(Unofficial translation)

DECREE OF THE MINISTRY OF HEALTH
OF THE REPUBLIC OF BELARUS
No. 126 dated December 21, 2021

On the complex of preliminary technical works preceding the state registration of strategically important medicinal products

Amendments and additions:
Decree of the Ministry of Health of the Republic of Belarus No. 37 dated April 22, 2022 (registered in the National Register - No. 8/38138 dated 25.05.2022);
Decree of the Ministry of Health of the Republic of Belarus No. 163 dated October 6, 2023 (registered in the National Register - No. 8/40832 dated 19.12.2023).

Based on parts two and three of clause 4 and clause 5 of the Provision on the procedure and terms of state registration of strategically important medicinal products, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 570 dated October 8, 2021, indent five of subclause 8.14^1 of clause 8 and subclause 9.1 of clause 9 of the Regulations on the Ministry of Health of the Republic of Belarus, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 1446 dated October 28, 2011, the Ministry of Health of the Republic of Belarus DECREES:

1. Establish a list of documents that make up the registration dossier of a strategically important medicinal product, and documents confirming the need to amend the registration dossier of a strategically important medicinal product, according to the Appendix.

2. Approve the Instruction on the procedure for conducting a complex of preliminary technical works related to expert examinations to confirm compliance of a strategically important medicinal product with safety, efficacy and quality requirements, to determine the possibility of emergency use of a strategically important medicinal product (attached).

3. Part two of clause 1 of the Instruction on the procedure for conducting a complex of preliminary technical works prior to the state registration of medicinal products, approved by the Decree of the Ministry of Health of the Republic of Belarus No. 93 dated November 2, 2020, shall be amended to read as follows:

"This Instruction does not apply to:

a complex of examinations carried out during registration (confirmation of registration) and other procedures related to the registration of medicinal products within the framework of the Eurasian Economic Union;

a complex of preliminary technical works that precede the state registration of medicinal products in a simplified manner in accordance with the Provision on the simplified procedure for the state registration of medicinal products, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 191 dated April 1, 2020;

a complex of preliminary technical works preceding the state registration of strategically important medicinal products in accordance with the Provision on the procedure and conditions for the implementation of state registration of strategically important medicinal products, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 570 dated October 8, 2021".

Official legal information
Information retrieval system "ETALON"
National Legal Information Center of the Republic of Belarus

4. This Resolution comes into force from the date of its official publication.

Minister ***D. L. Pinevich***

APPROVED
Ministry of Foreign Affairs
of the Republic of Belarus

Appendix
to the Decree
of the Ministry of Health
of the Republic of Belarus
№ 126 dated 21.12.2021

LIST
of documents that make up the registration dossier of a strategically important medicinal product

No.	Name of the document	Document Requirements
1. Preliminary technical works prior to the state registration (confirmation of state registration) of a strategically important medicinal product (hereinafter referred to as the strategic medicinal product) under the operating procedure, conditional state registration (confirmation of conditional state registration) of a strategic medicinal product		
1.1	application	the application shall contain the following information: the name and location of the holder of the registration certificate, the applicant, the manufacturer (manufacturers) of the strategic medicinal product, including the manufacturer producing the finished formulation, filling and (or) packaging, carrying out release quality control, issuing a permit for the release of a strategic medicinal product, and also other participants in the production and quality control of a strategic medicinal product; name and location of the manufacturer of the pharmaceutical substance; trade name; international non-proprietary name (in case of its absence, the generally accepted (grouping) name, scientific (chemical) name); the composition of the strategic medicinal product (indicating the name and quantity of active and additive substance); formulation indicating the dose of the active substance (for a one-component, two-component or three-component strategic medicinal product); information about the standard package (primary, secondary, intermediate - if available) indicating the number of doses in the package (filling). The material of the primary packaging, the type of primary packaging, the number of product units in the primary packaging, the secondary and, if available, the intermediate packaging, the number of primary packagings in the secondary (intermediate) packaging (including the number of blister packs in the secondary packaging), information on the presence of a moisture absorber, instructions for medical use (leaflet), completeness, information on the type and quantity in the package of bulk product (if any); method of using a strategic medicinal product (internal, external, for parenteral administration, etc.); pharmacotherapeutic group (anatomical-therapeutic-chemical classification code (hereinafter - ATC code); period of validity; storage conditions; protection by patents in the Republic of Belarus (patent owner, number, date of issue, validity period); information about the person authorized for pharmacovigilance in the Republic of Belarus; the location of the main pharmacovigilance activity; location of the pharmacovigilance system Master File; information that the marketing authorization holder takes responsibility for the efficiency, safety and quality of the strategic medicinal product;

		information that the marketing authorization holder (applicant) guarantees the accuracy of the information contained in the registration dossier and in the application, and that the rights of a third party protected by a patent are not violated in connection with the state registration of a strategic medicinal product; justification: on the possibility of applying the state registration of a strategic medicinal product under the operating procedure - for the state registration of a strategic medicinal product under the operating procedure; on the compliance of a strategic medicinal product with the conditions for applying the conditional state registration procedure - in case of conditional state registration of a strategic medicinal product; information about the contact person (if any), his location, telephone number. The application is submitted on the letterhead of the applicant or the marketing authorization holder, signed by an authorized person of the applicant or marketing authorization holder indicating his position of an employee, surname, first name, patronymic (if any)
1.1[1]	Justification (in case of conditional state registration of a strategic medicinal product that is a reproduced, hybrid, biosimilar medicinal product)	shall contain the following information: whether the claimed strategic medicinal product of domestic production is a reproduced, hybrid, biosimilar medicinal product produced with the fulfillment of all stages of the technological process, including the process of packaging, quality control, authorization for release for sale; whether the claimed strategic medicinal product of domestic production is the first, second or third: reproduced, hybrid, biosimilar medicinal product produced with the fulfillment of all stages of the technological process, including the process of packaging, quality control, authorization for release for sale; whether the claimed strategic medicinal product contains an active substance not previously registered in the Republic of Belarus; the strategic medicinal product is claimed for state registration in a new dosage or formulation not previously registered in the Republic of Belarus; assessment of the benefit-to-risk ratio due to submission of incomplete data on preclinical (non-clinical) studies, clinical studies (trials) and biopharmaceutical studies of the reproduced, hybrid, biosimilar strategic drug; a list of established additional risk minimization measures to ensure safe and effective use of the strategic medicinal product, full information on which shall be provided in Annex No. 6 to the risk management plan submitted pursuant to subclause 1.32 of this clause; a time-schedule of fulfillment of the warranty obligations specified in subclauses 1.272 and 1.292 of this clause
1.2	a copy of the document (documents) confirming the right to be a marketing authorization holder or an applicant (if the marketing authorization holder does not produce a strategic medicinal product) (contract, license agreement, other documents)	copies of the contract or license agreement shall be certified by one of the parties to this contract or license agreement. A contract or a license agreement drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by one of the parties to this contract or the license agreement. Other documents (as a rule, an extract from the Trade Register of the country of the marketing authorization holder or the applicant, a document confirming that the applicant is a member of an association that also includes the manufacturer of the medicinal product, the annual financial report of the marketing authorization holder or the applicant) are submitted in the form of originals or notarized copies of other documents. Other documents drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized). Documents shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus
1.3	a 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	the document is submitted in the form of the original document or its notarized copy with translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized)

	accordance with the legislation of foreign states, are the official representatives of the holder of the registration certificate for a strategic medicinal product	
1.4	a document confirming the registration of the medicinal product in the country of the registration certificate holder (manufacturer's country) (registration certificate or certificate of a pharmaceutical product according to the format recommended by the World Health Organization (hereinafter - WHO), issued by the authorized body of the country of the registration certificate holder (manufacturer's country) for a strategic medicinal product, or information from the official website of the regulatory authority in the wide area network Internet, confirming the registration of a strategic medicinal product (for a foreign-made strategic medicinal product)	the documents are submitted in the form of the original documents or their notarized copies with translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized). Documents shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus. In the absence of registration of a strategic medicinal product in the country of the holder of the registration certificate (manufacturer's country), an original or a notarized copy of the certificate of a pharmaceutical product indicating the reasons for the lack of registration or a notarized copy of another document issued by the authorized body of the country of the holder of the registration certificate (manufacturer's country) explaining the lack of registration shall be submitted with a translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized). Documents shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus. Information from the official website of the regulatory authority in the wide area network Internet should be made in the form of a printout of a graphic image of the screen (screenshot) of the Internet page of the official website of the regulatory authority in the wide area network Internet and be accompanied by a translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator’s signature shall be notarized). The term for making a printout should not be more than 3 months from the date of submission of documents
1.5	a license or other document issued by the authorized body of the country of manufacture and granting the right to manufacture a medicinal product, or information from the official website of the regulatory authority on the global network Internet, confirming the existence of a valid license or other valid document issued by the authorized body of the country of manufacture and granting the right to manufacture (for a foreign-made strategic medicinal product)	the documents are submitted in the form of their notarized copies with translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized). Documents shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus. Information from the official website of the regulatory authority on the global network Internet should be produced in the form of a printout of a graphic image of the screen (screenshot) of the Internet page of the official website of the regulatory authority on the global network Internet and accompanied by a translation into Belarusian or Russian (the accuracy of the translation or authenticity of the translator’s signature shall be notarized). The term for making a printout should not be more than 3 months from the date of submission of documents
1.6	document certifying the manufacture of the strategic medicinal product under the Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the medicinal product (for each participant in the production of the strategic medicinal product), or a printout of a graphic image of the screen (screenshot) of the Internet page of the official website of the regulatory authority in the wide area network Internet, containing information on the current document certifying the manufacture of the strategic medicinal product under the terms	the document is submitted in the form of its notarized copy with translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized). The document shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus. A printout of a graphic image of the screen (screenshot) Internet page of the official website of the regulatory authority of the country of manufacture of the strategic medicinal product on the global network Internet shall be accompanied by a translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator’s signature shall be notarized). The term for making a printout should not be more than 3 months from the date of submission of documents

