Draft Questions and Answers on Articles 13 &14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

Introduction

This document presents questions and answers on requirements related to importers and distributors under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)[1]. The term 'devices' will be understood to include medical devices, accessories for medical devices, products listed in Annex XVI of the MDR, in vitro diagnostic medical devices and accessories for in vitro medical device. References to the MDR should be understood to cover the corresponding IVDR articles.

The questions covered by the document aim to provide further detail on the operational and practical implementation of Article 13 and 14 and other related obligations for importers and distributors under the Regulations. Activities described in Article 16 of the Regulations will be covered in another guidance. This document should be read in conjunction with Regulation (EU) 2019/1020 on market surveillance[2] as applicable to the MDR and IVDR, the horizontal guidelines of the European Commission Blue Guide[3], and further complementary medical devices sectorial guidelines.[4]

Distinguishing importers and distributors

1.1 **Which economic operators meet the definition of importer or distributor?**

The definitions of a 'distributor' and 'importer' are set out in Article 2 of the MDR (and corresponding IVDR articles):

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;*

Article *2 (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;*

The definition of importer and distributor are to be read in conjunction with the following definitions:

Article *2(27) 'making available on the market' 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".*

Article *2 (28) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market.*

[1] Hereafter referred to as, 'the Regulations'.
[2] Note, Regulation (EU) 2019/1020 Regulation, applies also to the MDR and IVDR as listed in its Annex I.
[3] Please see 'COMMISSION NOTICE, The 'Blue Guide' on the implementation of EU products rules 2016 (Text with EEA relevance) (2016/C 272/01)'. It is noted that this document is currently under revision.
[4] Please see the Commission website, the webpage on "Authorised Representatives, Importers and Distributors" and "Factsheet for authorised representatives/importers/distributors

Article *2(29) 'Putting into service means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose*.'

For further elaborations on the above concepts, please consult the Blue Guide[5] based on the principles of the New Legislative Framework.[6]

1.2 What determines whether a natural or legal person acts as a distributor or an importer?

The differentiation between these two economic operators is under-pinned by the definition of 'placing on the market'. If a legal entity procures a device from an economic operator based in a third country and places it on the Union market for the first time (i.e. the first making available), that entity is acting as an importer. Where a legal entity sources (via a legal transfer of ownership) devices from importers, EU-based distributors or EU-based manufacturers and further distributes those devices to other entities (i.e. the operation of "making available" after "the first making available"), they are considered distributors.

It is noted that a device purchased by a consumer in a third country while physically present in that country and brought by the consumer into the EU for their personal use (outside of commercial activities)[7], is not considered as being placed on the market[8]. In this case, the consumer does not have to fulfil the obligations of Article 13 or Article 14 MDR.

1.3 What does 'putting into service' mean in the context medical devices distribution?[9]

Consultation Question:

This question is still under discussion with member states. We would appreciate some examples from stakeholders nonetheless of 'putting into service', bearing in mind the definition of a distributor.

1.4 Does an EU based distributor become an importer if it obtains its products directly from a non-EU based manufacturer?

Yes. Any operator including an EU based distributor who obtains (via a legal transfer of ownership) a device from a non-EU based manufacturer and makes it available on the Union market for the first time, or 'placing it on the market', will assume the role and responsibilities of an importer. As the concept of placing on the market refers to each individual product, not

[5] Note in particular sections of the 'Blue Guide' on 'making available on the market', "placing on the market" §§ 2.2, and §§ 2.3, §§ 3.3 (Importer), 3.4 (distributor)
[6] Please see the Commission Website.
[7] Note that regardless of whether the consumer purchases the device physically or online from a third country for personal use, the consumer does not become an importer or distributor if he or she does not place the product on the EU market or make it further available. However for 'distance sales' within the meaning of Article 6 MDR, the provisions of that article apply.
[8] For further information, see Section 2.3 of the 'Blue Guide'.
[9] The intended clarification regarding 'putting into service' is to be read in the context of the MDR only and is not a comment on the more horizontal concept of 'putting into service' across other EU product legislation.

the type of product,[10] this can take place, regardless of whether an importer already exists within the EU for the device model.

1.5 **Can there be multiple importers of a device model from one manufacturer?**

The obligations of device importers will apply to any entity meeting the definition of Article 2 (33) MDR (as described in Q.1). As the concept of placing on the market refers to each individual product, not the type of product,[11] and importers are any natural or legal persons who place individual physical devices on the EU market from a third country for the first time, it is possible to have multiple importers of a device model from one manufacturer. It is not possible however to have multiple importers of the same individual device.

