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HEALTHCARE AND LIFE SCIENCES

FEDERAL MINISTRY OF HEALTH DRAFT BILL ON THE ADAPTATION OF MEDICAL DEVICE LAW

As of 26 May 2020, Medical Device Regulation (EU) 2017/745 (MDR) shall be applied in the EU in a binding manner and shall replace the previously applicable national medical device laws. However, the regulations require implementation rules and specifications by the Member States in many areas.

On 29 August 2019, the Federal Ministry of Health introduced, to this end, a draft Act on the adaptation of German medical device regulations to the MDR (MPAnpG-E, available here).

Dr. Enno Burk, counsel at Gleiss Lutz specialising in medical device and pharmaceutical law, explains the most important content of the draft.

What is at issue?

The key component of the draft is the new Medical Device Implementing Act (Medizinprodukte-Durchführungsgesetz – **MDG**), which is based on the provisions of the MDR and replaces the previous MPG with effect as of 26 May 2020. The draft now being introduced by the Federal Ministry of Health is intended to allow the smooth application of the MDR with effect as of 26 May 2020 and the IVDR with effect as of 20 May 2022. The scope of application of the MDG will also extend to in vitro diagnostic medical devices upon the date of application of the Regulation on in vitro diagnostic medical devices ((EU) 2017/747, **IVDR**) on 20 May 2022.

The most important changes of the draft and their effects

1. Exemption from CE certification – special authorisation of medical devices by the competent higher Federal authority

- The MDR will increase the requirements for a positive conformity assessment, in particular where class III high-risk medical devices are concerned. The reaction to this is the possibility of national special authorisations of medical devices in section 5 MDG in conjunction with Article 59(1) MDR which have not yet been subject to the conformity assessment procedure.
- The Federal Ministry of Health expects that in the future special authorisations will have to be issued considerably more often since, in particular in the case of medical devices for rare diseases, the clinical evidence of a successful conformity assessment in accordance with the stricter requirements of the MDR will not yet be available.
- The authorisation procedures will be laid down by the Federal Ministry of Health in a regulation which shall also formulate the tasks of the competent higher Federal authorities with respect to the evidence to be furnished.

The special authorisation can be an alternative for suppliers of urgently needed medical devices to quickly place their products on the market and to collect data for the successful conformity assessment.

2. Classification of medical devices in the case of disputes

- Disputes between a manufacturer and its notified body on the classification of a medical device are to be presented to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und

- Medizinprodukte - BfArM) – as the sole higher Federal authority competent for this – to be decided on (section 9(1) in conjunction with section 52(2), no. 1 MDG). Upon application, the BfArM will decide on the classification or legal status of the medical device.

This procedure is likely to become more important from a practical standpoint given the foreseeable uncertainty with respect to the classification of medical devices in the risk classes of the MDR.

3. Obligation to preserve documents even after closure of a business or insolvency

- A new feature is that section 11(1) MDG obliges the suppliers of medical devices to keep regulatory documents available for the storage periods specified in the MDR, even if the business activity is ceased. This also applies in the case of insolvency. Further details are laid down in a regulation of the Federal Ministry of Health on the basis of section 11(3) MDG.
- The regulation can also specify that the manufacturers, sponsors or other responsible persons can be obliged by the regulation to jointly establish and maintain a depository that ensures the orderly preservation of documents in the event that their respective business activities are ceased. Comparable documentation requirements did not previously exist.

4. Supplementary requirements for clinical investigations of medical devices

- Sections 17 et seq. MDG contain supplementary national requirements for carrying out clinical investigations, in particular rules for the authorisation of clinical investigations and – where less risky products are investigated – their prior notification to the competent Federal authorities. Section 19 MDG governs the procedure before the ethics committee, whose consent to the clinical investigation generally continues to be required.
- The special category of "other clinical investigation" has been created. According to section 3(4) MDG, an "other clinical investigation" is a clinical investigation that is not a part of a systematic and planned process for product development or product monitoring of a current or future manufacturer and that is not carried out with the aim of demonstrating the conformity of a products with the requirements of the MDR.

5. Federal government centrally responsible for monitoring medical devices

- Section 38(1) MDG stipulates that it is the responsibility of the competent higher Federal authorities (Federal Institute for Drugs and Medical Devices, Paul Ehrlich Institute) to centrally fulfil the vigilance tasks assigned to the Member State authorities under the MDR in order to ensure the central evaluation of reports of serious incidents and field safety corrective actions.

