(Unofficial translation)

RESOLUTION OF THE COUNCIL OF MINISTERS OF THE REPUBLIC OF BELARUS
No. 254 dated April 1, 2015

On state registration (confirmation of state registration) of medicinal products

Amendments and additions:

Resolution of the Council of Ministers of the Republic of Belarus № 427 of June 6, 2017 (National Legal Internet Portal of the Republic of Belarus, 08.06.2017, 5/43801);

Resolution of the Council of Ministers of the Republic of Belarus № 191 of April 1, 2020 (National Legal Internet Portal of the Republic of Belarus, 08.04.2020, 5/47960);

Resolution of the Council of Ministers of the Republic of Belarus № 298 of May 19, 2020 (National Legal Internet Portal of the Republic of Belarus, 22.05.2020, 5/48075);

Resolution of the Council of Ministers of the Republic of Belarus № 611 of October 27, 2020 (National Legal Internet Portal of the Republic of Belarus, 30.10.2020, 5/48461);

Resolution of the Council of Ministers of the Republic of Belarus № 570 of October 8, 2021 (National Legal Internet Portal of the Republic of Belarus, 14.10.2021, 5/49520);

Resolution of the Council of Ministers of the Republic of Belarus № 175 of March 25, 2022 (National Legal Internet Portal of the Republic of Belarus, 09.04.2022, 5/50110);

Resolution of the Council of Ministers of the Republic of Belarus № 301 of May 10, 2023 (National Legal Internet Portal of the Republic of Belarus, 14.05.2023, 5/51653);

Resolution of the Council of Ministers of the Republic of Belarus № 441 of July 6, 2023 (National Legal Internet Portal of the Republic of Belarus, 13.07.2023, 5/51879)

On the basis of parts eighth, tenth, twelfth and twenty-fifth of Article 10 of the Law of the Republic of Belarus of July 20, 2006 № 161-З "On Circulation of Medicines" the Council of Ministers of the Republic of Belarus DECLARES:

1. Approve:

Regulations on the procedure and conditions for state registration (confirmation of state registration) of medicinal products (attached);

Regulations on the Structure, Procedure of Formation and Maintenance of the State Register of Medicinal Products of the Republic of Belarus (attached).

11. To establish that documents issued by authorized bodies of foreign states (registration certificate, or certificate of pharmaceutical product issued in accordance with the format recommended by the World Health Organization, or other document on registration of a medicinal product that confirms production of the medicinal product under Good Manufacturing Practice conditions issued by the authorized body of the state of manufacture of the medicinal product (for each participant in the production of the medicinal product), copy of the license issued by the authorized body of the state of manufacture that grants the right to manufacture the medicinal product), which expired (expires) from March 11, 2020 to December 31, 2021, will be considered valid until July 1, 2022.

2. To introduce into Resolution of the Council of Ministers of the Republic of Belarus № 1269 of September 2, 2008 "On Approval of the Regulations on State Registration (Re-registration) of Medicinal Products and Pharmaceutical Substances and the Regulations on State Registration (Re-registration) of Medical Devices and Medical Equipment" (National Register of Legal Acts of the Republic of Belarus, 2008, № 213, 5/28269; 2009, № 66, 5/29385; 2010, № 6, 5/30980; № 251, 5/32615; National Legal Internet Portal of the Republic of Belarus, 24.10.2012, 5/36375; 13.08.2014, 5/39243) the following amendments and additions:

2.1. the title of the resolution shall be amended to read as follows:

"On Approval of the Regulations on State Registration (Re-registration) of Medical Devices and Medical Equipment";

2.2. the words "and part ten of Article 8 of the Law of the Republic of Belarus of July 20, 2006 "On Medicines" shall be excluded from the preamble;

2.3. paragraph 1 to read as follows:

«1. To approve the attached Regulations on state registration (re-registration) of medical devices and medical equipment.";

2.4. The Regulation on State Registration (Re-registration) of Medicinal Products and Pharmaceutical Substances approved by this Decree shall be declared no longer in force;

2.5. in the Regulation on State Registration (Re-registration) of Medical Devices and Medical Equipment approved by this Decree:

add the words ", as well as the results of inspection of their production for compliance with the requirements established by the Ministry of Health" to the eighth paragraph of point 2;

paragraph 3 to read as follows:

«3. State registration (re-registration) of medical devices and medical equipment, introduction of amendments to the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus, is preceded by a set of preliminary technical works related to the conduct of:

primary examination of documents required for state registration (re-registration) of medical devices and medical equipment, amendments to the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus;

inspections of the production of medical devices and medical equipment;

sanitary and hygienic tests of these products and equipment of domestic and foreign production;

technical tests of domestically manufactured medical devices and medical equipment;

specialized examination of documents required for state registration (re-registration) of medical devices and medical equipment, amendments to the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus;

clinical trials of medical devices and medical equipment appointed by the Ministry of Health;

other studies.

The complex of preliminary technical works stipulated in part one of this paragraph shall be maintained by the Republican Unitary Enterprise "Center for Expertise and Testing in Healthcare" (hereinafter - RUE "Center for Expertise and Testing in Healthcare") in cases and in accordance with the procedure determined by the Ministry of Healthcare.

RUE "Center for Expertise and Testing in Healthcare" provides, in accordance with the procedure established by the legislation, record keeping and storage of documents related to the state registration (re-registration) of medical devices and medical equipment, amendments to the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus, as well as the acquisition, storage, execution and use of blank registration certificates. The form of the registration certificate shall be a form with a certain degree of security.";

to supplement the Regulation with paragraph^{31} as follows:

«3^{1}. The Ministry of Health shall establish a commission on medical devices and medical equipment to resolve issues of state registration (re-registration) of medical devices and medical equipment and to make amendments to the registration dossier for medical devices and medical

equipment previously registered in the Republic of Belarus.

The Regulations on the Commission on Medical Devices and Medical Equipment shall be approved by the Ministry of Health.";

in paragraph 7 the words ", stipulated in paragraph 3" shall be replaced by the words "in the presence of a positive conclusion of RUE "Center for Expertise and Testing in Healthcare" on compliance of medical devices and medical equipment with safety, efficiency and quality requirements, containing the results of expert examinations, inspections, tests and other studies, stipulated in the first part of paragraph 3";

in part one of paragraph 16 replace the words "Ministry of Health" with the words "RUE "Center for Expertise and Testing in Healthcare";

in paragraph 26:

After paragraph two, add a paragraph to the paragraph as follows:

"the fact of non-compliance of the quality of a medical device and medical equipment with the declared quality during their state registration (re-registration) and (or) negative results of sanitary-hygienic, technical and clinical tests have been obtained;";

Paragraphs three and four shall be deemed to be paragraphs four and five, respectively;

paragraph five shall be supplemented with the words "or a document authorizing the production, sale and use of a medical device and medical equipment";

in part four of paragraph 29 replace the words "Ministry of Health" with the words "RUE "Center for Expertise and Testing in Healthcare";

paragraph 31 after the words "decision to amend the registration dossier" add the words "after passing a set of preliminary technical works in the presence of a positive conclusion of RUE "Center for Expertise and Testing in Healthcare" on compliance of medical devices and medical equipment with safety, efficiency and quality requirements, containing the results of expert examinations, inspections, tests and other studies provided for in part one of paragraph 3 of the present Regulations,".

3. The Ministry of Health shall bring its regulatory legal acts in compliance with this resolution and take other measures for its implementation.

4. This Ordinance shall be effective as of May 21, 2015, with the exception of paragraph 3, which shall be effective upon its official publication.

Prime Minister of the Republic of Belarus **A. Kobyakov**

APPROVED

Decree
the Council of Ministers
of the Republic of Belarus
01.04.2015 № 254 (as amended
by Resolution of the Council of
Ministers of the Republic of
Belarus 27.10.2020 № 611)

REGULATION
on the procedure and conditions for state registration (confirmation of state registration) of medicinal products

CHAPTER 1
GENERAL PROVISIONS

1. These Regulations determine the procedure and conditions for state registration (confirmation of state registration) of medicinal products, conditional state registration (confirmation of conditional state registration) of medicinal products, amendments to the registration dossier, as well as suspension and termination of registration certificates.

