(Unofficial translation)

DECREE OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
No. 51 dated May 18, 2020

On establishment of a list of documents for carrying out a complex of preliminary technical works

Amendments and additions:

Decree of the Ministry of Health of the Republic of Belarus dated February 5, 2021 No. 8 (registered in the National Register - No. 8/36351 dated 17.02.2021)

Based on clause 5 of the Regulation on a simplified procedure for the state registration of medicinal products, approved by the Resolution of the Council of Ministers of the Republic of Belarus dated April 1, 2020 No. 191, and subclause 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 No. 1446, the Ministry of Health of the Republic of Belarus DECREES to:

1. Establish a list of documents for carrying out a complex of preliminary technical works related to the examination of documents prior to the state registration of medicinal products in a simplified procedure, according to the appendix.

2. This decree comes into force from the date of its official publication.

Minister **V.S. Karanik**

Appendix
to the Decree
of the Ministry of Health
of the Republic of Belarus
18.05.2020 No. 51

LIST
of documents for carrying out a complex of preliminary technical works related to the examination of documents preceding the state registration of medicinal products in a simplified procedure

1. An application for a complex of preliminary technical works related to the examination of documents preceding the state registration of medicinal products in a simplified procedure (hereinafter referred to as the application). The application shall contain the following information:

trade name;

international nonproprietary name (in case of its absence, common (grouping) name is indicated, scientific (chemical) name);

dosage form indicating the dose of the active substance (for a one-component or two-component (three-component) medicinal product);

standard packaging (primary, secondary, intermediate – if available) indicating the number of doses in the package (filling);

pharmacotherapeutic group (anatomical-therapeutic-chemical classification code (ATC code);

name and location of the applicant, the holder of the registration certificate, the manufacturer (manufacturers) of the medicinal product, including the manufacturer producing the finished dosage form, carrying out filling and (or) packaging, carrying out release quality control, as well as other participants in the production and quality control of the medicinal product;

name and location of the manufacturer of the pharmaceutical substance;

composition of the medicinal product (indicating the name and quantity of active substances and excipients);

method of use of the medicinal product (internal, external, for parenteral administration, etc.);

shelf life;

storage conditions;

protection by patents in the Republic of Belarus (patent owner, number, date of issue, validity period);

authorized person responsible for pharmacovigilance in the Republic of Belarus;

location of the main pharmacovigilance activities;

location of the pharmacovigilance system master file;

contact person (if available).

2. An original or a notarized copy of a document confirming the registration of a medicinal product, issued by an authorized body of one of foreign states specified in clause 1 of Appendix 1 to the Decree of the President of the Republic of Belarus dated December 31, 2019 No. 499 “On Medicine Circulation” (hereinafter referred to as the Decree), or a document confirming the registration of the medicinal product in the European Union (hereinafter referred to as the EU), issued by an authorized body of the EU on a centralized procedure for use in the territory of states specified in clause 2 of Appendix 1 to the Decree, or information from the official website of the World Health Organization (hereinafter referred to as the WHO) on the global computer network Internet, confirming that the medicinal product has passed the WHO prequalification program, with the translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator’s signature shall be certified by a notary). Documents shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus.

3. A notarized copy of the license issued by the authorized body of the country of manufacture and granting the right to manufacture a medicinal product, with the translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator’s signature shall be certified by a notary). Documents shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus.

4. A notarized copy of the document certifying the manufacture of a medicinal product in accordance with the Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the medicinal product (for each participant in the production of the medicinal product). If the country of manufacture of the medicinal product is not specified in clause 1 of Appendix 1 to the Decree and is not a member country of the Pharmaceutical Inspection Cooperation Scheme, a notarized copy of the document certifying the manufacture of the medicinal product in accordance with the Good Manufacturing Practice shall be submitted in addition, issued by the authorized body of one of foreign states specified in clause 1 of Appendix 1 to the Decree, or by the authorized body of the country that is a member of the Pharmaceutical Inspection Cooperation Scheme. If these documents do not contain any information about the date of the last inspection of the specified manufacture, the validity of these documents shall be considered not more than 3 years from the date of their issue. Documents shall be accompanied by the translation into Belarusian or Russian, the correctness of the translation or the authenticity of the translator’s signature shall be certified by a notary. Documents shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus.

5. A declaration of the holder of the registration certificate that in the registration dossier submitted for the state registration of the medicinal product in the Republic of Belarus in the format of a common technical document there are no differences from the approved registration dossier held by the authorized bodies of one of foreign states specified in clause 1 of Appendix 1 to the Decree, or the authorized body of the EU, or the WHO, with the translation into Belarusian or Russian, certified by the organization that carried out the translation.

