/Logotype/
EURASIAN ECONOMIC COMMISSION
BOARD

DECISION

July 24, 2018 **No. 116** city of Moscow

On Criteria for differentiation of elements of a medical product that are components of the medical product for the purpose of its registration

In accordance with paragraph 2 of Article 3, paragraphs 2 and 4 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 and paragraph 11 of the Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission dated February 12, 2016, and in accordance with paragraph 23 of the list of acts of the Eurasian Economic Commission on issues of regulation of common markets of drugs and medical products within the Eurasian Economic Union for 2017-2019 (Annex to Instruction No. 15 of the Council of the Eurasian Economic Commission dated May 17, 2017), the Board of the Eurasian Economic Commission **decided:**

1. To approve the attached Criteria for differentiation of elements of a medical product that are components of the medical product for the purpose of its registration.

2. This Decision shall enter into force after 30 calendar days have elapsed from the date of its official publication.

Chairman of the Board
of the Eurasian Economic Commission T. Sargsyan

Seal:
Eurasian Economic Commission. For documents

APPROVED
by Decision No. 116 of the Board of
the Eurasian Economic Commission
dated July 24, 2018

CRITERIA
of differentiation of elements of a medical product that are components of the medical product for the purpose of its registration

1. This document establishes the criteria for differentiation of elements of a medical product that are components of the medical product for the purpose of its registration.

2. For the purposes of this document's application the concepts are used having the following meanings:

"spare part of the medical product" – a part of the medical product intended to replace the same part which was in operation to maintain or restore medical product serviceability or working efficiency;

"main unit (part) of the medical product" - a product other than consumables to the medical product released into circulation on behalf of the manufacturer of the medical product that is not mechanically connected with other main units (parts) of the medical product during medical product supply and which ensures the functioning of the medical product in accordance with designation. The main units (parts) of the medical product include special software that is a medical product, and can include other medical products registered in accordance with the established procedure and admitted to circulation within the Eurasian Economic Union, and in accordance with the documentation of the manufacturer of the registered medical product designed to ensure its functioning in accordance with its purpose;

"medical product component" - a main unit (part) of the medical product, an accessory that complements a medical device and supplies to a medical device.

Other concepts are used in their meanings defined by the Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission dated February 12, 2016.

3. An element of the medical product is assigned to the component of the medical product for the purpose of its registration on the basis of the following criteria:

a) if an element is a product or material consumed when using the medical product which provide manipulation in accordance with the functional purpose of the medical product, then such element refers to consumables to the medical product. At the same time, another medical product, including registered in accordance with the established procedure and admitted to circulation within the Eurasian Economic Union, can be used as a consumable material to the medical product;

b) if an element is not a product or material consumed when using the medical product which provide manipulation in accordance with the functional purpose of the medical product and is released in circulation within the Eurasian Economic Union on behalf of the manufacturer of the medical product, and at the same time:

it is not a spare part of the medical product, then such element belongs to main units (parts) of the medical product;

it is a spare part of the medical product, then such element is an accessory to the medical product;

c) if an element is not a product or material consumed when using a medical product which provide manipulation in accordance with the functional purpose of the medical product and is released into circulation within the Eurasian Economic Union, not on behalf of the manufacturer of the medical product, but on behalf of a manufacturer of the element, at the same time:

it is a medical product, including registered in the established manner, admitted to circulation within the Eurasian Economic Union and designed in accordance with the documentation of the manufacturer of the registered medical product to ensure its functioning in accordance with the purpose, then such element belongs to main units (parts) of the medical product;

it is not a medical product and is specifically designed by its manufacturer for co-use with the medical product, then such element refers to accessories of the medical product;

it is not a medical product and is not specifically designed by its manufacturer for co-use with the medical product, then such element refers to the components to the medical product.

4. When assigning an element of the medical product to a component of the medical product, a typical algorithm is applied in accordance with the scheme according to the Annex. Deviations from this algorithm during identification of the components of the medical product should be substantiated by the applicant in the submitted registration dossier and is confirmed during the examination as part of the procedure of the medical product registration and introduction of changes to the registration dossier.

5. If another medical product is used as a consumable material to the medical product or a main unit (part) of the medical product, it can be registered individually or as a set in accordance with the established procedure and admitted to circulation within the Eurasian Economic Union.

Seal:
Eurasian Economic Commission. For documents

ANNEX
to the Criteria for differentiation of elements
of a medical product which are components of
the medical product for the purpose of its registration

SCHEME
of a typical algorithm used for assigning an element of the medical product to the medical product component