ECONOMIC OPERATORS UNDER THE EU MDR: THE NEW REQUIREMENTS

In this article, Beth Crandall, Managing Director, Global Solutions Delivery Leader at Maetrics, spells out the new requirements for economic operators under the EU Medical Device Regulation.

There is still a lot of confusion surrounding the EU Medical Device Regulation (MDR) and its implications for life sciences companies – notably regarding economic operator (EO) requirements. The delay of the EU MDR deadline to May 26, 2021 is therefore a welcome development for the industry. This additional time will allow businesses to better prepare for the complex changes in regulation and thoroughly address the specific requirements that relate to their EOs.

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In addition to medical device businesses, pharmaceutical, biopharma and biologics companies should also be informed of the implications of the EU MDR for any of their products that meet the definition of a medical device. Under the regulation, pharma companies will need to undergo much stricter oversight for the ancillary device component of their combination products and will therefore need to verify compliance throughout their supply chain and confirm that all EOs are fulfilling their responsibilities. In this article, we help to break down these new responsibilities into digestible parts with the aim of responding to some of the queries and concerns in the industry.

Previously, compliance for medical devices was a topic that mostly concerned device manufacturers. However, due to the changes to the rules defining medical devices in Europe, additional industry sectors will be impacted. One of the significant changes to the regulation – affecting any company with products that now qualify as medical devices – is the new concept of EOs. When the new EU MDR comes into effect, the responsibilities and requirements will extend to not only manufacturers but also importers, distributors and authorised representatives. Under the EU MDR, EOs share the duty of ensuring compliance. Issues from any one of the EO entities can have direct legal and compliance implications for the other EOs in the supply chain (Figure 1).

The manufacturer, importers and authorised representatives must also prepare to be registered. Given the delayed launch of the European Database on Medical Devices (EUDAMED), this process of registration is still uncertain. It will be important to stay up to date as new guidance is provided, as an alternative method of registration may be provided.

Figure 1: The economic operators affected by the EU Medical Device Regulation.

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MANUFACTURERS

Even as regulatory responsibility is being increasingly shared, manufacturers must still ensure compliance with the applicable regulations if they wish to continue placing their devices on the EU market. Manufacturers will continue to play a pivotal role in ensuring compliance with their specific requirements, as well as with the requirements of their EOs across the supply chain. Manufacturers should map out their supply chain and identify each EO entity as defined in Article 2 of the EU MDR. This important mapping will serve as a foundation for the overall efforts to assess and confirm the ability of their EOs to fulfil their responsibilities. Manufacturers should also confirm the right personnel are ready to manage EOs through supplier controls and audits.

There are many other new requirements for manufacturers which apply at different times, depending on the class of device and the CE mark expiration date for current devices on the market. Some requirements apply on the date of application, May 26, 2021, such as the requirement to register and comply with post-market surveillance requirements. Other new requirements will not be implemented until much later, including the requirement for having unique device identification (UDI) on the products, which will be implemented, based on the risk class of the device, from May 2025.

IMPORTERS

According to Article 2 of the EU MDR, importers are those entities which place devices from a third country on the EU market. Importers will see a significant change to their expectations and requirements. They must now meet specific regulatory requirements and verify information from the manufacturer. For example, they will have obligations relating to non-conforming products, product recalls and vigilance incidents. This means that, should importers identify a non-conforming device, they must have a system in place to notify the manufacturer, the authorised representative and the competent authority.

Other responsibilities include keeping a copy of the Declaration of Conformity of the device and copies of any certificates, amendments and supplements. They must also provide full co-operation to provide samples of the device and access to it. These duties are new to most importers and may require additional resources with specific expertise to be successfully implemented.

DISTRIBUTORS

Distributors, just like importers, previously had no responsibilities under the European Medical Device Directive (MDD). After the date of application, they will be attributed a more active role in ensuring the compliance of the products that they distribute. Although they are the only EO entity not specifically listed as being jointly and severally liable, they will be required to act with due care and ensure that storage or transport conditions comply with those set out by the manufacturer. They must also verify that instructions for use (IFUs) are included with each device (where required) and must ensure that the CE mark, Declaration of Conformity and any required unique device identification (UDI) is present. They must also report incidents to manufacturers within their distributor agreements.