6. A document of the manufacturer on the quality control of the medicinal product, corresponding to sections 3.2.P.5.1 and 3.2.P.5.2 of the module 3 of the list of documents in the modules of the registration dossier of the medicinal product of Appendix No. 4 to the Rules for the registration and examination of medicinal products for medical use, approved by the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 No. 78, in the format of a common technical document with the translation into Belarusian or Russian, certified by the organization that carried out the translation, and a draft regulatory document on the quality containing a specification (quality indicators, standards (permissible limits) and references to test methods of the State Pharmacopoeia of the Republic of Belarus and other pharmacopoeias), descriptions of methods for the quality control of a medicinal product (when using analysis methods included in the State Pharmacopoeia of the Republic of Belarus or the European Pharmacopoeia – a reference to them), as well as samples of spectra, chromatograms, electropherograms and etc.

7. Layouts of primary and secondary packaging (intermediate packaging – if available) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian in color for different fillings and dosages of the medicinal product, indicating color pantones and scales of primary and secondary packaging (intermediate packaging – if available). Information on primary and secondary packaging (intermediate packaging – if available) can be indicated in several languages, provided that the inscriptions contain identical information, which is confirmed by the translation into Belarusian or Russian certified by the applicant. Layouts of packaging labelled with a trade number in the form of a bar identification code shall be accompanied by its decoding.

8. Drafts of general characteristics of the medicinal product and instructions on medical use (instruction leaflet) of the medicinal product in Belarusian or Russian.

9. General characteristics of the medicinal product certified by the holder of the registration certificate, containing information for medical and pharmaceutical workers on the safe and effective medical use of the medicinal product, approved (agreed upon) by the authorized body of the EU, or the authorized body of one of foreign states specified in clause 1 of Appendix 1 to the Decree, or the WHO, with the translation into Belarusian or Russian language, certified by the organization that carried out the translation.

10. Results of the quality control of three batches of the medicinal product with the translation into Belarusian or Russian, certified by the organization that carried out the translation.

11. Results of the quality control of three batches of pharmaceutical substance (pharmaceutical substances) with the translation into Belarusian or Russian, certified by the organization that carried out the translation.

12. A document of the manufacturer, including information on the composition of the medicinal product, indicating the quantity of all ingredients, as well as all excipients per one dosage unit (for dosed medicinal products) or per unit of mass or volume (for non-dosed medicinal products) with reference to the quality control documents of the pharmaceutical substance and excipients with the translation into Belarusian or Russian language, certified by the organization that carried out the translation.

13. A copy of the final expert report on the assessment of the medicinal product, certified by the applicant, issued by the authorized body of one of foreign states specified in clause 1 of Appendix 1 to the Decree, by the authorized body of the EU during the initial registration of the medicinal product (hereinafter referred to as the expert report), as well as a list of all changes made to the registration dossier of the medicinal product from the moment of its state registration and expert reports on all changes approved, or an expert report valid as of the date of conclusion of the

contract for carrying out a complex of preliminary technical works preceding the state registration of the medicinal products in a simplified procedure, with the translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be certified by a notary).

14. A letter from the applicant about the state registration of the medicinal product that has passed the WHO prequalification program in a simplified procedure in accordance with the Joint Procedure between the WHO/PQT and NRA assessment and acceleration of the state registration of pharmaceuticals and vaccines prequalified by the WHO, dated May 16, 2018 (hereinafter referred to as the joint procedure) for medicinal products prequalified by the WHO.

15. A consent of the owner of the medicinal product that has passed the WHO prequalification program to exchange information under the form set out in Appendix 2 to the joint procedure for medicinal products prequalified by the WHO.

15^{1}. A copy of the report (copies of reports) of experts of the WHO on the assessment of the medicinal product within the framework of the WHO prequalification program (WHO/PQT), a copy of documents on all changes and actions taken by the WHO/PQT after the prequalification of the medicinal product (if any), certified by the applicant.

16. A copy of the registration dossier in electronic form in the format of a common technical document, consisting of five modules, including administrative documents, documents confirming the safety, effectiveness and quality of the medicinal product in Belarusian, Russian or English. The format of the common technical document is posted on the global computer network Internet on the official website of the International Conference on the Harmonization of Technical Requirements for the Registration of Medicinal Products for Medical Use.