The effect of these Regulations shall not apply to:

implementation of state registration of medicinal products named in Annex 1 to Decree of the President of the Republic of Belarus № 499 "On Circulation of Medicinal Products" dated December 31, 2019, in a simplified procedure;

registration (confirmation of registration) of medicinal products within the Eurasian Economic Union and other procedures related to the registration of medicinal products, which are maintained in accordance with internationallegal acts constituting the law of the Eurasian Economic Union;

implementation of state registration (confirmation of state registration) of strategically important medicinal products, introduction of amendments to the registration dossier, as well as suspension, termination of registration certificates issued for strategically important medicinal products.

2. In these Regulations terms and their definitions are used in the meanings established by the Law of the Republic of Belarus "On Circulation of Medicines", as well as the following term and its definition:

bulk product - an unpackaged medicinal product that has passed all stages of the technological process, except for the processes of filling and (or) packaging.

3. State registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal product, introduction of amendments to the registration dossier is preceded by a set of preliminary technical works related to expert examinations, approbation of methods of quality control of a medicinal product and quality control of this medicinal product with the use of such methods, other studies maintained to confirm the quality of the medicinal product and the quality of the medicinal product.

The complex of preliminary technical works is maintained by the Republican Unitary Enterprise "Center for Expertise and Testing in Healthcare" (hereinafter - the Center) in the order determined by the Ministry of Healthcare.

In order to maintain a set of preliminary technical works, the applicant shall submit to the Center the documents constituting the registration dossier, in accordance with Annex 1.

4. In accordance with the results of performance of a set of preliminary technical works, the Center issues a conclusion on compliance (non-compliance) of a medicinal product with safety, efficacy and quality requirements in the form approved by the Ministry of Health.

5. To consider 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 registration dossier, suspension, termination of validity of registration certificates, the Ministry of Health shall establish a commission for medicinal products (hereinafter referred to as the Commission).

The regulations on the commission shall be approved by the Ministry of Health. The composition of the commission is determined by the Ministry of Health.

CHAPTER 2
PROCEDURE AND TERMS OF STATE REGISTRATION (CONFIRMATION OF STATE REGISTRATION) OF MEDICINAL PRODUCTS, CONDITIONAL STATE REGISTRATION (CONFIRMATION OF CONDITIONAL STATE REGISTRATION) OF MEDICINAL PRODUCTS, MAKING AMENDMENTS TO THE REGISTRATION DOSSIER

6. For state registration (confirmation of state registration) of medicinal products, conditional state registration (confirmation of conditional state registration) of medicinal products, amendments to the registration dossier, the applicant shall submit to the Ministry of Health an application in the form prescribed by the Ministry of Health and the Center's opinion on compliance of the medicinal product with safety, efficacy and quality requirements.

In case of simultaneous introduction of several amendments to the registration dossier for a medicinal product, the applicant shall submit an application in the form prescribed by the Ministry of Health and the Center's opinion on compliance of the medicinal product with safety, efficacy and quality requirements for each amendment made separately.

To make a decision on the possibility (impossibility) of state registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal product, making amendments to the registration dossier, the

Center shall, with the written consent of the registration certificate holder , provide the Ministry of Health with access to the documents constituting the registration dossier.

7. Conditional state registration (confirmation of conditional state registration) of a medicinal product shall be maintained if the following conditions are met in the aggregate:

attribution of a medicinal product to the category of original medicinal products for treatment, medical prophylaxis or diagnostics of life-threatening or severe disabling diseases or to the category of medicinal products for treatment of orphan (rare) diseases;

absence in the Republic of Belarus of effective methods of medical care for treatment, medical prevention or diagnosis of the disease for which the medicinal product is intended.

To make a decision on conditional state registration (confirmation of conditional state registration) a medicinal product is subject to evaluation:

documents constituting the registration dossier in terms of completeness of information enabling to assess compliance of the medicinal product with safety, efficacy and quality requirements, except for data on clinical trials (tests) of the medicinal product, which may be submitted in incomplete volume;

the ratio of benefits to the patient or public health due to conditional state registration, availability of the medicinal product and the risk associated with the lack of complete clinical data on the medicinal product;

the possibility of obtaining full clinical data on the medicinal product after the completion of clinical trials, unless it is impossible to provide full clinical data.

The ability to obtain complete clinical data on a drug product is not evaluated when:

the indication(s) for which the medicinal product is intended to be used is (are) so rare that the registration certificate holder cannot reasonably be expected to obtain comprehensive confirmation of the evidence of efficacy and safety of the medicinal product;

with existing scientific research methods, it is not possible to provide complete information on the efficacy or safety of a medicinal product;

obtaining information on the efficacy or safety of a medicinal product would be contrary to the ethical principles established by the Declaration of Helsinki adopted by the 18th Assembly of the World Medical Association (Finland, 1964).

8. In case of conditional state registration (confirmation of conditional state registration) of a medicinal product, the registration certificate holder :

completes ongoing clinical trials or conducts new clinical trials in order to obtain the full scope of information to confirm a favorable benefit-to-risk ratio;

includes in the risk management system measures to ensure the safe use of the medicinal product;

conducts post-registration safety studies of the medicinal product;

takes other measures to ensure safe and effective use of the medicinal product in accordance with the requirements of the Rules of Good Pharmacovigilance Practice of the Eurasian Economic Union.

9. Amendments to the registration dossier are made in case of the following amendments to the information contained in the documents constituting the registration dossier:

introduction of a new indication and (or) a new method of use (administration) in the general characterization of the medicinal product (hereinafter - GCMP), instructions for medical use (leaflet-insert);

exclusion from the GCMP, instructions for medical use (insert sheet) of the previously provided indication for medical use and (or) method of use (administration);

amendments to the sections of GCMP, instructions for medical use (leaflet-insert), as well as pharmacological and clinical sections;

amendments to the composition of the medicinal product (replacement or introduction of an additional pharmaceutical substance manufacturer, introduction, exclusion or replacement of excipients);

amendments to the "Composition" section of the registration dossier for the medicinal product (if the changes do not affect the actual composition of the medicinal product);

amendments to the regulatory document on quality (as well as in case of availability of documents of the pharmaceutical substance manufacturer in the registration dossier for the

medicinal product, which includes this pharmaceutical substance) in case of amendments to quality indicators, control methods, test methods;

change in the expiration date of a medicinal product (as well as in case of availability of manufacturer documents of a pharmaceutical substance in the registration dossier for a medicinal product, which includes this pharmaceutical substance);

storage conditions change of the medicinal product (as well as in case of manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product, which includes this pharmaceutical substance);

submission of an updated draft regulatory document on quality (as well as in case of availability of documents of the pharmaceutical substance manufacturer in the registration dossier for the medicinal product, which includes this pharmaceutical substance) in case of changes in quality indicators, methods of control, methods of testing;

change of material, type of primary packaging, packaging components of a medicinal product (as well as in case of documents availability of the pharmaceutical substance manufacturer in the registration dossier for a medicinal product, which includes this pharmaceutical substance), change of packaging of bulk products;

amendments to the manufacturing process of a medicinal product (as well as in the case of manufacturer documents of a pharmaceutical substance in the registration dossier for a medicinal product that includes this pharmaceutical substance);

amendments to the layout design of the primary, and/or secondary, and/or intermediate packaging of the medicinal product (if any) or introduction of additional layouts of the primary, and/or secondary, and/or intermediate packaging with a different design (if any);

change in the number of doses in the primary, and/or secondary, and/or intermediate package of a medicinal product, or the number of a medicinal product in a bulk product package, or the number of a pharmaceutical substance in a pharmaceutical substance package;

change of the name of the medicinal product, name of the dosage form, method of dosage indication (for a medicinal product);

reorganization and (or) change of name and (or) address without changing the actual location of the manufacturer of the medicinal product, applicant and (or) holder of the registration certificate, as well as in case of manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product;

change of manufacturer, country of manufacturer (replacement or addition of a new production site for part or all of the manufacturing processes - for medicinal products, replacement or addition of a new production site for part of the manufacturing processes - for pharmaceutical substances) of a medicinal product, as well as in case of availability of manufacturer documents of a pharmaceutical substance in the registration dossier for the medicinal product;

change of the applicant and (or) the registration certificate holder .

