process the bill through final voting. For details on draft local implementation, see the answer to Q4. Following the recent elections, it is now expected that the Draft Bill, which already received general approval from the different public and private stakeholders, might be re-submitted for voting.

Until the Draft Bill is implemented, however, the outdated legal framework in Bulgaria, which does not allow full implementation of the MDR/IVDR and keeps the simultaneous application of previous rules and procedures, will remain in place. This framework also precludes the establishment of local notifying bodies to facilitate local conformity assessments, ease market access and support innovation.

Reimbursement of Medical Devices

The limited access to public reimbursement and the often high remaining cost to be borne by patients continue to be important hurdles. This contributes to the country's insufficient supply and diversity of medical devices, low patient satisfaction and delayed access to new and innovative technologies.

In Bulgaria, reimbursement of medical devices with public funds is mainly[2] maintained by the National Health Insurance Fund (NHIF) which operates a large part of the state budget and allows for reimbursement of treatment and medical devices costs on behalf of insured persons. The NHIF approves the medical devices to be reimbursed, their volume, reimbursement prices and the percentage of reimbursement covered by the NHIF on an annual basis. For years it has been publicly debated whether the number of medical devices admitted for reimbursement, especially those for hospital use, is insufficient to cover patients' needs and that oftentimes the share of the costs reimbursed is too low and the outstanding price to be paid by the patient remains too high. Furthermore, the NHIF applies additional policy measures for budget savings, such as individual agreements, clawbacks and unclear terms for reimbursement outside the approved volumes, which further discourage manufacturers and wholesalers from placing medical devices and innovative treatments on the Bulgarian market.

1 https://www.strategy.bg/FileHandler.ashx?fileId=33482

2 In addition to the NHIF, reimbursement of medical devices' costs in specific cases is also provided by the Minister of Health, Minister of Labour and Social Policy as well as public hospitals.

Transparency and control in the medical devices market

Another challenge that Bulgaria faces is transparency and information flow. The Bulgarian medical devices market lacks traceability and information on produced/supplied and re-sold medical devices. This leads to omissions in regulatory control and allows for non-compliance with European quality and safety standards for medical devices. Before the MDR/IVDR, Bulgaria only maintained a register for medical devices subject to reimbursement by the NHIF (which, as noted above, are few). The Draft Bill focused on improving public and medical professionals' access to information, reducing duplicate submissions, providing for better traceability on market demands and supplies and strengthening information sharing among EU Member States and with the European Commission. In order to achieve these objectives, the Draft Bill sets forth local rules facilitating the use of the European Database on Medical Devices (EUDAMED), including the implementation of local obligations for hospitals to keep registers with the unique identifier of each medical device that is supplied and used (UDI). However, given that the Draft Bill was not adopted, ensuring full technical and organisational functionality for EUDAMED's six modules, as well as UDI registers maintained within hospitals, remains a challenge.

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

The main regulatory authority for medical devices is the Executive Agency for Medicinal Products[3] (**"the Agency"**). Its role and powers are set out in the Medical Devices Act. Currently, due to the lack of local implementation of the MDR/IVDR, the Agency's key functions include:

- **Medical device registration**: the Agency is responsible for registering medical devices as a condition for market access in Bulgaria. Manufacturers and authorised representatives of medical devices are required to submit a registration application to the Agency.
- **Conformity assessment**: Before a device can be placed on the market, the Agency must issue authorisation for a conformity assessment.
- **Clinical trials**: The Agency issues authorisations to conduct clinical trials with medical devices to ensure their safety and effectiveness.

3 https://www.bda.bg

- **Control and supervision**: The Agency oversees the marketing, storage and safety of medical devices, as well as their placement on the market. The Agency also has the authority to issue penalties, fines and other measures, such as the seizure of products, in cases of non-compliance.
- **Incident registration**: The Agency maintains a system for recording and analysing reports of medical device incidents and takes measures to prevent risks.
- **Information exchange and international cooperation**: The Agency participates in the work of relevant international bodies, organisations and treaties to which the Republic of Bulgaria is a party; with the regulatory and control authorities of other countries and with organisations working in the field of medical device regulation.