	of Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the strategic medicinal product (for each participant in the production of the strategic medicinal product) (for a foreign-made strategic medicinal product)	
1.7	information on registration of a strategic medicinal product in other countries (for a foreign-made strategic medicinal product) - in case of state registration under the standard procedure, conditional state registration	information is presented in the form of a list of countries in which a strategic medicinal product is registered (indicating the name of the medicinal product, the number and date of the registration certificate, its validity period), or information that documents have been submitted for registration, refusal to register or suspension of the registration certificate (with indication of the date of adoption of decisions on refusal of registration, suspension of the validity of the registration certificate). Information in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer)
1.8	draft Summary of Product Characteristics of the medicinal product (hereinafter, unless otherwise stated - SmPC)	the document is submitted in Belarusian or Russian and shall comply with the Requirements for the instructions for the medical use of the medicinal product and the Summary of Product Characteristics of the medicinal product for medical use, approved by the Decision of the Council of the Eurasian Economic Commission No. 88 dated November 3, 2016. The draft SmPC should contain an indication of the procedure for the retail sale of a strategic medicinal product: “on doctor’s prescription” or “without a doctor’s prescription”. The draft SmPC is submitted on paper in A4 format with a sheet margin around the perimeter of at least 1.5 cm and a font size of at least 12 pt. The information contained in the draft SmPC shall correspond to the information in the SmPC approved by the authorized body of the country of the marketing authorization holder (manufacturer) - for foreign-made strategic medicinal products. The draft SmPC of a generic strategic medicinal product should be developed on the basis of the Summary of Product Characteristics of the original (reference) medicinal product registered in the Republic of Belarus. If the original (reference) medicinal product is not registered in the Republic of Belarus, the draft SmPC of the generic strategic medicinal product shall be developed on the basis of the Summary of Product Characteristics of the original (reference) medicinal product approved by the authorized body of the country of the registration certificate holder (manufacturer)
1.9	draft instructions for medical use (leaflet) (hereinafter, unless otherwise stated, the leaflet)	the document is submitted in Belarusian or Russian and shall comply with the Requirements for the instructions for the medical use of the medicinal product and the Summary of Product Characteristics of the medicinal product for medical use, approved by the Decision of the Council of the Eurasian Economic Commission No. 88 dated November 3, 2016 (user testing is submitted if available). The draft leaflet should contain an indication of the procedure for the retail sale of a strategic medicinal product: “on doctor’s prescription” or “without a doctor’s prescription”. The draft leaflet is submitted on paper in A4 format with a sheet margin around the perimeter of at least 1.5 cm and a font size of at least 12 pt. A draft leaflet for a medicinal product is developed on the basis of the information contained in the SmPC. The information contained in the draft leaflet should be presented in terms, which are understandable for patients (consumers)
1.10	layouts of primary and secondary packaging (intermediate packaging - if available)	the documents are submitted in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian in color in 3 copies for different packaging and dosages of a strategic medicinal product indicating color pantones and scales (sizes) of primary, secondary packaging (intermediate packaging - if available). Information on the primary and

		secondary packaging (intermediate packaging, if any) may be indicated in several languages, provided that the inscriptions contain identical information, which is confirmed by a translation into Belarusian or Russian certified by the applicant. The information of layouts of primary and secondary packages (intermediate packaging, if any) shall comply with the Requirements for Labeling Medicinal Products for Human Use and Veterinary Medicinal Products, approved by the Decision of the Council of the Eurasian Economic Commission No. 76 dated November 3, 2016, as well as the following requirements: indication of the names of formulations, types of primary packaging and components should be carried out in accordance with the Nomenclature of formulations approved by the Decision of the Board of the Eurasian Economic Commission No. 172 dated December 22, 2015; the indication of the dosage on the layouts of the packaging should be carried out in accordance with Appendix No. 9 to the Requirements for the instructions for the medical use of the medicinal product and the Summary of Product Characteristics of the medicinal product for medical use; indication of the dosage, names of formulations, types of primary packaging and components shall comply with other documents that make up the registration dossier. The full text of the leaflet may be applied to the primary or secondary packaging of a strategic medicinal product sold without a doctor's prescription. It is not allowed to put on the packaging any information of an advertising nature, or information that does not correspond to the leaflet. Packaging layouts containing information about marking with a product number in the form of a bar identification code, information printed using Braille, a QR code or information encrypted in another way, shall be accompanied by an appropriate decoding (explanation)
1.11	manufacturer's documents, including the scheme for the production of the pharmaceutical substance, methods for confirming the structure, reasoning of impurities, a declaration on the validation of the manufacturing process and, if available, a certificate of conformity with the European Pharmacopoeia monograph (hereinafter referred to as the CEP certificate) (documents are required for submission in the absence of registration of the pharmaceutical substance, declared by a domestic manufacturer (applicant) for the production of the strategic medicinal product of domestic manufacture) - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product in the absence of registration of a pharmaceutical substance	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). In the event the current version of the CEP certificate is submitted, the submission of a document containing methods for confirming the structure, a document containing the reasoning for impurities, and a declaration of validation of the manufacturing process are not required. The scheme of production (synthesis) should be a schematic presentation of the description of the process of manufacturing of the pharmaceutical substance; include information on the starting materials and materials used for the production of the pharmaceutical substance, indicating the stages of production at which they are used. For starting materials and materials that are critical in terms of the quality of the pharmaceutical substance, the production scheme should be accompanied by the presentation of information about their quality; the document containing methods for confirming the structure should include data on establishing the structure and other characteristics of the pharmaceutical substance, taking into account the capabilities of modern physicochemical, immunochemical, biological methods (depending on what is applicable); the document containing the reasoning for impurities should cover all impurities, the content of which is possible in the pharmaceutical substance; the declaration on the validation of the manufacturing process of the pharmaceutical substance shall confirm that the manufacturing process of the industrial batches of the pharmaceutical substance has been validated by the manufacturer with a positive result. Additionally, information should be provided on the successful validation of the aseptic and sterilization stages of the manufacturing process of the sterile pharmaceutical substance
1.12	document on the quality control of the	the document is submitted in the form of copy of document certified by the holder of the registration certificate

	pharmaceutical substance - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product in the absence of registration of a pharmaceutical substance	(applicant, manufacturer) and, if it is drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). The document shall contain the information provided for in sections 3.2.S.4.1 and 3.2.S.4.2 of module 3 of the list of documents in the modules of the registration dossier of the medicinal product of Appendix No. 4 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products for Medical Use, approved by the Decision of the Council of the Eurasian Economic Commission No. 78 dated 3 November 2016 (hereinafter referred to as the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products), or sections 3.2.S.4.1 and 3.2.S.4.2 of module 3 of the list of documents in the modules of the registration dossier of a medicinal product in the format of a general technical document posted on the global network Internet on the official website of the International Conference on Harmonization (ICH) (hereinafter referred to as the dossier in CTD format). In the case of using non-pharmacopoeial quality control methods, the quality control document of the pharmaceutical substance shall be accompanied by reports on the validation of such methods
1.13	the documents containing information on the primary packaging materials (components of the primary packaging) of pharmaceutical substances (documents are required for submission in the absence of registration of the pharmaceutical substance declared by the domestic manufacturer (applicant) for the production of the strategic medicinal product of domestic manufacture) - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product in the absence of registration of a pharmaceutical substance	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). The documents shall include a description of the packaging and/or closure system (components of the primary packaging), including a description of the materials from which each component of the primary packaging is made. The packaging (closure) system shall be suitable for packaging the pharmaceutical substance and correspond to its physical and (or) chemical properties
1.14	manufacturer's documents on the study of the stability of the pharmaceutical substance (documents are required for submission in the absence of registration of the pharmaceutical substance declared by the domestic manufacturer (applicant) for the production of the strategic medicinal product of domestic manufacture) - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product in the absence of registration of a pharmaceutical substance	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). Documents on the study of the stability of the pharmaceutical substance (plan, report, tables with the results of studies) shall comply with: Requirements for the study of the stability of medicinal products and pharmaceutical substances, approved by the Decision of the Board of the Eurasian Economic Commission No. 69 dated May 10, 2018; chapter 8 of the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission No. 89 dated November 3, 2016, or the guidelines of the International Conference on Harmonization (ICH)
1.15	manufacturer's document, including information on the composition of the strategic medicinal product	the document shall be drawn up in Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer) and contain the following information: the trade name of the strategic medicinal product; the name of the manufacturer producing the strategic medicinal product; type of formulation; dosage of the strategic medicinal product (if the strategic medicinal product contains one, two or three pharmaceutical substances);

		names of ingredients; the amount of each ingredient; information about the purpose of the ingredients; reference to the quality control document for each ingredient. The document indicates the amount of all ingredients, including all excipients, per dosage unit (for dosed strategic medicinal products) or unit of mass or volume (for non-dosed strategic medicinal products). Information about the names of the ingredients, the amount of each ingredient, the purpose of the ingredients, a reference to the quality control document for each ingredient is presented in the form of a table. If the pharmaceutical substance is a salt or hydrate, its amount is expressed in units of mass (units of biological activity) of the active part of the active substance molecule (base, acid or anhydrous salt). For frequently used pharmaceutical substances in the composition of a strategic medicinal product, the dosage of which is traditionally expressed in salt or hydrate form, the amount may be indicated in the form of salt or hydrate. For a pharmaceutical substance that is an ester or a prodrug, the amount must be reported as the amount of the ether or prodrug. In the case of powders for the preparation of a solution or suspension for oral administration, the amount of the pharmaceutical substance is indicated per dosage unit - for a single-dose strategic medicinal product or per volume unit after reconstitution - for a multi-dose strategic medicinal product. For metered-dose inhalation preparations, the amount of the pharmaceutical substance is indicated per delivered dose and (or) metered dose. For parenteral strategic medicinal products, with the exception of reducible powders, in the case of "full use of the contents of the primary package" - the amount of the pharmaceutical substance is indicated by the mass (volume) of the primary package or the total declared amount, in the case of "partial use of the contents of the primary package" - the amount of the pharmaceutical substance is indicated per milliliter and the total declared amount. Information on involved excesses of the amount of ingredients that make up the strategic medicinal product is indicated, if applicable. The composition of a strategic medicinal product does not list ingredients that are removed during the manufacturing process, but it does list ingredients that are used as needed. The flavors used in the composition of strategic medicinal products shall meet the requirements of the Technical Regulations of the Customs Union “Safety Requirements for Food Additives, Flavorings, and Technological Aides” (TR CU 029/2012), adopted by the Decision of the Council of the Eurasian Economic Commission No. 58 dated July 20, 2012. At the same time, information on the composition of flavors should be as complete as possible. It is allowed not to indicate confidential information about the flavor composition. In the case of inscriptions on tablets, capsules and other formulations of strategic medicinal products using printing, information on the composition of the ink used shall be provided. For strategic medicinal products in the form of coated tablets, the composition of the core and the composition of the shell are indicated separately, and for strategic medicinal products in the form of capsules, the composition of the capsule shell and its contents. Excipients are indicated in such a way that they are not mistaken for excipients of a similar chemical structure. For pharmaceutical substances and excipients, references to quality control documents should be given; for excipients, their functional purpose should be additionally indicated. For film-coated tablets, capsules and similar formulations, reference shall be made to the quality control document for both the finished film-coated mixture, the capsule shell and the ingredients they are composed of
1.16	pharmaceutical development document) - in case of state registration under the standard procedure,	the document is submitted in the form of copy of document certified by the holder of the registration certificate (applicant, manufacturer) and, if it is drawn up in a foreign language, shall be accompanied by a translation into