AUTHORISED REPRESENTATIVES

Where the manufacturer of a device is not established in a member state, the device may only be placed on the EU market if the manufacturer designates an authorised representative. Entities falling under this category must register themselves in EUDAMED – or whichever alternative EO registration system is adopted until EUDAMED is implemented. Authorised representatives must also have access to a person responsible for regulatory compliance (PRRC). After the date of application, authorised representatives will also need to allow for financial coverage with respect to any potential "liability", as they will be made

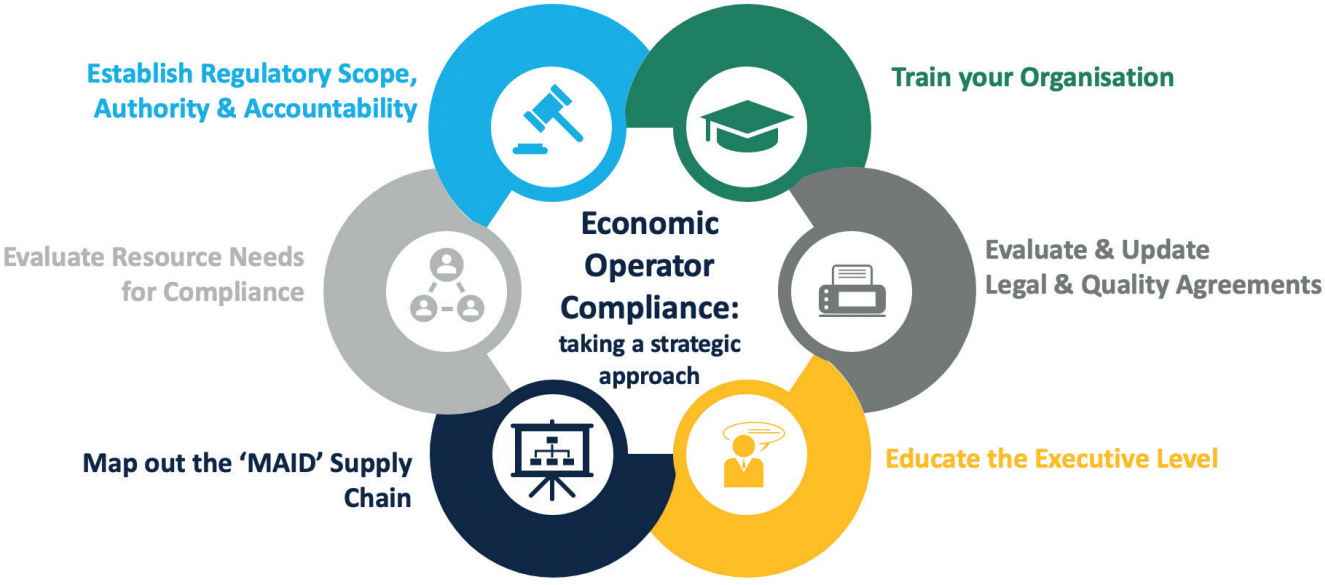

Figure 2: A strategic approach to economic operator compliance.

jointly liable for devices, alongside the importer and manufacturer. These new requirements and increased legal liability present new challenges for the role of authorised representatives, and may require organisational authority changes for certain businesses.

CONCLUSION

With so many new responsibilities spread across the EOs in the supply chain (Figure 2), manufacturers will do well to engage their regulatory teams and educate executive management about the implications of these changes. Involving the executive management of the company will help during assessments of legal impact, product portfolio decisions and resource implications, including decision-making authority and staffing levels. All EO entities alike should begin tackling these requirements now, in order to have all their systems and processes correctly set up before the EU MDR deadline.

The consequences of non-compliance – which may involve losing market access and facing new legal liability – must be carefully considered by executive management. Given the complexity of these changes, this is an ideal time for businesses to reach out to external experts for guidance, and to assess and confirm compliance across their EO network.

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 or global compliance needs. Maetrics is part of R&Q Holdings LLC.

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ABOUT THE AUTHOR

Beth Crandall is a respected leader who brings more than 15 years of experience in the life sciences industry, specialising in the regulated medical device market. She also has 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 has a Bachelor of Arts degree from the College of St Thomas (Saint Paul, MI, US) in business administration, human resource management.