REGULATORY FOCUS

MDR, IVDR, and compliance: A guide for distributors

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Distributors must prepare for new incoming requirements under EU medical device and in vitro diagnostic device regulations. The importance of establishing an effective quality management system, drafting comprehensive contractual agreements and, if required, engaging notified bodies, has created much uncertainty for distributors. To fulfil these new requirements and maintain device supply chains, it is essential for distributors to act early, ensure sufficient in-house competency, and consult with subject matter experts where needed.

Introduction

The new regulations for medical devices (EU Medical Device Regulation [MDR], 2017/745)[1] and in vitro diagnostic devices (EU In Vitro Diagnostic Regulation [IVDR], 2017/746)[2] will come into effect on 26 May 2021 and 26 May 2022, respectively. The new regulations focus more on postmarket distribution activities and distributors in the European Economic Area, when compared with the Medical Device Directive (93/42/EEC), In Vitro Diagnostic Directive (93/79/EC), and Active Implantable Medical Devices Directive (98/79/EC). The MDR and IVDR will serve to increase supply chain transparency to ensure

patient safety in the distribution of medical and in vitro diagnostic devices. In addition, the new requirements can be enforced by competent authorities, so a robust quality management system (QMS) will be needed to facilitate compliance with the requirements.

Regulatory requirements for distributors

Distributors of medical devices or in vitro diagnostic devices have specific obligations to fulfil under Article 14 of both the MDR and IVDR.[1,2] Specifically, distributors will have to verify whether:

- the device has the conformité Européenne (CE) mark and an EU Declaration of Conformity has been issued;
- the importer's name is affixed on each device or is in the attached documentation (where applicable);
- the device bears a unique device identifier assigned by the manufacturer (where applicable);
- the device is labelled properly and has instructions for use (IFUs) in an official language of the country in which it will be marketed.

In addition, distributors are responsible for:[1,2]

- ensuring storage and transportation of devices under appropriate conditions defined by the manufacturer; and
- notifying the manufacturer and competent authorities when they suspect a device has been falsified or presents a serious risk to patient health.

It is essential for distributors to collaborate with other economic operators to achieve an appropriate level of traceability for all nonconforming devices, complaints, recalls, and withdrawals. In addition, distributors are required to cooperate with competent authorities and provide them with all documentation and information at their disposal.

It is also worth mentioning that the MDR and IVDR include rules for designating notified bodies. The regulations set more control and monitoring requirements for national competent authorities and the European Commission. Therefore, distributors should establish and implement a suitable, adequate, and effective QMS to ensure all requirements are correctly implemented before placing a medical or in vitro diagnostic device on the market.

Implementing a QMS

An effective QMS is a valuable tool allowing stakeholders to coordinate and direct activities to demonstrate compliance with the MDR and IVDR. Although the regulations do not require distributors to have a QMS, implementing one will ensure maintenance of supply chain integrity and device safety, traceability, and continuous improvement (**Figure 1**).

The QMS should cover procedures that control the exchange of information, especially any corrective action taken by the manufacturer. To implement an effective QMS, it is essential to include well-defined processes, procedures, and

top management responsibilities based on MDR/IVDR requirements and current guidance documents and standards.

