MDCG 2021-27 Rev.1

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

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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MDCG 2021-27 (Dec 2021) **MDCG 2021-27 Rev 1 changes (Dec 2023)**	
General	Questions are renumbered from Q.11 onwards, due to addition of new questions The term 'legal entity' is replaced by 'natural or legal person' throughout the document
Introduction	Footnote 5 amended to reflect updated version of the 'Blue Guide' on the implementation of EU product rules 2022
Question 8	Second paragraph newly added, starting with '*To ensure the importer's details reach the end user,..'* Footnote 18 added
Question 11	New question added on 'fulfilment service providers'
Question 16	New question added on role of authorised representative and importer Footnote 26 added
Question 17	New question added on the role of importer and distributor
Question 18	Fourth, fifth and sixth paragraphs newly added, starting with '*It is noted that physical checks..'*
Question 23	Second and third paragraphs newly added to complement existing text
Question 24	New question added on system and procedure packs and the importer role Footnote 29 added
Question 25	New section added on system and procedure packs and the distributor role Footnote 30 added
Question 26	New question added on leasing companies
Example 2	Minor addition to title 'from its manufacturing facility'

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). 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 devices. References to 'the Regulations' should be understood to cover both the MDR and IVDR.

The questions covered by the document aim to provide further detail on the operational and practical implementation of Articles 13 and 14 and other related obligations for importers and distributors under the Regulations. Activities described in Article 16 of the Regulations are covered in other guidance documents, including MDCG 2018-6[1], MDCG 2021-23[2] and MDCG 2021-26[3].

Note: This document is non-exhaustive and should be read in conjunction with the MDR/IVDR. Of additional relevance are the Regulation (EU) 2019/1020 on market surveillance[4] where applicable to the MDR and IVDR, the horizontal guidelines of the European Commission's 'Blue Guide'[5] based on the principles of the New Legislative Framework[6], and further complementary medical devices sectorial guidance documents[7].

Questions and Answers

Distinguishing importers and distributors

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 the 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.*

[1] MDCG 2018-6 'Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation (EU) 2017/745 and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746'.
[2] MDCG 2021-23 'Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746'.
[3] MDCG 2021-26 'Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746'.
[4] Note, Regulation (EU) 2019/1020 is applicable to the MDR and IVDR as listed in its Annex I, in so far as there are no specific provisions with the same objective in the MDR or IVDR, which regulate in a more specific manner particular aspects of market surveillance and enforcement.
[5] Please see 'Commission Notice, The 'Blue Guide' on the implementation of EU products rules 2022'.
[6] Please see the Commission Website.
[7] Please see the Commission website, the webpage on "Authorised Representatives, Importers and Distributors" and "Factsheet for authorised representatives/importers/distributors".

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

Article *2(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;.*

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

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 horizontal elaborations on the above concepts, please consult the Blue Guide[8] based on the principles of the New Legislative Framework.[9]

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'.[10] If a natural or legal person established in the Union obtains (via a transfer of ownership, possession or any other property right, which does not necessarily require the physical handover of the product) a device from an economic operator established in a third country and places an individual device on the Union market (i.e. the first making available), that entity is acting as an importer of the individual device. Where a natural or legal person sources (via a legal transfer of ownership, possession or any other right, which does not necessarily require the physical handover of the product) devices from importers, distributors or manufacturers established in the Union 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 bought by a consumer in a third country while physically present in that country and brought by the consumer into the Union for their personal use (outside of commercial activities)[11], is not considered as being placed on the market[12]. In this case, the consumer does not have to fulfil the obligations of Article 13 or Article 14 of the Regulations.

[8] Note in particular sections of the 'Blue Guide' on 'making available on the market', "placing on the market" 2.2, and 2.3, and 3.3 (Importer), 3.4 (distributor).
[9] Please see the Commission Website.
[10] Please note that the concept of placing on the market refers to each individual product, not the type of product. For further information, see Section 2.3 of the 'Blue Guide'.
[11] 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 Union market or make it available. However for 'distance sales' within the meaning of Article 6 MDR, the provisions of that article apply.
[12] For further information, see Section 2.3 of the 'Blue Guide'.

3. **Does an EU based distributor become an importer if it obtains its products directly from a non-EU based manufacturer or distributor?**

Yes. Any operator including an EU based distributor who obtains (via a legal transfer of ownership, possession or any other property right) an individual device from a non-EU based manufacturer or distributor and places that individual device on the Union market (i.e., the first making available), will assume the role and responsibilities of an importer. The concept of placing on the market refers to each individual product, not to the type of product[13]. Placing on the market can therefore occur, regardless of whether another importer already exists within the EU for the same device model.