The proposed Draft Bill explicitly defines the Agency as the national competent authority for the implementation of the MDR and IVDR. The Draft Bill further grants the Agency duties and powers related to the supervision of notified bodies (assessment, approval, monitoring and supervision over local notified bodies) as well as to overseeing the medical devices market as per the MDR and the IVDR. Along with the Agency's competencies, the Draft Bill further entrusts the Minister of Health with the power to allow market access to devices without conformity assessments in accidental and ad hoc occasions. It remains to be seen if the same approach and allocation of competences would be kept in a final version of the local law.

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?

Bulgaria still has not implemented the MDR and IVDR into national legislation. Therefore, local market access registration procedures conformity assessments and technical procedures, such as those under the MDD/IVDD, are still applicable. The local Draft Bill provides for some insight into the legislator's intended scope and the country specifics of implementing the MDR/IVDR in Bulgaria, which aims to improve the functioning of the local market. However, it remains to be seen if that approach will be kept in the final version or whether additional hurdles will be created.

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

Bulgaria still lacks local implementing legislation of the MDR and IVDR (see Q1 above). The envisaged national specifics of implementation are reflected in the Draft Bill, which sets forth the national regulatory bodies for the purposes of the MDR/IVDR. It aligns local registration and information requirements with the EUDAMED system and the information required therein. The Bill also develops rules for local notifying bodies, modernises clinical trial procedures and unifies local procedures on liability, penalties and fines attributable to the different parties in the value chain. Notably, the Draft Bill further provides for some interesting solutions to deal with country-specific problems. For example, the Draft Bill creates legal opportunity for hospitals to develop and use medical devices exclusively for their own purposes, subject to prior registration. This would act as an additional supply channel to outweigh issues with the supply/reimbursement of medical devices in Bulgaria, particularly for hospital use. It strictly prohibits single-use medical devices to be further re-used (as a measure to counter local practices where this is considered possible and safe for patients) and imposes stricter regulations for on-demand medical devices to counter various unfair local practices.

However, the Draft Bill does not introduce amendments to the local rules for wholesale, distribution and retail of medical devices or for their promotion, advertising and marketing.

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

Under the current Medical Devices Act, the manufacturer shall be liable for those medical devices it places on the market or puts into services. Where the manufacturer is not established within the territory of an EU/EEA Member State, they shall authorise a local representative. Their liability may arise from the omission of the mandatory conformity assessment, insufficient labelling, lack of instructions and non-compliance with the expiry date of the product. Wholesalers of medical devices also have liability under the Medical Device Act with regards to the maintenance of medical devices storage facilities and the storage of the medical devices themselves (in accordance with the requirements specified by the manufacturer). Wholesalers are also liable for non-compliance with the expiry date of a product. In addition, the head of a medical or healthcare institution may be held liable for allowing the use of medical devices without instructions or with wrong labelling, subsequent to their expiry date. The levels of penalties generally vary between EUR 1,500 and EUR 10,000.

The Draft Bill introduces additional liability provisions (e.g. for the particular official at fault who committed the offence, etc.) and elaborates on the sanctions and penalty ranges for the infringements already prescribed in the MDR/IVDR to make them enforceable. The penalties for non-compliance in the Draft Bill are higher than current penalties under the Medical Devices Act (EUR 2,500 – EUR 20,000), especially for repeating infringements.

Under Bulgarian law, product liability attributable to medical devices is further regulated by the following acts:

- Directive 85/374/EEC is transposed in the Bulgarian Consumer Protection Act (**the CPA**). Under the CPA, a medical device is considered a dangerous product if it does not conform to generally accepted expectations of normal use, taking into account factors such as quality, presentation, advertising and when the product was put on the market. The CPA imposes strict liability on the producer of a defective product, which means that the producer may be liable even without negligence or fault. "The producer" does not refer only to the manufacturer, but also to the importer of the product, any person putting their name on the product and the person supplying a product whose producer or importer cannot be identified (e.g. wholesaler, distributor, etc.). The CPA also lists defences available to producers to avoid liability, such as lack of involvement in placing the product on the market or if the defect arose after the product was sold. The Act outlines two types of damages that can be compensated to a natural person: Personal injury or death and damage to property. While there is no minimum or maximum claim amount for personal injury, in order for property damage to be covered, the property in question should be valued at no less than 500 euros and intended for personal use. There is still no local draft bill considering the implementation of the EU new Product Liability Directive.
- the EU General Product Safety Regulation (GPSR) 2023/988[4] will also apply to companies that sell medical devices as consumer products. A draft bill for the amendment of the Consumer Protection Act has already been issued and, if accepted, will create the conditions for the implementation of the Regulation.[5]
- General provisions of contract law as well as tort law, where the above special regimes are not applicable.

