MDCG 2021-26

Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

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1. Introduction

This document presents questions and answers about obligations introduced by Article 16(2) to (4) under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). Reference to 'the Regulations' should be understood to cover both the MDR & IVDR.

Article 16(1) of the Regulations outlines cases where the obligations of manufacturers also apply to importers, distributors or other natural or legal persons, and is not in the scope of this questions and answers document.

Article 16(2) of the Regulations specifies the cases in which certain activities of importers and distributors are not considered modifications of a device, within the meaning of Article 16(1)(c), that could affect its compliance with the applicable requirements. In such cases, importers and distributors do not assume the obligations of the manufacturer.

These cases include:

a) supplying of information, translation of information supplied by the manufacturer including the Instructions for Use (IFU), necessary to market the device in the Member State in question (relabelling)
b) changes to the outer packaging of a device already placed on the market, necessary to market the device in the Member State in question (repackaging).

For the importers and distributors identified in Article 16(2) (often referred to as 'parallel traders'[1]) there are certain obligations, other than those of the manufacturer, which are described in Articles 16(3) and (4) of the Regulations.

Further guidance on the quality management system referred to in Article 16(3) of the Regulations and related certification activities carried out by the notified bodies, is provided in MDCG 2021-23 '*Guidance for notified bodies on certification activities according to Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746*'.

2. Scope

The questions covered by this document aim to guide economic operators carrying out any of the activities mentioned in points (a) and (b) of Article 16(2) of the Regulations concerning relabelling and repackaging of devices.

It is not intended to address the quality management system and related certification activities, which is provided in MDCG 2021-23[2], nor elaborate on Article 16(1) of the Regulations.

It is also noted that Article 16(2), (3) and (4) of the Regulations do not apply to operators subcontracted by the manufacturer (that may also qualify as importers or distributors), who also carry out relabelling and/or repackaging activities on behalf and under the control of the manufacturer.

[1] Please see Recital 37 of Regulation (EU) 2017/745/ Recital 36 of Regulation (EU) 2017/746
[2] MDCG 2021-23 '*Guidance for notified bodies on certification activities according to Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746*'

3. Questions and Answers

Question 1

Do Article 16(2), (3) and (4)[3] apply only to importers and distributors or also "other natural or legal person" as mentioned in Article 16(1)?

Given that Article 16(3) sets out requirements for importers and distributors and in doing so, cross-references activities performed in points (a) and (b) of Article 16(2), it is considered that Article 16(2), (3) and (4) apply only to importers and distributors.

It is noted that Article 16 (2), (3) and (4) do not apply in cases where a health institution or hospital splits up a large pack of devices, which they have received, into smaller pack sizes or individual units for use or circulation within the health institution/hospital. In this example, the activities are not performed in order to market the devices in the relevant Member state, and are therefore not within the scope of Article 16 (2), (3) and (4).

Question 2

Do Article 16(3) and (4) of the MDR apply to 'legacy devices'?

No, Article 16(3) and (4) of the MDR do not apply to 'legacy devices'. However, this is without prejudice to the possibility for economic operators to follow any MDR requirements also for 'legacy devices', especially if they deal with both 'legacy devices' and MDR devices and want to apply the same procedures for all devices.

Question 3

For the activities mentioned in points (a) and (b) of Article 16(2), what is meant by 'necessary in order to market' the device in the relevant Member State'?

'Necessary in order to market' refers to conditions that should be met in order to market the device in that Member State. Whether a relabelling or repackaging activity is necessary, should be analysed on a case-by-case basis.

Examples of the abovementioned conditions may include (non-exhaustive list):

- national language requirements for device information supplied by the manufacturer;
- the need to supply in a new package, a specific number of devices different from the number of devices supplied in the original packaging by the manufacturer, for reasons of:
    - providing the healthcare system with pack sizes that are suitable for the needs of health institutions in that Member state;
    - national practices authorising only a certain packaging size;
    - health insurance rules making the reimbursement of medical expenses dependent on the size of the packaging;
    - well-established medical prescription practices.

[3] Henceforth references to Article 16 and its subparagraphs in this document, should be understood as Article 16 of the Regulations (MDR/IVDR).

Question 4

Is the splitting-up of large quantities of devices in shipping containers[4] into smaller quantities of devices in packages or individual units covered by Article 16(2)?