1.6 **Are individual shops, pharmacies, retailers, considered distributors?**

A distributor is any economic operator 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)) MDR. As such, individual shops, pharmacies or retailers meeting this definition, are considered distributors.

For example, a pharmacy or an individual shop, which buys and then sells type II medical face masks to customers, such as other shops or companies, are considered to supply[12] a medical device and thereby fall within of the definition of a distributor. These entities will be expected to comply with Article 14 of the Regulations and any applicable national registration requirements.

General Obligations

1.7 **Who is responsible for indicating the importer on the device, its packaging or accompanying documentation?**

Importers are responsible for including their information on the device, its packaging or in accompanying documentation in accordance with Article 13 (3) MDR. Distributors are responsible for verifying this obligation has been fulfilled before making the device further available (Article 14(2) (c) MDR).

Whilst the inclusion of the importers details before the device has physically entered the EU is not mandatory, the importer's details must be included on the device (or accompanying documentation) before the device is placed on the EU market and so is made available for the first time. The absence of the importers details at customs control should therefore not be considered as a noncompliance with the MDR/IVDR.[13]

[10] For further information, see Section 2.3 of the 'Blue Guide'.

[11] For further information, see Section 2.3 of the 'Blue Guide'.

[12] Please also note, that Recital 28 MDR provides 'For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices'.

[13] However, checks on the importer's plans to update the device labelling/packaging/accompanying documentation before the device is placed on the market, could be performed.

1.8 What should an importer do in the case an individual device already mentions an importer on its packaging?

The requirements outlined in Article 13(3) MDR should be linked to the importer who first placed the individual device in the EU market. An importer should therefore consider each individual device it imports as new to the EU market.

In the unusual case where an importers details already appears on the packaging of an individual device, the importer should verify if the individual device has previously been placed on the EU market, for example by using the EUDAMED database[14] or by contacting the manufacturer. In addition, the importer should replace any previous details with their own.

1.9 What is meant by 'accompanying documentation' under Article 13(3) MDR?

'Accompanying documentation' containing the importers details, may be separate from or affixed to the individual device, as long as it accompanies the individual device throughout the supply chain and reaches the end user. The accompanying documentation should allow the importer to be located (Article 13(3)) MDR and healthcare professionals, patients or users to report suspected incidents to them (Article 13(8) MDR) to the importer. Examples may include a sticker affixed to the label, or the IFU.

Where any additional label is used to provide importer's information, it should not obscure the information on the label provided by the manufacturer in accordance with Annex I 23.2 MDR.

It is also noted that the distributor should refrain from selling products where documentation or the importer's information is missing (see Article 14(2)(c) MDR).

1.10 Are companies providing third party logistics (3PLs such as transportation or storage) considered importers under the MDR?

Not normally. Some companies which provide transportation services[15] or hold devices on a consignment basis only may not be considered an importer, provided there is a clearly defined agreement between both parties setting out the responsibilities of each party. The importer is usually the natural or legal person with legal ownership of the device, meeting the definition provided for in the MDR (i.e. placing the device on the market for the first time). That party is required to affix their details to the device, label or accompanying documentation in accordance with Article 13(3) MDR. Although transportation or storage activities may be subcontracted outside of the importer's organisation, the importer retains responsibility over storage and transport conditions and as such must ensure the sub-contractor's conditions do

[14] Please see Article 33 MDR.

[15] Please note that 'Fulfilment service providers' as defined in Article 3(11) of Regulation (EU) 2019/1020 on market surveillance are now considered economic operators under that Regulation 2019/1020 and should meet any associated obligations. A 'fulfilment service provider' means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council (31), parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council (32), and any other postal services or freight transport services. See also, Commission Notice on the market surveillance of products sold online Text with EEA relevance. (europa.eu))

not jeopardise compliance with the general safety and performance requirement of Annex I, (Article 13(5) MDR). Any details relating to the transportation of the device by 3PLs may be addressed on the outer packing/delivery pack.

1.11 Are companies providing third party logistics (3PLs such as transportation or storage) considered distributors under the MDR?

