Whitepaper

EU MDR Impact on Importers and Distributors?

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White paper

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This paper focusses on the requirements for importers and distributors under the new European Medical Device Regulation [1], but is also relevant to manufacturers, small and large, to understand which new responsibilities are relevant in the supply chain of medical devices. If you have a role in the supply chain of medical products and you have not recently made or seen any changes in your companies approach towards these products or towards internal processes, you might like to read this white paper to be prepared!!!

And after reading this, do not hesitate to share this information with your higher management, to secure company compliance. They are used for therapeutic (destruction of diseased body cells) and diagnostic purposes (detection of radiation and transforming into images).

Introduction

The new EU MDR - European Medical Device Regulation (2017/745) – as published in 2017 will become effective as of May 26th, 2020. On this date new legal requirements will apply to many stakeholders active in the medical device business. The most affected are manufacturers that market medical device products under their own name, but new are also explicit requirements for authorised representatives, importers and the distributors. In the EU MDR these four stakeholders (manufacturer, authorised representatives, importers, distributors) are referred to as Economic Operators and three of them have now been named to be also legally liable for defective devices when not complying to the general obligations of this new regulation.

With the new provisions both importers and distributors are wise to read, understand and implement the relevant requirements of the new EU MDR.

This paper does not focus on the EU IVDR (2017/746) [2], for in vitro diagnostic devices, but the requirements relating to importation and distribution are essentially the same in both Regulations.

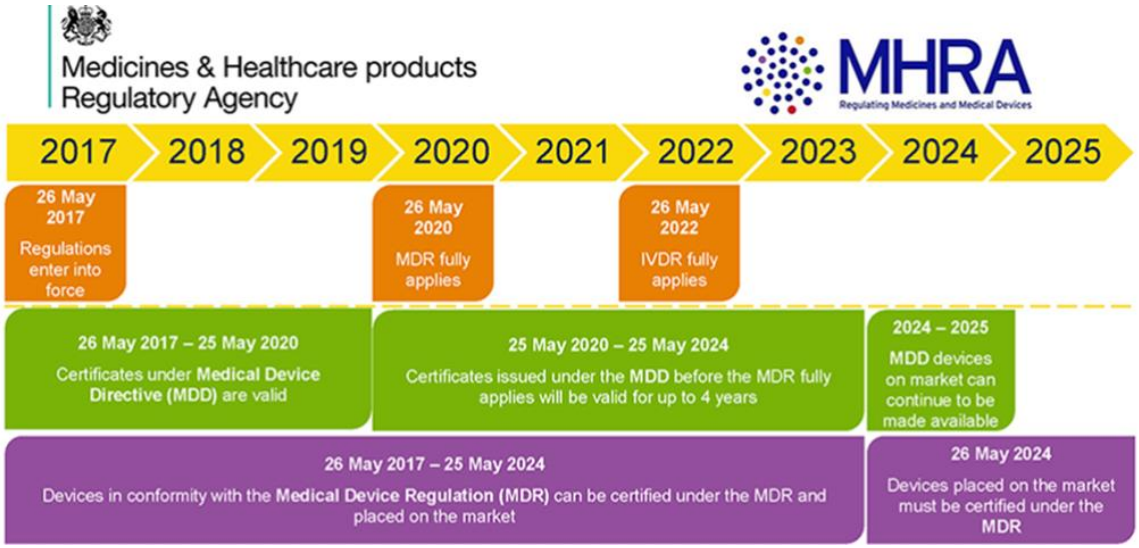
The new EU regulation on medical devices

The predecessors of the EU MDR were the EU Medical Device Directive (MDD) [3] and the Active Implantable Medical Device (AIMD) [4]. These two directives focused on manufacturers and the role of importers and distributors was scarcely mentioned. In the new EU MDR, which includes both medical devices, implantable devices and now even devices with no medical intent[1]) (but with a similar risk profile), the role of importers and distributors cannot be overlooked. The term "importer" is found 54 times and that of "distributor" 34 times.