It is not a "relabelling" or "repackaging" activity within the meaning of Article 16(2), if the importer or distributor is simply splitting-up larger quantities of devices (for example in a shipping container) into smaller quantities (for example packages, lots or individual units) for further supply in the distribution chain, including to the final user, provided that the outer packaging[5] of the device in question is not affected (e.g. maintaining in particular, a device's sterile condition). Such splitting-up of packages is a common wholesale or retail practice and is not considered to fall within the scope of Article 16(2) of the Regulations.

An example of this is a distributor that buys syringes in large quantities, which are received in large pack sizes in a shipping container. The distributor then splits up the large packs into smaller quantities (e.g. sales packages consisting of individual units) in order to provide them to vaccination centres and general practitioners.

The general obligations of distributors laid down in Article 14 of the Regulations also apply, which include verification that the devices they make available are CE marked and are accompanied by the information to be supplied by the manufacturer (such as the label and IFU).

Question 5

What information should be notified to the manufacturer according to the Article 16(4)?

In accordance with Article 16(4), importers and distributors performing relabelling and/or repackaging activities should:

- inform the manufacturers of the intention to make the relabelled or repackaged device available on the market, at least 28 days prior to making the device available on the market and;
- upon request, provide the manufacturer with a sample or mock-up of the relabelled or repackaged device, including any translated label and IFU;

While this is not a requirement for importers and distributors under the Regulations, they may provide information in order to allow for effective field safety corrective actions (FSCA) and post-market surveillance (PMS) by the manufacturer. This may include (non-exhaustive list):

- name of the concerned device and information allowing for the unambiguous identification of the device: model, product number, reference or UDI-DI etc.;
- activities performed (repackaging, relabelling and/or translation);
- the reason why the activity performed is needed;

[4] Annex VI Part C MDR/IVDR defines 'A shipping container' as 'a container in relation to which traceability is controlled by a process specific to logistics systems.' Please see further Article 27(4) MDR/Article 24(4) IVDR and sections 3.2, and 4.1 of Annex VI Part C MDR/IVDR, which clarify that shipping containers are 'logistics units', and are not considered higher levels of device packaging.

[5] The 'outer packaging' is the packaging in which the device is made available to the end user as intended by the manufacturer.

- Member States where the repackaged/relabelled and/or translated IFU devices will be made available;
- in case of translation, languages in which the label and IFU[6] are translated;
- the changes to the package and number of devices included in the new packaging;
- when the device is planned to be made available;
- information on the notified body issuing the certificate in accordance with Article 16(4) and a copy of the certificate.

Question 6

What information should be notified to the competent authority according to the Article 16(4)?

In accordance with Article 16(4) of the Regulations, importers and distributors performing relabelling and/or repackaging activities, at least 28 days prior making the device available on the market, should:

- inform the competent authority (of the Member State where they plan to make the device available) of the intention to make the relabelled or repackaged device available on the market, and;
- submit to the competent authority the necessary certificate as per Article 16(4) of the Regulations as described in MDCG 2021–23[7].

Moreover, upon request, importers and distributors performing relabelling and/or repackaging activities should provide the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use.

While it is not a requirement for importers and distributors under the Regulations, they may wish to further inform competent authorities about: (non-exhaustive list):

- manufacturer and authorised representative (if applicable) details;
- name of the concerned device and information allowing for the unambiguous identification of the device: model, product number, reference or UDI-DI etc.;
- activities performed (repackaging relabelling and/or translation);
- the reason why the activity carried out/performed is needed;
- in case of translation, languages in which the label and IFU[8] are translated;
- the changes to the package and number of devices included in the new packaging;
- when the device is planned to be made available.

[6] Please see (where applicable), exemptions regarding provisions of the IFU outlined in Annex I, Chp III, 23.1(d) MDR and Annex, Chp III, 20.1.(d).
[7] MDCG 2021-23 '*Guidance for notified bodies on certification activities according to Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746*'.
[8] Please see (where applicable), exemptions regarding provisions of the IFU outlined in Annex I, Chp III, 23.1(d) MDR and Annex, Chp II, 20.1.(d).

Question 7

Do the manufacturer and competent authority have to be notified each time an individual device or batch of devices is being relabelled or repackaged?

There are no specific requirements in the Regulations.