10. In case of the review of the documents submitted by the applicant and the documents constituting the registration dossier, the Ministry of Health shall take one of the following decisions with the consideration of the recommendations of the commission:

on refusal to accept the application with indication of the reasons for refusal;

on state registration (confirmation of state registration) of the medicinal product;

on conditional state registration (confirmation of conditional state registration) of a medicinal product with indication of obligations imposed on the registration certificate holder ;

on the state registration of a pharmaceutical substance;

on amendments to the registration dossier;

refusal of state registration (confirmation of state registration) of a medicinal product with indication of reasons for refusal;

refusal of conditional state registration (confirmation of conditional state registration) of a medicinal product with indication of reasons for refusal;

on refusal of state registration of a pharmaceutical substance with indication of the reasons for refusal;

on refusal to amend the registration dossier, indicating the reasons for the refusal.

The decision specified in part one of this paragraph shall be formalized by an order of the Ministry of Health.

11. The Ministry of Health may refuse an applicant in state registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal product, in making amendments to the registration dossier in cases provided for in Article 25 of the Law of the Republic of Belarus № 433-Z of October 28, 2008 "On the Basis of Administrative Procedures" and in part twenty-second of Article 10 of the Law of the Republic of Belarus "On Circulation of Medicinal Products".

12. The applicant shall be notified in writing by the Ministry of Health of the decision taken in accordance with clause 10 of these Regulations not later than seven working days from the date of its adoption, and in the case of a decision on state registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal product, state registration of a pharmaceutical substance - also of the need to pay the state duty in accordance with clause 10 of these Regulations.

13. Upon receipt of a written notice of state registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal product, state registration of a pharmaceutical substance, the applicant or the holder of a registration certificate shall pay the state duty in accordance with the legislation.

14. the registration certificate holder in accordance with the results of state registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal product or state registration of a pharmaceutical substance after confirmation of payment of the state duty to the republican budget in the manner prescribed by the Tax Code of the Republic of Belarus shall be issued by the Ministry of Health:

within five working days - registration certificate;

within thirty business days - documents specified in parts eighteenth and nineteenth of Article 10 of the Law of the Republic of Belarus "On Circulation of Medicines".

15. A registration certificate is issued by the Ministry of Health:

on state registration (confirmation of state registration) of a medicinal product in the form in accordance with Annex 2;

on state registration of the pharmaceutical substance in the form in accordance with Annex 3;

on conditional state registration (confirmation of conditional state registration) of a medicinal product in the form in accordance with Annex 4.

In case of state registration (confirmation of state registration), conditional state registration (confirmation of conditional state registration) of a medicinal product:

simultaneously in several dosage forms, a registration certificate is issued for each of its dosage forms;

produced by pharmaceutical enterprises (their separate structural subdivisions) located in different countries shall be issued one registration certificate;

simultaneously in one dosage form, but with different dosages, one registration certificate is issued. In case of subsequent state registration of a new dosage(s), a new registration certificate for the new dosage(s) shall be issued;

in the same dosage form, but having different flavors (flavor additives), different registration certificates are issued.

The registration certificate shall be signed by the Minister of Health or his authorized deputy.

16. The form of the registration certificate (as well as its annex) is a blank document with a certain degree of protection.

17. If changes made to the registration dossier simultaneously entail changes in the information contained in the State Register of Medicinal Products of the Republic of Belarus (hereinafter - the State Register), as well as changes in the information contained in the previously issued registration certificate and (or) its Annex, the Ministry of Health, subject to the provisions contained in paragraph 1 of Article ^{281} of the Law of the Republic of Belarus "On the Basis of Administrative Procedures", issues a new registration certificate with its Annex. The validity period of such registration certificate shall be established within the validity period of the registration certificate issued in the course of state registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal

product, state registration of a pharmaceutical substance.

The decision on issuance of a new registration certificate with its Annex shall be formalized by an order of the Ministry of Health.

The Center, in accordance with the decisions of the Ministry of Health on state registration (confirmation of state registration) of a medicinal product, state registration of a pharmaceutical substance, conditional state registration (confirmation of conditional state registration) of a medicinal product, on amendments to the registration dossier, on issuance of a new registration certificate with its Annex, shall include information on these medicinal products in the State Register within 5 business days.

18. State registration (confirmation of state registration) of a medicinal product, conditional state registration (confirmation of conditional state registration) of a medicinal product, state registration of a pharmaceutical substance, introduction of amendments to the registration dossier shall be maintained within the terms provided for in subparagraphs 9.4.1-9.4.3, 9.4.5 and 9.4.6 of paragraph 9.4 of the unified list of administrative procedures maintained in relation to business entities approved by the resolution of the Council of Ministers of the Republic of Belarus.

CHAPTER 3
PROCEDURE AND CONDITIONS OF SUSPENSION, TERMINATION OF REGISTRATION CERTIFICATE VALIDITY

19. The Ministry of Health may decide to suspend the validity of the issued registration certificate for a period not exceeding six months in the cases provided for in part twenty-third of Article 10 of the Law of the Republic of Belarus "On Circulation of Medicines".

A decision to suspend the validity of a registration certificate specifying the circumstances leading to such suspension, the date from which its validity is suspended, established with the consideration of the possible foreseeable consequences of the use of a medicinal product, and the period of suspension shall be formalized by an order of the Ministry of Health.

20. The Center on the basis of the decision of the Ministry of Health on suspension of the registration certificate shall include this information in the State Register within 5 working days from the date of the decision.

21. For the period of suspension of the registration certificate, its validity shall not be prolonged, except for cases when the suspension is recognized as unlawful by a court decision.

22. the registration certificate holder shall be notified in writing by the Ministry of Health of the decision to suspend the registration certificate no later than three working days from the date of the decision, but no later than the date from which the registration certificate is suspended, specifying the circumstances and the period of suspension.

23. the registration certificate holder during the period for which the registration certificate is suspended shall eliminate the circumstances that led to the suspension of its validity. the registration certificate holder shall notify the Ministry of Health in writing on the elimination of the above circumstances with the Annex of supporting documents.

During the period of suspension of the registration certificate, no changes shall be made in the registration dossier, except when it is necessary to eliminate the circumstances that led to the suspension of its validity.

A written notification on elimination of the circumstances that led to the suspension of the registration certificate, with supporting documents attached, must be submitted to the Ministry of Health not later than 30 calendar days before the expiration of the specified period of suspension.

24. The decision on renewal of the registration certificate with indication of the date of renewal shall be executed by the order of the Ministry of Health.

The Center shall include this information in the State Register within 5 working days from the date of the decision of the Ministry of Health on renewal of the registration certificate.

the registration certificate holder shall be notified in writing by the Ministry of Health on renewal of the registration certificate within three working days from the date of such decision.

25. The decision to terminate the registration certificate in the cases provided for in part twenty-four of Article 10 of the Law of the Republic of Belarus "On Circulation of Medicines", except for the case provided for in paragraph two of the said part, shall be executed by the order of

the Ministry of Health.

The Center shall, within 5 working days from the date of the decision of the Ministry of Health to terminate the registration certificate, exclude information about this medicinal product from the State Register.

the registration certificate holder shall be notified in writing by the Ministry of Health of the termination of the registration certificate not later than three working days from the date of adoption of the said decision, but not later than the day from which the registration certificate is terminated, indicating the grounds for its termination.

26. Upon expiry of a registration certificate for a medicinal product which has not undergone the procedure of confirmation of state registration (conditional state registration), information on the date of termination of the registration certificate shall be entered in the State Register.