Some importers or distributors might have been reassured by their manufacturers that for their products not much will change and no urgent activities are needed. Such reassurance may come from confident manufactures that have long established and high-quality medical devices that can still be marketed under the current MDD certificates. In part this reassurance is true, however it may only apply to the actual product, but not towards the increased responsibilities of the importer and distributors and their legal liability. How does this work?

As per introduction of the MDR, there has been granted a possibility to still market medical devices after May 26th 2020 with valid MDD product certificates. MDD product certificates may have validity dates that go well beyond the May 2020 date, since MDD certificates, both new and re-certified before May 2020, can be valid for 5 years counting from the certification date. The MDR transition period is clarified in the following scheme, and shows that medical device products potentially can be placed on the market until May 2024 or until the validity date of the MDD certificate (whichever comes first).

[1] *Guidance on product without a medical intent (MDR Annex XVI products)*
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/748131/Guidance_leaflet_on_Annex_XVI_products_.pdf



Source: https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr#introductory-guide-to-mdr-ivdr

So, in summary, from a manufacture's perspective, products with a valid MDD certificate can still be brought to the market and these products will likely still be shipped to the same importers and distributors. However, what is also true, is that manufactures may have become very busy with transitioning their own technical documentation to MDR compliance, make portfolio decisions, have focus on re-evaluation and/or gathering of clinical safety and performance data and setting up post-market surveillance procedures. Manufactures may rely on the other Economic Operators to do their own home work. So, confidence is good but being prepared and compliant is better, especially for importers and distributors, because also for them many new MDR requirements kick in immediately, whether or not they supply MDD certified products or MDR certified products to the market.

Importer or distributor? – Know your role under the EU MDR

To understand the new responsibilities under the EU MDR, each party should know one's role. The current understanding of the role might not be very different as it was in the past, see also the descriptions in the EU blue guide[2]). The MDD did not provide any definitions, but the MDR does:

[2] *The 'Blue Guide' on the implementation of EU product rules 2016*
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG

EU MDR Article 2:

(33) 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market;

28) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;

(34) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(27) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

For the role of importer, it is relevant that the medical devices are being purchased from a manufacturer that is not based in the EU. If so, such non-EU manufacturers will also have assured their representation by a European based authorised representative in one of the member states. If the product is manufactured outside the EU, but caries the name of an EU based manufacturer, then there is actually no importation but only distribution. As a purchasing party, you should therefore always check where the manufacturer resides; is it EU based or not (please consider also the end date of the UK Brexit transition period of January 1st, 2021 for UK based manufacturers)?

The importer's role has become more emphasized because they are the first party in the whole medical device supply chain that can execute EU regulatory compliance tasks and check for counterfeits on a daily operational level.

For clarity here are also the definitions of the manufacturer and the authorised representative:

EU MDR Article 2:

(30) 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

(32) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(35) 'economic operator' means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

The usual role of a distributor is the purchasing of products from EU based manufactures, importers or other distributors, the making available of product to end-customers, but also storage and transport of product. Distributors may also provide services like instruction provision, installation and repairs. For the role of distributor, the same applies as for importers, if you purchase product and provide product supply related activities, one should confirm that the product originates from an EU based manufacturer. If the manufacturer resides outside the EU, one should check if the information of an importer in the EU is mentioned on the product information to avoid that non-EU conforming products enter the market and you become unintentionally liable as an importer of these non-EU based medical device products.

A further note is given, to both importers and distributors, that when they put their name on the device in the absence of the name of the actual manufacturer, they might become the manufacturer with all responsibilities related. The MDR has very much focused on assurance that the roles are clear and that there is no doubt who has the role of “legal” manufacturer. Also, in line with that, the MDR has principally banded the constructs between Original Equipment Manufacturers (OEM) and (multiple) Private Label Manufacturers (PLM) where, in the past, it was not always clear, if product compliance was secured.

Opportunities to change products are restricted to the manufacture’s role in principle, however importers/distributors may provide information for a product, including translations for relevant markets or change the external packaging (see MDR article 16(2)). Off course this can only be allowed for importers and distributors when such changes are not considered to have any impact on the conformity of product or usability. In any case it is wise to share or contractually agree on these undertakings with the actual manufacturer. This allows a manufacturer to provide products to one or more distributors with a general label (or even in bulk) and the distributor to make the general label specific for their purpose or even completely make the label under the manufacturer’s responsibility. Alternatively, the manufacturer provides the product in a packaging format agreed with the distributor. It is to be noted that, for such activities which resemble the ex-OEM-PLM constructs, under the MDR now both activities and parties should be identifiable on the label. This was not the case under the MDD, which lacks such clarity. See for the next section what the additional MDR requirements are for such activity.

General obligations for importers and distributors

The MDR provides for two dedicated articles which specifically describe the obligations for importers and distributors. Other MDR articles relate to additional obligations for documentation and record keeping, traceability of product in the supply chain, including UDI information storage for high risk devices. Here the main obligations are explained [3]):

General Obligations for Importers (Article 13)

Importers should verify that the device:

1. caries the CE symbol
2. states the name of the manufacturer and the authorised representative
3. has a label and instruction for use in accordance to the relevant regulation
4. has an unique device identification number (UDI) issued by the manufacturer [4])
5. has been registered in EUDAMED by the manufacturer (when in place)

Upon verification the importer should fulfill the following tasks:

1. archive the manufacturers EU declaration of conformity and applicable conformity assessment certificate(s).
2. place own name and contact address on the device or its label and indicate if specific translations or repackaging occurs under their responsibility.
3. store and transport the product in compliance with the requirements and the manufacturers product specifications.
4. register the importers details in EUDAMED, if not done by the manufacturer.
5. not place the device on the market if not all conditions have been met, and seek resolution of the non-conformity and inform the manufacturer and authorised representative.
6. inform the competent authority if a device presents serious risk or if the product is falsified (details of non-conformance and corrective actions taken, need to be included)

[3] *Guide for Distributors of Medical Devices [IA-G0004-1 8 FEBRUARY 2018]* *https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/ia-g0004-guide-for-distributors-of-medical-devices-v1.pdf?sfvrsn=13*

[4] *Note: The obligation to have it on the label may vary in time and per device risk class. It starts as of May 2021 [Unique Device Identification (UDI) System under the EU Medical Device Regulations 2017/745 and 2017/746; 12/08/2019]* 2017/745 and 2017/746m/documents/36664

7. keep register of complaints, of non-conforming devices, recalls and withdrawals and forward information on suspected product incidents from users, patient or health professionals immediately to the manufacturer and its AR.
8. Co-operate with competent authorities on risk mitigation actions to be taken on marketed product and provide samples.

General Obligations for Distributors (Article 14)

Distributors should verify that the device:

1. caries the CE symbol
2. states the name and address of the manufacturer, and if applicable the authorised representative and importer.
3. has a label and instructions for use as per the requirements of MDR Annex I section 23 (or as per MDD for products with MDD certificates).
4. has an UDI issued by the manufacturer [5])

Upon verification the distributor should fulfill the following tasks:

1. store and transport the product in compliance with the conditions set by the manufacturer.
2. not make products available on the market until non-conforming products are brought into conformity and inform the manufacturer and if applicable the authorised representative and importer.
3. inform the competent authority if a device presents serious risk or if the product is falsified (details of the non-conformance and corrective actions taken, need to be included).
4. keep register of complaints, of non-conforming devices, recalls and withdrawals and forward information on suspected product incidents from users, patient or health professionals immediately to the manufacturer and its authorised representative and importer.
5. co-operate with the other economic operators and the competent authorities on risk mitigation actions to be taken on marketed product and provide samples. place own name and contact address on the device or its label and indicate if specific translations or repackaging occurs under their responsibility.

[5] *Note: The obligation to have it on the label may vary in time and per device risk class. It starts as of May 2021 [Unique Device Identification (UDI) System under the EU Medical Device Regulations 2017/745 and 2017/746; 12/08/2019]* 2017/745 and 2017/746m/documents/36664

Comparison and discussion of the importer and distributor roles

In general, both importers and distributors may no longer rely on the manufacturer for compliance. They should check products and documentation rigorously to assure the product and provided documentation are still valid. In regards to non-conforming products equal responsibilities for importers and distributors are described in the MDR, however as per recital (35) of the MDR, importers equal to the manufacturers (or the AR) could be jointly and severally liable.

Distributors have a lower level of responsibility per MDR than importers in regards to verification of compliance; distributors may apply a representative sampling method and not check every device, when performing the verification as described in the obligations overview.

Both importers and distributors are allowed to request each other's information on product complaints. Notably, all economic operators have become part of the post-market surveillance system and must support co-operation and exchange of information. Also, product traceability is very much related to the activities of post market surveillance [6]).

Both parties can also add value to the products by providing information in the local language and perform re-packaging activities. These activities were referred to earlier in this white paper and may not be considered substantial changes. As per MDR article 16(3)-(4) the importer or distributor, that performs these activities, shall mention this on the product label but also have in place evidence, by a certificate, that a notified body assessed the Quality Management System (QMS) related to these activities of (re-)labeling and (re-)packaging. When making relabeled or repackaged devices available to the market, 28 days prior to such action, the party should notify the manufacturer and the competent authority of such action and provide the relevant QMS certificate and a sample of mock-up of the changed product information. The added value of a QMS is explained in the next section.

There is difference between the registration of the importers and the distributors. As per MDR (article 30 and 31) there will be an EU system of registration of manufacturers, authorised representative and importers. As opposed to distributors, importers have a specific duty to assure that the registration of economic operators is checked and filled in correctly in this EU system. For distributors the EU member states may maintain or introduce national registration systems, however distributors are **not** mentioned in the EU system. This EU system, also referred to as EUDAMED, will

[6] *Factsheet for Authorised Representatives, Importers and Distributors of Medical Devices and in vitro Diagnostic Medical Devices [05/02/2019]*
https://ec.europa.eu/docsroom/documents/33862

contain different modules on actors, UDI & devices, notified bodies & certificates, vigilance, clinical investigations and performance studies and market surveillance [7]).

Both importers and distributors may only place compliant product on the market, but do not require to have available a person responsible for regulatory compliance, which poses a requirement for manufacturer and ARs.

The value of a Quality Management System

In order to meet the obligations, it is recommended that importers and distributors have a quality system in place. A system that meets all the obligations of manufactures, as per article 10, may not be required but certainly there are components of a QMS required. To re-collect, articles 13 and 14 refer to: verification activities and record keeping of regulatory documentation, complaints, withdrawals/recalls and post market surveillance data. Notably, for the (re-)labeling and (re-)packaging there is the obligation to have certified quality procedures in place for these activities; see the earlier referred article 16(3). An effective QMS provides assurance that only compliant devices are distributed, that traceability is maintained and that noncompliant, defective or unsuitable (e.g. falsified) medical devices can be detected. A QMS may also assure adequate change control activities. The ISO 13485 standard is the most commonly used quality framework in the medical device industry; however, it is not a requirement that a quality management system is officially certified/ accredited to any specific standard.

Examples of relevant importer and distributor activities that usually are controlled in the QMS are:

- Procedures to adequately control human resources, with emphasis on assuring that persons with appropriate training and qualifications conduct key tasks.
- Procedures on key operational tasks such as:
    - incoming and outgoing goods handling,
    - labeling checks,
    - reporting on non-conformities,
    - segregation of product to avoid mix-ups,
    - storage and transport
- Other procedures (supportive and governance) such as:

[7] *European database on medical devices (EUDAMED); [The official web address of the EUDAMED public site will be: https://ec.europa.eu/tools/eudamed]; The public site will be available when the EUDAMED is in production, not before. https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en*

- document control,
- purchasing and supplier selection,
- management of waste and return goods,
- audits,
- control of changes,
- effectiveness review of the management system (management review),
- quality risk management,
- handling of non-conformities (incl. corrective actions/recalls

As an importer or distributor, one should be aware that manufacturers prefer QMS certified partners as this will substantially reduce their need to audit their distribution network. Furthermore, with the increased attention of compliant products, battle against counterfeit and post-market information related to product complaints, both manufactures, notified bodies and competent authorities look particularly to those parties closest to the end user or patient. Especially for tracking of complaints and reporting there are overlapping responsibilities and activities between parties, but clearly agencies find it necessary to be able to get such information from multiple sources within the supply chain. Taking responsibility, propagate this, provide assurance of quality and have in place relevant quality control procedures seems to be, more than ever, essential for performing business as an importer or distributor.

