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EURASIAN ECONOMIC COMMISSION
BOARD

DECISION

September 26, 2017 **No. 123** city of Moscow

On Regulation on the Advisory Committee for Medical Products

In accordance with paragraphs 7 and 44 of the Regulation on the Eurasian Economic Commission (Annex No. 1 to the Treaty on the Eurasian Economic Union dated May 29, 2014) and paragraph 34 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, the Board of the Eurasian Economic Commission **decided:**

1. To approve the attached Regulation on the Advisory Committee for Medical Products.

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

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APPROVED
by Decision No. 123 of the Board of the
Eurasian Economic Commission
dated September 26, 2017

REGULATION
on the Advisory Committee for medical products

I. General provisions

1. The Advisory Committee for medical products (hereinafter referred to as the "Committee") is established under the Board of the Eurasian Economic Commission (hereinafter referred to as the "Commission") in accordance with paragraphs 7 and 44 of the Regulation on the Eurasian Economic Commission (Annex No. 1 to the Treaty on the Eurasian Economic Union dated May 29, 2014).

The Committee is an advisory body of the Commission, which provides preparation of proposals, recommendations and consultations on issues related to circulation of medical products.

2. The Committee is guided in its activities by the Treaty on the Eurasian Economic Union dated May 29, 2014, 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, other international agreements and acts that make up the right of the Eurasian Economic Union (hereinafter referred to as the "Union"), as well as this Regulation.

II. Main tasks of the Committee

3. Main tasks of the Committee are:

a) settlement of disputes between a reference state and a Member State concerned with regard to the approval of expert opinion on the assessment of safety, quality and efficacy of medical products during registration (hereinafter referred to as the "expert opinion") in accordance with paragraph 34 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;

b) settlement of disputes on the issues of assignment of products to medical products, as well as to medical products subject to assignment to measuring instruments during their registration;

c) preparation of proposals on the improvement of the acts included in the law of the Union, in the field of circulation of medical products.

III. Composition and procedure for the Committee formation

4. The composition of the Committee is formed from representatives of the authorized authorities of the Member States of the Union in health care (hereinafter, referred to as the "authorized authority", "Member States", respectively), expert organizations designated by the authorized authorities to conduct an expert examination of safety, quality and efficacy of medical products (hereinafter referred to as the "expert organization") (at most 5 people from a Member State), on the basis of proposals of the Member States.

The composition of the Committee is approved by the order of the Board of the Commission.

5. The Member States promptly inform the Commission of the need to replace the representatives of authorized authorities in the Committee, as well as submit proposals for changes in its composition.

6. Representatives of health care organizations, expert organizations, manufacturers of a medical product and other specialists (hereinafter referred to as the "invited persons") may be invited, upon request of the authorized authorities, to participate in the consideration of the issue discussed during the Committee meeting, where applicable.

On the proposal of the Chairman of the Committee, officials and employees of the Commission, whose competence includes matters considered at the Committee meeting, may participate in the Committee meetings.

7. A member of the Board of the Commission, whose competence includes issues of circulation of medical products (hereinafter referred to as the "Chairman of the Committee") presides at the Committee meetings and manages the work of the Committee.

8. The Chairman of the Committee:

a) guides activities of the Committee and organizes work to fulfill the tasks assigned to the Committee;

b) approves agenda of Committee meeting and determines date, time and place of its holding;

c) conducts Committee meetings;

d) signs minutes of Committee meetings;

e) informs the Board and the Council of the Commission about the proposals and recommendations developed by the Committee;

f) appoints an authorized secretary of the Committee;

g) represents the Committee at meetings of the Board and the Council of the Commission and in relations with other authorities and organizations;

h) performs other functions.

9. The Chairman of the Committee is entitled to request materials and information on issues within the competence of the Committee from the authorized authorities and members of the Committee.

10. The Head of the structural unit of the Commission, who is responsible for handling of medical products, is appointed as the Deputy Chairman of the Committee.

11. The Deputy Chairman of the Committee acts as the Chairman of the Committee, provided for in paragraph 8 hereof, in the absence of the Chairman of the Committee or on his behalf.

12. The authorized secretary of the Committee is appointed from the employees of the Commission.

Information on appointment of the authorized secretary of the Committee is entered in the minutes of the Committee meeting.

13. The authorized secretary of the Committee:

a) ensures preparation of the draft agenda of the Committee meeting on the basis of proposals from authorized authorities, the Chairman and members of the Committee and submits it for approval to the Chairman of the Committee;

b) sends the draft agenda of the Committee meeting and materials for it to the members of the Committee;

c) informs Committee members about date, time and place of the Committee meeting;

d) exercises control over the preparation and submission of materials for the draft agenda and the Committee meeting;

e) keeps the minutes of the Committee meeting and submits it for signature to the Chairman of the Committee;

f) organizes preparation and submission of the final documents of the Committee prepared based on the results of the Committee meeting to the members of the Committee;

g) exercises control over the implementation of protocol resolutions of the Committee.

IV. Rules of Procedure of the Committee

14. Generally, meetings of the Committee are held every month.

15. The draft agenda of the Committee meeting is formed on the basis of proposals of the authorized authorities, Chairman and members of the Committee.

16. Proposals on drafting the agenda of the Committee meeting and materials for it are sent by the authorized authorities to the authorized secretary of the Committee (in electronic or paper form) not later than 20 calendar days prior to the date of the Committee meeting. Proposals received later are included in the agenda of the next Committee meeting.

The Chairman and the members of the Committee, who proposed issues for inclusion in the agenda of the Committee meeting, ensure that relevant materials on these issues are submitted to the authorized secretary of the Committee.

On issues that require urgent consideration, the Chairman and the members of the Committee can directly suggest on the Committee meeting to include an additional issue on the agenda of the Committee meeting.

