MDCG 2019-2

Guidance on application of UDI rules to device-part of products referred to in Article 1(8), 1(9) and 1(10) of Regulation 745/2017

February 2019

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.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

1. Scope

Article 1(8),1(9), 1(10) of the Medical Device Regulation (EU) 2017/745 (MDR) set the basic criteria to determine whether and to what extent the relevant legislation on medical devices, medicinal products, human tissue and cells apply to certain products containing a medical device part. In particular,

"8. Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the device, shall be assessed and authorised in accordance with this Regulation.

However, if the action of that substance is principal and not ancillary to that of the device, the integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004 of the European Parliament and of the Council, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.

9. Any device which is intended to administer a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC shall be governed by this Regulation, without prejudice to the provisions of that Directive and of Regulation (EC) No 726/2004 with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part of the single integral product are concerned."

10. Any device which, when placed on the market or put into service, incorporates, as an integral part, non-viable tissues or cells of human origin or their derivatives that have an action ancillary to that of the device shall be assessed and authorised in accordance with this Regulation. In that case, the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.

However, if the action of those tissues or cells or their derivatives is principal and not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned".

2. Application to UDI rules to the device part of products referred to in point 1 that are governed by the medical device Regulations

EXAMPLES:

- Catheters coated with heparin or an antibiotic
- Soft tissue fillers incorporating local anaesthetics
- Implantable infusion pump
- Spacer devices for use with metered dose inhalers
- Bone void filler with an antibiotic
- Bone void filler with animal growth factors, where the action of the growth factors is demonstrated to be ancillary to that of the physical filler

If a product referred to in point 1 is assessed and authorised in accordance with the Medical device regulations, the device part will be subject to all UDI-related obligations.

3. Application to UDI rules to the device part of combination products that do not fall under the medical device Regulations

EXAMPLES:

- Non-reusable autoinjectors containing a medicinal product as integral part
- Nebulizers precharged with a specific medicinal product
- Patches for transdermal drug delivery
- Wound dressings impregnated with an antibiotic, where the primary intended purpose is to administer the antibiotic to the wound
- Bone void filler with animal growth factors, where the action of the growth factors cannot be demonstrated to be ancillary to that of the physical filler

In general terms, if a product referred to in point 1 is governed by the medicinal product or tissue and cell legislation, the device part is required to comply only with the relevant general safety and performance requirements set out in Annex I to the Regulation on medical devices. This cannot be interpreted as meaning that the relevant obligations related to UDI, as laid down in Chapter III and Annex VI of the Regulation on medical devices, apply to the medical device part or the package of the relevant combination. For this reason, the medical device part is not mandatorily required to comply with any UDI-related obligation. This also means that a UDI is not needed on the package that combines the medicinal product and the medical device[1] [2].

[1] However, if the medical device part bears a UDI on its label, that should not be deemed as being in contrast with the applicable medical device legislation

[2] For products such as prefilled syringes which are made on the basis of a UDI direct part marked (MDR compliant) syringe it shall be noted that, while UDI rules do not apply to the device part of the integral product, the direct mark UDI on the syringe shall not be removed unless that mark compromises the safety and performance of the integral product.