Annex 1
to the Regulations on the Procedure and Conditions of State Registration (Confirmation of State Registration) of Medicinal Products (as amended by Resolution of the Council of Ministers of the Republic of Belarus № 611 of 27.10.2020)

LIST
of the documents comprising the registration dossier

1. Documents constituting a registration dossier for state registration (confirmation of state registration), conditional state registration (confirmation of conditional state registration) of a medicinal product:

statement;

document (documents) confirming the right to be the registration certificate holder or applicant (if the registration certificate holder does not manufacture the medicinal product) - contracts, license agreements confirming such right, other documents;

original or copy of the document confirming that a legal entity of the Republic of Belarus, an individual entrepreneur registered in the Republic of Belarus, a foreign legal entity, a foreign organization established in accordance with the legislation of foreign states is the official representative of the registration certificate holder for the medicinal product;

original or copy of a document confirming that the applicant is a member of an association which also includes a medicinal product manufacturer - if the applicant and the medicinal product manufacturer are members of the same association;

original or copy of the document confirming registration of the medicinal product in the country of the registration certificate holder (country of manufacturer) (registration certificate or certificate of pharmaceutical product in accordance with the format recommended by the World Health Organization) issued by the authorized body of the country of the registration certificate holder (country of manufacturer). In the absence of registration of the medicinal product in the country of the registration certificate holder (country of manufacturer), a copy of the certificate of the pharmaceutical product with an indication of the reasons for the absence of registration and an explanatory note of the registration certificate holder with justification of the absence of registration data or a notarized copy of another document issued by the authorized body of the country of the registration certificate holder (country of manufacturer) explaining the absence of registration shall be submitted.

copy of the license issued by the authorized body of the country of production and granting the right to manufacture the medicinal product;

copy of a valid document certifying the production of the medicinal product under Good Manufacturing Practice conditions, issued by the authorized body of the country of production of the medicinal product (for each participant in the production of the medicinal product), or a printout of a graphic screen image (screenshot) of the official website of the regulatory authority in the

global computer network Internet, containing information on the valid document certifying the production of the medicinal product under Good Manufacturing Practice conditions (for each participant in the production of the medicinal product)

copy of a document (certificate) confirming compliance of industrial production of medicinal products with the requirements of Good Manufacturing Practice issued by the Ministry of Health, or a document (certificate) confirming compliance of industrial production of medicinal products with the requirements of the Rules of Good Manufacturing Practice of the Eurasian Economic Union issued by an authorized body of a member state of the Eurasian Economic Union (for each participant of production) - if available. If these documents do not contain information on the date of the last inspection of the said production, their validity shall be deemed to be no more than 3 years from the date of issue;

information on registration of the medicinal product in other countries - in case of state registration, conditional state registration of the medicinal product (for medicinal products manufactured abroad);

GCMP Project;

draft instructions for medical use (insert sheet);

layouts of primary and secondary packaging (intermediate packaging, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian;

copies of the manufacturer's documents as well as description of the manufacturing process of the pharmaceutical substance, brief production scheme, information on the size of the industrial series, methods of structure confirmation, justification of impurities, declaration on validation of the manufacturing process or CEP certificate (if any), reports on validation of quality control methods - in case of state registration, conditional state registration of the medicinal product in case of absence of registration of the pharmaceutical substance;

copy of the quality control document for the pharmaceutical substance;

copies of documents on quality control of primary packaging materials of a pharmaceutical substance (components of primary packaging) and copies of documents confirming that primary packaging materials (components of primary packaging) are suitable for use for packaging of pharmaceutical substances - in case of state registration, conditional state registration of a medicinal product in case of absence of registration of a pharmaceutical substance;

copies of the manufacturer's documents containing the results of stability studies of the pharmaceutical substance (plan, report, tables with the results of studies) - in case of state registration, conditional state registration of the medicinal product in case of absence of registration of the pharmaceutical substance;

manufacturer's document as well as information on the composition of the medicinal product indicating the quantity of all ingredients, as well as all excipients per dosage unit (for dosage formulations) or unit of mass or volume (for non-dosage formulations) with reference to quality control documents for the pharmaceutical substance and excipients;

copy of the document on pharmaceutical development - in case of state registration, conditional state registration of a medicinal product;

copies of reports on physicochemical and biological studies to confirm comparability with the original (reference) medicinal product - in case of state registration of a biosimilar medicinal product;

copies of the manufacturer's documents, as well as a description of the manufacturing process of the medicinal product, quality control of intermediates, brief production scheme, manufacturing formula, volume of the industrial series, manufacturing process validation report or manufacturing process validation plan and a guarantee obligation to provide the manufacturing process validation report, as well as a report on the fulfillment of the manufacturing process validation obligations (submitted as the obligations are realized, but at least once a year) - under the state registration, conditional state registration of a medicinal product of domestic manufacture;

copies of the manufacturer's documents including a description of the manufacturing process of the medicinal product, quality control of intermediates, brief production scheme, production formula, volume of the industrial series, report on validation of the manufacturing process, - in case of state registration, conditional state registration of a foreign medicinal product and in case of placing an order by a domestic holder of a registration certificate (manufacturer) to perform one or

several stages of the technological process of manufacturing a medicinal product outside the Republic of Belarus;

copies of documents on quality control of excipients - in case of state registration, conditional state registration of the medicinal product;

draft regulatory document on quality;

copies of reports on validation of methods of quality control of a medicinal product - in case of state registration, conditional state registration of a medicinal product;

copies of documents confirming the quality of one series of a medicinal product, pharmaceutical substance, auxiliary substances;

copies of documents confirming the quality of standard samples used in quality control of the medicinal product;

copies of documents on quality control of primary packaging materials (primary packaging components) and copies of documents confirming that primary packaging materials (primary packaging components) of a medicinal product are suitable for use for packaging of a medicinal product - in case of state registration, conditional state registration of a medicinal product;

copies of documents confirming the quality of one series of primary packaging materials of a medicinal product (components of primary packaging) - in case of state registration, conditional state registration of a medicinal product;

copies of the manufacturer's documents containing the results of stability studies of the medicinal product (plan, report, tables with the results of studies) - in case of state registration, conditional state registration of the medicinal product;

copies of reports on preclinical (non-clinical) studies of a medicinal product (except for reproduced medicinal products) - in case of state registration, conditional state registration of a medicinal product;

copies of reports on clinical trials (tests) of the medicinal product of phases I-III (stages) conducted in accordance with Good Clinical Practice for original medicinal products - in case of state registration, of phases I, II (stages) for original medicinal products - in case of conditional state registration;

copies of reports on bioequivalence (bioavailability) studies (trials) in accordance with Good Clinical Practice and reports on biopharmaceutical studies for reproduced medicinal products, hybrid medicinal products - in case of state registration of a medicinal product (not submitted for a medicinal product from medicinal plant raw materials);

copies of reports on comparative pharmacokinetic and (or) comparative pharmacodynamic and (or) comparative clinical trials (tests) conducted in accordance with Good Clinical Practice and reports on biopharmaceutical studies for reproduced medicinal products, hybrid medicinal products - in case of state registration of a medicinal product (if bioequivalence (bioavailability) study (test) is not applicable);

copies of reports on comparative preclinical (non-clinical) studies of the medicinal product and on comparative clinical trials or tests (pharmacokinetic (pharmacodynamic) studies or immunogenicity tests) conducted in accordance with Good Clinical Practice to confirm comparability with the original (reference) medicinal product - in case of state registration of a biosimilar medicinal product;

reviews of preclinical and clinical data, information on experience in the use of the medicinal product (scientific articles, monographs, publications, clinical protocols, methodological guidelines) - in case of state registration, conditional state registration of the medicinal product, in case of confirmation of state registration (not submitted for medicinal products from medicinal plant raw materials);

copy of the master file of the pharmacovigilance system of the registration certificate holder (or a brief description of the pharmacovigilance system if the company has a valid version of the pharmacovigilance system master file) - in case of state registration, conditional state registration of the medicinal product;

risk management plan for a medicinal product - in case of state registration, conditional state registration of a medicinal product;

copy of periodically updated report on safety of a medicinal product - in case of confirmation of state registration, confirmation of conditional state registration of a medicinal product (not

submitted for a medicinal product from medicinal plant raw materials);

justification of the registration certificate holder on compliance of the medicinal product with the requirements for application of the conditional state registration procedure - in case of conditional state registration of the medicinal product;

copy of the report with the documentary confirmation submission of obligations fulfillment established under conditional state registration - in case of confirmation of conditional state registration;

manufacturer's declaration containing data on environmental risk assessment of medicinal products containing genetically modified components - in case of state registration, conditional state registration of a medicinal product;

copy of the manufacturer's document on quality control of the medicinal product (for medicinal products of foreign manufacture and (or) if one or several stages of the technological process (as well as the process of packaging, quality control, issuance of the release authorization) are maintained by different manufacturers);

documents confirming the cost of samples of the medicinal product required for testing of quality control methods - at the applicant's initiative;

other documents submitted at the applicant's initiative, which contain information confirming safety, and (or) efficacy, and (or) quality of the medicinal product.