	conditional state registration of a strategic medicinal product	Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). The document shall contain information about development studies conducted to prove that the formulation, composition, manufacturing process, selected packaging (closure) system, microbiological characteristics, instructions for preparing a strategic medicinal product for use correspond to the intended use specified in the registration dossier. The information contained in the document on the pharmaceutical development of a strategic medicinal product shall confirm that the development was carried out in accordance with the guidelines of the International Conference on Harmonization (ICH) or international legal acts constituting the law of the Eurasian Economic Union in the field of circulation of medicinal products
1.17	reports on physical-chemical and biological studies to confirm comparability with the original (reference) medicinal product (for a biosimilar strategic medicinal product) - in case of state registration of a biosimilar strategic medicinal product, conditional state registration of a biosimilar strategic medicinal product	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). Reports on physical-chemical and biological studies to confirm the comparability of a biosimilar strategic medicinal product with the original (reference) medicinal product should include data on the establishment and comparison of physical-chemical and biological characteristics, as well as the interpretation of any differences between the biosimilar and the original (reference) medicinal product and confirm: that the studies were carried out in accordance with the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union; the ability of the applied methods to detect minor differences between the parameters that affect the assessment of the quality of a biosimilar strategic medicinal product. At the same time, in order to qualify and standardize methods for comparability studies, it is necessary to use reference samples and materials (pharmacopoeial reference materials and materials or WHO pharmacopoeial reference samples and materials). Comparison of physical-chemical properties should include not only the assessment of the relevant parameters, but also the establishment of the structure of related compounds and related impurities. The definition of composition, physical properties, primary structure and higher order structures, amino acid sequence should be provided. Where appropriate, N- and C-terminal amino acid sequences, free SH groups and disulfide bridges should be matched. All modifications and/or truncations should be assessed and intrinsic or expression system-mediated variability described. It is necessary to compare post-translational modifications, carbohydrate structures. In order to determine biological activity, it is necessary to use appropriate biological assay methods based on various complementary principles. It shall be confirmed that quantitative biological methods are sensitive, specific and have sufficient discriminatory (distinctive) ability. Where possible, the results of the relevant biological method are presented in units of activity calibrated (graduated) according to international or national standard samples (if available)
1.18	manufacturer’s documents, including a description of the manufacturing process of a strategic medicinal product, quality control of intermediate products, a brief scheme of production, a production formula, the volume of an industrial batch, a report on the validation of the manufacturing process (for strategic medicinal products of domestic manufacture that are not related to non-standard products or processes, it is allowed to present a manufacturing process validation plan and a guarantee obligation to	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). The manufacturer's documents shall meet the following requirements: the description of the manufacturing process (production methods) of a strategic medicinal product should be presented in the way allowing to form an idea of the nature of the operations performed, be comprehensive, consistent as well as to draw a conclusion about which parameters are critical for the manufacturing process, and which are of an auxiliary nature. If necessary, the description of the manufacturing process (production methods) of a strategic medicinal product should include a description of the individual details of the process, information on the type (size) of the equipment used. The description of the manufacturing process shall be substantiated by the design data (in particular, with regard to all conditions and ranges of values of the parameters of this manufacturing process). The information on the manufacturing

	provide a manufacturing process validation report instead of a manufacturing process validation report) - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product	sites involved in the manufacturing process of the strategic medicinal product (name and address of manufacturing site) shall correspond to those specified in the registration dossier. For biological strategic medicinal products, the description of the manufacturing process of the strategic medicinal product shall be accompanied by a description of the manufacturing process of the pharmaceutical substance; quality control of intermediate products shall be consistent with the established critical stages of the manufacturing process, include all types of in-process control and be accompanied by the presentation of specifications for intermediate products and information on quality control techniques; an overview of manufacturing process design should be a brief schematic description of the methods of obtaining the strategic medicinal product, indicating each stage of the manufacturing process, the corresponding in-process controls, and designating each stage at which materials are introduced into manufacture; the production formula shall reflect the information on the composition of the standard industrial batch. If there are batches of different sizes, the composition of each batch is indicated. The production formula shall contain the names and quantities of all ingredients used in the manufacturing process, including information on the excesses involved. Ingredients that are removed during the manufacturing process of a strategic medicinal product shall also be specified, but their content may be specified as a range of values, ingredients that are used as needed are also specified. If the quantity of a pharmaceutical substance to be used is calculated from the actual quantity of the pharmaceutical substance in question (factoring), such data shall be stated and substantiated; the volume of the industrial batch shall contain information about the number of dispensed units; report on validation of the manufacturing process of a strategic medicinal product shall be submitted for foreign-made strategic medicinal products and in case of order placement by a domestic registration certificate holder (manufacturer) to perform one or more stages of the technological process of manufacture of a strategic medicinal product outside the Republic of Belarus. The document shall include a description, validation results and comply with the Guidance on validation of the manufacturing process of medicinal products for medical use (Annex to Recommendation of the Board of the Eurasian Economic Commission No. 19 dated September 26, 2017) or the guidelines of the International Conference on Harmonization (ICH). For biological strategic medicinal products, the validation of the manufacturing process of the strategic medicinal product shall be accompanied by providing data on validation of the manufacturing process of the pharmaceutical substance; the validation plan for the manufacturing process of a strategic medicinal product shall define the scope and procedure for validation studies and comply with the requirements for the validation plan for the manufacturing process set out in Appendix No. 1 to the Guidance on validation of the manufacturing process of medicinal products for medical use (Annex to Recommendation of the Board of the Eurasian Economic Commission No. 19 dated September 26, 2017). If a manufacturing process validation report is not submitted with the validation plan by the domestic manufacturer, a warranty commitment shall be submitted to conduct validation studies and submit a manufacturing process validation report for the first three industrial batches of the strategic medicinal product prior to marketing. At the same time, warranty obligations cannot be submitted for non-standard products or processes set out in Appendix No. 2 to the Guidance on validation of the manufacturing process of medicinal products for medical use (Annex to Recommendation of the Board of the Eurasian Economic Commission No. 19 dated September 26, 2017). In such cases, industrial-scale batches validation data shall be given in the registration dossier. Manufacturer’s documents shall comply with international legal acts constituting the law of the Eurasian Economic Union in the field of medicinal products circulation
1.19	draft regulatory quality document and manufacturer's quality control document for the	the document is submitted in Belarusian or Russian and shall contain the following sections: title page; specification; description of test methods; packaging; labeling.

	strategic medicinal product (manufacturer's quality control document for the strategic medicinal product is required for submission in case one of the participants of manufacture (of finished, bulk or intermediate products) is foreign)	The title page should contain the following information: stamp of record agreement; name of the medicinal product; formulation; dosage; international nonproprietary name (in its absence - the generally accepted (grouping); name and country of the registration certificate holder (applicant), manufacturer (manufacturers) of the strategic medicinal product, including the manufacturer producing the finished formulation, filling and (or) packaging, performing quality control, issuing approval for the release of the strategic medicinal product. The specification shall comply with the original manufacturer's specification (as a rule, it shall comply with Section 3.2.P.5.1 of Module 3 of the list of documents in the drug registration dossier modules of Appendix 4 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products). The specification is presented in the form of a table consisting of 3 columns: quality indicators, standards (allowable limits), references to test methods. The sections “Packaging” and “Labeling” are not required to be included in the specification. Names of quality indicators are specified in accordance with the pharmacopoeial articles of the State Pharmacopoeia of the Republic of Belarus. Quality indicators and standards (allowable limits) are established in accordance with the requirements of general pharmacopoeial articles of the State Pharmacopoeia of the Republic of Belarus, and in their absence - in accordance with the requirements of general pharmacopoeial articles (monographs) of Pharmacopoeia of the Eurasian Economic Union and (or) European Pharmacopoeia, taking into account the specific characteristics of a particular pharmaceutical form, depending on the physical, chemical (biological) properties of the pharmaceutical substance. The draft quality regulatory document should include descriptions of universal tests applicable to all medicinal products, as well as descriptions of specific tests specific to certain formulations. Universal tests include: description, authenticity (identification); quantification; accompanying impurities. If a test is not included in the draft quality standard document, a justification shall be provided. Inclusion in the draft regulatory document on the quality of those or other specific tests is determined by the characteristics of this particular formulation. The manufacturer's specification may provide for the establishment of more stringent eligibility criteria for the release of a strategic medicinal product than the eligibility criteria applied during the shelf life of the medicinal product. For some specific tests, the specification may specify the frequency of testing. The specification may not include in-process tests that are used to correct process parameters within the operating range established for a given manufacturing process. Justification for the exclusion of a test from the specification should be guided by data from the development and validation of the manufacturing process of the medicinal product (if applicable). The description of the testing methods for a strategic medicinal product for all quality indicators specified in the specification, with references to the State Pharmacopoeia of the Republic of Belarus, is given in accordance with the original description of the testing methods for the manufacturer's medicinal product (as a rule, the description of the testing methods should comply with Section 3.2.P.5.2 of Module 3 of the list documents in the modules of the registration dossier of the medicinal product of Appendix No. 4 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products). When describing quality control methods after the title of the section, it is advisable to indicate: reference to the section, pharmacopoeia article or page of the State Pharmacopoeia of the Republic of Belarus in accordance with the method

