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Liability challenges to the medical devices industry

European Parliament adopts the new MDR

On 5 April 2017, despite uncertainties about the regulatory legal scope, the practical applicability of certain provisions, and the law's realizability within the given transition period, the European Parliament adopted the Medical Device Regulation ("MDR"). Together with the In Vitro Diagnostics Regulation ("IVDR"), the regulation intends to significantly reinforce the existing regulatory approach and at the same time improve health and safety through transparency and traceability measures. The regulations were formally published in the Official Journal of the European Union on 5 May 2017. They will come into effect on 25 May 2017. They will be applied into law on 26 May 2020 and 26 May 2022 respectively.

New scope and new definitions

The scope of application of the MDR was significantly broadened compared to the current Medical Device Directive (Directive 93/42/EEC). Products used for the cleaning, disinfection or sterilization of medical devices will be considered medical devices themselves. Certain groups of products with a medical character will fall under the MDR even if they do not meet the current definition of medical devices, such as contact lenses and auxiliary products, subcutaneous anti-wrinkle treatment, fat removal devices, etc.

New roles and potential personal liabilities

The MDR introduces new roles with new duties as well as new responsibilities into medical devices law.

Authorized representatives established in a Member State and appointed by manufacturers based outside of the European Union shall be legally liable for defective devices "on the same basis as, and jointly and severally with, the manufacturer". While the exact design of liability is yet to be seen, it is expected, that authorized representatives will face significantly higher liability risks.

Also, manufacturers – with the exception of micro and small businesses – will have to appoint a "person responsible for regulatory compliance". This person will have to oversee the manufacturer's quality management and post-market surveillance system "in a manner that is proportionate to the risk class and the type of device". Meanwhile, it remains unclear what exact requirements the European and national legislators will set in the future when implementing the MDR, and what this means for liability risks.

While not obliged to employ a "person responsible for regulatory compliance", micro and small businesses will at least have to have such a person "at their disposal" on a permanent basis.

The distribution of liability between such an independent individual and a respective micro or small business raises further inquiries, which we will continue to address over time.

Reprocessing and further use of single-use devices will only be allowed under strict limitations and where permitted by national law. The reprocessor of a single-use device will thusly be considered the manufacturer of the device and have to face the same responsibilities as a manufacturer and "producer" of medical devices. In other words, producer's liability will be placed on the reprocessor.

New challenges for the industry

The MDR may have significant impact on companies' product liability and product compliance policies.

While the grounds for the product liability regime are still set in the Product Liability Directive (Directive 85/374/EEC), the MDR requires manufacturers to have measures in place providing "sufficient financial coverage" in respect of their potential liability. While according to the MDR, such measures shall be proportionate to the risk class, type of device and the size of the enterprise, the law does not further specify the scope and the extent of this obligation. It will be on the Member States to further specify the extent of and calculation basis for financial coverage, as well as respective sanctions in cases of non-compliance.

The MDR asks for rules which will enable the competent authority to facilitate the provision of information to persons who may have been injured by a defective device.

With the publication in the Official Journal of the European Union the transition period has begun. Equipped with a three and five year transition period, the MDR will be applied in 2020, and the IVDR in 2022. During this period, we will be there to support you to best adapt to these new requirements.

Band 1 for Dispute Resolution and Life Sciences in Chambers Global 2017.

Your contacts

Dr. Matthias M. Schweiger
Partner, Munich
T +49 89 29012 327
matthias.schweiger@hoganlovells.com

Nicole Boeck
Senior Associate, Munich
T +49 89 29012 260
nicole.boeck@hoganlovells.com

www.hoganlovells.com