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EURASIAN ECONOMIC COMMISSION
BOARD

DECISION

December 29, 2015 **No. 177** city of Moscow

On Rules for Keeping Medical Product Nomenclature

In accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, indent 2 of paragraph 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, paragraph 24 of Annex No. 2 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and in order to implement Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 "On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union" , the Board of the Eurasian Economic Commission **decided:**

1. To approve the attached Rules for keeping medical product nomenclature.
2. To designate the Federal Service for Surveillance in Health Care as the operator of medical product nomenclature of the Eurasian Economic Union.
3. That the Eurasian Economic Commission together with the authorized authorities of the Member States of the Eurasian Economic Union should consider establishment of a working group to coordinate work on creation and maintenance of the medical product nomenclature of the Eurasian Economic Union in health care.
4. This Decision shall enter into force after 30 calendar days have elapsed from the effective date 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, or of the Protocol signed on December 2, 2015 on the accession of the Republic of Armenia to 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, whichever comes later, but not earlier than 30 calendar days have elapsed from the date of the official publication of this Decision.

Chairman of the Board of the
Eurasian Economic Commission V. Khristenko

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APPROVED
by Decision No. 177 of the Board of
the Eurasian Economic Commission
dated December 29, 2015

RULES
for keeping medical product nomenclature

I. General provisions

1. These Rules are developed in accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and the second indent of paragraph 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, apply to medical products registered within the Eurasian Economic Union (hereinafter referred to as the "Union") and determine the procedure for creating and keeping medical product nomenclature of the Union.

2. For the purposes of these Rules the concepts are used having the following meanings:

"Agency of the Global Medical Device Nomenclature" – organization responsible for creation and maintenance of the Global Medical Device Nomenclature;

"medical product type" - a set of medical products having a similar or identical purpose and (or) design;

"Global Medical Device Nomenclature" - a systematized nomenclature classifier of types of medical products used for identification of medical products;

"medical product nomenclature of the Union" - a systematized nomenclature classifier of types of medical products harmonized with the Global Medical Device Nomenclature and used within the Union.

II. Procedure for creating and keeping medical product nomenclature of the Union

3. The medical product nomenclature of the Union contains a list of types of medical products with the indication of nomenclature names, unique codes and descriptions of types of medical products, including the classification characteristics of medical products depending on the purpose of medical products and (or) their design.

4. Name and description of each type of medical products included in the medical product nomenclature of the Union should correspond to the name and description of the type of medical products included in the Global Medical Device Nomenclature.

5. For the purposes of systematizing the types of medical products included in the medical product nomenclature of the Union, the categories of medical products included in the Global Medical Device Nomenclature are used.

6. The medical product nomenclature of the Union is included in the unified system of regulatory and reference information of the Union formed in accordance with paragraphs 4, 5 and 7 of the Protocol on Information and Communication Technologies and Information Interaction within the Eurasian Economic Union (Annex No. 3 to the Treaty on the Eurasian Economic Union dated May 29, 2014).

7. Medical product nomenclature of the Union is created and maintained by the operator of the medical product nomenclature of the Union in electronic form, is placed by the Eurasian Economic Commission (hereinafter referred to as the "Commission") on the Union's information portal on the Internet information and telecommunication network (hereinafter referred to as the "Internet"), is publicly available and is provided for users on a free and non-discriminatory basis.

8. The operator of medical product nomenclature of the Union carries out the following functions:

a) provides translation of the types of medical products and descriptions of their types included in the Global Medical Device Nomenclature into Russian and introduces them into the medical product nomenclature of the Union with assignment of unique codes;

b) provides translation of the names of new types of medical products and descriptions of their types, received from the Global Medical Device Nomenclature, into Russian, as well as information on changes introduced to the names of types of medical products and descriptions of their types, included into the Global Medical Device Nomenclature, and introduces changes in the medical product nomenclature of the Union;

c) ensures assignment of unique codes to new types of medical products included in the medical product nomenclature of the Union;

d) on the basis of information on exclusion of certain types of medical products from the Global Medical Device Nomenclature received from the Agency of the Global Medical Product Nomenclature, provides exclusion of relevant types of medical products and descriptions of their types from the medical product nomenclature of the Union;

e) sends information on changes made to the medical product nomenclature of the Union to the Commission using the integrated information system of the Union to update it on the Union's information portal on the Internet network;

f) considers applications and requests of users of the medical product nomenclature of the Union concerning its application;

g) analyzes and summarizes comments and suggestions of users of the medical product nomenclature of the Union in terms of its structure and content;

h) forms and submits proposals to amend these Rules for consideration of the Commission on the results of the analysis of comments and proposals of users of the medical product nomenclature of the Union.

9. The authorized authorities of the Member States of the Union enter into agreements with the Agency of the Global Medical Product Nomenclature on the use of original codes for the types of medical products included in the Global Medical Device Nomenclature, as well as on the inclusion of new types of medical products in the Global Medical Device Nomenclature.

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