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

Yes. The obligations of device importers will apply to any entity meeting the definition of Article 2(33) MDR/Article 2(26) IVDR (as described in Q.1). As the concept of placing on the market refers to each individual product and not to the type of product,[14] individual devices (of the same type) may be placed on the market by various natural or legal persons, each considered an importer and subject to the respective provisions of the Regulations on importers. This can occur, regardless of whether another importer already exists within the EU for the same device model. It is not possible however, to have multiple importers of the same individual device.

5. **Can individual shops, community pharmacies, retailers, or other persons be considered distributors?**

Yes. A distributor is 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 (see Article 2(34) MDR/Article 2(27) IVDR). As such, individual shops, pharmacies or retailers or other natural or legal persons meeting this definition, are considered distributors.

For example, a community pharmacy[15], an individual shop, retailer or other person, which buys and then sells type II medical face masks to customers (whether online or physically), such as other shops or companies or private individuals, are considered to supply[16] medical devices and thereby fall within the definition of a distributor. These entities will be expected to comply with Article 14 of the Regulations and any applicable national registration requirements.

Furthermore, these operators will assume the role and responsibilities of an importer if they obtain the device directly from a non-EU based manufacturer or distributor and are expected to comply with Article 13 of the Regulations.

[13] For further information, see Section 2.3 of the 'Blue Guide'
[14] For further information, see Section 2.3 of the 'Blue Guide'.
[15] Please note that hospital pharmacies, circulating devices for internal use within hospital departments, will not be considered distributors as described above.
[16] Please also note, that Recital 28 MDR/Recital 26 IVDR provides 'For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices'.

6. **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) of the Regulations. The importer may add this information themselves or sub-contract this task, however the importer remains responsible for the correct execution of the obligation, regardless of the means chosen. Distributors are responsible for verifying this obligation has been fulfilled before making the device further available (Article 14(2) (c) of the Regulations).

Whilst the inclusion of the importer's details before the device has physically entered the Union is not mandatory, the importer's details must be included on the device (or on its packaging, or in a document accompanying the device) when the device is placed on the Union market (i.e. the first making available). The absence of the importer's details at customs control should therefore not be considered as a non-compliance with the Regulations.[17]

7. **What should an importer do in the case where an individual device already mentions another importer's details on its packaging?**

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

In the unusual case where details of another importer already appear on the packaging of an individual device (for example, the individual device has been exported and then re-introduced to the Union market), the importer should verify if the individual device has previously been placed on the Union market. This may be done by contacting the manufacturer. The importer should replace any previous importer details with their own, if having investigated the issue, they determine themselves to be the correct importer. The label with the previous details will be void.

If having investigated the issue, they determine the other importer already mentioned on the packaging as the entity that placed the devices on the market, they will assume the role of distributor for this device and thus should comply with Article 14 of the Regulations.

8. **What is meant by 'accompanying documentation' under Article 13(3) of the Regulations?**

'Accompanying documentation' containing the importer's 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 and contacted (Article 13(3) of the Regulations) and allow healthcare professionals, patients or users to report suspected incidents (Article 13(8) of the Regulations)

[17] However, checks by customs or competent authorities on the importer's plans to update the device labelling/packaging/accompanying documentation before the device is placed on the market, could be performed.

to the importer. The importer may choose the appropriate accompanying documentation, as long as it reaches the end user. Examples may include a sticker affixed to the label or a leaflet.

To ensure the importer's details reach the end user, the importer should consider providing the accompanying documentation with the smallest saleable package of the device (i.e., the smallest package that can be purchased by the end user as determined by the manufacturer). In cases where there is a risk of jeopardising the device's compliance with the general safety and performance requirements, the importer may carry out this activity in cooperation with the manufacturer. For a device delivered in multiple boxes due to its size or its configuration, the accompanying document may be provided once rather than on each individual box provided it is supplied to a single user or location.[18]

Where any additional label is used to provide the importer's information, it should not obscure the information on the label provided by the manufacturer in accordance with Annex I 23.2 MDR/Annex I 20.2 IVDR.

It is also noted that the distributor may not sell products where documentation or the importer's information is missing (see Article 14(2)(c) of the Regulations).

9. **Are companies providing third party logistics (3PLs) (such as transportation or storage) considered importers under the Regulations?**

Not normally. Some 3PL companies which provide transportation services or hold devices on a consignment basis only (i.e. where devices are held at a site by the 3PL, but the 3PL does not have legal ownership of those devices), may not be considered an importer provided there is a clearly defined agreement between both parties setting out the responsibilities of each party[19]. The importer is the natural or legal person meeting the definition of Article 2(33) MDR/Article 2(26) IVDR, with ownership, possession or any other property right over the device. That party is required to affix their details to the device, label or accompanying documentation in accordance with Article 13(3) of the Regulations. 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 not jeopardise compliance with the general safety and performance requirement of Annex I of the Regulations (see Article 13(5) of the Regulations).

10. **Are companies providing third party logistics (3PLs) (such as transportation or storage) considered distributors under the Regulations?**

Not normally. As explained in Q.9, transportation is not a distribution activity and therefore a 3PL conducting transportation only, even if this includes short term in transit storage to facilitate

[18] Note this applies exclusively to devices delivered to a single user or healthcare facility, to ensure the importer's details reach the end user.

[19] Please also 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)).

transportation, would not be considered a distributor[20]. The distributor is the person with ownership, possession or any other right over the device, who meets the definition provided for in Article 2(34) MDR/Article 2(27) IVDR (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) of the Regulations shall ensure that while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

11. **Are Fulfilment service providers (FSP) as defined in Article 3(11) of Regulation 2019/1020 on market surveillance (MSR), considered economic operators under MDR/IVDR?**

Fulfilment service providers (FSP) as defined in Article 3(11) of Regulation 2019/1020 on market surveillance (MSR) are not defined as economic operators under Article 2(35) MDR/Article 2(28) IVDR, and as such do not need to fulfil the economic operators' obligations under those Regulations.[21]

However, where an FSP, carries out activities which also meets the definitions of an importer or distributor under the MDR/IVDR, the related roles and obligations outlined in Article 13 and 14 of the Regulations apply.

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) of the Regulations 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) of the Regulations might be done based on a sampling method representative of the device supplied. Checks outlined in Article 14(2)(c) should be performed on the imported devices (Article 14(2) of the Regulations).

For information on reporting obligations to the competent authorities, see Question 13.

13. **Do importers and distributors have a duty to report complaints and cooperate with the member state competent authorities for medical devices[22]?**

Yes. In accordance with Article 14(2) of the Regulations the distributor is required to inform the competent authority (of the Member State in which it is established) if they believe the device presents a serious risk[23] or is falsified. General complaints not meeting the definition of a serious risk or a falsified device however, are not reportable. Article 14(6) of the Regulations

[20] See above footnote.
[21] See also footnote 18.
[22] Please see the Commission website for the list of member state competent authorities for medical devices.
[23] Please see the MDCG 2023-3 'Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices' for further information on the term 'serious risk'.

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. In addition, under Article 14(6) of the Regulations 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) of the Regulations). Where the device presents a serious risk, importers have the additional obligation to inform the notified body that issued the device certificate, if applicable. The importer should in such cases give details, in particular, of the non-compliance and of any corrective action taken.

14. **Do importers and distributors have a duty to report complaints to manufacturers?**

Yes. 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) of the Regulations). 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) of the Regulations).

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

15. **Do the requirements of Article 13 and 14 of the Regulations also apply to devices certified under the Directives[24] or 'legacy devices'[25]?**

For 'legacy devices', the obligations outlined in Articles 13 and 14 of the Regulations should be read in conjunction with the transitional provisions in Article 120(3) MDR/Article 110 IVDR for such devices. Some of these obligations, serving to support a well-functioning vigilance and market surveillance system as well as proper registration of economic operators and devices, therefore apply. These include in particular, for importers Article 13(2), last paragraph, (4), (6)-(8), (10) of the Regulations related to reporting and cooperation and for distributors, Article 14(2), last paragraph, (4)-(6). However, verification obligations related to labelling and UDI Requirements established under the Regulation do not apply.

16. **Can the same natural or legal person assume the role of authorised representative as well as importer for one individual device under the MDR/IVDR?**

It is possible for the same natural or legal person to act as both authorised representative[26]

[24] Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1) and Directive 98/79/EC (OJ L 331, 7.12.1998, p. 1).
[25] For further information on 'legacy devices' please see MDCG 2021-25 'Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC' and MDCG 2022-8 'Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC'.
[26] Please see 'MDCG 2022-16 Guidance on Authorised Representatives Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)' for further information on the roles and obligations of the authorised representative, including concerning their mandate covering one specific generic device group of the manufacturer.

and importer for a specific device (i.e., an individual device). The natural or legal person acting as both roles would need to fulfil the obligations of each economic operator outlined in Article 11 and Article 13 of the Regulations respectively and be able to demonstrate compliance to the applicable requirements.

17. **Can the same natural or legal person assume the role of importer as well as distributor for one individual device under the MDR/IVDR?**

In line with the definition of a distributor under the Regulations, the same a natural or legal person cannot fulfil the role of importer and distributor for an individual device, given that the distributor is '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'.

Verification Obligations

18. **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 Regulations, and have been assigned a UDI where applicable.

For importers, ensuring devices are CE-marked and labelled in accordance with the Regulations can involve physical checks (for example visual inspection of the device and/or its outer packaging) in order to be able to confirm whether any non-conformity exist. Verifying that the EU declaration of conformity of the device has been drawn up, should involve the importer requesting and keeping available a copy of this document as specified in Article 13(9) of the Regulations. Verifying that a manufacturer has been identified and that an authorised representative has been designated (in accordance with Article 11 of the Regulations) can be performed via the EUDAMED database. In addition, this can be verified using the up to date version of the EU declaration of conformity (Annex IV of the Regulations), the device labelling, or where verifying that an authorised representative has been designated, by contacting them directly. These methods where available, may also be used to confirm UDI assignment, (noting however the EU declaration of conformity is only required to contain the Basic UDI-DI), and otherwise, the manufacturer 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) of the Regulations. However, verification activities (e.g. physical checks) should be performed on the devices supplied, e.g. to verify that the importer's information appears on the label or accompanying documentation (Article 14(2) (c) of the Regulations).

It is noted that physical checks are an essential tool for ensuring device compliance, detecting non-compliances and preventing such non-compliant devices from being made available on the market. When physical checks for Art 14(2)(c) cannot reasonably be achieved for every device (e.g. without compromising the integrity of the packaging and compliance of the device), in exceptional and justified cases, the verification should be based on documentation checks

(e.g. checks of records provided by the manufacturer). To allow for the verification checks outlined in Article 14(2)(b) of the Regulations, manufacturers and/or importers should allow the distributor access to the EU declaration of conformity upon its request.

Importers and distributors should be able to demonstrate to the competent authority (e.g., during an inspection) that the above verifications have been performed, through their internal records or procedures. Whilst importers and distributors may use subcontractors to carry out some of these operational activities, this does not absolve them from their legal obligations.

Lastly, it should also be noted that importers and distributors may also be subject to national provisions (e.g., language requirements for information supplied with the device) which member states have established for devices that are made available on their territory.

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 potential 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 of the Regulations. The rationale behind this is to facilitate oversight of the supply chain and to help ensure traceability.

Registration Obligations

20. **Do importers and distributors have registration obligations in EUDAMED?**

Importers of a device shall register in EUDAMED[27] in accordance with Article 31 MDR/Article 28 IVDR, providing in particular the information referred to in Section 1 of Part A of Annex VI of the Regulations.

Distributors do not have to register in EUDAMED, however, per Article 30(2) MDR/Article 27(2) IVDR they may be subject to national registration requirements of member states in which they have made the device available.

In cases where importers, distributors or other natural or legal persons according to Article 16 (1) of the Regulations assume the obligations incumbent on manufacturers, they should register as manufacturers in EUDAMED. For further information see MDCG 2021-13.[28]

21. **Do importers have additional verification obligations in EUDAMED?**

In addition to registration (Article 31 MDR/Article 28 IVDR), importers have various verification obligations in EUDAMED. These include:

[27] 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'.
[28] MDCG 2021-13, 'Q&A on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and Importers subject to the obligations of Article 31 MDR and Article 28 IVDR'.

- verifying the device is registered (Article 13(4) of the Regulations);
- 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/Article 27(3) IVDR);
- the importer must verify its own registration information is complete, accurate and up to date at the intervals defined in Article 31(5) MDR/Article 28(5) IVDR.

Other

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

The prohibitions outlined in Article 7 of the Regulations apply to anyone, 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 user or the patient with regard to the device's intended purpose, safety and performance. Article 7 (a) – (d) of the Regulations 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.

23. **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.

Medical device traceability by importers and distributors may be achieved through maintaining adequately detailed records in relation to the sourcing and supply of medical devices. For example, in the event of a Field Safety Corrective Action (FSCA) it may be necessary to determine the customers that received the medical device that was affected by the FSCA.

In addition, under Article 27(8) MDR/24(8) IVDR, importers and distributors have the specific obligation to store UDIs for class III implantable devices and the devices, categories or groups of devices determined by a measure referred to in Article 27(11) (a) MDR and devices, categories or groups of devices that may be determined by a measure referred to in Article 24(11)(a) IVDR which they have supplied or with which they have been supplied. They do not need to store UDIs for other devices.

24. **Is an operator who assembles a system and procedure pack (SPP) in accordance with Article 22(1) or (3) MDR using devices from a third country manufacturer (not yet placed on the Union market), considered an importer?**

Where a system or procedure pack (SPP) consists of one and more individual CE-marked devices from a third country manufacturer, the system or procedure pack producer (SPPP) established in the Union will be considered as the importer of the individual devices in the SPP,

if they are the entity that places such devices on the Union market (i.e., the first making available). As an importer of the individual devices, they will assume all applicable obligations under the MDR, including Article 13 MDR[29] and will, in their role as SPPP, also be subject to the obligations under Article 22 MDR, including drawing up the statement referred to in Article 22(2) MDR.

25. **Is an operator who assembles a system or a procedure pack (SPP) in accordance with Article 22(1) or (3) MDR using devices already placed on the Union market, considered a distributor?**

Yes, where a system or procedure pack (SPP) consists of one or more individual CE-marked device(s) already placed on the Union market, the system or procedure pack producer will be considered as a distributor of the individual devices in the SPP. As a distributor of the individual device(s), they will assume the obligations under Article 14 MDR[30] and will also be subject to the obligations under Article 22 MDR, including drawing up the statement referred to in Article 22(2) MDR.

26. **Can leasing companies be considered importers or distributors under the Regulations?**

Taking into consideration the definitions of "importer" and "distributor" as laid down in Article 2 (33) and (34) MDR/Article 2 (26) and 2 (27) of the IVDR respectively, leasing companies may be regarded as importers or distributors according to the specific activities they may carry out with respect to placing on the market or making available of a device.

In such a case where the leasing company's activities fall under the scope of those of an importer or distributor, the related obligations (e.g. Article 13 and 14 MDR/IVDR) would apply to it.

Where leasing companies are not a part of the supply chain at all (i.e. do not carry out any of the activities with respect to the first placing on the market or making available of a device) they should not be considered to act as an importer or distributor. This would include the case where they offer purely credit/finance services in support of the activities of manufacturers or other economic operators.

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 Union. Thereafter, it stipulates a logistics contract with entity (Y) to physically transport the products to the Union 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

[29] Please note in cases where the individual CE marked device(s) in the SPP is an IVD, the importer will assume the obligations under Article 13 IVDR.
[30] Please note in cases where the individual CE marked device(s) in the SPP is an IVD, the distributors will assume the obligations under Article 14 IVDR.

market of products. Entity (X) is considered the importer, responsible for compliance with the Article 13 of the Regulations.[31]

Example 2: A manufacturer (M) established in the Union has a manufacturing facility in a third country. Can (M) send devices directly from its manufacturing facility to an EU based distributor (Z) without (Z) becoming an importer?

If the manufacturer (M) is established in the Union, but its devices are produced at its manufacturing site located outside the Union, (M) is considered the entity placing the product on the Union market, even if the actual importation of the products is done by another company. In this case, because (M) is established in the Union, there is no importer within the importer definition under the Regulations and (Z) is acting as distributor.

Example 3: Entity (X) physically brings medical devices manufactured in a third country into the Union. However, the devices are not placed on the Union market (e.g. only in transit) and are supplied directly on to a third country distributor (entity Y). A legal transfer of ownership has taken place between entity (X) and entity (Y). Entity (Y) supplies the devices on to a distributor in the EU (entity Z) and the devices are placed on the Union market for the first time.

Is entity (X) considered an importer even though they are not placing devices on the Union market? Or is entity (Z) considered the importer?

As entity (X), despite bringing the devices into the Union, never placed the devices or made them available on the Union market, they are not acting as an importer for those devices. Instead, entity (Z) will undertake the roles and responsibilities of an importer if they place the devices on the Union market (i.e. perform the first making available). Adapting the lines of transfer of legal property of the goods could be a means of limiting the number of EU importers. The physical goods could go from the third country manufacturer to distributor (Z) and may physically transit a third country.

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