2. Documents constituting the registration dossier for state registration of a pharmaceutical substance:

statement;

information on development - when registering a new pharmaceutical substance or a pharmaceutical substance for the production of biological medicinal products;

report copies of physiochemical and biological testing on confirmation of comparability with the original (reference) medicinal product - in case of state registration of a pharmaceutical substance used for production of a biosimilar medicinal product;

copies of the manufacturer's documents, as well as a description of the production process of the pharmaceutical substance, a brief scheme of production (synthesis), information on the size of the industrial series, methods of structure confirmation, justification of impurities, a plan for validation of the production process and a guarantee obligation to provide a report on validation of the production process or a report on validation of the production process, a report on validation of quality control methods or a CEP certificate (if available) - in case of state registration of pharmaceutical substances.

copies of the manufacturer's documents as well as a description of the production process of the pharmaceutical substance, a brief scheme of production (synthesis), information on the size of the industrial series, methods of structure confirmation, justification of impurities, declaration of validation of the production process, report on validation of quality control methods or CEP certificate (if available) - in case of state registration of pharmaceutical substances of foreign production;

draft regulatory document on quality;

copy of the manufacturer's document confirming the quality of one series of the pharmaceutical substance;

copies of documents confirming the quality of standard samples used in quality control of the pharmaceutical substance;

copies of documents on quality control of primary packaging materials (primary packaging components) and documents confirming that primary packaging materials (primary packaging components) are suitable for use for packaging of pharmaceutical substances;

copies of documents confirming the quality of one series of primary packaging materials (primary packaging components);

copies of the manufacturer's documents containing the results of the stability study of the pharmaceutical substance (plan, report, tables with the results of the study);

original or copy of the document confirming the registration of the pharmaceutical substance in the country of manufacturer in case of necessity of its registration in accordance with the requirements of the legislation of the country of manufacture - in case of state registration of foreign pharmaceutical substances manufacture;

copy of the license issued by the authorized body of the country of production and granting the right to manufacture the medicinal product - in case of state registration of pharmaceutical substances of foreign production;

copy of the document certifying the production of the pharmaceutical substance under conditions of Good Manufacturing Practice, issued by the authorized body of the production country of the pharmaceutical substance (for each participant in the production of the pharmaceutical substance). In the absence of information in the present document on the date of the last inspection of the said production, its validity shall be deemed to be no more than 3 years from the date of issue. To be submitted in the course of state registration of foreign pharmaceutical substances manufacture;

original or copy of the document confirming that a legal entity of the Republic of Belarus, an individual entrepreneur registered in the Republic of Belarus, a foreign legal entity, a foreign organization established in accordance with the legislation of foreign states is the official representative of the registration certificate holder for the pharmaceutical substance;

a letter signed by an authorized person on quality and sealed by a legal entity of the Republic of Belarus holding a license to maintain pharmaceutical activities, on compliance of the conditions of production of a pharmaceutical substance with the requirements of the Rules of Good Manufacturing Practice - in case of state registration of pharmaceutical substances of foreign production by a legal entity of the Republic of Belarus holding a license to maintain pharmaceutical activities.

3. Documents constituting the registration dossier for amendments to the registration dossier for a medicinal product:

3.1. when introducing a new indication and (or) a new method of use (administration) in the GCMP, instructions for medical use (insert sheet):

statement;

justification for the change being made;

GCMP Project;

draft instructions for medical use (insert sheet);

copies of reports on preclinical (non-clinical) studies of the medicinal product (if necessary) and clinical studies (trials) of the medicinal product for a new indication for medical use or a new method of use (administration) in accordance with Good Clinical Practice (except for a reproduced medicinal product);

the drug product's risk management plan;

3.2. in case of exclusion from the GCMP, instructions for medical use (insert sheet) of the previously provided indication for medical use and (or) method of use (administration):

statement;

justification for the change being made;

GCMP Project;

draft instructions for medical use (insert sheet);

manufacturer's document confirming the need to exclude the previously provided indication for medical use and (or) method of use (administration);

3.3. when changes to the sections of GCMP, instructions for medical use (leaflet-insert), as well as pharmacological and clinical sections:

statement;

justification for the change being made;

GCMP Project;

draft instructions for medical use (insert sheet);

3.4. when changes are made to the composition of the medicinal product (replacement or introduction of an additional pharmaceutical substance manufacturer, introduction, exclusion or replacement of excipients):

statement;

justification for the change being made;

the draft GCMP if the changes made affect this section of the registration dossier;

draft instructions for medical use (insert sheet), if the changes made affect this section of the registration dossier;

layouts of the primary and secondary packages (intermediate package, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian, if the changes made affect this section of the registration dossier;

copies of the manufacturer's documents as well as a description of the manufacturing process of the pharmaceutical substance, a brief scheme of production (synthesis), information on the size of the industrial series, methods of structure confirmation, justification of impurities, declaration of validation of the manufacturing process or CEP certificate (if available) and report on validation of quality control methods, in case of replacement or introduction of an additional manufacturer of the pharmaceutical substance included in the medicinal product;

copies of the quality control documents for the pharmaceutical substance and excipients, if the changes made affect this section of the registration dossier;

copies of the manufacturer's documents containing the results of stability studies of the pharmaceutical substance (plan, report, tables with the results of the studies), in case of replacement or introduction of an additional manufacturer of the pharmaceutical substance included in the medicinal product;

manufacturer's document as well as information on the composition of the medicinal product indicating the quantity of all ingredients, as well as all excipients per dosage unit (for dosage formulations) or unit of mass or volume (for non-dosage formulations) with reference to the quality control documents of the pharmaceutical substance and excipients;

copies of the manufacturer's documents as well as a description of the new manufacturing process of the medicinal product, quality control of intermediates, brief production scheme, manufacturing formula, volume of the industrial series, report on validation of the manufacturing process, in case the change of the formulation entails a change of the manufacturing process;

a draft on amendments to the quality normative document, if the changes made affect this section of the registration dossier;

copies of reports on validation of quality control methods for the medicinal product, if the changes made affect this section of the registration dossier;

copies of manufacturer's documents confirming the quality of one series of the medicinal product and (or) excipients;

copies of the manufacturer's documents containing the results of stability studies of the medicinal product (plan, report, tables with the results of the studies), if the changes made affect this section of the registration dossier;

copies of reports on the results of bioavailability comparative study of a medicinal product with a new and previously registered formulation;

other documents of the registration dossier affecting changes in the composition of the medicinal product;

3.5. when changes are made to the "Composition" section of the registration dossier for a medicinal product (if the changes do not affect the actual composition of the medicinal product):

statement;

justification for the change being made;

the draft GCMP if the changes made affect this section of the registration dossier;

draft instructions for medical use (insert sheet), if the changes made affect this section of the registration dossier;

a manufacturer's document as well as information on the composition of the medicinal product indicating the quantity of all ingredients, as well as all excipients per dosage unit (for dosage formulations) or unit of mass or volume (for non-dosage formulations), with reference to current quality control documents for the pharmaceutical substance and excipients;

a draft on amendments to the quality normative document, if the changes made affect this section of the registration dossier;

copies of the manufacturer's documents confirming the quality of one series of a medicinal product, and (or) pharmaceutical substance, and (or) excipients, if the changes made affect these sections of the registration dossier;

other documents of the registration dossier concerning the change of the section "Composition";

3.6. in case of changes in the regulatory document on quality (as well as in case of

manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product, which includes this pharmaceutical substance) in case of changes in quality indicators, methods of control, methods of testing:

statement;

justification for the change being made;

the draft GCMP if the changes made affect this section of the registration dossier;

draft instructions for medical use (insert sheet), if the changes made affect this section of the registration dossier;

layouts of the primary and secondary packages (intermediate package, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian, if the changes made affect this section of the registration dossier;

project on amendments to the normative document on quality;

copies of reports on validation of quality control methods for the medicinal product, if the changes made affect this section of the registration dossier;

copy of the manufacturer's document confirming the quality of one series of the medicinal product;

copies of documents confirming the quality of standard samples used in quality control of the medicinal product, if the changes made affect this section of the registration dossier;