4 https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32023R0988

5 https://www.mi.government.bg/?post_type=public_discussion&p=20094

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?

Important amendments to the national health regulations were adopted on 25 September 2024, which introduce general provisions on telemedicine and the digitalisation of healthcare services and medical records, namely:

- The Medical Institutions Act now explicitly addresses telemedicine and provides for a general definition thereof. The Act defines telemedicine as *diagnostic, medical, rehabilitation and prevention activities to be carried out remotely using modern information technology.* However, it prescribes for mandatory prior consent from the patient for being subject to remote medical examination, imposes a requirement for the use of adequate IT tools and contains an explicit requirement that any telemedicine tool shall ensure the protection of related health data. The Act clarifies that medical practitioners shall abide by the same medical standards of care and quality of medical services as in-person checks and assigns them the ultimate responsibility for the remote medical examination. It is envisaged that a secondary legislation will further develop telemedicine procedures. The Act remains silent on whether telemedicine services shall be reimbursed by the NHIF. There is significant public pressure in favour of introducing such regulation given that telemedicine is quite popular among businesses and patients and its possible reimbursement would make it much more affordable. For example, many patients in rural areas and regions without available medical specialists may prefer using telemedicine for examination purposes.
- Key amendments in the Health Act aim to reduce any paper records of health data and impose a mandatory requirement that all medical data for patients be duly recorded in the electronic health record in a timely manner, including those not covered by the National Health Insurance Fund (NHIF). Another important element is the creation of a new regime for the evaluation of medical software products to ensure the protection of personal health data and the accuracy of the data records submitted.
- A 2022 amendment to Ordinance N4 of 4 March 2009 on the conditions and procedures for prescribing and dispensing medicinal products, sets forth that healthcare specialists are entitled to prescribe medicines by means of electronic prescriptions through the website of the NHIF. Currently, this amendment still requires that the patient be present at the doctor's office for examination, which contradicts the newly introduced telemedicine rules.

The Medical Devices Act recognises that the software within health apps and other software facilitating telemedicine can be classified as a "medical device", where it complies with the respective definition in the Supplementary Provisions of the Act. Namely, the software within a digital app shall be intended to be used, independently or in combination with other devices, on human beings for one or more of the medical purposes defined therein. Where the software is classified as SaMD, it will be further subject to conformity and state-of-the-art requirements, as well as general liability rules for medical devices attributable to the manufacturer (see 5. above).

In 2020, the Council of Ministers adopted the Concept for the Development of Artificial Intelligence in Bulgaria until 2030. The Concept aims to establish and maintain a National Access Point for providing a national and cross-border secure exchange of electronic health records (with medical and health data from treatments, therapies, tests and medical imaging). With the planned development of such a data base in Bulgaria, the Concept would make it possible to apply AI tools for pattern and predictive analytics to detect diseases and risk factors based on large quantities of pseudonymised data collected from Bulgarian patients. Upon detection of the likelihood of risk of a disease, it would be possible to send a message to at-risk patients and their physicians, for prevention purposes, within an integrated health information system. In this way, new models for the treatment and prevention of different diseases would be explored based on big data analysis with AI tools.

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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.

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Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Czech Republic

Wolf Theiss

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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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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Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Poland

Wolf Theiss

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.

Poland

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Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Romania

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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.

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Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Slovak Republic

Wolf Theiss

Introduction

A number of factors cause delays in market entries and restrict access to the supply chain in the Slovak Republic. The complexity of the regulatory pathway and the need to submit extensive documentation can be challenging, particularly for smaller companies or new products. The intricacies of regulatory requirements, including the language requirements for documentation, create administrative burdens. Additionally, meeting conformity assessment and compliance requirements before marketing a device may pose challenges, especially if these steps are not completed promptly or correctly.

Reimbursement schemes exist for various types of distribution, from hospitals and pharmacies to tailor-made devices. Reimbursement costs, however, are often limited to the cost of cheaper products or are set by the authorities. Advertising of medical devices is subject to fewer restrictions compared to medicinal products and is governed by the general provisions for all products.

