EU MDR DEADLINE DELAY: WHAT DOES IT MEAN FOR THE MEDICAL DEVICE INDUSTRY?

With the compliance deadline for the EU Medical Device Regulation recently delayed by a year due to the novel coronavirus pandemic, Beth Crandall, Managing Director, Global Solutions Delivery Leader at Maetrics, looks at what it means for the medical device industry.

The medical device industry has been working hard for some time to meet the EU's Medical Device Regulation (MDR) compliance deadline – and it has been a challenging journey for many. The recent delay of a full year to the date of application is therefore a welcome development, especially now that businesses are facing new and extraordinary challenges due to the global health crisis. However, it is important to be aware of the changes that have actually been made and also what is not changing, to fully understand the scope of this recent development.

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THE DETAIL

The MDR's new date of application – May 26, 2021 – was approved by the European Parliament in an amendment to the original regulation. The vote to delay was approved by an overwhelming margin on April 17, 2020 and the amendment was published in the Official Journal of the European Union on April 23, 2020. The delay only applies to the MDR – and the regulatory requirements remain the same for medical device manufacturers, notified bodies, authorised representatives, importers and distributors. There is no change to the In Vitro Diagnostic Regulation (2017/746).

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KEY TAKEAWAYS

Firstly, there is no change to the transition dates for CE Mark certificates under the previous EU Medical Device Directive (MDD). CE Mark certificates under the MDD will still expire no later than May 26, 2024 and devices in service or already on the market as of May 26, 2021 may continue to be made available until May 26, 2025. However, Article 120 now clarifies that the transition dates also apply to Class I devices for which an assessment to the EU MDR requirements would require a notified body.

Secondly, the amendment introduces staggered implementation dates for reusable devices which bear the Unique Device Identification (UDI) carrier on the device itself. This is a clarification welcomed by the industry, as the implementation of the UDI requirements impacts regulatory documents and product labelling. The earliest UDI date is now May 26, 2023 for implantable devices and Class III devices. Class IIa and IIb devices are May 26, 2025, and Class I devices are May 26, 2027.

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There are also updates to Article 59 – Derogations from the conformity assessment procedures. This pertains to exceptions to the rules for conformity assessments that allow non-CE marked products deemed of "humanitarian use" to be used for the good of public health. The amendment also now specifically references the corresponding articles in the MDD (Article 11.13) and Active Implantable Medical Device (Article 9.9). By including these references to the directives, the derogations adopted under the directives may apply or be extended using Implementing Acts once the May 26, 2021 date of application is reached. This is important in the context of the efforts to get products quickly and yet safely on the market related to the global pandemic.

IMPLICATIONS FOR DRUG-DEVICE COMBINATION PRODUCTS

Pharmaceutical, biopharm and biologic companies must increasingly stay informed about the implications of EU MDR and EU In Vitro Diagnostic Regulation. EU MDR particularly impacts combination products currently regulated as medicinal products. These are ancillary drugs or biologically active components that function as the principal therapy outcome mechanism of the device. An insulin pump is an example of one such product, where the medical device's intended purpose is the delivery mechanism for the integral drug or biologic component. EU MDR inclusion results from combination devices' increasing design and production complexity, thus ensuring equivalent risk management and safety scrutiny as a standalone device must demonstrate.

Under EU MDR, combination products are categorised as Class III devices by the presence of a medicinal substance. The product Class III classification implications are significant regarding the clinical investigation structure, clinical evaluation report data collection and analysis methods. Standard drug company practice of three production lots for product validation is insufficient to demonstrate device compliance under EU MDR. This extension greatly benefits biopharm companies for whom clinical investigations and data gathering protocols are more aligned with traditional pharmaceutical development practices versus the enhanced clinical requirements of EU MDR, affording them more time to prepare.

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Another important consideration for biopharm combination devices as a result of the EU MDR extension is the degree of substantial changes to product design, and addition and replacement of components or medicinal substances that manufacturers should consider during the extension period. Biopharm combination products currently authorised for sale in the EU should assess EU MDR requirements for any proposed or future device changes until the conclusion of the extension to ensure those changes do not impact the device's current market access status. Significant or substantial changes during the extension period could result in regulatory review and approval being required prior to the extension conclusion.

So there are significant hurdles that biopharma, biologic and pharmaceutical companies may not be set up for, as opposed to their medtech company counterparts. Partnering with a regulatory consultancy that can bring relevant industry insight and hands-on experience can be a critical strategic move to hit the new May 2021 deadline.

OPPORTUNITIES FOR MANUFACTURERS

With this delay comes a significant opportunity for manufacturers to use this time wisely. Being ready for quality and regulatory compliance will give companies an edge over their competitors and reduce the risk of products being taken off the market. Many businesses were struggling to meet the deadline fully and will be able to use the additional time to make sure they are completely prepared by, for example, reviewing their clinical evaluations and technical file documentation, assessing post-market surveillance documentation and properly evaluating economic operator relationships and agreements. The clarification in UDI timelines also allows for more robust planning and implementation.

ABOUT THE COMPANY

Founded in 1984, Maetrics is a global life sciences consulting firm focused exclusively on regulatory, quality and compliance solutions for medical device, diagnostic, pharmaceutical and biotechnology companies. With offices throughout Europe and North America, Maetrics can assist with local, regional and global compliance needs.

ABOUT THE AUTHOR

Beth Crandall is a respected leader who brings over 15 years of experience in the life sciences industry, specialising in the regulated medical device market. She also possesses a strong background of leading large quality system programmes and implementing changes to related policies, procedures and systems. Ms Crandall uses organisational change techniques to maximise productivity while achieving business and compliance objectives. She gained a BA from the College of St Thomas (MN, USA) in Business Administration, Human Resource Management.