		used; the norm (allowable limits), equipment (if necessary), the list of reference materials and their qualification, the method of preparing reagents and (or) solutions, if not described in the State Pharmacopoeia of the Republic of Belarus, and the test procedure. When testing by methods that provide spectra, chromatograms, electrophoregrams and other graphic information, their samples should be included in the draft regulatory document on quality. If the State Pharmacopoeia of the Republic of Belarus has a description of the characteristics of the reagents, standard solutions, buffer solutions and materials used in the tests, their names are indicated by the symbol "P" after the name. If there is no description in the State Pharmacopoeia of the Republic of Belarus of the characteristics of the reagents, standard solutions, buffer solutions and materials used, their designations, qualifications and (or) quality regulating documents of their manufacturer with indication of its name should be specified. When using standard samples in the tests, their qualification and the name of the manufacturer or a reference to the relevant pharmacopoeia is indicated. Calculation formulas shall be presented in expanded and abbreviated forms and be accompanied by an explanation of the physical quantities indicated in them. Designations of physical quantities should be given in accordance with the requirements of the State Pharmacopoeia of the Republic of Belarus. It is not allowed to transfer a part of the formula to another line. To measure the physical quantities specified in the draft quality standard document, the units of measurement provided by the International System of Units (SI) and the units of measurement used along with them shall apply. Requirements for individual sections of the quality regulatory document: in the "Description" section, the color is characterized by the names of the colors within the shades. The permissible range of colors should be within shades. In the case of shade colors, the color contained in the lesser degree comes first, the predominant color is indicated with a hyphen. In particular, "tablets are green with a brownish tint or brownish-green in color". For weakly colored specimens, the color name is characterized by the suffix "-ish" or indicated by "light-". Smell is characterized by the terms: "odorless", "with a characteristic odor", "with a faint odor"; section "Residual quantities of organic solvents" shall be included in the regulatory quality document in accordance with the approaches given in the general pharmacopoeia article of the State Pharmacopoeia of the Republic of Belarus "5.4. Residuals of organic solvents"; the "Microbiological purity" section indicates the presence or absence of antimicrobial action, a description of sample preparation with the amount of sample and diluent (for each dilution). In the case the membrane filtration method is used, the amount of washing fluid is indicated; a brief description of the method and conditions of seeding on nutrient media is given; in the sections "Abnormal toxicity", "Pyrogenicity", and "Content of histamine-like substances", the test doses, method of administration, and observation period are indicated; the section "Bacterial endotoxins" indicates the presence (absence) of interfering factors, the concentration in the stock solution (preparation conditions, if necessary); a brief description of the methods (direct seeding or membrane filtration) is given in the "Sterility" section. If the test method and (or) methodology specified in the regulatory quality document is described in the general pharmacopoeia of the State Pharmacopoeia of the Republic of Belarus, a reference to the source is indicated without a description of the test method and (or) methodology, indicating the sample preparation if necessary. When incorporating methods described in the pharmacopoeias of other states, the draft regulatory document on quality shall include a full description of the methods and (or) test procedures used. Terms, designations and definitions shall be in accordance with the State Pharmacopoeia of the Republic of Belarus. When using terms and designations that are not defined in the State Pharmacopoeia of the Republic of Belarus and are

		not universally recognized, their definitions shall be given in the text. The text of the draft regulatory document on quality should be concise, without repetition and exclude the possibility of ambiguous interpretation. Abbreviations in the text, names of figures and diagrams are not allowed, with the exception of abbreviations contained in the specification and established by the State Pharmacopoeia of the Republic of Belarus. The quality requirements for a strategic medicinal product are stated in the imperative form, and the test methods are stated in the third person plural form. It is not allowed in the text: the use of colloquialisms; the use of different terms for the same concept, close in meaning (synonyms), as well as foreign words and terms in the presence of equivalent words and terms in Russian; abbreviations of units of measurement, if they are used without digits; replacing words with alphabetic notations (except for tables and formulas); the use of mathematical signs without numbers. The text of the draft regulatory document on quality should be designed as follows: single-sided printing; the size of the margins: left - 30 mm, right - 15 mm, top and bottom - 20 mm; paragraph indent - 12.5 mm; font Times New Roman, size 14 (for the number of the normative document on quality - 16); headings and the name of the medicinal product begin with a capital letter and are highlighted in bold; the main text is printed 1.5 line spacing, the text in the specifications and notes is printed 1 line spacing, the text in the headings is 1 line spacing; pages of the draft regulatory document on quality should be numbered. However, the first page is not numbered; figures, diagrams, charts, graphs, spectra and chromatograms may be presented on separate pages or given in the text of the draft regulatory document on quality. The “Packaging” section shall refer to the appropriate section (clause) of the application. No additional information is required. The “Labeling” section of the draft regulatory document on quality shall contain the phrase “In accordance with the submitted layouts of packaging”. No additional information is required in this section. The manufacturer's document on quality control of a strategic medicinal product shall be submitted as a certified copy of the document by the holder of the registration certificate (applicant, manufacturer) and, if it is in a foreign language, shall be accompanied by a translation into the Belarusian or Russian language (correctness of translation or authenticity of the translator's signature shall be certified by a notary)
1.20	documents confirming the quality of reference materials used for quality control of pharmaceutical substance and medicinal product	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). The documents shall contain the name of the reference material, name of the manufacturer of the reference material, series number, general description, scope of application, certified (attested) values of properties, each of which is accompanied by an indication of uncertainty, method used to obtain property values, shelf life, storage conditions. The document confirming the quality of the secondary reference material shall reflect their traceability to the primary reference material. When pharmacopoeial reference materials are used for a purpose other than the prescribed use, proof of suitability for the other purpose shall be provided

1.21	validation reports on strategic medicinal product quality control methodologies (hereinafter referred to as methodology validation reports) - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). Method validation reports shall be developed in accordance with the requirements of Section 5.3.2 "Validation of Analytical Methods and Tests" of the State Pharmacopoeia of the Republic of Belarus and (or) in accordance with the Guidance on Validation of Analytical Methods for Testing Medicinal Products, approved by the Decision of the Eurasian Economic Commission Board № 113 dated July 17, 2018, and (or) the International Conference on Harmonization (ICH) guidelines. Method validation reports shall include a description of the validated methods or unambiguous references to them, and include (or be attached to the reports) samples of graphic information (including spectra, drawings, chromatograms, photographs). In the case of a wider range of experiments and tests than provided for by the methodology included in the quality standard document, a full description of the relevant experiments, tests and the results obtained for them shall be given. It is not allowed to present the method validation report in the form of a brief summary of the tests performed. Values of suitability parameters (including the number of theoretical plates, resolution) obtained during method validation shall be commensurate with the suitability criteria given in the draft quality standard document. Method validation reports shall be supplemented by information on the transfer of test procedures, including a comparative analysis of results obtained in the sending and receiving laboratories, if the validation of procedures and quality control are carried out in different laboratories
1.22	documents confirming the quality of one batch of a strategic medicinal product, pharmaceutical substance, excipients	the documents are submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, if they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). A document confirming the quality of one batch of a strategic medicinal product shall include the name of the manufacturer of the strategic medicinal product, the country of manufacture, the trademark (if any), the name of the strategic medicinal product, the type of formulation, the size and type of package, the dosage or activity (for one-, two- and three-component strategic medicinal products), batch number, production date and expiration date, quality indicators and standards established for them, references to analytical methods, test results, date of signing and signature of the authorized person who issued the authorization to release the batch, position, confirmation that the batch of strategic medicinal product was produced in accordance with the requirements of Good Manufacturing Practice and the registration dossier. If some of the above requirements cannot be met, the document certifying the quality of one batch of a strategic medicinal product shall be accompanied by an appropriate justification. The quality indicators and the standards established for them included in the document confirming the quality of one batch of a strategic medicinal product shall comply with the indicators and standards specified in the specification of the draft regulatory document on the quality of the release of the batch. For immunological strategic medicinal products (vaccines, anatoxins, toxins, sera, immunoglobulins), the manufacturer submits a document confirming the quality of one batch (lot), including a summary protocol for the batch (lot) of immunological strategic medicinal product in accordance with the WHO recommendations. A document certifying the quality of a single batch of a pharmaceutical substance should generally include the name of the manufacturer of the pharmaceutical substance, the country of manufacture, the trademark (if any), the name of the pharmaceutical substance, information about the manufacturing site, the batch number, the production date and expiration date (date of repeat tests), quality indicators and their established standards, references to analytical methods, test results, the date signed and the signature of the authorized person who issued the approval to release the batch,