The regulation for the provision of healthcare services via electronic communication technologies was adopted back in 2020 and electronic prescription systems have been regulated since 2018. However, despite their growing use in practice, telemedicine devices and software are not fully regulated.

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
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.
	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
	Shortage of expertise and resources
	Other example(s)

Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on Amendments and Supplements to Certain Acts, has been amended several times to implement the Medical Devices Regulation (MDR) and in vitro diagnostic medical devices regulation (IVDR) of the European Union. These regulations were implemented gradually through three amendments, which came into effect in 2020, 2021 and 2023. The amendments aimed to harmonise requirements for compliance, risk management and conformity assessment of medical devices, in order to enhance patient protection and ensure the safety and transparency of these devices.

Currently, there is only one notified body in the Slovak Republic that is designated for both MDR and IVDR compliance – 3EC International. This organisation is responsible for the conformity assessment of medical devices under MDR and IVDR regulations. Its role is to verify that medical devices meet stringent requirements for safety, quality and performance, thereby ensuring that they can be marketed and used in the Slovak Republic and across the European Union (EU). The organisation's work supports vigilance processes and helps maintain supply chain stability for medical devices.

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

The State Institute for Drug Control (**ŠÚKL**) plays a significant role in ensuring compliance, vigilance and the safety of medical devices and in vitro diagnostic medical devices. Its primary activities include maintaining the national register of medical devices. Distributors responsible for making devices available on the market are registered for a period of five years. The ŠÚKL also verifies the accuracy and compliance of data that is submitted to the electronic registration system by manufacturers, authorised representatives and importers.

Furthermore, the ŠÚKL fulfils the role of regulatory authority of a Member State. This includes overseeing clinical evaluations, conducting health technology assessments (HTA) and ensuring risk management during market surveillance of medical devices. The institute is also responsible for the conformity assessment of diagnostic in vitro medical devices through performance studies and for vigilance to monitor adverse events.

In addition to its national activities, the ŠÚKL actively cooperates with EU Member States to address supply chain disruptions, ensure proper risk classification and promote the safe and effective use of medical devices, thereby protecting public health.

Responsibility for notified bodies lies with the Slovak Office of Standards, Metrology and Testing, which oversees their authorisation, notification and regulatory pathways to meet EU obligations. This ensures alignment with Medical Devices Regulation (MDR) and compliance with the Product Liability Directive for safe market entry.

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?

Placing medical devices on the market

In order to market a medical device or an in vitro diagnostic medical device in the Slovak Republic, several legal and safety requirements must be met. According to Act No. 362/2011 Coll. on Medicinal Products and Medical Devices, manufacturers must ensure that devices are correctly installed, maintained and used in compliance with their intended purpose, thus ensuring safety and avoiding adverse events for patients or users. During exhibitions and trade fairs, in vitro diagnostic medical devices that do not yet meet regulatory compliance may be displayed, provided there is a visible notice stating that their use will be allowed only after meeting the regulatory requirements. Marketing mercury thermometers for measuring body temperature and sphygmomanometers for the general public, for instance, is prohibited.

Before placing a device on the market, a manufacturer, authorised representative, importer or distributor must notify the ŠÚKL within 14 days of the device becoming available on the market. This process involves submitting the necessary documentation, such as the EU Declaration of Conformity, conformity assessment certificate and instructions for use. The obligation to provide documentation does not apply to Class I medical devices or Class A in vitro diagnostic medical devices, unless requested by the ŠÚKL.

The ŠÚKL oversees the national register of medical devices and conducts vigilance activities, including the notification and registration of medical devices. After a device is placed on the market, the ŠÚKL assigns a unique code to the device and updates the database.

Reimbursement of medical devices

Medical devices provided in hospitals are fully reimbursed, except for those listed in special schedules. If interchangeable devices are available, reimbursement is limited to the cost of the least expensive device.

In outpatient care, medical devices included in the categorised medical devices list may be fully or partially reimbursed, provided they are prescribed and used in accordance with prescription guidelines, indication limits, quantity restrictions and their cost does not exceed financial limits set by health insurance providers.