Not normally. As explained in Q.10 transportation is not a distribution activity and therefore a 3PL conducting transportation only, even if this includes short term storage (i.e. <48hr) to facilitate transportation would not be considered a distributor. The distributor is the person with legal ownership of the device, who meets the definition provided for in the MDR (i.e. making available on the market up until the point of putting into service). Although transportation or storage activities may be subcontracted outside of the distributor's organisation, the distributor in accordance with Article 14(3) MDR shall ensure that while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

1.12 What are the obligations of importers and distributors with respect to suspected non-compliant products?

Importers and distributors have the obligation to verify whether the requirements mentioned in Article 13(2) and 14(2) MDR respectively, are met before making the device available on the market. Moreover, if an importer or distributor considers or has reason to believe that devices are not in conformity with the Regulations, they have the obligation to inform relevant parties (manufacturers and where applicable authorised representatives or importers) and to not make these devices available.

For distributors, the verification checks mentioned in Article 14(2) subparagraphs (a), (b) and (d) might be done based on a sampling method representative of the device supplied, except for the Article 14(2)(c) checks on imported devices.

1.13 Do importers and distributors have a duty to report complaints and cooperate with the member state competent authorities for medical devices[16]?

In accordance with Article 14(2) MDR the distributor should inform the competent authority (of the Member State in which it is established) if they believe the device presents a serious risk or is falsified. General complaints not meeting the definition of a serious risk or a falsified device however, are not reportable. Article 14(4) MDR outlines that distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

For importers, the above also applies (Article 13 (7) MDR), though in the cases of complaints regarding 'serious risk or a falsified device', importers have the additional obligation to inform,

[16] Please see the Commission website for the list of member state competent authorities for medical devices.

as applicable, the notified body that issued the device certificate, giving details, in particular, of the non-compliance and of any corrective action taken.

1.14 Do importers and distributors have a duty to report complaints to manufacturers?

Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. (Article 14(5) MDR). Distributors should keep a register of complaints of non-conforming devices, recalls and withdrawals and keep the manufacturer, and where available the authorised representative and importer, informed of such monitoring. They should also provide manufacturers with any information upon their request (Article 14(5)).

Importers also have related obligations regarding reports and registry of complaints and non-conforming devices in accordance with Article 13(6) and 13(8) MDR.

1.15 Do the requirements of Article 13 and 14 MDR also apply to devices certified under the Directives[17] 'legacy devices'[18]?

This is still under discussion by Regulators.

Registration and Verification Obligations

1.16 Article 13(2) and 14(2) of the Regulations set out various verification obligations for importers and distributors. How can these checks be performed?

Importers and distributors are responsible for making sure that the devices they place or make available on the market respectively, bear the CE marking, are accompanied by the required information and labelled in accordance with the Regulation, and have been assigned a UDI where applicable.

For importers, ensuring devices are CE-marked and labelled in accordance with the Regulation may involve physical checks (for example of device packaging). Verifying that the EU declaration of conformity of the device has been drawn, should involve the importer requesting and keeping available a copy of this document as specified in Article 13(9) MDR. Verifying that a manufacturer has been identified and an authorised representative designated can be performed via the EUDAMED database, and in addition, the using the up to date version of the EU declaration of conformity (Annex VI of the Regulations) or the device labelling. These methods where available, may also be used to confirm UDI assignment, (noting however the EU DoC contains only the Basic UDI-DI), and otherwise the manufacturers should be contacted.

For distributors, a sampling method representative of the devices supplied can be used to verify information in Article 14(2)(a)(b) and (d) MDR can be used. However, checks (e.g.

[17] Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1), Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176)

[18] 'Legacy devices' are devices which can continue to be placed on the market under Directive certificates by virtue of Article 120(3) MDR/Article 110(3) IVDR from their respective dates of application. Please see MDCG 2019-5 and MDCG 2020-6 Guidance for further information.

physical checks) that the importers information appears on the label or accompanying documentation (Article 14(2)(c) MDR),should be performed on all devices supplied.

1.17 Do importers and distributors have registration obligations in EUDAMED?

Importers of a devices shall register in EUDAMED[19] in accordance with Article 31 MDR, providing in particular the information referred to in Section 1 of Part A of Annex VI.

Distributors do not have to register in EUDAMED, however they may be subject to national registration requirements of member states in which they have made the device available in accordance with Article 30(2) MDR.

1.18 Do importers have additional verification obligations in EUDAMED?

In addition to registration (Article 31 MDR), importers have various verification obligations in EUDAMED. These include:

- verifying the device is registered (Article 13(4) MDR)
- verifying that the manufacturer or authorised representative have reported the necessary information to EUDAMED, within two weeks of a device (other than a custom-made device) being placed on the market and reporting back to those actors where such information is incomplete or incorrect.(Article 30(3) MDR)
- the importer must verify its own registration information is complete, accurate and up to date at the intervals defined in Article 31(5) MDR.