		position. Documents confirming the quality of a single batch of a pharmaceutical substance are drawn up by the manufacturer of the pharmaceutical substance and the manufacturer of the strategic medicinal product (results of incoming inspection). If a quality certificate for a pharmaceutical substance issued by a supplier is presented, information on the manufacturer of the pharmaceutical substance shall be specified. The document certifying the quality of one batch of excipients should generally include the name of the manufacturer of the excipients, the country of manufacturer, the trademark (if any), the name of the excipient, information on the manufacturing site, the batch number, the date of production and the expiry or retest date, quality indicators and the standards established for them, references to analytical methods, test results. Additional information is allowed. The document confirming the quality of one batch of excipients is drawn up by the manufacturer of the excipients and the manufacturer of the strategic medicinal product (results of incoming inspection). In the case of a new excipient, the document confirming the quality of one batch shall be accompanied by a description of the quality control techniques of this excipient. If an excipients quality certificate issued by the supplier is presented, information on the manufacturer of the excipients shall be specified
1.23	documents on quality control of primary packaging materials (primary packaging components) and documents confirming that the primary packaging materials (primary packaging components) of a strategic medicinal product are suitable for the packaging of the strategic medicinal product - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product	the documents shall be submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) with a translation into the Belarusian or Russian language, certified by the holder of the registration certificate (applicant, manufacturer). The documents shall include: a description of the packaging or closure system (components of the primary packaging), including a description of the materials from which each component of the primary packaging is made; specifications for primary packaging materials. Specifications for packaging materials shall include, if applicable, descriptions, dimensional requirements, drawings, data, and characteristics as defined by the formulation. When non-pharmacopoeial methods (techniques) are indicated in the specification, information on their use shall be given; copies of documents confirming that the primary packaging materials (primary packaging components) of a strategic medicinal product are suitable for the packaging of strategic medicinal products. For strategic medicinal products for oral and external use, it is allowed to submit documents confirming the possibility of using the materials of the primary packaging in the food industry. For strategic medicinal products for external use, it is allowed to provide documents confirming the use of primary packaging materials in the manufacture of cosmetics
1.24	manufacturer's documents on strategic medicinal product stability studies - in case of state registration under the standard procedure, conditional state registration of a strategic medicinal product	the documents shall be submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) with a translation into the Belarusian or Russian language, certified by the holder of the registration certificate (applicant, manufacturer). The manufacturer's documents for the study of the stability of a strategic medicinal product (plan, report, tables with the results of the studies) shall confirm that the studies were carried out in accordance with the Requirements for the study of the stability of medicinal products and pharmaceutical substances, Chapter 8 of the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union, or the guidelines of the International Conference on Harmonization (ICH)
1.25	reports on preclinical (non-clinical) studies (except for reproduced strategic medicinal products)	the documents are submitted electronically in Belarusian, Russian or English in the form of the copies of the documents certified by the holder of the registration certificate (applicant, manufacturer). A brief description of preclinical (non-clinical) studies of a medicinal product, attached to the report on preclinical (non-clinical) studies of a medicinal product, drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer).

		The preclinical (non-clinical) research report includes the following sections: 1. Pharmacology 1.1 Primary pharmacodynamics 1.2 Secondary pharmacodynamics 1.3 Pharmacological safety 1.4 Pharmacodynamic drug interactions 2. Pharmacokinetics 2.1 Analytical methods and validation reports 2.2 Absorption 2.3 Distribution 2.4 Metabolism 2.5 Excretion (elimination) 2.6 Pharmacokinetic drug interactions 2.7 Other pharmacokinetic studies 3. Toxicology 3.1 Toxicity at a single administration 3.2 Toxicity at multiple administration 3.3 Genotoxicity 3.4 Carcinogenicity 3.5 Reproductive and Ontogenetic Toxicity: Fertility and Early Embryonic Development, Embryophyte Development, Prenatal and Postnatal Development, Studies on Immature Offspring with Follow-Up 3.6 Local tolerance 3.7 Other toxicological studies: antigenicity, immunotoxicity, mechanism of action studies, drug dependence, metabolites, impurities and other studies 4. Copies of used literary sources If no section (subsection) may be completed in the preclinical (non-clinical) research report, a justification with references to normative legal acts or to publications in peer-reviewed scientific medical journals shall be presented. Reports on preclinical (non-clinical) studies must contain information confirming compliance of the conducted preclinical (non-clinical) studies with the requirements of the Guidelines of Good Laboratory Practice of the Eurasian Economic Union in the Circulation of Medicines, approved by the Decision of the Eurasian Economic Commission Council No. 81 dated November 3, 2016. For original strategic medicinal products, reports on preclinical (non-clinical) studies are submitted in accordance with the requirements for the registration dossier documents listed in Module 4 of Appendix 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products. Reports on preclinical (non-clinical) safety studies shall confirm that the preclinical (non-clinical) studies were conducted in accordance with the Guidelines for Preclinical Safety Studies for Clinical Trials and Registration of Medicinal Products, approved by Decision of the Board of the Eurasian Economic Commission No. 202 dated November 26, 2019. For biotechnological strategic medicinal products, reports on preclinical (non-clinical) safety studies shall confirm that preclinical (non-clinical) studies have been conducted in accordance with the requirements of Chapters 5.3 and 5.4 of the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union
1.26	reports on clinical studies (trials) conducted in accordance with Good Clinical Practice	the documents are submitted electronically in Belarusian, Russian or English in the form of the copies of the documents certified by the holder of the registration certificate (applicant, manufacturer).

		Reports on clinical trials (studies) of I-III phases (stages) conducted in accordance with Good Clinical Practice for original strategic medicinal products - are submitted during the state registration of strategic medicinal products under operating procedure, I, II phases (stages) for original strategic medicinal products - are submitted during conditional state registration. The section of the report on clinical trials (tests) that contains a brief description of a clinical trial (hereinafter referred to as synopsis) drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). Reports on clinical trials (studies) conducted in accordance with Good Clinical Practice shall be submitted in accordance with the requirements for the registration dossier documents given in Module 5 of Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products. At the same time, the types and purposes of clinical trials are determined in accordance with the Guidelines on General Issues of Clinical Trials (Appendix to the Recommendation of the Board of the Eurasian Economic Commission No. 11 dated July 17, 2018). The structure and content of the report on clinical trials (studies) conducted in accordance with Good Clinical Practice shall comply with the requirements set out in Appendix No. 1 to the Guidelines on Good Clinical Practice of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission No. 79 dated November 3, 2016. Reports on clinical trials (studies) conducted in accordance with Good Clinical Practice for a biological strategic medicinal product shall be submitted in accordance with clause 12 of the special requirements for registration dossier documents for certain types of medicinal products of Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products and contain information confirming compliance with the requirements of the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union. Reports on clinical trials (studies) conducted in accordance with Good Clinical Practice for a radiopharmaceutical strategic medicinal product shall be submitted in accordance with clause 13 of the special requirements for the registration dossier documents for certain types of medicinal products in Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products. Reports on clinical trials (studies) conducted in accordance with Good Clinical Practice for the original combined strategic medicinal product shall contain information confirming that these studies were conducted in accordance with the Guidelines on preclinical and clinical development of combined drugs (Appendix to the Recommendation of the Board of the Eurasian Economic Commission No. 25 dated September 2, 2019). Reports on clinical trials (studies) conducted in accordance with Good Clinical Practice for herbal strategic medicinal products shall be submitted in accordance with clause 15 of the special requirements for the registration dossier documents for certain types of medicinal products in Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products.
1.27	report on bioequivalence (bioavailability) trials (studies) in accordance with Good Clinical Practice and report on biopharmaceutical studies for reproduced strategic medicinal products, hybrid strategic medicinal products – in case of state registration of a strategic medicinal product under the standard procedure (not submitted for herbal strategic medicinal products)	the documents are submitted electronically in Belarusian, Russian or English in the form of the copies of the documents certified by the holder of the registration certificate (applicant, manufacturer). Sections of the report on a clinical trials (studies) that contain a brief description of the bioequivalence trials (studies) (synopsis) and a brief description of a biopharmaceutical study drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). Reports on trials (studies) of bioequivalence (bioavailability) and biopharmaceutical studies (in vitro studies (including a comparative dissolution kinetics test), studies establishing the correlation of results obtained under in vitro and in vivo conditions) shall confirm that these studies were carried out in accordance with the Guidelines for Conducting Bioequivalence Studies of Medicinal Products within the framework of the Eurasian Economic Union, approved by the

		Decision of the Council of the Eurasian Economic Commission No. 85 dated November 3, 2016. The bioequivalence (bioavailability) trials (studies) report shall comply with Appendix No. 7 to the Guidelines for Conducting Bioequivalence Studies of Medicinal Products within the Eurasian Economic Union. The report on the trials (studies) of bioequivalence for generic or hybrid strategic medicinal products with modified release shall contain information confirming compliance with the Guidelines for Conducting Bioequivalence Studies of Medicinal Products within the framework of the Eurasian Economic Union. The bioequivalence trials (studies) report for a reproduced combined strategic medicinal product shall contain information confirming compliance with the Guidelines for Preclinical and Clinical Development of Combined Medicinal Products (Appendix to the Recommendation of the Board of the Eurasian Economic Commission No. 25 dated September 2, 2019)
1.27[1]	report on biopharmaceutical studies for reproduced strategic medicinal products, hybrid strategic medicinal products and report on bioequivalence (bioavailability) trials (studies) in accordance with Good Clinical Practice (if available) (not submitted for herbal strategic medicinal products) – in case of conditional state registration of a reproduced or hybrid strategic medicinal products	the documents shall comply with the requirements set forth in subclause 1.27 of this clause
1.27[2]	documents related to incomplete clinical data (absence of a report on bioequivalence (bioavailability) study (trial) in accordance with Good Clinical Practice for reproduced strategic medicinal products, hybrid strategic medicinal products - in case of conditional state registration of a strategic medicinal product	the documents shall contain the following information: a list of missing reports on bioequivalence (bioavailability) studies (trials) in accordance with the Rules for conducting bioequivalence studies of medicinal products within the Eurasian Economic Union; warranty obligations on the terms of providing complete data in accordance with the requirements of the Rules for conducting bioequivalence studies of medicinal products within the Eurasian Economic Union. The term of warranty obligations shall not exceed the term of validity of the issued registration certificate
1.28	reports on comparative pharmacokinetic and (or) comparative pharmacodynamic and (or) comparative clinical trials (studies) conducted in accordance with Good Clinical Practice and reports on biopharmaceutical studies for reproduced strategic medicinal products, hybrid strategic medicinal products - – in case of state registration of a strategic medicinal product under the standard procedure (if bioequivalence trials (studies) are not applicable)	the documents are submitted electronically in Belarusian, Russian or English in the form of the copies of the documents certified by the holder of the registration certificate (applicant, manufacturer). Synopsis and brief description of biopharmaceutical study (sections of these reports) written in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). Reports on conducted pharmacodynamic or clinical studies shall contain information confirming the conduct of studies in accordance with Appendix No. 2 or No. 3 to the Guidelines for conducting bioequivalence studies of medicinal products within the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission No. 85 dated November 3, 2016. These reports are prepared in accordance with Appendix No. 1 to the Good Clinical Practice of the Eurasian Economic Union. For hybrid strategic medicinal products, reports are submitted in accordance with clause 7 of the special requirements for medicinal product registration dossier modules of Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products. For liposomal strategic medicinal products for intravenous administration, reports are submitted in accordance with the Guidelines for Pharmacokinetic and Clinical Bioequivalence Studies of Liposomal Medicinal Products for Intravenous Administration, approved by the Decision of the Board of the Eurasian Economic Commission No. 111 dated September

		15, 2020. For block copolymer micellar strategic medicinal products, reports shall be submitted in accordance with Appendix No. 1 to the Recommendation of the Board of the Eurasian Economic Commission No. 15 dated September 15, 2020 "On guidelines for quality assessment and bioequivalence studies of certain groups of medicinal products". For strategic medicinal products for parenteral administration coated with nanoparticles and strategic medicinal products based on colloidal iron for intravenous administration reports are submitted in accordance with Appendix 2 to the Recommendation of the Board of the Eurasian Economic Commission No. 15 dated September 15, 2020 "On guidelines for quality assessment and bioequivalence studies of certain groups of medicinal products". For strategic inhaled and nasal strategic medicinal products, reports are submitted in accordance with the Guidelines for the Preparation of Clinical Documentation (conducting clinical trials, confirming therapeutic equivalence) for inhaled medicinal products used to treat bronchial asthma in adults, adolescents and children and chronic obstructive pulmonary disease in adults (Appendix to the Recommendation of the Board of the Eurasian Economic Commission No. 1 dated January 14, 2020). For strategic medicinal products with modified release whose active ingredient is registered as part of a medicinal product with a different release rate, reports shall be submitted in accordance with the requirements of the Guidelines for Conducting Bioequivalence Studies of Medicinal Products within the framework of the Eurasian Economic Union. For corticosteroid strategic drugs for topical application, reports shall be submitted in accordance with the Guidelines for Conducting Bioequivalence Studies of Medicinal Products within the framework of the Eurasian Economic Union.
1.28[1]	reports on biopharmaceutical studies for reproduced strategic medicinal products, hybrid strategic medicinal products and reports on comparative pharmacokinetic and (or) comparative pharmacodynamic and (or) comparative clinical trials (studies) conducted in accordance with Good Clinical Practice (if available) - in case of conditional state registration of a reproduced or hybrid strategic medicinal products	the documents shall comply with the requirements set forth in subclause 1.28 of this clause
1.28[2]	documents relating to incomplete clinical data (absence of a report on comparative pharmacokinetic and (or) comparative pharmacodynamic and (or) comparative clinical trials (studies) conducted in accordance with Good Clinical Practice) studies for reproduced, hybrid medicinal products - in the case of conditional state registration of a strategic medicinal product	the documents shall comply with the requirements set forth in subclause 1.28 of this clause
1.29	reports on comparative preclinical (non-clinical) studies and on comparative clinical studies or trials (pharmacokinetic (pharmacodynamic) studies or immunogenicity tests) conducted in accordance with Good Clinical Practice to confirm comparability with the original	the documents are submitted electronically in Belarusian, Russian or English in the form of the copies of the documents certified by the holder of the registration certificate (applicant, manufacturer). Reports on comparative preclinical (non-clinical) studies and on comparative clinical studies or trials (pharmacokinetic (pharmacodynamic) studies or immunogenicity tests) conducted in accordance with Good Clinical Practice to confirm comparability with the original (reference) medicinal product should contain information confirming that studies have been carried out in accordance with clause 10 of the special requirements for the modules of the registration dossier of a

	(reference) medicinal product – in case of state registration of a biosimilar strategic medicinal product under the standard procedure	medicinal product of Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products and the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union. A brief description of a preclinical (non-clinical) study and synopsis (report sections) written in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer)
1.29[1]	reports on comparative preclinical (non-clinical) studies and on comparative clinical studies or trials (pharmacokinetic (pharmacodynamic) studies or immunogenicity tests) conducted in accordance with Good Clinical Practice to confirm comparability with the original (reference) medicinal product (if available) – in case of conditional state registration of strategic medicinal product	the documents shall comply with the requirements set forth in subclause 1.29 of this clause
1.29[2]	documents related to incomplete comparative preclinical (non-clinical) studies and incomplete comparative clinical studies or trials (pharmacokinetic (pharmacodynamic) studies or immunogenicity trials) to confirm comparability with the original (reference) medicinal product - in case of conditional state registration of a biosimilar strategic medicinal product	shall contain the following information: a list of missing comparative preclinical (non-clinical) data, which shall contain information in accordance with clause 10 of the special requirements for the modules of the registration dossier of a medicinal product of Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products and the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union; list of missing comparative clinical data (pharmacokinetic (pharmacodynamic) studies, immunogenicity trials) to confirm the comparability of the biosimilar strategic medicinal product with the original (reference) medicinal product required in accordance with clause 10 of the special requirements to the modules of the registration dossier of the medicinal product of Appendix No. 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products and the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union; reports on non-comparative preclinical (non-clinical) and clinical trials; interim reports (data) on ongoing preclinical (non-clinical) and clinical trials, including non-comparative trials - if available; warranty obligations on the terms of submission of complete preclinical (non-clinical) and clinical data in accordance with the requirements of the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union. The term of warranty obligations shall not exceed the validity period of the issued registration certificate
1.30	reviews of preclinical and clinical data, information on the experience of using a strategic medicinal product (scientific articles, monographs, publications, clinical protocols, methodological guidelines)	reviews of preclinical and clinical data are submitted on electronic media in the form of certified copies of documents by the holder of the registration certificate (applicant, manufacturer). Reviews of preclinical and clinical data drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). For original strategic medicinal products, reviews of preclinical and clinical data shall be submitted with a summary of preclinical (non-clinical) studies and a summary of clinical data in accordance with clause 2 of the Requirements for the registration dossier documents given in Module 2 of Appendix 1 to the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products. Information on the experience of using a strategic medicinal product shall be submitted in electronic format in Belarusian, Russian or English
1.31	master file of the pharmacovigilance system of the holder of the registration certificate (or a brief	the document is submitted electronically in Belarusian, Russian or English in the form of the copy of the document certified by the holder of the registration certificate (applicant, manufacturer).

	description of the pharmacovigilance system if the Republican Unitary Enterprise “Center for Examinations and Tests in Health Service” has a valid version of the master file of the pharmacovigilance system)	The master file of the pharmacovigilance system of the registration certificate holder shall be submitted if the Republican Unitary Enterprise “Center for Examinations and Tests in Health Service” does not have a valid version of the master file of the pharmacovigilance system. A brief description of the pharmacovigilance system drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer). These documents shall comply with the requirements of the Guideline on good pharmacovigilance practices of the Eurasian Economic Union approved by the Decision of the Council of the Eurasian Economic Commission No. 87 dated November 3, 2016
1.32	risk management plan	the document is submitted electronically in Belarusian, Russian or English. Risk management plan shall comply with the requirements of the Guideline on good pharmacovigilance practices of the Eurasian Economic Union. Part of the risk management plan containing a summary and application materials on additional risk minimization measures, drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer)
1.33	manufacturer's declaration containing environmental risk assessment data for strategic medicinal products that contain genetically modified constituents	the document is submitted in any form in Belarusian, Russian or English. The document drawn up in English shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer)
1.33[1]	documents confirming the fulfillment of obligations imposed on the holder of the registration certificate under conditional state registration - in case of confirmation of conditional state registration	the documents are submitted as originals or copies certified by the holder of the registration certificate (applicant) and shall be accompanied by a translation into Belarusian or Russian certified by the holder of the registration certificate (applicant)
1.34	other documents submitted at the initiative of the applicant, which contain information confirming safety, and (or) effectiveness, and (or) quality of the strategic medicinal product (if available)	the documents are submitted in Belarusian, Russian or English in the form of a copy of the documents certified by the holder of the registration certificate (applicant, manufacturer)
2. Preliminary technical works preceding the conditional state registration of a strategic medicinal product for emergency use		
2.1	application	the application shall contain the following information: the name and location of the holder of the registration certificate, the applicant, the manufacturer (manufacturers) of the strategic medicinal product, including the manufacturer producing the finished formulation, filling and (or) packaging, carrying out release quality control, issuing a permit for the release of a strategic medicinal product, and also other participants in the production and quality control of a strategic medicinal product; name and location of the manufacturer of the pharmaceutical substance; trade name; international non-proprietary name (in case of its absence, the generally accepted (grouping) name, scientific (chemical) name) shall be indicated; the composition of the strategic medicinal product (indicating the name and quantity of active and additive substance); formulation indicating the dose of the active substance (for a one-component, two-component or three-component strategic medicinal product); information about the standard package (primary, secondary, intermediate - if available) indicating the number of doses in the package (filling). The material of the primary packaging, the type of primary packaging, the number of units in the

		primary packaging, the secondary and, if available, the intermediate packaging, the number of primary packagings in the secondary (intermediate) packaging, information on the presence of a moisture absorber, instructions for medical use (leaflet), completeness, information on the type and quantity in the package of bulk products (if any) shall be indicated; the method of application of the strategic medicinal product (including internal, external, for parenteral administration); pharmacotherapeutic group (ATC code); period of validity; storage conditions; protection by patents in the Republic of Belarus (patent owner, number, date of issue, validity period); information about the person authorized for pharmacovigilance in the Republic of Belarus; the location of the main pharmacovigilance activity; location of the pharmacovigilance system Master File; information that the marketing authorization holder takes responsibility for the efficiency, safety and quality of the strategic medicinal product; information that the marketing authorization holder (applicant) guarantees the accuracy of the information contained in the registration dossier and in the application, and that the rights of a third party protected by a patent are not violated in connection with the state registration of a strategic medicinal product; substantiation of the possibility of applying the procedure of conditional state registration of a strategic medicinal product for emergency use; information about the contact person (if any), his location, telephone number. The application is submitted on the letterhead of the applicant or the marketing authorization holder, signed by an authorized person of the applicant or marketing authorization holder indicating his position of an employee, surname, first name, patronymic (if any)
2.2	the document confirming registration and (or) authorization for emergency use of a strategic medicinal product in the country of the marketing authorization holder (manufacturer) or in the country for which it was produced (marketing authorization, or authorization for emergency use, or a certificate of a pharmaceutical product, or a certificate of free sale), or a printout of a graphic image of the screen (screenshot) of the Internet page of the official website of the regulatory authority in the wide area network Internet, containing information on the registration of a strategic medicinal product, or permission for emergency use, or a certificate of a pharmaceutical product, or a certificate of free sale in the country of the registration certificate holder (manufacturer) or in the country for which it was produced, or information on the listing of a WHO strategic medicinal product on the Emergency use listing (EUL), indicating the site	the documents are submitted as an original document or a notarized copy of the document with a translation into Belarusian or Russian (the accuracy of the translation or the authenticity of the translator’s signature shall be notarized). The document shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus. A printout of a graphic image of the screen (screenshot) of the website of the official website of the regulatory authority of the country of manufacture of the strategic medicinal product in the wide area network Internet shall be accompanied by a translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized). The term for making a printout should not be more than 3 months from the date of submission of documents

