

THE COUNTDOWN FOR THE MDR IS ON: 175 DAYS TO GO – IS THE GERMAN LEGISLATOR READY YET?

The Medical Device Regulation (“**MDR**”) and the In vitro Diagnostic Medical Devices Regulation (“**IVDR**”) entered into force on 25 May 2017. Without doubt, among the major innovations of the MDR are certainly the stricter regulations with regard to the safety and traceability of medical devices as well as stricter regulations regarding medical devices as software. In addition, the new classification rules for medical devices are definitely among the major changes of the MDR.

Due to the far-reaching implications of the MDR and IVDR for the medical device industry as well as for the numerous national regulations and laws associated with it, a national transition period of three (MDR) and five (IVDR) years applies. Now, approaching the end of the transition period for the MDR, the focus for all stakeholders of the industry (including medical device companies, retailers, OEMs, notified bodies and national authorities) is on the final steps of preparation to ensure compliance with the new regulations of the MDR as of 26 May 2020.

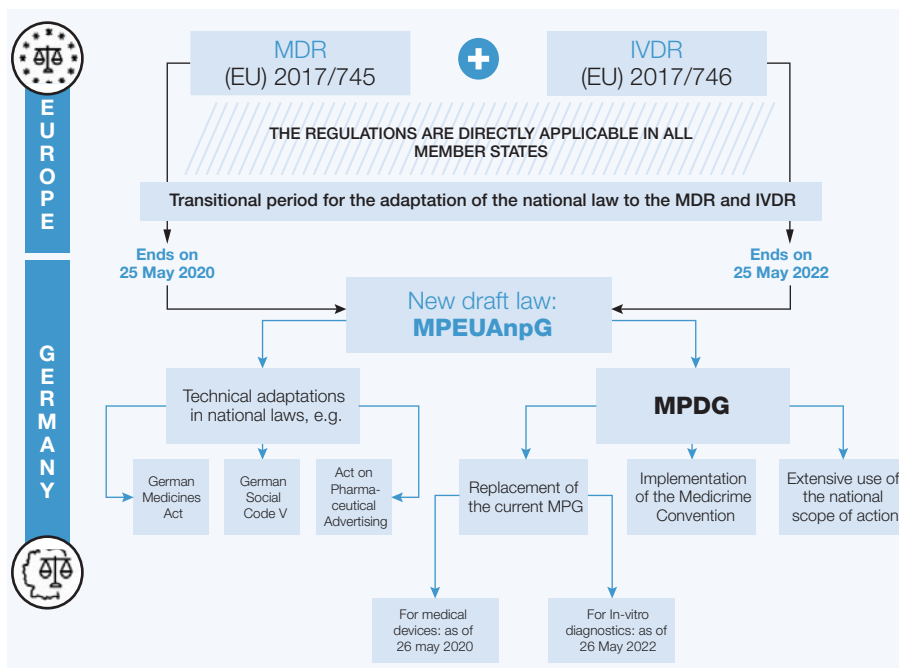
However, although the MDR is a piece of European legislation which will be directly applicable in all member states, it requires several adaptations of the current national legal frameworks. Thus, the focus is not only on preparations of the industry, but also on the process of the national legislators in implementing and reflecting the MDR in the national laws, which must be completed on time.

1. Setting the Scene in Germany: The ‘EU Medical Devices Adaptation Act’

In order to implement German medical device law and adapt it to the upcoming EU legal framework governed by the MDR, on 6 November 2019, the German Federal Government adopted the draft of the EU Medical Devices Adaptation Act (*Medizinprodukte-EU-Anpassungsgesetz*; ‘**MPEUAnpG**’).

On the one hand, this draft law serves to achieve the technical adaptation of the national medical device laws to the MDR. This includes, primarily, the modification of references in corresponding laws, the synchronisation of definitions, etc. In some cases, the MDR also contains further implications to be observed in corresponding national regulations. These changes not only affect the former German Act on Medical Devices (*Medizinproduktegesetz*, ‘**MPG**’), but also require adaptations of, for example, the German Medicines Act (*Arzneimittelgesetz*), the German Social Code V (*Sozialgesetzbuch V*) as well as the German Act on Pharmaceutical Advertising (*Heilmittelwerbegesetz*).