However, it is considered that a notification to the manufacturer and relevant competent authority (of the Member state where the repackaged or relabelled device is intended to be made available), is only due when a device is going to be relabelled and/or repackaged for the first time. The notification does not have to be repeated on a unit-by-unit or batch-by-batch basis.

Question 8

Under which conditions should a notification to the manufacturer and the competent authority be performed?

In accordance with Article 16(4), importers and distributors performing relabelling and/or repackaging activities should inform the manufacturer and competent authority (of the Member State where they plan to make the device available), of the intention to make the relabelled or repackaged device available on the market, at least 28 days prior.

A notification to the manufacturer should be performed when one or more of the following conditions occur (non-exhaustive list):

- when a device is planned to be made available in a Member State not previously notified;
- when relabelling and/or repackaging will be applied to a device not previously notified;
- when the information supplied with the device will be translated into a language not previously notified.

A notification to the concerned competent authority should be performed when one or more of the following conditions occur (non-exhaustive list):

- when relabelling and/or repackaging will be applied to a device not previously notified;
- when the information supplied with the device will be translated into a language not previously notified;
- when the information supplied with the device or the outer packaging will be modified;
- when there are changes to the certificate issued by the notified body (including certificate renewal);
- when changing notified body.

Question 9

Do the manufacturer and competent authority have to be notified when an importer or distributor ceases to perform relabelling and/or repackaging activities?

Whilst this is not a requirement for importers and distributors under the Regulations, they may wish to inform the manufacturer and competent authority of the Member State concerned, of the cessation of their relabelling and/or repackaging activities. This information could be useful in relation to FSCA processes.

Question 10

To which notified bodies may importers and distributors apply to obtain the certification referred to in Article 16(4)?

Importers and distributors have to apply to a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of Article 16(2)[9].

Importers and distributors can find the information regarding the type of devices for which notified body is designated by consulting the Nando (New Approach Notified and Designated Organisations) Information System.[10]

Question 11

Do relabelling and/or repackaging activities performed on Class I devices and class A *in vitro* diagnostic devices also involve a notified body review within the meaning of Article 16(4)?

Since Class I devices and class A *in-vitro* diagnostic devices are not explicitly exempted, Article 16(2) to (4) apply also in case of repackaging and/or relabelling of those devices.

Question 12

Can the importer or distributor provide additional information concerning the batch number whilst performing relabelling and/or repackaging activities?

The manufacturer's batch number cannot be changed and should appear on the label.

However additional information can be provided by the importer or distributor for clarity e.g. the sub-lot number of the relabelled or repackaged devices or other information which ensures traceability of those devices.

[9] Notified bodies providing such certifications are required to be designated for the type of devices that are subject to activities mentioned in points (a) and (b) of Article 16(2) of the Regulations. Please see also COMMISSION IMPLEMENTING REGULATION (EU) 2017/ 2185 - of 23 November 2017 - on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/ 745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/ 746 of the European Parliament and of the Council (europa.eu)

[10] Please consult https://ec.europa.eu/growth/tools-databases/nando/

Question 13

In the case of translation of the IFU, is it necessary to keep the original version of these instructions in the packaging?

Whilst there is no a specific requirement in the Regulations, in case of translation of the IFU, the original version of these instructions may be included in the packaging. The translated IFU should always be an exact translation of the original version provided by the manufacturer of the device.

Question 14

Do entities carrying out relabelling and/or repackaging activities in accordance with Article 16(2) of the Regulations have any obligations related to traceability and Unique Device Identification (UDI[11])?

Importers and distributors performing relabelling and/or repackaging activities should implement solutions to meet traceability obligations outlined in Article 25 MDR/Article 22 IVDR. They should also verify UDI assignment as set out in Article 13(2)(d) and Article 14(2)(d) of the Regulations respectively.

In addition, importers and distributors are subject to the Article 27(8) MDR/Article 24(8) IVDR obligations for economic operators to store UDIs for devices which they have supplied or which have been supplied to them. This requirement applies to the class III implantable devices, and devices, categories or groups of devices as determined by measures referenced in Article 27(8) MDR and in Article 24(8) IVDR.

[11] Article 27 MDR/Article 24 IVDR introduce a Unique Device Identification (UDI) system, which among other functions aims to improve the identification of devices, facilitate the traceability of devices and enhance the effectiveness of post-market safety-related activities for devices.