3.7. in case of change of expiration date of the medicinal product (as well as in case of manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product, which includes this pharmaceutical substance):

statement;

justification for the change being made;

the draft GCMP if the changes made affect this section of the registration dossier;

draft instructions for medical use (insert sheet), if the changes made affect this section of the registration dossier;

layouts of the primary and secondary packages (intermediate package, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian, if the changes made affect this section of the registration dossier;

copy of the manufacturer's document confirming the quality of one series of the medicinal product;

copies of the manufacturer's documents containing the results of the stability study of the medicinal product (plan, report, tables with the results of the study);

other documents of the registration dossier affecting changes in the shelf life of the medicinal product;

3.8. in case of storage conditions change of the medicinal product (as well as in case of manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product, which includes this pharmaceutical substance):

statement;

justification for the change being made;

the draft GCMP if the changes made affect this section of the registration dossier;

draft instructions for medical use (insert sheet), if the changes made affect this section of the registration dossier;

layouts of primary and secondary packaging (intermediate packaging, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian;

copy of the manufacturer's document confirming the quality of one series of the medicinal product, if the changes made affect this section of the registration dossier;

copies of the manufacturer's documents containing the results of the stability study of the medicinal product under new storage conditions (plan, report, tables with the results of the study);

other documents of the registration dossier affecting changes in storage conditions of the medicinal product;

3.9. when submitting an updated draft regulatory document on quality (as well as in the case of documents of the pharmaceutical substance manufacturer in the registration dossier for the medicinal product, which includes this pharmaceutical substance) in case of changes in quality indicators, control methods, test methods:

statement;

justification for the changes to be made;

the draft GCMP if the changes made affect this section of the registration dossier;

draft instructions for medical use (insert sheet), if the changes made affect this section of the registration dossier;

layouts of the primary and secondary packages (intermediate package, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian, if the changes made affect this section of the registration dossier;

draft updated normative document on quality;

copies of reports on validation of quality control methods for the medicinal product, if the changes made affect this section of the registration dossier;

copy of the manufacturer's document confirming the quality of one series of the medicinal product;

copies of documents confirming the quality of standard samples used in quality control of the medicinal product, if the changes made affect this section of the registration dossier;

3.10. in case of change of material, type of primary packaging, packaging components of the medicinal product (as well as in case of manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product, which includes this pharmaceutical substance), change of packaging of bulk products:

statement;

justification for the change being made;

the draft GCMP if the changes made affect this section of the registration dossier;

draft instructions for medical use (insert sheet), if the changes made affect this section of the registration dossier;

layouts of the primary and secondary packages (intermediate package, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian, if the changes made affect this section of the registration dossier;

copies of documents on quality control of new packaging materials (new packaging components, new primary packaging components) and documents confirming that new primary packaging materials (new packaging components, new primary packaging components) of the medicinal product are suitable for packaging, contact with medicinal products;

copies of documents confirming the quality of one series of new primary packaging materials (new packaging components, new primary packaging components);

copies of the manufacturer's documents containing the results of stability studies of the medicinal product in a package made of new material or a new type of primary packaging (plan, report, tables with the results of studies), if the changes made affect this section of the registration dossier;

other documents of the registration dossier justifying the change of material, type of primary packaging, packaging components of the medicinal product (pharmaceutical substance);

3.11. when changes are made in the manufacturing process of a medicinal product (as well as in case of manufacturer documents of a pharmaceutical substance in the registration dossier for a medicinal product, which includes this pharmaceutical substance):

statement;

justification for the change being made;

report copies of physiochemical and biological research on confirming comparability of a drug product, using a new and previously made approved process for a biotechnology drug product;

, -

copies of the manufacturer's documents, as well as a description of the new process of production of the pharmaceutical substance with justification of the changes made, brief production scheme, size of the industrial series, methods of structure confirmation, justification of impurities, report on validation of the production process or CEP certificate (if available), if the changes made affect these sections of the registration dossier - when changes in the process of production of the pharmaceutical substance of domestic or foreign production;

copies of the manufacturer's documents, as well as a description of the new pharmaceutical substance manufacturing process with justification of the changes made, a brief production scheme,

production series size, structure confirmation methods, justification of impurities, declaration of validation of the manufacturing process or CEP certificate (if available), if the changes made affect these sections of the registration dossier - when changes are made to the manufacturing process of a pharmaceutical substance and there are documents of the manufacturer of the pharmaceutical substance in the registration dossier for the medicinal product, which includes this pharmaceutical substance, or when changes are made to the manufacturing process of a pharmaceutical substance of foreign manufacture, registered at the request of a legal entity of the Republic of Belarus holding a license to conduct pharmaceutical activities;

copies of the manufacturer's documents as well as a new description of the medicinal product manufacturing process, quality control of intermediates, brief production scheme, manufacturing formula, volume of the industrial series;

a copy of the validation report for the new manufacturing process of the medicinal product, if the changes made affect this section of the registration dossier;

copy of the manufacturer's document confirming the quality of one series of the medicinal product;

copies of the manufacturer's documents containing the results of stability studies of the medicinal product produced using the new manufacturing process (plan, report, tables with the results of the studies);

copies of reports on preclinical (non-clinical) studies and clinical studies (trials) to confirm the comparability of a medicinal product manufactured using new and previously approved manufacturing processes (in the absence of convincing evidence of comparability In accordance with reports on physicochemical and biological studies) - for a biotechnological medicinal product;

copies of reports on the results of bioavailability comparative study of a medicinal product manufactured using new and previously approved manufacturing processes (except for biotechnological medicinal product);

other documents of the registration dossier justifying changes in the manufacturing process of the medicinal product;

A drug product risk management plan for a biotechnology drug product;

3.12. when changes are made to the layout of primary, and (or) secondary, and (or) intermediate packages of a medicinal product (if any) or when additional layouts of primary, and (or) secondary, and (or) intermediate packages with a different layout are introduced (if any):

statement;

justification for the change being made;

layouts of primary and secondary packages (intermediate package - if any) of the medicinal product with new labeling in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian;

3.13. when changing the number of doses in primary, intermediate or secondary packages of a medicinal product, or the number of a medicinal product in a package of bulk products, or the number of a pharmaceutical substance in a package of a pharmaceutical substance:

statement;

justification for the change being made;

GCMP Project;

draft instructions for medical use (insert sheet);

layouts of primary and secondary packaging (intermediate packaging, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian;

project on amendments to the normative document on quality;

copy of the manufacturer's document confirming the quality of one series of the medicinal product;

copies of the manufacturer's documents containing the results of stability studies of the medicinal product (plan, report, tables with the results of the studies), if the changes made affect this section of the registration dossier;

3.14. when changing the name of the medicinal product, name of the dosage form, method of dosage indication (for a medicinal product):

statement;

justification for the change being made;

GCMP Project;

draft instructions for medical use (insert sheet) (for a drug product);

layouts of primary and secondary packaging (intermediate packaging, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian;

other documents of the registration dossier affecting changes in the name of the medicinal product, name of the dosage form, method of dosage indication (for a medicinal product);

3.15. in case of reorganization and (or) change of name and (or) address without change of actual location of the manufacturer of the medicinal product, applicant and (or) holder of the registration certificate, as well as in case of manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product:

statement;

justification for the change being made;

notarized copy of the document confirming reorganization and (or) change of name and (or) address without changing the actual location of the medicinal product manufacturer, applicant and (or) holder of the registration certificate;

documents of the registration dossier affecting reorganization and (or) change of name and (or) address without change of the actual location of the manufacturer of the medicinal product, applicant and (or) holder of the registration certificate, as well as in the case of documents of the manufacturer of the pharmaceutical substance in the registration dossier for the medicinal product;

