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Legal Alert

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European Commission proposes more changes for medical devices

EU regulations on medical devices (MDR[1]) and in vitro diagnostic medical devices (IVDR[2]) have been applied for several years now (MDR – start of application: 26th May 2021; IVDR – start of application: 26th May 2022). On 23rd January 2024, the European Commission proposed another amendment, which includes, among other things, new obligations for manufacturers.

The draft proposes changes in both the MDR and IVDR areas, below are the most important ones.

New transition periods for IVDR and conditions to be met to take advantage of them

For manufacturers of medical devices as well as in vitro diagnostic medical devices, the proposed conditions will not be new. The amendment implies analogous conditions for taking advantage of the transition period to those already in place for MDR, including adjusting the Quality Management System by 26th May 2025, applying to a notified body within a timeframe that depends on the risk class, and signing a contract with a notified body within a timeframe that depends on the risk class of the in vitro diagnostic device.

Fulfilment of the above conditions will enable further and longer marketing of so-called *Legacy devices*:

- until 31st December 2027 – a transitional period for Class D devices;
- until 31st December 2028 – a transitional period for Class C devices;
- until 31st December 2029 – a transitional period for Class B devices and Class A devices that are placed on the market in a sterile state.

New obligations for manufacturers

If a manufacturer considers that there will be an interruption in the supply of a device (both a medical device and an in vitro diagnostic medical device) and the interruption is likely to cause serious harm or a risk of serious harm to patients or public health, the manufacturer will be obliged to inform the following of the anticipated interruption: the authority of the Member State in which it or its authorized representative is established and the economic operators, public health institutions and healthcare professionals to whom it will directly supply the device.

The amendment provides for the obligation to notify the above-mentioned entities min. 6 months prior to the anticipated interruption.

The mandatory use of EUDAMED could be faster

Not long ago, the European Commission released new information on the estimated date of full functionality of the EUDAMED database. Should the European Parliament and the Council adopt this amendment, it may become outdated.

The European Commission proposes audits of modules of the base instead of an overall audit. In case of a positive audit result for a particular module and after a "transitional period", the use of a specific part would be mandatory.

As a reminder, the modules on Actors and Devices are already available.

The full contents of the draft amending the MDR and IVDR can be found at LINK.

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[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU