COCIR Position Paper

Economic Operators under the Medical Device[1] Regulation

Introduction

The obligations of the different economic operators are laid down explicitly for the first time in the newly adopted Medical Device Regulation (MDR) 2017/745 and In-Vitro Medical Device Regulation (IVDR) 2017/746. Parts of the New Legislative Framework (NLF) – Decision 768/2008 (& Blue Guide) are already applicable to consumer products and similar obligations are applicable to Medical Devices because of the RoHS directive (see Annex I). However, as the MDR and IVDR go beyond the NLF, some uncertainties remain and potential for overlap and duplication remains both in the pre- and post-market phase of the Regulations.

This paper outlines the COCIR members' common understanding of the functioning of the supply chain under the MDR and IVDR. The main content of the paper is structured in the form of Questions and Answers focusing on the most pressing issues economic operators (here focussing on manufacturers, importers and distributors) are facing. A dedicated document outlining specific challenges for digital business models has been developed as well.

Overview of economic operators

The MDR (2017/745, 2017/746) commonly defines the following economic operators, which are depicted in the figure below:

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; (Article 2(30))

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; Article 2(32))

Importer

means any natural or legal person established within the Union that places a device from a third country on the Union market; Article 2(33))

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; (Article 2(34))

User

means any healthcare professional or lay person who uses a device; (Article 2(37))

Note 1: Users are actors but not economic operators in the sense of MDR; also the second-hand sales is excluded from the scope of the EU MDR.

Note 2: There is also the "system & procedure pack producer" role related to 'systems and procedure packs" (MDR Article 22) that is not covered in this paper.

1 Also applicable to the In-Vitro Medical Device Regulation (EU) 2017/746

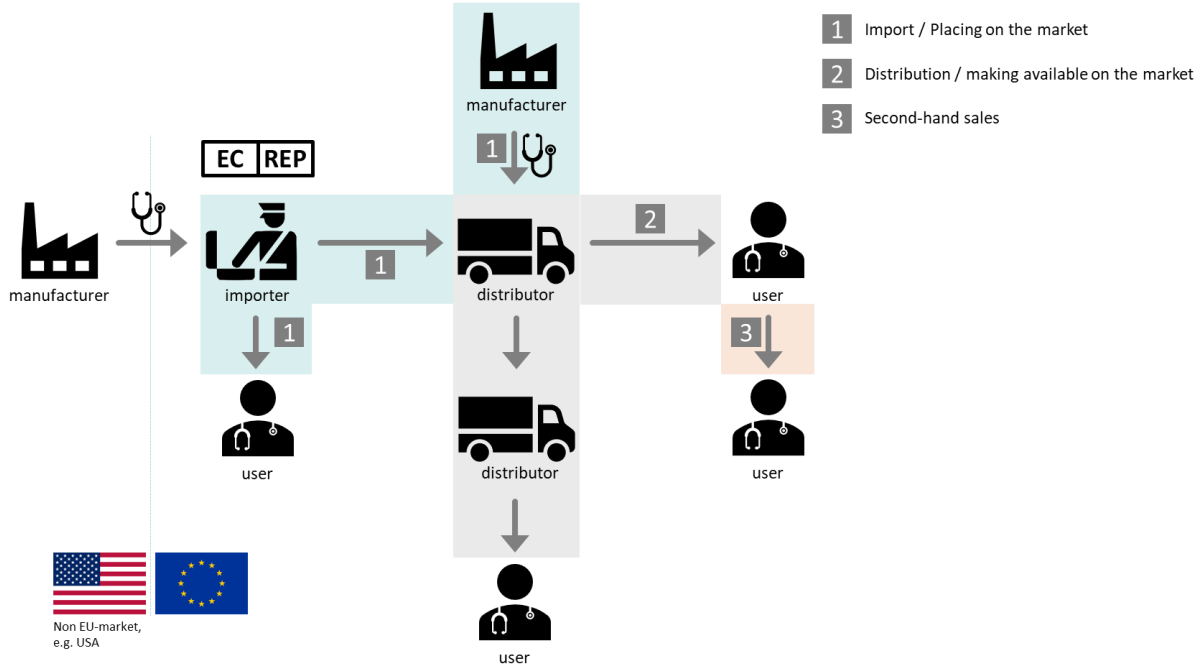

Figure 1: Illustration of the import and distribution of medical devices in the European Union

COCIR understanding related to Economic Operators

Pre-market obligations

Q1: There is a clear overlap of roles and responsibilities between economic operators (see Annex II). Can we avoid redundant verification activities?

A: Quality agreements can be set up between manufacturers, importers and distributors to streamline and simplify verification activities.

This way, the manufacturer may perform activities within the importer or distributor verification requirements under MDR Articles 13 and 14. Consequently, the procedure ensures that only devices are being released into the supply chain for which the manufacturer has checked that the respective requirements have been met.

It does not matter if the economic operator is part of the same company or the same Quality Management System; or not (independent / external). The Regulations do not prohibit the delegation of activities. However, the legal responsibility always remains with the legally specified economic operator.

Q2: Importers shall verify the CE marking of devices before placing them on the market. The MDR and IVDR explicitly mention that distributors may use a sampling method, but not importers. How can importers handle their verification requirements? *(same for distributors related to the verification of Importer's name and address)*

A: COCIR does not consider it realistic to ensure a physical check of all individual devices placed on the market, especially in the context of direct shipments that are commonly used, e.g. for capital equipment[2]. While COCIR agrees with the necessity to ensure device compliance, it would significantly increase delivery times and product handling costs.

2 CAPEX, OR CAPITAL EXPENDITURE is a business expense incurred to create future benefit (i.e., acquisition of assets that will have a useful life beyond the tax year). For example, a business might buy new assets, like buildings, machinery, or equipment, or it might upgrade existing facilities so their value as an asset increases (source: COCIR eHealth Toolkit – Glossary)

COCIR considers that, under provision that the verification process is validated and regularly controlled, verification activities should be:

- Proportionate to the safety risk (classification of the device, implantable, devices intended to administer medicinal substances…)

- In accordance with good practices for goods receipt verification

- Partly executed through documentary process (as currently done for Customs clearance)

- As part of a validated and controlled process

COCIRs interpretation is, based on the considerations above, that importers may choose to apply, a sampling method to fulfil their verification requirements, under provision the adequate quality agreements and controls between the manufacturer and importer are in place and effective (see also Q1).

Q3: Shall importers and distributors have a quality management system?

A: It is not required by the EU MDR, except in some specific cases, when importers, distributors or other persons executing activities as follows (MDR 16(2)):

- provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I

- changes to the outer packaging of a device already placed on the market, including a change of pack size.

Nevertheless, in order to meet the legislative requirements and to ensure that only medical devices that comply with the legislation are made available for supply as well as ensuring the necessary contribution to the post-market surveillance activities, COCIR recommends that distributors and importers have an adequate quality management system in place.

While not requiring that the quality system is officially certified, this brings additional transparency and could make the relationship between the different economic operators easier.

Post-market obligations

Q4: What must be considered as 'suspected incidents'?

A: The EU MDR 'incident' definition is broad as it includes any malfunction, deterioration in the characteristics or performance, use error, undesirable side-effect and inadequacy in the information provided by the manufacturer.

COCIR members' complex devices ("big capital" equipment) require quite some servicing activities during their lifetime that can be long (10 or 15 years is not unusual). Most of users' calls are related to corrective maintenance requests that are related to suspected malfunction or deterioration of the performance and, consequently, are in the scope of the 'incident' definition.

Q5: How to cope with the distributors' requirement to notify stakeholders immediately about all suspected 'incidents'?

A: The distributors are required to notify immediately the manufacturer and the Authorised Representative and the importer (Article 14 (4 & 5)) about all complaints and reports about suspected incidents that they become aware of.

When servicing devices they are making available, this could lead to a very significant number (possibly millions) of interactions per year. It can be easily managed when importers and distributors belong to the same company, as usually they are using the same IT infrastructure or interconnected IT systems as the manufacturer.

On the contrary, this is a major challenge for third party distributors unless they work directly in the manufacturer's IT system. Notifying to other stakeholders (EU Authorised Representative, Importers) is even more challenging due to the difficulty of governing the activity.

COCIR considers that an agreement may be in place between the distributor and the manufacturer specifying responsibilities relating to the handling of complaints, incidents and vigilance, under provision there are adequate training and controls in place.

However, delegation of these activities does not change the legal responsibilities of economic operators under the Regulations. It is important that the ultimate goal to submit 'serious incident' reports to Competent Authority within 10/15 days (from the date the manufacturer becomes aware) by the manufacturer is achieved.

Q6: There will be multiple suspected incidents information flows between economic operators. How will they all interface with each other?

A: All manufacturers and Authorized Representatives will have to interface with several importers and distributors and vice versa as well as distributors with importers.

COCIR would consider several solutions to address this issue:

1) Standardize the data exchange

The data format and the IT solutions used will be so diverse that a major part of the data exchange will remain manual. While it will not be an issue when the number of suspected incidents is low, we must also consider "big capital" equipment that require a significant amount of servicing activity and for which every user call for a corrective maintenance is a suspected incident per the new definition of 'incident' of the EU MDR.

While not planned in the EU MDR, COCIR would be in favour of an industry understanding to define the required data set to be sent to the manufacturer and other involved economic operators. COCIR is currently developing a draft for such industry understanding.

2) Contractual agreements between the economic operators

As already mentioned above, contracts may be in place between the stakeholders specifying responsibilities, activities and duties. It should also apply to the: a) handling of complaints, b) incidents and vigilance, c) recording of data/documentation, and d) access to the relevant information e.g. DoC, and under provision there are adequate training and controls in place.

Such contractual agreement should not be limited to the economic operators belonging to the same organisation but should also be possible between independent economic operators.

The ultimate goal is to ensure 1) the manufacturer is notified and 2) the stakeholders have access to the information. Again, delegating execution of activities does not change the legal responsibilities of economic operators under the Regulations.

Annex I: Overview of importer's and distributors' obligations under the Medical Device Regulation compared to other NLF legislations

Obligations	Decision 768/2008/EC	Directive 2014/35/EU Low voltage	Directive 2014/30/EU EMC	Directive 2009/48/EC Toys	Directive 2011/65/EU RoHS	Directive 2014/53/EU RED	(EU) 2017/745 EU MDR
CE mark and Declaration of Conformity have been drawn up before placing a device on the market	Ensure	Ensure	Ensure	Ensure	Ensure	Ensure	**Imp/Dist: Verify +**
Verify Authorized Representative has been designated*							**Imp:** ✓ **Dist :** -
Label compliance & IfUs delivered (imported products)	Imp: Ensure Dist: Verify	Imp: Ensure Dist: Verify	Imp: Ensure Dist: Verify	Imp: Ensure Dist: Verify	Imp: Ensure Dist: Verify	Imp: Ensure Dist: Verify	**Imp/Dist: Verify +**
Verify UDI assigned to the device*							**Imp/Dist:** ✓
Notify Manufacturer (and EU Authorized Rep. and Importer where relevant) on Non-conformity & complaints	✓	✓	✓	✓	✓	✓	**Imp/Dist:** ✓ **+ Suspected incidents, immediately**
Notify Competent Authority on serious risk & falsified product	✓	✓	✓	✓	✓	✓	**Imp/Dist:** ✓
Have the importer's name & address on the label or on the document accompanying the device	✓	✓	✓	✓	✓	✓	**Imp:** ✓ **Dist:** -
Verify product registration in Eudamed*							**Imp:** ✓ **Dist:** -
Keep register of complaints, non-conforming products, FSCAs*					Imp : ✓	Imp : ✓	**Imp/Dist:** ✓
Ensure storage & transport conditions comply with manuf. requirements	✓	✓	✓	✓	✓	✓	**Imp:/Dist:** ✓
Keep copy of DoC & CE certificates available to Competent Authorities	✓	✓	✓	✓	✓	✓	**Imp:** ✓ **Dist:** -
Keep a copy of the technical documentation available to Competent Authorities	✓	✓	✓	✓	✓	✓	**AR:** ✓
Cooperate with CA & provide free MD sample (or grant access)*	✓	✓	✓	✓	✓	✓	**Imp/Dist:**✓**+**
Verify importer/manufacturer comply with his obligations	✓	✓	✓	✓	✓	✓	**Imp/Dist:** ✓
Ensure traceability*					✓	✓	**Imp/Dist:**✓
Economic operator registration in Eudamed*							**Imp:**✓ **Dist:** -

Notes:

The main obligations of importers and distributors are outlined in MDR Articles 13 and 14 respectively.

"+" means MDR/IVDR obligations goes beyond (see the regulation text)

"" means this obligation goes beyond the New Legislative Framework established by the Decision 768/2008/EC*

Annex II: Obligations of Importers, Distributors and Authorised Representatives under the MDR

Obligations	Importer (EU MDR/IVDR Art. 13)	Distributor (EU MDR/IVDR Art. 14)	Authorized Representative (EU MDR/IVDR Art. 11)
Pre-market			
Register in Eudamed*	X	NA	X
Have Person Responsible for Regulatory Compliance permanently and continuously available*	NA	NA	X
Verify CE mark and Declaration of Conformity have been drawn up before placing a device on the market	X	X (sampling)	X
Verify correct conformity assessment procedure has been carried out	NA	NA	X
Verify Manufacturer is identified and Authorized Representative has been designated*	X		NA
Verify Label compliance	X	NA	NA
Verify IfUs delivered	X	X (sampling)	NA
Verify UDI assigned to the device*	X	X	X
Notify Manufacturer (and EU Authorized Rep. and Importer where relevant) on Non-conformity & complaints	X (excl. importer)	X	X (excl. importer & Auth. Rep.)
Notify Competent Authority on serious risk & falsified product	X	X	NA
Label imported product with importer's name & address	X	NA	NA
Verify importer name and address included	NA	X	NA
Verify product registration in Eudamed*	X	NA	X
Keep copy of DoC & CE certificates available to Competent Authorities	X	NA	X
Keep a copy of the technical documentation available to Competent Authorities	NA	NA	X
Post-Market & Notifications			
Keep register of complaints, non-conforming products, FSCAs*	X	X	"Implicit"
Cooperate with CA (corrective & preventive actions) & provide free MD sample (or grant access)*	X	X	X
Other			
Ensure storage & transport conditions comply with manuf. requirements	X	X	NA
Ensure traceability* (MDR Art. 25)	X	X	NA
Store UDI for certain category of devices (e.g. Class III implantable)*	X	X	NA
Terminate his mandate if manufacturer acts contrary to its obligations	NA	NA	X

Note:

"" means this obligation goes beyond the New Legislative Framework established by Decision 768/2008/EC*