On the other hand, the MPEUAnpG itself contains a draft bill for a new act, the Medical Devices Implementation Act (*Medizinproduktedurchführungsgesetz*; ‘**MPDG**’). With effect from 26 May 2020, it will replace the previous MPG and will provide for the required national framework to support the regulations of the MDR. To the extent that in-vitro diagnostics are concerned, the MPDG will not enter into force until 26 May 2022 (i.e. after the end of the transition period of the IVDR).



However, the MPDG, as the new key legislative source for German medical device law, is not limited to the implementation of, and adaptation of, the provisions of the MDR, but also contains other innovations, going beyond the mandatory scope of the MDR.

2. The Medicrime Convention

The MPDG will provide for offences relating to the counterfeiting of medical devices. These are based on the provisions of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health ("**Medicrime Convention**").

The Medicrime Convention is the first international treaty that obliges the contracting states to make punishable certain activities, such as the manufacturing of counterfeit medical devices and pharmaceuticals or their supply, offering for sale or trade. Furthermore, the manufacturing and placing on the market of medical devices which do not fulfil the conformity requirements imposed on them will also be made a criminal offence.

3. Further regulations

In addition, the current draft of the MPDG makes extensive use of the scope of action which the MDR leaves to the national legislator:

Responsibilities of authorities

With respect to risk assessment and the allocation of rights and duties between German federal and state authorities, the current draft of the MPDG provides for an enormous shift of responsibilities in favour of the German Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*; '**BfArM**').

Currently, the BfArM is responsible for assessing the risk and recommending appropriate measures to the responsible local authorities at state level. Based on this recommendation, it was for the local authority at state level to decide whether, and which, measures should be taken to avert risks.

Looking forward, this responsibility should lie with the BfArM. The responsible authorities at state level should only act in cases of imminent danger. In the draft bill, this shift of responsibilities in favour of the BfArM is justified by the fact that the MDR provides for a “central” evaluation for these tasks.

In addition, the BfArM should also play a decisive role in intra-European communication, for example with regard to agreements with corresponding institutions of other EU countries.

Involvement of ethics committees

With regard to the participation of ethics committees, the draft law provides for a clear, graduated procedure in which the consenting opinion of the relevant ethics committee at the state level must form a part of the application for approval filed with the BfArM.

Innovations with regard to clinical trials

In the future, the MPDG will also contain detailed regulations for so-called ‘other clinical trials’. These are, in particular, merely scientific studies which are not directly related to product introduction or product monitoring (i.e. which do not serve to prove the benefit, safety or performance of the product). The new regulations include various notification obligations and the involvement of the ethics committee.

In addition, the regulations currently contained in the German Regulation on Clinical Trials of Medical Devices (*Verordnung über klinische Prüfungen von Medizinprodukten*; “MPKPV”) on the requirements for investigators, recording and notification obligations and monitoring will also be regulated in the MPDG. As a result, the MPKPV will be repealed.

Language regime

The MPDG also takes account of the importance of the English language and allows the documents for conformity assessment to be submitted solely in English. However, the necessary information for users and patients (labelling and instructions for use) should still be available in German. For professional users, though, the information intended for them can only be made available in English (or another language that is easily understood by the professional users of the medical device).

Subsidiary legislation

Finally, the draft law contains numerous authorisations of the German Federal Ministry of Health (*Bundesgesundheitsministerium*; ‘BMG’) to issue various regulations. They may relate, for example, to the use of software as a medical device (e.g. medical apps). Since the provisions of the Medical Device Operator Regulation (*Medizinproduktebetriebsverordnung*), in its current version, are tailored to the use of material medical devices, the BMG is authorised to issue special provisions tailored to the use of software as a medical device.

4. Next steps in the legislative process

In the next step in the legislative process, the German Federal Council will be involved in a first hearing, which is scheduled for 20 December 2019. The three readings in the German Parliament will follow between January and mid-February 2020. The second hearing, aimed to obtain the required consent of the Federal Council, is planned for March 2020. Bearing in mind the approaching deadline of the MDR in May 2020, this tight schedule would then leave industry players (and authorities) approximately two months to adapt to the new regulations.

Against this background, for all players involved in the medical device sector, it is therefore essential to follow closely the further legislative process of this bill and to make themselves familiar with these innovations in national medical device law immediately.

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Clifford Chance, 10 Upper Bank Street,
London, E14 5JJ

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