Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Ukraine

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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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