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HEALTHCARE AND LIFE SCIENCES

THE MDR COUNTDOWN HAS STARTED. A SUMMARY OF THE LATEST LEGAL DEVELOPMENTS

The MDR will come into effect on 26 May 2021, a year later than planned owing to the Covid-19 pandemic. Although the pandemic has not yet finished, there will be no further postponement. We summarize here the most important legal developments over the last year.

1. Bottlenecks at the notified bodies not yet removed

Notification of the respective bodies continues to be sluggish.[1] In response to a request by the FDP parliamentary party in late October 2020, Germany's Federal Government stated that it expected 25 notified bodies to have been successfully notified by May 2021 such that they could carry out certifications under the MDR[2]. As of 21 March 2021, however, only 19 have in fact been notified. Given the speed at which the medical technology industry innovates, and thus the need for notified bodies that can act and react rapidly, this is worrying. In the event that there are bottlenecks in conformity assessments after 26 May 2021, the Federal Government plans to facilitate more special authorisations in cases where urgently needed medical devices would otherwise be unavailable.

2. No transitional arrangements for existing certificates

Although the MDR's entry into force has been postponed by a year, the deadlines by which existing certificates must have been used has not changed. Pursuant to Article 120, subparagraph 2 MDR, certificates issued under the old MDD up to 26 May 2021 will lose their validity no later than 27 May 2024. Even certificates issued just before 26 May 2021 under current law will therefore be valid for little more than three years.

3. EUDAMED – registrations possible since 1 December 2020

It is expected that the European Database on Medical Devices (EURAMED) will not be fully operational and functional before May 2022. In the light of experience to date, it is doubtful whether full functioning can be guaranteed by this date, which is just over a year away. All the same, on 1 December 2020 the Commission activated the first module on Actor Registration. This module permits the single registration number (SRN) stipulated in Article 31 MDR to be issued. Any economic operator – i.e. both EU and non-EU manufacturers, authorised representatives and importers – can be registered as an actor in EUDAMED and provide the necessary information.

3.1 Contradictory recommendations by the MDCG and Germany's Federal Ministry of Health as regards actor registration

There is no duty to register as an actor until all six EUDAMED modules are fully functional. Nevertheless, the Medical Devices Coordination Group (MDCG) recommends that actors register now. Federal Ministry of Health representatives, however, recently criticised the fact that the Commission has enabled actor registration despite the MDR not yet being in force.[3] The Commission approved the module "without having previously analysed all the legal consequences, above all of the competent public authorities issuing SRNs early". Under section 93(3), no. 2 of Germany's Medical Devices Implementation Act (*Medizinprodukte-Durchführungsgesetz*) improper registration is subject to criminal liability. This is one reason why the Federal Ministry of Health representatives recommend that

public authorities should not issue SRNs through the activated EUDAMED module before 26 May 2021. In addition to this, the Federal Ministry of Health intends to draw on the transitional regulations and will validate this EUDAMED module's functionality. So it remains an open question whether and when actor registration will be functioning and binding for undertakings based in Germany.

3.2 Stop-gap guidelines

Irrespective of the first EUDAMED module's activation, in February 2021 the MDCG published detailed guidelines with stop-gap solutions until EUDAMED becomes functional.[4] These guidelines provide tables giving detailed explanations of alternative technical solutions for submitting or exchanging information. This is to standardise administrative practice across the Member States as far as possible.

Overall, therefore, the situation as regards EUDAMED's implementation and functioning remains confusing and unsatisfactory for the undertakings concerned. Eudamed Module II (for UDI/device registration) and Module III (for certificates and notified bodies) are to be available by September 2021.

4. Increased use of special authorisations as a stop-gap solution where there are bottlenecks in conformity assessment

Article 59 MDR facilitates special authorisations by public authorities. It came into effect on 24 April 2020. According to this rule, any competent public authority in a Member State may upon request approve the medical device's placing on the market and putting into service, such approval being limited to the respective Member State's territory.

4.1 Requirements for authorisation to be issued

The rule does not provide that the authorisation procedure be subsidiary to the conformity assessment in standard cases. Use of the medical device for which authorisation is requested must be "in the interest of public health or patient safety or health". Special authorisations are supposed to range from individual authorisations on humanitarian grounds to product group authorisations to secure the entire population's needs as regards medical devices. Applications for special authorisations are possible where patients' lives and/or health are at risk because the corresponding medical device is not available or represents an urgently needed product innovation.[5] The Federal Institute for Drugs and Medical Devices is responsible for issuing authorisations. Not only manufacturers but in principle anyone – such as healthcare facilities, healthcare professionals, or patients – is entitled to file such request.[6] Special authorisations are issued at the due discretion of Germany's Federal Institute for Drugs and Medical Devices (BfArM). In contrast to the current legal situation, a time limit is now no longer provided for. As this constitutes an administrative act,[7] those affected may avail themselves of legal protection under the Administrative Courts Code (*Verwaltungsgerichtsordnung*), including injunctions for a special authorisation to be issued.

4.2 Special authorisations as a solution for bottlenecks at notified bodies

Special authorisation does not fit well into medical device law, shaped as it is by the conformity assessment conducted by notified bodies. In the light of the Covid-19 pandemic, however, this tool has gained in importance over the last twelve months. In response to our request for information, the Medical Devices Department (*Abteilung Medizinprodukte*) of the Federal Institute for Drugs and Medical Devices stated that 234 applications for special authorisation had been filed between February 2020 and 19 January 2021. Of these, 212 were linked to the Covid-19 pandemic[8]. Given the potential certification bottlenecks with the current 19 notified bodies, it is possible that the special authorisation procedure will become even more important for certifying medical devices under the MDR. But this remains to be seen. It will largely depend on how the administrative practice of the Federal Institute for Drugs and Medical Devices develops. In any event, German legislators expect a long-term increase in the number of applications for special authorisation, compared with practice to date, where these applications concern medical devices for rare diseases.[9]

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[1] Bundestag printed paper. 19/24164.

[2] Bundestag printed paper 19/24164, p. 3.

[3] Knauer/Neumann, *MPR* 2021, 1 et seq.

[4] *Medical Device Coordination Group*, Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional, February 2021, at: Guidance - MDCG endorsed documents and other guidance | Public Health (europa.eu).

[5] Willhöft/Schwind, *MPR* 2020, 46 (50).

[6] Bundestag printed paper. 19/15620, 123.

[7] Rehmann/Wagner/Wagner, *MPG*, 3rd edition (2018), § 11 margin no. 12.

[8] E-mail from Federal Institute for Drugs and Medical Devices, Medical Devices Department, dated 19 January 2021 – 126-2020#6126.

[9] Draft Act to Harmonize Medical Device Law with EU Regulations (*Medizinprodukte-EU-Anpassungsgesetz*), 104 et seq.; Bundestag printed paper 19/15620, 123.

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