3.16. in case of change of manufacturer, country of manufacturer (replacement or addition of a new production site for part or all production processes - for medicinal products, replacement or addition of a new production site for part of production processes - for pharmaceutical substances) of the medicinal product, as well as in case of manufacturer documents availability of the pharmaceutical substance in the registration dossier for the medicinal product:

statement;

justification for the change being made;

original or copy of the document confirming registration of the medicinal product in the country of the registration certificate holder (country of manufacturer) (registration certificate or certificate of pharmaceutical product in accordance with the format recommended by the World Health Organization) issued by the authorized body of the country of the registration certificate holder (country of manufacturer). In the absence of registration of the medicinal product in the country of the holder of the registration certificate (country of the manufacturer), a notarized copy of the certificate of the pharmaceutical product shall be submitted indicating the reasons for the absence of registration and an explanatory note of the holder of the registration certificate justifying the reasons for the absence of registration data or a notarized copy of another document issued by the authorized body of the registration certificate holder's (manufacturer's) country explaining the absence of registration - in case of state registration, conditional state registration of the medicinal product;

original or copy of the document confirming the registration of the pharmaceutical substance in the country of manufacture, unless otherwise provided by the requirements of the country of manufacture;

copy of the license issued by the authorized body of the country of production and granting the right to manufacture the medicinal product;

copy of a valid document certifying the production of the medicinal product under Good Manufacturing Practice conditions, issued by the authorized body of the country of production of the medicinal product (for each participant in the production of the medicinal product), or a printout of a graphic screen image (screenshot) of the official website of the regulatory authority in the global computer network Internet, containing information on the valid document certifying the production of the medicinal product under Good Manufacturing Practice conditions (for each participant in the production of the medicinal product)

copies of the new manufacturer's documents, as well as a description of the manufacturing process of the pharmaceutical substance, a brief production scheme, the size of the production series, methods of structure confirmation, justification of impurities, declaration or report on validation of the manufacturing process (depending on which of the documents must be submitted

for registration of medicinal products), CEP certificate (if available), if the changes made affect these sections of the registration dossier - for the pharmaceutical substance;

manufacturer's document as well as information on the composition of the medicinal product indicating the quantity of all ingredients, as well as all excipients per dosage unit (for dosage formulations) or unit of mass or volume (for non-dosage formulations), with reference to the quality control document of the pharmaceutical substance and excipients;

copies of documents of the new manufacturer, as well as a description of the manufacturing process of the medicinal product, quality control of intermediates, a brief production scheme, production formulation, volume of the industrial series;

copies of validation reports on the manufacturing process of the medicinal product if the changes made affect this section of the registration dossier;

copies of manufacturer's documents confirming the quality of one series of the medicinal product;

copies of the manufacturer's documents containing the results of stability studies of the medicinal product (plan, report, tables with the results of the studies), if the changes made affect this section of the registration dossier;

copies of reports on the results of bioavailability comparative study of the medicinal product manufactured at the new and previously approved production sites, if the changes made affect this section of the registration dossier;

other documents of the registration dossier affecting changes in the manufacturer (country of manufacturer) of the medicinal product;

3.17. in case of the applicant change of the medicinal product and (or) the registration certificate holder:

statement;

justification for the change being made;

document (documents) confirming the right to be the registration certificate holder or applicant (if the registration certificate holder does not manufacture the medicinal product) - contracts, license agreements confirming such right, other documents;

original or copy of the document confirming that a legal entity of the Republic of Belarus, an individual entrepreneur registered in the Republic of Belarus, a foreign legal entity, a foreign organization established in accordance with the legislation of foreign states are official representatives of the registration certificate holder for the medicinal product;

GCMP Project;

draft instructions for medical use (insert sheet);

layouts of the primary and secondary packages (intermediate package, if any) in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian, if the changes made affect this section of the registration dossier;

other documents of the registration dossier affecting changes in the applicant of the medicinal product and (or) the registration certificate holder .

Annex 2
to the Regulations on the Procedure and Conditions for State Registration (Confirmation of State Registration) of Medicinal Products
(as amended by Resolution of the Council of Ministers of the Republic of Belarus № 441 of 06.07.2023)

Form

MINISTRY OF HEALTH
REPUBLIC OF BELARUS

REGISTRATION CERTIFICATE
on state registration (confirmation of state registration)
of the medicinal product
№ _____

This registration certificate is issued by (name of the holder

of the registration certificate with indication of the country of the holder, its location)
and is a confirmation that the Ministry of Health registered the

_____,
(trade name of the medicinal product)

_____
(international nonproprietary name of the medicinal product (in case of absence of international nonproprietary name the common (grouping) name, scientific (chemical) name shall be indicated)

in a dosage form _____

The present registration certificate does not guarantee the purchase of the specified medicinal product.

The information about the medicinal product is presented in accordance with the Annex on l. in ex.

Date of state registration (confirmation of state registration)
_____20__

Valid through
_____ 20__

Minister of Health
(Deputy Minister) _____ _____
(signature) (initials (initials of the first name), last name)

Official seal

Annex
to the registration certificate on state registration (confirmation of state registration) of medicinal product №

INFORMATION
about the medicinal product

1. trade name of the medicinal product

2. International non-proprietary name of the medicinal product (if there is no international non-proprietary name, the common (grouping) name, scientific (chemical) name shall be indicated)

3. Pharmaceutical Dosage Form _____

4. Dosage(s) _____

5. Formulation (name of pharmaceutical substance(s)) _____

6. Form of release (type of primary package, number of doses, weight, volume in primary and secondary packages) _____

Form of bulk product release (if any) (type of packaging and quantity in bulk product packaging)

7. Participants in the manufacture of a medicinal product:

(name of pharmaceutical substance manufacturer, location of production site(s)
)

_____ ,
(name of the manufacturer of bulk products, location
of the production site(s) (if any))

_____ ,
(name of the manufacturer who prepacks the medicinal product, location
of the production site(s) (name of the manufacturer who packages the medicinal product, location of the production site(s)
(name of the manufacturer responsible for quality control of the medicinal product, location
of the production site(s))
(name of the manufacturer responsible for quality control of the medicinal product,
location of the production site(s)
(name of the production site(s) responsible for authorizing the release of the medicinal product series,
location of the production site(s)
(names of other participants in the production of the medicinal product (pharmaceutical substance),
location of production sites (if any) with indication of the type of work)

8. Expiration date of the medicinal product _____

9. Storage conditions _____

10. The medicinal product is marketed by (underline required):
with a doctor's prescription;
without a doctor's prescription;
for the provision of medical care in inpatient settings.

11. Is (is not) a narcotic drug (underline required).

12. Is (is not) a psychotropic substance (underline needed).

13. Assigned (not assigned) to the "A" list (underline needed).

Date of state registration (confirmation of state registration) _____20__ Valid through 20__

Date of amendment of the registration dossier 20__ Valid through 20__

Minister of Health
(Deputy Minister) _____
(signature)

Official seal

(initials (initial of own name), surname)

Annex 3
to the Regulations on the Procedure and Conditions for State Registration (Confirmation of State Registration) of Medicinal Products
(as amended by Resolution of the Council of Ministers of the Republic of Belarus № 441 of 06.07.2023)

Form

MINISTRY OF HEALTH
REPUBLIC OF BELARUS

REGISTRATION CERTIFICATE
on state registration of pharmaceutical substance
№ _____

This registration certificate is issued by (name of the holder

of the registration certificate with indication of the country of the holder, its location)
and is a confirmation that the Ministry of Health has registered the

_____,
(trade name of pharmaceutical substance)

_____
(international nonproprietary name of the medicinal product (in case of absence of international nonproprietary name the common (grouping) name, scientific (chemical) name shall be indicated)

This registration certificate does not guarantee the purchase of the specified pharmaceutical substance.

Information on the pharmaceutical substance is presented in accordance with the Annex on l. in ex.

