Medical devices in CEE & SEE

Navigating the challenges to modern healthcare

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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