Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

Bulgaria

Wolf Theiss

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.

Authors:

Hristina Dzhevlekova
Counsel
E hristina.dzhevlekova@wolftheiss.com
T +359 2 8613 700

Yana Madzharova
Associate
E yana.madzharova@wolftheiss.com
T +359 2 8613 752