Date of state registration (confirmation of state registration)
_____20__

Valid through
_____ 20__

Minister of Health
(Deputy Minister) _____ _____
(signature) (initials (initials of the first name), last name)

Official seal

Annex
to the registration certificate on the state registration of the pharmaceutical substance
№ _____

INFORMATION
pharmaceutical substance

1. Trade name of the pharmaceutical substance

2. International non-proprietary name of the medicinal product (in case of absence of the international non-proprietary name the common (grouping) name, scientific (chemical) name shall be indicated)

3. Composition _____

4. Participants in the production of a pharmaceutical substance:

_____ ,
(name of pharmaceutical substance manufacturer, location of production site(s)
)

_____ ,
(name of the manufacturer that performs the filling and packaging of the pharmaceutical substance (if available), location of the production site(s))

(other stages of production and quality control of pharmaceutical substance, location of production site(s))

5. Shelf life _____

6. Storage conditions _____

7. Is (is not) a narcotic drug (underline required).

8. Is (is not) a psychotropic substance (underline needed).

9. Assigned (not assigned) to the "A" list (underline needed).

Date of state registration 20__ Valid through 20__

Date of amendment of the registration dossier 20__ Valid through 20__

Minister of Health (Deputy Minister) _____ _____
(Signature) (initials (initial of own name), surname)

Annex 4
to the Regulations on the Procedure and Conditions for State Registration (Confirmation of State Registration) of Medicinal Products
(as amended by the resolution the Council of Ministers of the Republic of Belarus 06.07.2023 № 441)

Form

MINISTRY OF HEALTH
REPUBLIC OF BELARUS

REGISTRATION CERTIFICATE
on conditional state registration (confirmation of conditional state registration) of a medicinal product
№ _____

This registration certificate is issued by _____
(name

the registration certificate holder with indication of the holder's country, its location) and is a confirmation that the Ministry of Health has registered the following

(trade name of the medicinal product)

(international nonproprietary name of the medicinal product (in case of absence of international nonproprietary name the common (grouping) name, scientific (chemical) name shall be indicated)

in a dosage form _____

The present registration certificate does not guarantee the purchase of the specified medicinal product.

The information about the medicinal product is presented in accordance with the Annex on l. in ex.

The date of the conditional state registration (confirmations of conditional state registration) 20__

Valid through _____ 20__

Minister of Health (Deputy Minister) _____ _____

(signature) (initials (initials of the first name), last name)

Official seal

Annex
to the registration certificate of conditional state registration
registration (confirmation of conditional state registration)
medication № _

INFORMATION
about the medicinal product

1. Trade name of the medicinal product _____

2. International non-proprietary name of the medicinal product (if there is no international non-proprietary name, the common (grouping) name, scientific (chemical) name shall be indicated)

_____

3. Pharmaceutical Dosage Form _____
4. Dosage(s) _____
5. Formulation (name of pharmaceutical substance(s)) _____

6. Form of release (type of primary package, number of doses, weight, volume in primary and secondary packages) _____

Form of bulk product release (if any) (type of packaging and quantity in bulk product packaging)

_____

7. Participants in the manufacture of a medicinal product:

_____,
(name of pharmaceutical substance manufacturer, location of production site(s)
)

_____,
(name of bulk product manufacturer, location of production site(s) (if any)

(name of the manufacturer that prepacks the medicinal product, location of the production site(s))
(name of the manufacturer packaging the medicinal product, location of the production site(s))
(name of the manufacturer responsible for quality control of the medicinal product, location of the production site(s))
(name of the manufacturing participant that issues authorization for the release of a series of medicinal product, location of the production site(s))
(names of other participants in the production of the medicinal product (pharmaceutical substance), location of production sites (if any) with indication of the type of work)

8. Expiration date of the medicinal product _____
9. Storage conditions _____
10. The medicinal product is marketed by (underline required):
with a doctor's prescription;
without a doctor's prescription;
for the provision of medical care in inpatient settings.
11. Is (is not) a narcotic drug (underline required).
12. Is (is not) a psychotropic substance (underline needed).
13. Assigned (not assigned) to the "A" list (underline needed).
14. Obligations established under conditional state registration (confirmation of conditional state registration) of a medicinal product,

The date of the conditional state registration (confirmations of conditional state registration)
_____20__

Valid through 20__

Valid through 20__

Date of change on the registration dossier
_____20__

Minister of Health (Deputy Minister)

_____
(Signature)

_____
(initials (initial of own name), surname)

APPROVED
Decree
of the Council of Ministers of
the Republic of Belarus
01.04.2015 № 254
(as amended by Resolution of
the Council of Ministers of the
Republic of Belarus № 441 of
06.07.2023)

REGULATION
on the structure, procedure of formation and maintenance of the State Register of Medicinal Products of the Republic of Belarus

1. The present Regulations define the structure, procedure of formation and maintenance of the State Register of Medicinal Products of the Republic of Belarus (hereinafter - the State Register).

2. The present Regulation uses terms and their definitions in the meanings established by the Law of the Republic of Belarus "On Circulation of Medicines", the Law of the Republic of Belarus No. 455-3 dated November 10, 2008 "On Information, Informatization and Protection of Information", Regulations on the Procedure and Conditions for State Registration (Confirmation of State Registration) of Medicinal Products approved by the resolution approving these Regulations, Regulations on the Procedure and Conditions of State Registration of Strategically Important Medicinal Products approved by Resolution of the Council of Ministers of the Republic of Belarus No. 570 dated October 8, 2021, as well as in the meanings defined by international legal acts constituting the law of the Eurasian Economic Union in the sphere of circulation of medicines.

3. The State Register is a state information resource containing data on registered medicinal products, as well as strategically important medicinal products (hereinafter, unless otherwise specified - medicinal products).

4. The owner of the State Register is the Ministry of Health.

5. The operator of the State Register is the Republican Unitary Enterprise "Center for Expertise and Testing in Healthcare" (hereinafter - the Center).

6. Formation and maintenance of the State Register shall be maintained by the Center.

7. The following information shall be included in the State Register:

trade name of the medicinal product;

international nonproprietary name of the medicinal product (in case of absence of international nonproprietary name the common (grouping) name, scientific (chemical) name shall be indicated);

anatomical-therapeutic-chemical classification code (ATX code);

name of the registration certificate holder, country of the holder, its location;

name of the manufacturer of the pharmaceutical substance, location of the production site(s);

name of the bulk product manufacturer, location of the production site(s), type of packaging and quantity of bulk product in the package (if any);

name of the manufacturer that is engaged in the prepackaging of the medicinal product, location of the production site(s);

name of the manufacturer packaging the medicinal product, location of the production site(s);

name of the manufacturer responsible for quality control of the medicinal product, location of the production site(s);

name of the manufacturing participant that is responsible for issuing the authorization for the release of a series of the medicinal product, location of the manufacturing site(s);

names of other participants in the production of the medicinal product (pharmaceutical substance), location of production sites (if any) with indication of the type of work;

registration certificate number;

date of state registration of the medicinal product (confirmation of state registration);

the date of amendment of the registration dossier;

date and reasons for suspension, renewal, termination of the registration certificate;

the date of issuance of a new registration certificate;

the date of expiration of the registration certificate;

number, date of approval by the Ministry of Health and validity period of the regulatory document on quality;

the dosage form and dosage of the medicinal product;

composition of the medicinal product (name of the pharmaceutical substance(s) included in the composition);

information on the type of medicinal product (radiopharmaceutical, biological, immunological, vaccine, homeopathic medicinal product, herbal, traditional Chinese medicine medicinal product, other);

information on categorization of a medicinal product as original medicinal product, reproduced medicinal product (generic), hybrid medicinal product, bioanalogous medicinal product;

information on classification of a medicinal product as a narcotic drug or psychotropic substance;

information on classification of the medicinal product to medicinal products of List "A";

information on the procedure for sale of the medicinal product;

the expiration date of the drug product;

information on obligations imposed on the registration certificate holder under conditional state registration (confirmation of conditional state registration), conditional state registration for emergency use;

instructions for medical use (insert sheet) and general characterization of the drug product;

the date on which the information was entered into the State Register.

8. Information on a medicinal product registered following the results of conditional state registration (confirmation of conditional state registration), conditional state registration for emergency use, state registration (confirmation of state registration) in a simplified procedure shall be entered in the State Register with a mark "Conditional state registration", "Conditional state registration for emergency use", "State registration in a simplified procedure" in accordance with the following procedure: "Conditional state registration", "Conditional state registration for emergency use", "State registration in a simplified procedure".

9. The State Register shall be placed on the official website of the Ministry of Health in the global computer network Internet.

10. Information contained in the State Register shall be open and available for familiarization.