1.19 Can an authorised representative or manufacturer perform verification checks on behalf of importers or distributors?

No. All economic operators must fulfil their obligations in accordance with Regulations. It is not possible to delegate these legal responsibilities to upstream economic operators. It is understood that some operational activities may be sub-contracted out to other organisations, however this does not absolve an importer or distributor from their legal obligations or liability. Furthermore, it is not possible for one importer to delegate their legal responsibilities to another importer, as no such provision is stipulated in the definition of an importer or in Article 13 MDR. The rationale behind this is to facilitate oversight of the supply chain and to help ensure traceability.

Other

1.20 Does the prohibition regarding 'misleading claims' outlined in Article 7 of the Regulations apply to importers and distributors?

The prohibitions outlined in Article 7 apply to all actors in the supply chain who place a device on the market or make it available to users, including importers and distributors. The Article indicates that it is prohibited for such actors on the labelling, instructions for use, or with regards to the making available, putting into service and advertising of devices, to use text, names, trademarks, pictures and figurative or other signs that may mislead the

[19] Prior to the full functionality of EUDAMED , reference should be made to 'MDCG 2021-1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional'.

user or the patient with regard to the device's intended purpose, safety and performance. Article 7 (a)–(d) elaborates and specifies the type of misleading information/claims which include assigning incorrect functions and properties to the device, or creating an incorrect impression of the treatment or diagnosis which the device can provide to the end user.

1.21 **Do importers and distributors have any obligations with regards to device traceability?**

Importers and distributors should implement solutions to meet traceability obligations outlined in Article 25 MDR/Article 22 IVDR. In addition, they are subject to the Article 27(8) MDR/Article 24(8) IVDR obligations for economic operators to store UDIs for class III and implantable devices for device which they have supplied or which have been supplied to them.

1.22 **Is an operator who assembles a system or procedure pack[20] in accordance with Article 22(1) or (3) MDR using devices from a third country (not yet placed on the EU market), considered an importer?**

Where a system or procedure pack (assembled inside or outside the EU) consists of individual CE-marked devices from a third country manufacturer not yet placed on the EU market, then the system or procedure pack producer located in the EU will be considered as an importer of the individual devices. As an importer, they will assume the obligations under Article 13 MDR and will also be subject to the obligations under Article 22 MDR, including drawing up the statement referred to in Article 22(2) MDR.

Practical Examples

Example 1: Determining the importer when the physical operation (e.g. transportation or storage) of 'placing the device on the market' is sub-contracted.

Entity (X) stipulates a contract of sale with a third-country manufacturer to import products into the EU. Thereafter, it stipulates a logistics contract with entity (Y) to physically transport the products to the EU market or provide short-term storage activities. In this case, entity (Y) acts like a "subcontractor" of entity (X) performing the logistics to enable the placing on the market of products. Entity (X) is considered the importer, responsible for compliance with the Article 13 MDR requirements.[21]

Example 2: With reference to cases where the legal manufacturer is located outside the EU, but has an agreement with an EU-based company to produce the device in question, would an actor assume the role of the importer?

The importer will be the entity, which makes the device available on the EU market for the first time independent of whether the device was physically manufactured in the EU or not. The EU based company that physically manufacturers the device will only be considered the

[20] For definitions and elaborations on systems and procedures packs, please see MDCG 2018-3 Guidance.

[21] Please see the 'General Obligations' section of this document for more information on third party logistics.

importer if it fulfills the definition outlined in Article 2(33) MDR and the legal ownership of the device is transferred to it.

Example 3: The factory of a legal manufacturer is situated in third country (X) but has a registered EU based Office (Y). Can (X) send orders directly to EU based distributor (Z) without (Z) becoming an Importer?

As the factory of the legal manufacturer is located in a third country, a 'distributor' will typically become an importer for the country in the EU (as the European Office will not be default be an importer).

However, adapting the lines of transfer of legal property of the goods could be a means of limiting the number of EU importers. In this case the legal property could go from manufacturer (X) to their European office (Y)(an importer), to distributor(s), whilst physically the goods could go directly from manufacturer (X) to distributor (Z). Accommodating this would likely require the European office (Y) to subcontract some of the operations outlined in Article 13 MDR, for which it would nonetheless remain legally liable as an importer.