What to expect from manufacturers?

In light of the increased responsibilities, manufactures may re-evaluate their full supply chain and contracts made with stakeholders. On the other side importers and distributors also have increased responsibilities that add to the overall activity of assuring regulatory compliance of devices. To assure both parties understand and appreciate their new roles and responsibilities over the full life-cycle of their medical devices, parties will need to:

- re-define each other's responsibilities
- understand the joint and several liability (including also that of the authorised representative)
- re-negotiate contracts regarding responsibilities for products under both MDD and MDR certification
- find alignment between respective quality systems and consider the ISO 13485:2016 within this effort
- discuss specifically the exchange of information on:
  - registration requirements,
  - country specific labeling,
  - packaging,
  - storage and transport specifications,

  - other suppliers or distributors in the supply chain and their roles and responsibilities
  - complaints, and other market feedback (post-market surveillance)
  - agency interactions during changes, corrective actions, and inspections.
- agree that the compliance efforts are not a one-time-action but need to be revisited periodically to meet the life-cycle expectations of the new EU MDR.

EU MDR per May 26th 2020

Manufactures, authorised representatives, importers and distributors are all significantly impacted in regards to meeting compliance with the new MDR. Much more focus has been given to clarify responsibilities between parties within the supply chain, and to assure product compliance over the life-cycle of medical device products. For legacy devices with MDD product certificates a few requirements of the MDR may not apply, but for MDR certified products all requirements will apply as of May 26th 2020, except for some that may be delayed. In regards to the latter, reference is made to the European Database (EUDAMED) and some UDI labeling requirements.

As time moves fast, it is recommended to make good use of these last few months and weeks and take the opportunity to apply a few finishing touches.

References

[1] EU MDR - European Medical Device Regulation (2017/745)

[2] EU IVDR – Regulation (EU) 2017/746 on in vitro diagnostic medical devices

[3] Council Directive 93/42/EEC on Medical Devices (MDD) (1993)

[4] Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)

About Starodub

Reliable, Efficient and Knowledgeable

Starodub BV was founded in May 2014. The company started with one employee, the founder Valentyna Starodub. By today, our team has grown to round 20 employees and has a valuable network of specialized experts. We partner with (bio)pharmaceutical and medical device companies worldwide to ensure that regulatory requirements are met and business goals, such as quick market access and compliance, are achieved. Please check the Our services page to learn how we can support you with meeting your business goals.

Our lean and powerful team strives to be of added value to our clients. All employees are highly educated and obtained degrees in pharmacy, chemistry, biology or related. Our short reporting lines are key to finding the most efficient road to your success. One of our experts will be your primary contact and the team's collective knowledge and resources are available to give reliable advice and execute projects in the most efficient way. Together, we connect the dots and look beyond the scope of projects to make sure all aspects of importance are addressed.

At Starodub BV consistency and assurance of quality are considered as being highly important. A quality management system has been implemented and we strive to comply with GxP and ISO 9001/13485 constantly. In addition, we have an external board of control, acting as the sparring partner to set the optimal course for our company.

We strive to be a true partner to Our clients, who rate our services as ≥4.5 on a scale of 1 (poor) to 5 (excellent). This motivates us to maintain the highest professional standards and to implement continuous improvement.

About the Author

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Erwin Waas is a former Senior RA Manager of Starodub BV (2014-2020). He is an expert on medical devices. In case you would like to ask a question on this white paper, please contact Valentyna Starodub at info@starodub.nl