Authorized authorities and the members of the Committee who submitted proposals on inclusion of issues in the agenda of the Committee meeting ensure submission of materials on these issues to the authorized secretary of the Committee (in electronic or paper form).

17. When forming the agenda of the Committee meeting, issues on settlement of disputes arising during registration and examination of safety, quality and efficacy of medical products are priority issues.

18. Materials on the agenda of the Committee meeting include:

a) a statement (on a pre-printed form) of the authorized authority of the reference state on the need to settle disputes with respect to the expert opinion, with indication of the information on subject of disputes and results of negotiations and consultations;

b) a written consent of the applicant (the producer who is a resident of the Member State or his authorized representative) to grant access to the authorized authorities (expert organizations) of the Member States, not specified by him as a reference state or Member State concerned, to the registration dossier and materials which have been formed at examination in the referent state, including correspondence of the applicant and the authorized authority (expert organization) of the reference state on issues to eliminate remarks and to the documents submitted by the applicant during registration and examination of medical products;

c) materials substantiating the position of authorized authorities of the reference state and Member State concerned on the agenda of the Committee meeting;

d) reference on the issue under consideration (if necessary);

e) draft of the document proposed for consideration (if necessary);

f) reference and analytical materials (if necessary);

g) draft protocol decisions and recommendations for the Commission (if necessary).

19. The Committee takes the necessary measures to protect confidentiality of the information provided in accordance with the laws of the Member States.

20. The authorized secretary of the Committee, within at most 2 working days from the date of receipt of application specified in subparagraph “a” of paragraph 18 hereof and materials attached to it from the authorized authority of the reference state sends requests to submit materials confirming their position on agenda of the Committee meeting to the authorized authorities of the Member State concerned in electronic form via telecommunications channels.

21. The authorized authorities of the Member State concerned send a response to the request specified in paragraph 20 hereof, within at most 10 working days from the date of receipt of this request.

22. The authorized secretary of the Committee, not later than 5 working days prior to the date of the Committee meeting, sends the approved agenda of the Committee meeting and materials for it, including in electronic form via electronic mailing to e-mail addresses (with the exception of documents containing information assigned to state secrets (state confident information) or to information of limited dissemination in accordance with the legislation of the Member States) to the members of the Committee.

23. Meetings of the Committee are held, as a rule, in the premises of the Commission.

On the proposal of the Chairman or the members of the Committee, the Committee meetings can be held in videoconference mode.

Meeting of the Committee can be held in any of the Member States upon the decision of the Chairman of the Committee, adopted on the basis of proposals of the authorized authorities (expert organizations). In this case, the receiving authorized authority (expert organization) provides all necessary conditions to organize and hold the Committee meeting.

24. Meetings of the Committee are held if there is a quorum of at least two thirds of the total number of the members of the Committee, including at least 1 representative from each Member State.

Members of the Committee participate in Committee meetings personally, without the right for substitution.

In the exceptional case, if presence of a member of the Committee at the Committee meeting is impossible, he is entitled to present his position on the issues in writing at least 2 working days prior to the date of the Committee meeting, and (or) send an authorized official of the authorized authority to participate in the Committee meeting without the right to vote.

25. Decisions of the Committee for settlement of disputes on the assignment of products to medical products, as well as to medical products subject to measuring instruments during their registration, are adopted by consensus, on other issues by a simple majority of votes of the members of the Committee participating in the meeting. When voting, regardless of the number of members of the Committee from each Member State, each of the Member States has 1 vote.

Members of the Committee participate in voting. Voting is conducted without the presence of invited persons.

26. The results of the Committee meeting are drawn up by a protocol in which the positions of the members of the Committee are specified.

27. Generally, the protocol is signed by the Chairman of the Committee on the day of the Committee meeting after its approval by the members of the Committee participating in the Committee meeting.

In case if the Committee meeting is held in videoconference mode, the authorized secretary of the Committee ensures that the draft minutes of the Committee meeting is sent to the members of the Committee participating in the Committee meeting via e-mail.

Members of the Committee are entitled to submit their proposals on the draft to the authorized secretary of the Committee via e-mail within 2 working days from the date of sending the Committee draft minutes by the authorized secretary of the Committee.

Within 2 working days from the date of receipt of proposals from the members of the Committee, the authorized secretary of the Committee ensures the completion of the minutes of the Committee meeting taking into account the proposals received and submits it for signature to the Chairman of the Committee.

In case the Committee meeting is held in videoconference mode, the minutes of the Committee meeting is signed by the Chairman of the Committee within 7 working days from the date of the Committee meeting.

If a member of the Committee has a dissenting opinion on the issue under consideration by the Committee, it is stated in writing and attached to the minutes of the Committee meeting.

28. Within 1 working day from the date of signing of the minutes of the Committee meeting by the Chairman of the Committee, the authorized secretary of the Committee sends a copy to the members of the Committee in electronic form via telecommunications channels. Invited persons can, by decision of the Chairman of the Committee, send a copy of the minutes of the Committee meeting or an extract from it in electronic form via telecommunications channels.

29. Minutes of the Committee meetings are kept in the structural subdivision of the Commission, the competence of which refers to circulation of medical products.

30. The authorized authorities inform the Chairman of the Committee, in accordance with the terms established by the minutes of the Committee meeting, on the implementation of the recommendations and proposals of the Committee on the assignment of products to medical products, as well as to medical products subject to assignment to measuring instruments during their registration.

31. Organizational and technical support of the Committee activities is carried out by the Commission.

Expenses related to the participation of the members of the Committee and representatives of authorized authorities (expert organizations) in the Committee meetings are borne by their authorized authorities (expert organizations).

The said persons incur on their own the expenses related to the invited persons' participation.

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