	where such information has been posted (for a foreign-made strategic medicinal product)	
2.3	license or other document issued by the authorized body of the country of manufacture and granting the right of manufacture, or information from the official website of the regulatory authority on the global network Internet, confirming the existence of a valid license or other valid document issued by the authorized body of the country of manufacture and granting the right of manufacture (for a foreign-made strategic medicinal product)	the documents shall comply with the requirements established in subclause 1.5 of clause 1 of this Appendix
2.4	document certifying the manufacture of the strategic medicinal product under the Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the medicinal product (for each participant in the production of the strategic medicinal product), or a printout of a graphic image of the screen (screenshot) of the Internet page of the official website of the regulatory authority on the global network Internet, containing information on the current document certifying the manufacture of the strategic medicinal product under the terms of Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the strategic medicinal product (for a foreign-made strategic medicinal product)	the documents shall comply with the requirements established in subclause 1.6 of clause 1 of this Appendix. If the country of manufacture of a strategic medicinal product is not indicated in indent two of part two of clause 10 of the Provision on the procedure and terms of state registration of strategically important medicinal products and is not a country participating in the Cooperation Scheme for Pharmaceutical Inspections, a notarized copy of the document certifying the production of strategic medicinal product under the conditions of Good Manufacturing Practice issued by the authorized body of one of the foreign states specified in indent two of part two of clause 10 of the Provision on the procedure and terms of state registration of strategically important medicinal products, or by the authorized body of the country - a member of the Cooperation Scheme for Pharmaceutical Inspections, with translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator's signature shall be notarized). The document shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus.
2.5	layouts of primary and secondary packaging (intermediate packaging - if available)	layouts of primary and secondary packaging (intermediate packaging, if any) shall comply with the requirements established in subclause 1.10 of clause 1 of this Appendix
2.6	draft Summary of Product Characteristics (SmPC)	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements set forth in subclause 1.8 of clause 1 of this Appendix
2.7	draft instructions for medical use (leaflet)	draft instructions for medical use (leaflet) shall comply with the requirements established in subclause 1.9 of clause 1 of this Appendix
2.8	SmPC approved (agreed) by the authorized body of one of the foreign states specified in indent two of part two of clause 10 of the Provision on the procedure and terms of state registration of strategically important medicinal products, or by WHO, or by the authorized body of a foreign state in which the production of a strategic medicinal product is carried out or in which there is an	the document is submitted as a copy of the document certified by the holder of the registration certificate (applicant, manufacturer) with a translation into the Belarusian or Russian language (correctness of the translation or authenticity of the translator's signature shall be notarized). The document shall be approved (agreed) by the authorized body that issued the document submitted under subclause 2.2 of this clause, or approved (agreed) by WHO in the case of information submitted under subclause 2.2 of this clause on the inclusion of a WHO strategic medicinal product in the Emergency use listing (EUL)

	approval of a strategic medicinal product for emergency use (if any)	
2.9	instructions for medical use (leaflet) approved (agreed) by the authorized body of one of the foreign states specified in indent two of part two of clause 10 of the Provision on the procedure and terms of state registration of strategically important medicinal products, or by WHO, or by the authorized body of a foreign state in which the production of a strategic medicinal product is carried out or in which there is an approval of a strategic medicinal product for emergency use (if any)	the document is submitted as a copy of the document certified by the holder of the registration certificate (applicant, manufacturer) with a translation into the Belarusian or Russian language (correctness of the translation or authenticity of the translator's signature shall be notarized). The document shall be approved (agreed) by the authorized body that issued the document submitted under subclause 2.2 of this clause, or approved (agreed) by WHO in the case of information submitted under subclause 2.2 of this clause on the inclusion of a WHO strategic medicinal product in the Emergency use listing (EUL)
2.10	manufacturer's document, including information on the composition of the strategic medicinal product	the document shall comply with the requirements established in subclause 1.15 of clause 1 of this Appendix
2.11	draft regulatory quality document and manufacturer's quality control document for a strategic medicinal product	the documents shall comply with the requirements established in subclause 1.19 of clause 1 of this Appendix
2.12	manufacturer's document confirming the quality of one batch of a strategic medicinal product	the document shall comply with the requirements established in subclause 1.22 of clause 1 of this Appendix
2.13	reviews of preclinical and clinical data	reviews of preclinical and clinical data shall comply with the requirements established in subclause 1.30 of clause 1 of this Appendix
3. Preliminary technical works preceding the state registration (confirmation of the state registration) of a strategic medicinal product in a simplified procedure		
3.1	application	the application shall contain the following information: the name and location of the holder of the registration certificate, the applicant, the manufacturer (manufacturers) of the strategic medicinal product, including the manufacturer producing the finished formulation, filling and (or) packaging, carrying out release quality control, issuing a permit for the release of a strategic medicinal product, and also other participants in the production and quality control of a strategic medicinal product; name and location of the manufacturer of the pharmaceutical substance; trade name; international non-proprietary name (in case of its absence, the generally accepted (grouping) name, scientific (chemical) name) shall be indicated; the composition of the strategic medicinal product (indicating the name and quantity of active and additive substance); formulation indicating the dose of the active substance (for a one-component, two-component or three-component strategic medicinal product); standard package (primary, secondary, intermediate - if available) indicating the number of doses in the package (filling). The material of the primary packaging, the type of primary packaging, the number of units in the primary packaging, the secondary and, if available, the intermediate packaging, the number of primary packagings in the secondary (intermediate) packaging, information on the presence of a moisture absorber, instructions for medical use (leaflet), completeness, information on the type and quantity in the package of bulk products (if any) shall be indicated; the method of application of the strategic medicinal product (including internal, external, for parenteral administration);

		pharmacotherapeutic group (ATC code); period of validity; storage conditions; protection by patents in the Republic of Belarus (patent owner, number, date of issue, validity period); information about the person authorized for pharmacovigilance in the Republic of Belarus; the location of the main pharmacovigilance activity; location of the pharmacovigilance system Master File; information that the marketing authorization holder takes responsibility for the efficiency, safety and quality of the strategic medicinal product; information that the marketing authorization holder (applicant) guarantees the accuracy of the information contained in the registration dossier and in the application, and that the rights of a third party protected by a patent are not violated in connection with the state registration of a strategic medicinal product; substantiation of the possibility of applying the simplified procedure for state registration of a strategic medicinal product; information about the contact person (if any), his location, telephone number. The application is submitted on the letterhead of the applicant or the marketing authorization holder, signed by an authorized person of the applicant or marketing authorization holder indicating his position of an employee, surname, first name, patronymic (if any)
3.2	document confirming the registration of a strategic medicinal product issued by the authorized body of one of the foreign states specified in the indent two of part one of clause 11 of the Regulation on the Procedure and Conditions for State Registration of Strategically Important Medicinal Products (hereinafter referred to as the Regulation), or a document confirming registration of a strategic medicinal product in the European Union (hereinafter - the EU), issued by the authorized body of the EU under a centralized procedure (hereinafter - the authorized body of the EU), or a document confirming the registration of a strategic medicinal product of traditional Chinese medicine issued by the State Administration of Traditional Chinese Medicine of the People's Republic of China (hereinafter referred to as the authorized body of the PRC), or information from the official website of the authorized body of one of the states specified in the indent two of part one of clause 11 of the Regulations, or the EU, or the authorized body of the PRC on the global network Internet, confirming the registration of a strategic	the document is submitted in the form of the original document or its notarized copy with translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator’s signature shall be notarized). The document shall have legalization or apostille, unless otherwise provided by international treaties of the Republic of Belarus. Information from the official website of WHO in the wide area network Internet should be made in the form of a printout of a graphic image of the screen (screenshot) of the Internet page of the official website of WHO in the wide area network Internet and be accompanied by a translation into Belarusian or Russian (the correctness of the translation or the authenticity of the translator’s signature shall be notarized). The term for making a printout should not be more than 3 months from the date of submission of documents

	medicinal product or information from the official WHO website on the global network Internet, confirming the completion of the WHO pre-qualification program by the medicinal product	
3.3	a license or other document issued by the authorized body of the country of manufacture and granting the right of manufacture, or information from the official website of the regulatory authority on the global network Internet, confirming the existence of a valid license or other valid document issued by the authorized body of the country of manufacture and granting the right of manufacture (for a foreign-made strategic medicinal product)	the documents shall comply with the requirements established in subclause 1.5 of clause 1 of this Appendix
3.4	a valid document certifying the manufacture of the strategic medicinal product under Good Manufacturing Practice conditions issued by the authorized body of the country of manufacture of the strategic medicinal product (for each participant in the manufacture of the strategic drug), or a printout of a graphic screen image (screenshot) of the website of the official website of the regulatory body of the country of manufacture of the strategic medicinal product on the global network Internet, containing information on the valid document certifying the manufacture of the strategic medicinal product (for the foreign-made strategic medicinal product)	the document shall comply with the requirements established in subclause 2.4 of clause 2 of this Appendix
3.5	declaration of the holder of the registration certificate that the copy of the dossier submitted in accordance with subclause 3.16 of this clause in the CTD format does not differ from the registration dossier held by the authorized body of one of the foreign states specified in indent two of part one of clause 11 of the Regulation, or by the authorized body of the EU or WHO, except for the difference between the holder of the registration certificate for the strategic medicinal product in the Republic of Belarus and the holder of the registration certificate in one of the states specified indent two of part one of clause 11 of the Regulation, or in EU, or in the authorized	the document is submitted in any form in Belarusian, Russian or English. The declaration shall indicate the authorized body that issued the document submitted in accordance with subclause 3.2 of this clause (or WHO in the case of submission in accordance with subclause 3.2 of this clause of information from the official WHO website in the wide area network Internet, confirming that the strategic medicinal product has passed the WHO pre-qualification program). The document drawn up in English shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer)