In pharmacy care, medical devices listed in the categorised devices list are reimbursed fully or partially under public health insurance if prescribed and used according to restrictions set by health insurance companies, including prior authorisation when necessary.

Custom-made medical devices and special materials are eligible for reimbursement only if they meet certain requirements and are approved by health insurance providers or equivalent bodies.

Barriers to market entry

The complexity of the regulatory pathway and the need to submit extensive documentation can be challenging, particularly for smaller companies or new products. The intricacies of regulatory requirements, including the obligation to provide documentation in Slovak, Czech or English, creates administrative burdens. Additionally, meeting conformity assessment and compliance requirements before marketing a device may pose challenges, especially if these steps are not completed promptly or correctly. Such obstacles can delay market entry and restrict access to the supply chain, impacting the overall distribution of medical devices.

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

Language accessibility

In the Slovak Republic, manufacturers, authorised representatives, importers and distributors must ensure that all information accompanying medical devices and in vitro diagnostic medical devices for users and patients is in Slovak. An exception applies to devices intended exclusively for professionals, where labelling may be in English, provided instructions for use are in Slovak.

Availability of categorised medical devices

Manufacturers, authorised representatives and importers of medical devices listed in the national register of medical devices must ensure delivery within 72 hours of receiving an order from a pharmacy. This obligation is essential to ensuring the timely availability of medical devices in critical situations.

Advertising of medical devices

The advertising of medical devices is subject to fewer restrictions compared to medicinal products. While advertisements for medicines are heavily regulated, advertising of medical devices is governed by the general provisions of the Advertising Act. Advertisements must adhere to compliance standards, be truthful, non-misleading and not endanger the health of users, while respecting ethical principles.

Voluntary registration of distributors

The voluntary registration of distributors of medical devices with the ŠÚKL offers the benefit of them being included in the official register, thus enhancing their credibility in the market. Registration, which is valid for five years, ensures adherence to compliance and transparency.

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

In the Slovak Republic, product liability for medical devices primarily rests with manufacturers, who must ensure that their products meet all safety and performance requirements throughout their lifecycle. Additionally, distributors are responsible for ensuring that the medical devices they place on the market comply with regulations, are properly labelled and meet all required standards. If these obligations are not met, distributors may also face civil liability for damages. Furthermore, healthcare providers are responsible for reporting any adverse events involving medical devices or in vitro diagnostic medical devices to the ŠÚKL.

Non-compliance with regulations may lead to administrative fines. The ŠÚKL, as the regulatory authority, has the power to impose fines on manufacturers and distributors who fail to comply with requirements for registration, conformity assessments or product safety. Penalties for non-compliance can reach up to €50,000, depending on the severity of the violation.

If a medical device poses a risk to public health or fails to meet compliance standards, the ŠÚKL can issue an administrative decision to withdraw the product from the market. Manufacturers may also be required to initiate recalls of defective products to protect the public.

Under the Product Liability Directive, manufacturers and distributors are obligated to compensate injured parties for harm caused by defective medical devices. Affected individuals may seek damages for injuries, illnesses or death resulting from product defects.

Severe negligence or fraud, such as falsifying medical devices or endangering users with unsafe products, can lead to criminal liability under the Slovak Criminal Code. These offenses may result in criminal penalties, demonstrating the critical importance of risk management and vigilance throughout the lifecycle of a medical device.

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?

Telemedicine in the Slovak Republic is currently not fully regulated. According to the Act on Medicinal Products, a medical device is defined as a tool, instrument, device or software intended for diagnostic, preventive or therapeutic purposes. This framework may include telemedicine devices, but national legislation does not explicitly define the term "telemedicine".

In practice, telemedicine in the Slovak Republic saw significant development during the COVID-19 pandemic. Legislation passed in 2020 allowed the provision of healthcare services via electronic communication technologies, such as telephone or email consultations, eliminating the need for in-person visits to healthcare providers. This form of healthcare delivery requires the verification of the patient's identity and their relationship with a health insurance provider. A notable example of telemedicine implementation was the e-quarantine application, which monitored individuals under quarantine.

Despite its growing implementation, telemedicine remains a widely debated topic in the Slovak Republic. For example, the Slovak Society for Telemedicine and Digital Health, a group of healthcare professionals and physicians, aims to promote the concept of digital health in the country. However, there is still no comprehensive regulatory framework for telemedicine in place, presenting challenges for its further development.

