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New Medical Device Act in Austria

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Introduction

The term "medical device" covers a wide range of products, including plasters, implants, pacemakers and x-ray units. Another product group that falls under the category of medical devices is in vitro diagnostics, which covers, among other things, pregnancy tests and – particularly relevant in the context of the covid-19 pandemic – antibody and polymerase chain reaction tests.

In May 2017 the EU Medical Device Regulation[(1)] (MDR) and the EU In Vitro Diagnostics Regulation(2) (IVDR) entered into force. EU Regulation 2020/561 postponed the effective dates of the MDR and the IVDR until 26 May 2021 and 26 May 2022, respectively. Both regulations are directly applicable in all member states. However, the MDR does not cover all aspects of medical device law (it does not cover, for example, advertising rules) and provides for implementation obligations and enabling provisions.

In June 2021, against this background, the Austrian legislature enacted a new Medical Device Act 2021(3) (MDA 2021) to replace the Medical Device Act 1996. Like the old act, the MDA 2021 governs both medical devices and in vitro diagnostics.

Competent authority

In section 2 of the MDA 2021, the Federal Agency for Safety in Healthcare (BASG) is designated as the competent national authority as per the meaning of the MDR and the IVDR. The BASG is responsible for keeping the market under surveillance.

Language

According to section 7 of the MDA 2021, medical devices may be provided to users and patients only if the information about them is provided in German. If the use of a medical device is limited exclusively to professional users, information in English is sufficient.

Upon a request from a user or patient, an EU declaration of conformity must be provided in German. The BASG may request additional information in connection with the evidence of conformity in German.

The field safety notices, as provided for by article 89(8) of the MDR, must also be provided in German. Audit, assessment and inspection reports of the notified body can be provided in German or English. However, no such provision exists for documents submitted by conformity assessment bodies according to articles 38 and 39 of the MDR to require these documents to be provided in German.

In-house devices

With the exception of the general safety and performance requirements set out in Annex I of the MDR, the MDR does not apply to devices that are manufactured and used only within health institutions. Section 9 of the MDA 2021 provides that the Ministry of Social Affairs, Health, Care and Consumer Protection may enact a regulation prohibiting health institutions from manufacturing and using specific medical devices.

Declaratory ruling

According to section 10 of the MDA 2021, manufacturers may apply to the BASG for a declaratory ruling as to whether a product is:

- a medical device;
- an accessory for a medical device;
- a custom-made device; or
- an active, implantable or invasive device.

Manufacturers can also apply for the classification of the device.

Clinical evaluation

The confirmation of a medical device's conformity with general safety and performance requirements and the evaluation of undesirable side effects and the benefit-to-risk ratio will be based on clinical data. To that end, manufacturers must plan, conduct and document a clinical evaluation.

For implantable devices and Class III devices, clinical investigations must be performed. The principles of clinical investigations are laid

down in articles 63 to 80 of the MDR. According to article 67 of the MDR, member states may maintain additional measures regarding:

- persons performing mandatory military service;
- persons deprived of liberty;
- persons who, due to a judicial decision, cannot take part in clinical investigations; or
- persons in residential care institutions.

The MDA 2021 made use of this provision and excludes these persons in section 25 as study subjects.

According to article 62(3) of the MDR, clinical investigations will be subject to scientific and ethical review. The ethical review will be performed by an ethics committee in accordance with national law. Member states must ensure that the procedures for review by ethics committees are compatible with the procedures set out in the MDR for the assessment of the application for authorisation of a clinical investigation. According to section 20(1) of the MDA 2021, the ethics committee must evaluate the study protocol and provide a clear approval or denial of the clinical trial. The sponsor must inform the BASG and the ethics committee of any adverse effects according to section 22 of the MDA 2021.

According to article 69 of the MDR, member states must ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation are in place in the form of insurance, a guarantee or a similar arrangement. Section 26 of the MDA 2021 provides that the sponsor must be responsible for putting in place personal injury insurance and provide study participants with a contact point where they can obtain information.

If a clinical investigation is conducted without approval or notification under the MDR, IVDR or MDA 2021, the data generated must not be published or used in the course of a conformity assessment or approval process. Any publications must be withdrawn (section 34 of the MDA 2021).

Registration

Under the MDR and the IVDR, only manufacturers, authorised representatives and importers must be registered. The MDA 2021 also provides for the registration of manufacturers of custom-made products and retailers. Until the EUDAMED database is functional, registration must be made with Gesundheit Österreich GmbH.

In addition to the economic operator, as provided for by article 31 of the MDR, the MDA 2021 also provides for the surveillance of institutions and persons applying and using medical devices professionally, such as cosmetic studios or fitness studios. The intent of the legislature was to include these businesses because they also use devices for liposuction, lipolysis or lipoplastics.

Advertising

Similar to the old Medical Devices Act, the MDA 2021 provides for advertising rules similar to those for medicines. According to section 70 of the MDA 2021, information on the intended use must be provided on a device's label and in the instruction leaflet. According to section 71 of the MDA 2021, advertising for consumers is prohibited for medical devices that are:

- subject to prescription;
- to be used only by healthcare professionals; or
- used by consumers in connection with a medical or dental treatment.

Section 73 of the MDA 2021 provides that advertising for consumers must not:

- imply that the effect of a treatment is superior to that of another medical device;
- be intended primarily for children; or
- imply that a medical treatment is unnecessary.

The advertisement must contain:

- the name of the medical device;
- a short description of the intended purpose;
- essential information on the application of the device; and
- a clear indication that the medical device may have adverse effects or that its application requires safety precautions.

With regard to advertising for professionals, section 75 of the MDA provides that in connection with promotion, healthcare professionals must not be granted premiums or financial or other advantages unless they are of minor value and relevant for the medical practice.

Penalties

Infringements are penalised by both administrative fines and private enforcement through competitors and self-regulation (via the Austromed-Code of Conduct and the Medtech-Code of Conduct). According to article 113 of the MDR, penalties must be effective, proportionate and dissuasive. Accordingly, section 80(1) of the MDA 2021 provides for administrative fines. However, the fines may be a maximum of €25,000 (or €50,000 where an offence is repeated).

Comment

Through the new MDA 2021, the Austrian legislature fulfils its implementation obligations under EU law. Unlike the previous Medical Devices Act, the MDA 2021 is only a national supplement to the directly applicable EU regulations on medical devices and in vitro diagnostics. Where the regulations do not cover certain aspects (eg, advertising) the MDA 2021 basically corresponds to the previous Medical Devices Act.

The most significant improvements of the MDA 2021 are:

- the permission to use English;
- the expansion of surveillance to persons supplying and using medical devices professionally other than healthcare professionals; and

- the Act's adaption to the Act on Medicines.

For further information on this topic please contact Rainer Herzig at Preslmayr Attorneys at Law by telephone (+43 1 533 16 95) or email (herzig@preslmayr.at). The Preslmayr Attorneys at Law website can be accessed at www.preslmayr.at.

Endnotes

(1) 2017/745/EU.

(2) 2017/746/EU.

(3) BGBl I 2021/122.