UNOFFICIAL TRANSLATION

RESOLUTION OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
No. 97 dated November 17, 2020

(National Legal Internet Portal of the Republic of Belarus, 27.11.2020, 8/36081)

On approval of the Regulation on the Commission on medicinal products

On grounds of the second paragraph of sub-clause 8.14^2 of clause 8 and sub-clause 9.1 of clause 9 of the Regulation on the Ministry of Health of the Republic of Belarus, approved by the Resolution of the Council of Ministers of the Republic of Belarus dated October 28, 2011, part two of clause 5 of the Regulation on the Procedure and Conditions for State Registration (confirmation of State Registration) of medicinal products, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 254 dated April 1, 2015, the Ministry of Health of the Republic of Belarus RESOLVES:

1. To approve the Regulation on the Commission on medicinal products (attached).

2. The Resolution of the Ministry of Health of the Republic of Belarus No. 56 dated April 23, 2015 "On approval of the Regulation on the Commission for Medicinal Products and Pharmaceutical Substances and declaring the Resolution of the Ministry of Health of the Republic of Belarus No. 182 dated October 31, 2008 to be no longer in force" shall be deemed to have lost force.

3. This Resolution comes into force after its official publication.

Acting Minister **D.L. Pinevich**

APPROVED

Resolution of
the Ministry of Health
of the Republic of Belarus
No. 97 dated November 17, 2020

REGULATION
on the Commission on medicinal products

1. This Regulation defines the procedure for the work of the Commission on medicinal products (hereinafter - the Commission).

2. In its work, the Commission shall be guided by this Regulation, other legislative acts, international legal acts that constitute the law of the Eurasian Economic Union in the field of medicine circulation.

3. In these Regulation, the main terms and their definitions are used in the meanings established by the Law of the Republic of Belarus No. 161-Z “On Medicine Circulation” dated July 20, 2006.

4. The Commission makes decisions in the form of recommendations on issues related to State Registration (confirmation of State Registration) of medicinal products, conditional State Registration (confirmation of conditional State Registration) of medicinal products, amendments to the master file, suspension, termination of the validity of registration certificates, including:

conditional State Registration (confirmation of conditional State Registration) of medicinal products;

on amendments to the master file for a medicinal product previously registered in accordance with the procedure and conditions for the implementation of conditional State Registration;

on the State Registration of a reproduced medicinal product (hereinafter referred to as Generic) if such a medicinal product is the first generic product registered in the territory of the Republic of Belarus;

on the State Registration of a medicinal product with a new active substance not previously registered in the Republic of Belarus;

on other issues in the field of medicine circulation within the competence of the Commission.

5. The Commission has the right to:

get access to the documents constituting the master file, provided by the republican unitary enterprise Center for Expertise and Testing in Healthcare (hereinafter referred to as the Center), with the written consent of the holder of the registration certificate or the applicant;

give recommendations to the holder of the registration certificate or the applicant on the compliance with expert comments on the results of a Package of preliminary technical works preceding the State Registration of medicinal products (confirmation of State Registration of medicinal products), conditional State Registration (confirmation of conditional State Registration) of medicinal products, amendments to the master file (further - Preliminary Package);

make proposals to the Center on issues related to the implementation of the Preliminary Package.

6. The Commission consists of a personal composition of at least fifteen members with the right to vote, as well as expert groups of the Commission.

The personal composition of the Commission and expert groups of the Commission shall be approved by the order of the Ministry of Health and shall be formed out of employees of the Ministry of Health and health organizations, scientific organizations, teaching staff of educational institutions that provide training, advanced training and (or) retraining of specialists with higher medical and pharmaceutical education.

The experts included in the expert groups of the Commission shall assess the documents that make up the master file of the medicinal product in order to confirm the compliance of the medicinal product with the safety, efficacy and quality requirements within the framework of the Preliminary Package.

7. The Commission is headed by the Chairman of the Commission, and during his absence - by the Deputy Chairman of the Commission.

The Chairman of the Commission is the Deputy Minister of Health in charge of the relevant area of activity.

8. The Chairman of the Commission shall:

organize the work of the Commission, including approve the agenda of the meeting of the Commission, determine the date, time and place of its holding;

give instructions to members of the Commission on issues of its activities, monitor their implementation;

take urgent measures to prevent a conflict of interest or resolve it upon receipt of information about a conflict of interest or the possibility of its occurrence in connection with the performance of the duties of a member of the Commission;

invite, if necessary, to meetings of the Commission, persons with special knowledge in the development and industrial production of medicinal products, who have conducted preclinical (non-clinical) studies of medicinal products or clinical research (trials) of medicinal products, as well as other persons, including holders of registration certificates or applicants.

9. When approving the personal composition of the Commission out of its members who are employees of the Center, two secretaries of the Commission shall be appointed for the preparation of materials for consideration at the meetings of the Commission (one - based on the results of the clinical and pharmacological examination of the documents that make up the master file, the second - the chemical and pharmaceutical examination).

10. Secretaries of the Commission shall:

prepare materials for Commission meetings;

summarize materials received for consideration;

prepare the draft agenda for the meetings of the Commission;

provide an opportunity for members of the Commission to familiarize themselves with the documents and materials submitted for consideration before the meeting;

keep records of the commission;

notify the members of the Commission and invited persons about the date, time and place of the meeting of the Commission and its agenda;

familiarize the members of the Commission with the minutes of the meeting of the Commission;

keep and issue the minutes of the Commission meetings;

keep records and ensure the storage of the minutes of the meetings of the Commission as well as materials to them.

11. Members of the Commission shall:

personally attend the meetings of the Commission;

maintain the confidentiality of information received during the work of the Commission;

without delay notify the Chairman of the Commission in writing about the occurrence of a conflict of interest or the possibility of its occurrence in connection with the performance of the duties of a member of the Commission;

perform other duties provided for by this Regulation and other legislation on Medicine Circulation.

12. The members of the Commission shall not be entitled to represent the interests of organizations with which they are in labor relations or have concluded civil law contracts.

13. The work of the Commission is organized in the form of meetings. The meetings of the Commission shall be held as needed, but at least once every two months. The decision to convene a Commission shall be taken by the Chairman of the Commission independently or on the proposal of at least one third of its members. By the decision of the Chairman of the Commission, meetings of the Commission may be held in absentia or via video conference.

The Commission shall be competent to take a decision provided that at least two thirds of its nominal list is present at its meeting.

In the absence of the required number of members of the Commission for making a decision at its meeting, the Chairman of the Commission sets the date for a new meeting.

14. The decisions of the Commission on each issue on the agenda of the meeting shall be adopted by a simple majority of votes by open voting (unless another form of voting was adopted at the meeting of the Commission). With an equal number of votes, a decision shall deem to be made, if the Chairman of the meeting voted for it.

The decisions of the Commission shall be registered in the minutes of the meeting of the commission, which is signed by the chairperson of the meeting and the secretaries, which indicates:

date and place of the meeting of the Commission;

information about the members of the Commission who took part in its meeting, as well as information about the participants in the meeting of the Commission who are not its members and who are entitled to attend the meeting of the Commission (if any) (the list of those present is compiled separately and attached to the minutes with the signatures of those present);

the agenda of the meeting of the Commission, the content of the issues and materials under consideration;

voting results and decisions made by the Commission;

information about the materials attached to the minutes of the Commission meeting, which are stored together with the minutes of the Commission meeting.

15. The Center provides technical support for the work of the Commission.