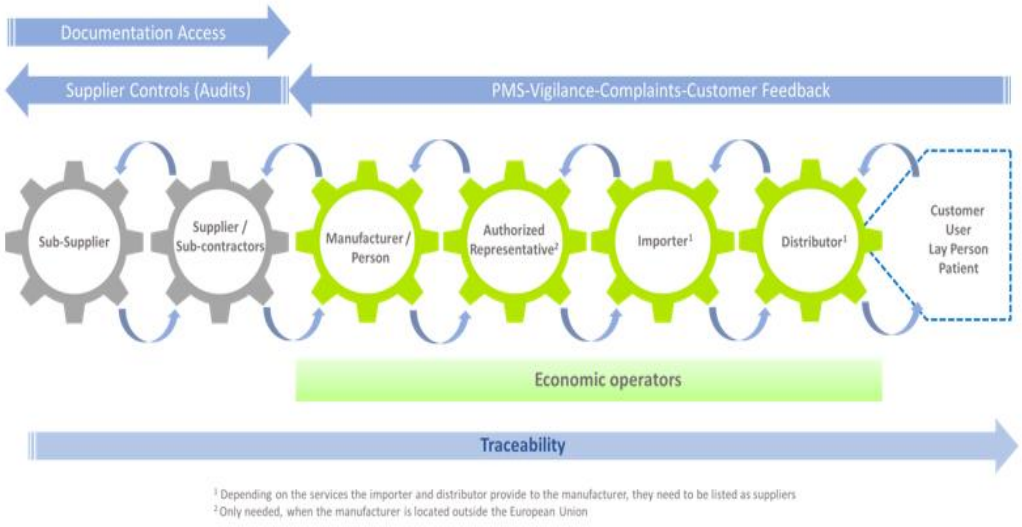

FIGURE 1 Supply chain control Source: QUNIQUE

Most importantly, management representatives must control quality system processes and activities and provide adequate resources for QMS implementation and maintenance (**Figure 2**). To achieve a sustainable and compliant QMS, all activities should be clearly documented in standard operating procedures and systematically reviewed to avoid any discrepancies and noncompliance that may affect device distribution.[3]

An effective quality system guarantees that only medical devices or in vitro diagnostic devices compatible with legislative requirements will be distributed. Moreover, it ensures traceability of devices that must be withdrawn from the market if they are deemed noncompliant, defective, poor quality, falsified, or unsuitable.

It is important to note that distributors performing certain activities are obligated to implement a QMS that has been certified by a notified body, as outlined in Article 16 of the MDR and IVDR.[1,2] This requirement is not fulfilled by having an ISO 13485 certificate. Distributors falling under Article 16 must have QMS procedures to support the following activities:

- provision, including up-to-date translation of the device label or instructions for use and any information necessary to market the device in the relevant member state; and
- the repackaging necessary to market the device in the member state and carried out so that the original condition of the device cannot be affected.

When performing the above activities, distributors must inform the manufacturer and relevant competent authority of its intent to place the device on the market at least 28 days before it is placed.

FIGURE 2 Procedures for distributors Source: QUNIQUE

Distributors should be mindful of the availability of the notified body to perform Article 16-related QMS certification. Under MDR and IVDR, the number of notified bodies will be reduced by as much as one fifth, diminishing their capacity. On top of that, distributors have to select a notified body designated for the appropriate scope for their business needs, making it challenging for them to find a willing notified body within the appropriate scope and with sufficient capacity to certify their QMS.

Choosing the right distributor early on

Considering the aforementioned requirements, manufacturers should select a distributor well in advance of the regulations becoming effective. It will take time to set up functional contractual agreements and communication processes. Engaging a competent, well-prepared economic operator during this time of change will provide the supply chain stability needed for continued market access.

Conclusion

The MDR and IVDR regulations present challenges for all economic operators and it is important to act early. Distributors have specific obligations under the MDR and IVDR and need to understand which requirements apply in each case

and how much time and what resources will be needed. It is critical to begin now to set up a compliant QMS to ensure that distributor supply chains are maintained. It is also important to select and apply to an appropriate notified body, if required, to draft contractual agreements with relevant economic operators, and to have sufficient internal competencies. If there are knowledge gaps, it is important for distributors to engage a subject matter expert for external support in assisting with training personnel, preparing MDR/IVDR compliant processes, and conducting internal readiness audits.

Abbreviations

CE, conformité Européenne; **IFU,** instruction for use; **ISO,** International Organization for Standardization; **IVDR,** In Vitro Diagnostic Regulation; **MDR,** Medical Device Regulation; **PMS,** postmarket surveillance; **QMS,** quality management system; **SOP,** standard operating procedure.

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