6. Federal government responsible for measures to avert danger

- Sections 44, 45 MDG stipulate a departure from the previous system for allocating responsibilities between the higher Federal authorities and the competent authorities of the Federal States with regard to averting risks. To date, the higher Federal authorities have been responsible for the central recording and evaluation of incident reports, while the application of measures to avert risks has been the responsibility of the competent authorities of the Federal States, which decide on the necessary measures.
- According to the MDG, the monitoring authority which has responsibility under the law of the respective Federal State will transfer the incident to the competent higher Federal authority for risk assessment if there is a well-founded suspicion of an unacceptable risk arising from a product.
- The higher Federal authority will then, pursuant to section 45(1), sentence 1 MDG, itself order the measures necessary to protect health (such as public warnings, an order for a product recall or a ban on placing a product on the market, section 45(2) MDG.
- In the event of imminent danger, the competent Federal State authority will still be able to take any and all measures necessary to protect the health or safety of patients or other persons.

Whether the Federal States will raise objections under constitutional law to the transfer of their administrative responsibility will become clear during the further course of the legislative procedure.

7. Monitoring of the manufacturers and suppliers of medical devices

- Pursuant to section 42(1) MDG, companies and institutions that manufacture medical devices or handle them or place them on the market will be subject to monitoring. The details will be laid down in an administrative regulation, with the responsibility remaining with the Federal State authorities.
- Section 42(3) MDG now expressly stipulates that the competent authorities must have the necessary personnel and material resources to fulfil their tasks and must ensure adequate further training for the employees carrying out the monitoring.

8. Introduction of DMIDS (Deutsches Informations- und Datenbanksystem über Medizinprodukte – German Information and Database System for Medical Devices)

- The German Institute of Medical Documentation and Information is to bring the current information system for medical devices in line with the requirements of the MDR. The new "German Information and Database System for Medical Devices" (DMIDS) should be fully functional by 31 December 2021 at the latest and ensure that data can be exchanged with the European Database on Medical Devices (EUDAMED).
- The national database system is essentially only to be accessible to public authorities. Access rights are also provided for professionally active third parties such as notified bodies. Free access to information for users and patients is not planned. Further details will be laid down in an ordinance to be issued by the Federal Ministry of Health.
- Should the introduction of the central European Database on Medical Devices EUDAMED or of the DMIDS be delayed, the Federal Ministry of Health may announce how the notification obligations can be fulfilled temporarily.

9. Provisions on penalties in the MDG

- Section 59 et seq. MDG contain various provisions on penalties which stipulate, in particular, imprisonment and fines in the event of the placing on the market, manufacture or storage of products that are potentially unsafe or hazardous to health. The same applies to counterfeit products, counterfeit accessories for medical devices or components.
- Depending on the severity of the cases, the intentional commission of an offence may result in imprisonment of between one and five years or a fine. The negligent commission of an offence is punishable by imprisonment of up to one year or a fine.
- Further provisions regulate the penalties for conducting clinical investigations of medical devices without obtaining the necessary authorisation or without prior notification of the competent authority. Also of practical relevance is that, in addition to having consequences under competition law (in particular injunctive relief), misleading information in advertising for medical devices can also result in criminal liability. In addition, less serious violations of the law are sanctioned as administrative offences.

10. Manufacturers of medical devices not obliged to have liability insurance

- The draft does not stipulate that manufacturers of medical devices must have insurance cover with specific minimum amounts. The general provision in Article 10(16), subparagraph 2 MDR, which merely requires manufacturers to make reasonable provision for potential liability cases, will continue to apply.

What happens next?

The Act must be approved by the Bundesrat. In particular, the centralisation of responsibilities for medical device monitoring at the Federal level is likely to lead to debate due to the associated loss of powers by the Federal State authorities. Industry associations have already voiced fears that the personnel resources of the Federal authorities are insufficient to cover the increased tasks.

The draft bill is currently with the other departments for discussion. It is to be expected that the Federal Ministry of Health will push ahead with the consultation and legislative process despite foreseeable reservations, so that a functioning regulatory framework will be in place on 26 May 2020 when the MDR comes into force.

Healthcare and Life Sciences

LAWYERS

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