Europe's New Medical Device Regulation (MDR) Overview

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Recently new EU regulations on medical devices were adopted. These replace the existing Directives:

> Regulation (EU) 2017/745[1] 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
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> Regulation (EU) 2017/746[2] 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

The new rules will only apply after a transitional period. Three years after entry into force for the Regulation on medical devices (spring 2020) and five years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices.

The EU Commission welcomes the adoption of these two new medical devices regulations which establish a modernized and more robust EU legislative framework to ensure better protection of public health and patient safety.

Medium and high risk medical devices are not subject to a pre-market authorization by a regulatory authority but to a conformity assessment which, involves an independent third party, Notified Body. Once certified, devices bear the CE marking which allows them to circulate freely in the EU/EFTA countries and Turkey.

What are the existing EU Medical device regulations issues?

• Existing EU rules dating back to the 1990s have not kept pace with the enormous technological and scientific progress in the past 20 years.

• EU countries interpret and implement the current rules in different ways.

• It is not always possible to trace medical devices back to their supplier. New rules on traceability are needed.

• Patients, healthcare professionals and other interested parties do not have access to essential information on how medical devices have been assessed, and what clinical evidence there is to show they are safe and effective.

• The need for greater transparency has been highlighted by two recent scandals: faulty silicone breast implants, French health authorities found that a French manufacturer (Poly Implant Prothèse, PIP) over several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval provided by the notified body, causing potential harm to thousands of women around the world, and problems with some metal-on-metal hip replacements.

What exactly will change?

• Wider, clearer scope for EU legislation on medical devices

• Stronger supervision of independent notified bodies by national authorities

• More powers for notified bodies to ensure thorough testing and regular checks on manufacturers, including unannounced factory inspections

• Clearer rights and responsibilities for manufacturers, importers and distributors

• Extended Eudamed database on medical devices – will provide comprehensive information on products available on the EU market. Non-confidential data will be publicly available

• Better traceability of medical devices throughout the supply chain – enabling a swift and effective response to safety problems (e.g. recalls). Implementation of unique device identification (UDI).

• Device manufacturers will be required to identify at least one person within their organization who is ultimately responsible for all aspects of compliance with the requirements of the new MDR.

• Stricter requirements for clinical evidence to support assessments of medical devices

• Updated classification rules dividing medical devices into 4 different risk categories and health & safety requirements, including labelling rules – to keep pace with technological and scientific progress

• Better coordination between national surveillance authorities, with the Commission providing scientific, technical and logistic support.

• Essential requirements (Annex I) are called General Safety and Performance Requirements. There will be an emphasis on risk management and Common Specifications (CS) will exist where there are no harmonized standards.

• An 'own brand labeler' (OBL) is a person or company who places their own label/brand name and name and address on a medical device which they have not designed and do not manufacture and which is already CE marked and on the market in the name of another company, the OBL Company becomes the legal 'manufacturer' under the medical device regulations and must take full responsibility for, and meet all the requirements of the medical device regulations.

• International guidelines to be incorporated into EU law.

Next Steps

Upon expiry of the transition periods in 2020 (MDR) and 2022 (IVDR), the new Regulations will become fully applicable.

During the transition periods, manufacturers may choose whether they want a medical device to be certified under the old or the new regime. However, four years after the effective date of the MDR, *i.e.*, in 2024, all CE-certificates issued under the old rules of the MDR will expire. By then at the latest, all medical devices marketed in the EU will have to comply with the new regime.

The transition periods are not as long as some would have hoped, given the significance of the changes. These changes will require medical device manufacturers to review and evaluate current operations and systems to ensure compliance with new and enhanced requirements. While the new Regulations reflect a trend toward greater harmonization of EU and US requirements, companies with global operations, distributions and products should take a holistic approach to compliance and implement regulatory and compliance processes that are appropriate, adaptable and scalable for a global marketplace.

1 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:117:FULL&from=EN

2 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:117:FULL&from=EN