The integration of telemedicine into the Slovak healthcare system has the potential to enhance healthcare delivery, but establishing a clear regulatory pathway and ensuring compliance with national and EU regulations will be crucial for its sustained growth.

AI is a frequently discussed topic. For instance, the hospital in Košice has become the first to utilise AI in emergency departments to identify fractures. The University Hospital in Bratislava also uses advanced, AI-powered robotic technology for complex spinal surgeries. However, the use of AI remains without specific legislative regulation, with oversight currently limited to the EU level.

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Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Ukraine

Wolf Theiss

Introduction

Ukraine's medical devices sector faces many challenges, ranging from those caused by the war with Russia to a lack of transparency in public procurement and limited state financing. In addition, complicated registration and certification procedures, as well as a limited local production base, create further hurdles.

The country has a draft law that aims to adapt the national regulations to the provisions of MDR and IVDR, but it has been stagnant in Parliament since mid-2022.

The reimbursement system for medical devices is underdeveloped and currently covers only blood sugar tests for type 1 diabetes. Certain medical device purchases are fully or partially funded by the state or from local budgets.

The amendments to the law in 2023 loosened the rules for advertising medicinal products somewhat.

Another law adopted in 2023 introduced a number of definitions in the telemedicine sphere and allowed the provision of medical and rehabilitation care online. Russian and Belarusian citizens are, however, prohibited from providing such services. The use of ICT systems for such services from Russia and Belarus is also prohibited.

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)
	Lack of sufficient number / limited access to notified bodies / notified body bottlenecks
X	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
X	Other example(s): deficiencies in public procurement system

Under the Agreement on Association between Ukraine and the European Union, Ukraine has an obligation to adapt its national legislation to EU regulations.

In line with this obligation, the draft law "On Medical Devices" No. 7585 (the "**Draft Law**"), aimed at adapting current Ukrainian regulations to the provisions of MDR and IVDR, was submitted to the Ukrainian Parliament in mid 2022. As of the date of this publication the document has not been adopted. It is expected that the Ministry of Health will adopt additional Technical Regulations ("**TRs**"), providing further details to the rather general provisions of the Draft Law.

A number of factors cause supply delays and increases in the prices of medical devices. The war in Ukraine has brought a number of challenges in terms of fostering growth in the medical devices market, including the destruction of medical institutions; warehouses and manufacturers of medical devices; blockages of borders; ports; challenges with supply chains originating in China; the destruction of energy infrastructure and a lack of medical personnel due to their mobilisation and massive domestic and international migration.

The public procurement system lacks transparency, there are risks of corruption and delays in tender procedures. The lack of state financing prevents the replacement of outdated medical devices.

Complicated registration and certification procedures increase the price of imports and often prevent foreign manufacturers from entering the Ukrainian market. At the same time, local manufacturers often lack financing for the development and manufacturing of new medical devices.

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

In order to be put into circulation in Ukraine, medical devices should comply with TRs. Conformity assessment bodies assess the compliance of medical devices with TR requirements. Customs authorities are tasked with controlling the quality of imported products *inter alia* via checking the relevant documents.

Once medical devices are in Ukraine and put into circulation, the State Service of Ukraine on Medicines and Drugs Control (in Ukrainian: *Державна служба України з лікарських засобів та контролю за наркотиками*, "**SSUM**") is the primary regulatory authority responsible for overseeing medical devices. The SSUM maintains the Register of Persons Responsible for Putting Medical Devices on the Market, based on information received from manufacturers or their authorised representatives. The SSUM is entitled to conduct planned and unplanned (unannounced) inspections to assess the compliance of medical devices with TRs. These inspections were suspended as a result of the onset of full-scale war with Russia; they were, however, renewed in 2024.

Planned inspections are performed based on annual or sectoral plans. The list of legal entities to be inspected, based on the annual plan, is published online in December of the preceding year. The list of legal entities and individuals-private entrepreneurs subject to

inspections is not available for sectoral plans, however, sectoral plans do specify the names of those medical devices that will be subject to inspections and publish them on the SSUM website. Unannounced inspections are conducted based on reports from stakeholders (i.e. consumers, executive bodies, law enforcement agencies and consumer associations), which contain information on the distribution of products that have caused harm to the public interest or have defects that may cause such harm.

If the SSUM determines that a medicinal product in circulation must not be used further, said medicinal product should be withdrawn from circulation (e.g., recalled or destroyed).

Violations detected during SSUM inspections are subject to fines. The amount of a fine depends on the nature and the degree of risk of the violations detected.

Compliance of manufacturers and sellers of medical devices with the requirements of Ukrainian competition regulations is overseen by the Ukrainian competition authority (the Antimonopoly Committee of Ukraine, the "**AMC**"). In cases of unfair competition, those legal entities and individuals-private entrepreneurs that are in violation of competition regulations can be fined by the AMC.

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?

Although Ukraine introduced the reimbursement of medical devices for patients on 1 July 2023, this currently only covers blood sugar test strips for patients with type 1 diabetes.

Certain medical device purchases are fully or partially funded by the state or from local budgets.

In terms of regulatory approvals, manufacturers must ensure their devices comply with legal requirements and obtain a conformity assessment from the authorised body. Manufacturers who introduce devices into the Ukrainian market for the first time must apply to be listed in the Register of Persons Responsible for Placing Medical Devices on the Market.

With regard to the potential barriers to entry, as noted in the answer to question 1 above, complicated registration and certification procedures increase the price of imports and often prevent foreign manufacturers from entering the Ukrainian market. At the same time, local manufacturers often lack financing for the development and manufacturing of medical devices.

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

Amendments to the Law of Ukraine "On Advertisement" were introduced in 2023. Those relating specifically to medical devices are the following:

- A disclaimer stating that: "*Self-medication can be harmful to your health*" must now be played at least once during audio advertisements (or at least once every minute) at the same volume as the rest of the audio track;
- Persons engaged in the production and/or sale of medicines, medical equipment, methods of prevention, diagnosis, treatment and rehabilitation, may now also sponsor websites, concerts, sporting events and other events and projects; whereas previously they were allowed to sponsor only a limited number of events (e.g., radio and television programmes).

Ukraine has a separate registration system for medical device manufacturers and their authorised representatives (authorised representatives are appointed in cases where manufacturers are not residents of Ukraine). Under TRs, manufacturers who introduce devices into the Ukrainian market for the first time must register to be listed in the Register of Persons Responsible for Placing Medical Devices on the Market, which is maintained by the SSUM.

Finally, Ukrainian authorities are empowered to impose financial penalties of up to approximately EUR 8,000 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?

In 2023, the Ukrainian Parliament adopted the Law "On Protection of Customers' Rights". This law was developed to approximate national consumer protection legislation to EU legislation and harmonise the consumer protection system in Ukraine with EU principles, approaches and practices. However, it will become effective only after the termination or cancellation of martial law.

The currently effective Law "On Protection of Customers' Rights" from 1991 (with subsequent changes) provides a possibility for end users of medical devices to apply to the courts for reimbursement of material and non-material damages that are caused as a

result of product defects. Moreover, the law provides for the possibility to impose a fine for the manufacturing or the sale of products that do not meet the regulatory requirements related to health and safety, private property and the environment, in the amount of 300% of the value of goods manufactured or received for sale.

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 Ukrainian healthcare system, including the increasing use of technology in diagnosis and treatment, requires the adjustment of the national regulatory frameworks to reflect these technological advancements.

In 2023, the Law "On Amending Certain Legislative Acts of Ukraine regarding Functioning of Telemedicine" was adopted. It introduced a number of definitions in the telemedicine sphere and allowed the provision of medical care and rehabilitation care using telemedicine and tele-rehabilitation by registered foreign individuals, except for citizens of Russia and the Republic of Belarus. The latter are expressly prohibited from providing telemedicine and tele-rehabilitation services. The law also directly prohibits the provision of relevant services via information and communication systems, the rights to which are registered in the Russian Federation or the Republic of Belarus. However, the law is rather general and does not cover all the necessary aspects related to telemedicine.

Under TRs for medical devices, the software provided by a manufacturer for diagnostic and/or therapeutic purposes, which is necessary for the proper functioning of a medical device, is also considered a medical device.

Despite the widespread discussion of AI in Ukraine and the fact that many software producers utilise AI algorithms, no national regulations have been adopted in this area.

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