	body of the PRC, or upon the completion of the WHO pre-qualification program by the medicinal product	
3.5[1]	a document of the holder of the registration certificate on the transfer of its rights to another holder, including the right to change the trade name of the strategic medicinal product or without the right to change the trade name of the strategic medicinal product - in case the holder of the registration certificate for a strategic medicinal product in the Republic of Belarus differs from the holder of the registration certificate in one of the states specified in the indent two of part one of Clause 11 of the Regulations, or in the EU, or in the authorized body of the People's Republic of China, upon the completion of the WHO pre-qualification program by the medicinal product	the document is submitted in any form in Belarusian, Russian or English. It shall indicate the authorized body that issued the document submitted in accordance with subclause 3.2 of this clause. The document drawn up in English shall be accompanied by a translation into Belarusian or Russian, certified by the holder of the registration certificate (applicant, manufacturer)
3.6	draft Summary of Product Characteristics (SmPC)	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements set forth in subclause 1.8 of clause 1 of this Appendix
3.7	draft instructions for medical use (leaflet)	draft instructions for medical use (leaflet) shall comply with the requirements established in subclause 1.9 of clause 1 of this Appendix
3.8	SmPC approved (agreed) by the authorized body of one of the foreign states specified in the indent two of part one of Clause 11 of the Regulations, or by the authorized body of the EU, or WHO, or the authorized body of the People's Republic of China	the document shall comply with the requirements established in subclause 2.8 of clause 2 of this Appendix. The document shall be approved (agreed) by the authorized body that issued the document submitted in accordance with subclause 3.2 of this clause, or approved (agreed) by WHO in the event that information is submitted in accordance with subclause 3.2 of this clause from the WHO official website on the global network Internet, confirming that the strategic medicinal product has passed the WHO pre-qualification program
3.9	instructions for medical use (leaflet) approved (agreed) by the authorized body of one of the foreign states specified in the indent two of part one of Clause 11 of the Regulations, or by the authorized body of the EU, or WHO, or the authorized body of the People's Republic of China	instructions for medical use (leaflet) shall comply with the requirements established in subclause 2.9 of clause 2 of this Appendix. The instructions for medical use (leaflet) shall be approved (agreed) by the authorized body that issued the document submitted in accordance with subclause 3.2 of this clause, or approved (agreed) by WHO in the event that information is submitted in accordance with subclause 3.2 of this clause from the WHO official website on the global network Internet, confirming that the strategic medicinal product has passed the WHO pre-qualification program
3.10	layouts of primary and secondary packaging (intermediate packaging - if available)	layouts of primary and secondary packaging (intermediate packaging, if any) shall comply with the requirements established in subclause 1.10 of clause 1 of this Appendix. For the strategic preparation of Traditional Chinese Medicine, the phrase “Traditional Chinese Medicine Preparation” shall be additionally indicated in the secondary package labeling
3.11	manufacturer's document, including information on the composition of the strategic medicinal product	the document shall comply with the requirements established in subclause 1.15 of clause 1 of this Appendix
3.12	draft regulatory quality document and manufacturer's quality control document for a strategic medicinal product	the documents shall comply with the requirements established in subclause 1.19 of clause 1 of this Appendix

3.13	manufacturer’s documents confirming the quality of one batch of a strategic medicinal product and one batch of a pharmaceutical substance(s)	the documents shall comply with the requirements established in subclause 1.22 of clause 1 of this Appendix
3.14	the final expert report on the assessment of a strategic medicinal product issued by the authorized body of one of the foreign states specified in the indent two of part one of Clause 11 of the Regulations, or by the authorized body of the EU (hereinafter referred to as the final expert report), as well as a list of all changes made to the registration dossier of the strategic medicinal product from the moment of its state registration and expert reports on all approved changes, or an expert report relevant as of the date of submission of documents, or a report (reports) of WHO experts on the evaluation of a strategic medicinal product under the WHO pre-qualification program (WHO/PQT), documents on all changes and actions undertaken by WHO/PQT after pre-qualification of a strategic medicinal product	the documents are submitted as copies of the documents certified by the holder of the registration certificate (applicant, manufacturer) with a translation into the Belarusian or Russian language (correctness of the translation or authenticity of the translator's signature shall be notarized). The final expert report shall include an analysis of the quality, safety, and efficiency data with a final evaluation of the strategic medicinal product's benefit-risk ratio. Expert reports shall be issued by the authorized body that issued the document submitted in accordance with subclause 3.2 of this clause, or issued by WHO in the event that information is submitted in accordance with subclause 3.2 of this clause from the official WHO website in the global network Internet, confirming that the strategic medicinal product has passed the WHO/PQT pre-qualification program
3.15	a copy of the risk management plan approved (agreed) by the authorized body of one of the foreign states specified in in the indent two of part one of Clause 11 of the Regulations, or by the authorized body of the EU (if any)	the document is submitted as a copy of the document certified by the holder of the registration certificate (applicant, manufacturer) with a translation into the Belarusian or Russian language (correctness of the translation or authenticity of the translator's signature shall be notarized)
3.16	copy of the dossier in CTD format If it is impossible to submit a copy of the dossier CTD format for the strategic preparation of traditional Chinese medicine, the following documents shall be submitted: documents on quality control of active pharmaceutical substances and excipients (monographs from the Pharmacopoeia of the People's Republic of China or documents of the manufacturer of the strategic preparation of traditional Chinese medicine in the absence of monographs in the Pharmacopoeia of the People's Republic of China); documents confirming the quality of active pharmaceutical substances and excipients; manufacturer's documents, including a description of the manufacturing process of the strategic	shall be submitted electronically in Belarusian, or Russian, or English

	preparation of traditional Chinese medicine, a brief scheme of production, production formula, volume of industrial batches, report on validation of the manufacturing process (if any); reports on validation of quality control methods for the strategic preparation of traditional Chinese medicine; documents (specifications) 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 the strategic preparation of traditional Chinese medicine; manufacturer's documents on stability study of the strategic preparation of traditional Chinese medicine	
4. Preliminary technical works prior to amendments to the registration dossier for a strategic medicinal product		
4.1	when introducing a new indication and (or) a new method of use (administration) in the general characterization of the strategic medicinal product, instructions for medical use (leaflet):	
4.1.1	application	the application shall contain the following information: the holder of the registration certificate, name and location; applicant, name and location; name and location of the manufacturing site(s) of the participants in the manufacture of the strategic medicinal product: manufacturer of pharmaceutical substance, manufacturer of bulk product (if any); manufacturer responsible for filling the strategic medicinal product; manufacturer responsible for packaging of the strategic medicinal product; the manufacturer responsible for quality control of the strategic medicinal product, the manufacturing participant responsible for authorizing the release of a batches of the strategic medicinal product; other participants of manufacture of the strategic medicinal product (pharmaceutical substance), location of manufacturing sites (if any) with indication of the type of work; trade name of medicinal product; international non-proprietary name (in case of its absence, the generally accepted (grouping) name, scientific (chemical) name) shall be indicated; the composition of the strategic medicinal product (indicating the name and quantity of active and additive substance); formulation indicating the dose of the active substance (for a one-component or two-component strategic medicinal product); standard packaging (primary, secondary, intermediate, if any) with indication of the number of doses in the package (the material of primary packaging (polyvinylchloride film, aluminum foil, etc.) is indicated); information on the form of release of bulk product (if available) (type of packaging and quantity in the package of bulk product); type of primary packaging (ampuls, vials, blister packs and other), number of units in primary packaging (number of

		tablets in blister packs and other), secondary and, if available, intermediate packaging, number of primary packages in secondary (intermediate) packaging (number of blister packs in secondary packaging and other), information on presence of moisture absorber, leaflet (instructions for medical use), completeness (needle, dropper, measuring spoon and other); method of use of the medicinal product (internal, external, for parenteral administration and other); pharmacotherapeutic group, anatomical-therapeutic-chemical classification code (ATC code); period of validity; storage conditions; sections of the registration dossier to which changes are made (composition, labeling, packaging, and other); information that the marketing authorization holder takes responsibility for the efficiency, safety and quality of the strategic medicinal product; information that the marketing authorization holder (applicant) guarantees the accuracy of the information contained in the registration dossier and in the application, and that the rights of a third party protected by a patent are not violated in connection with the state registration of a strategic medicinal product; justification of the possibility to apply state registration of a strategic medicinal product under the standard procedure - in case of state registration of a strategic medicinal product under the standard procedure; compliance of a strategic medicinal product with the conditions for application of the conditional state registration procedure - in case of conditional state registration of a strategic medicinal product; information about the contact person (if any), his location, telephone number. the application shall be submitted on the letterhead of the applicant or the holder of the registration certificate, shall be signed by an authorized person of the applicant or the holder of the registration certificate indicating his/her position, surname, first name, patronymic (if any)
4.1.2	justification of the amendment made, indicating the sections of the Summary of Product Characteristics (SmPC) and the instruction for medical use ((leaflet) to which the change is made	the justification shall contain information on the essence and reasonability of the amendment being made and should be presented in the form of a table “old version and new version”
4.1.3	draft Summary of Product Characteristics (SmPC)	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements set forth in subclause 1.8 of clause 1 of this Appendix
4.1.4	draft instructions for medical use (leaflet)	draft instructions for medical use (leaflet) shall comply with the requirements established in subclause 1.9 of clause 1 of this Appendix
4.1.5	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)	shall be certified by the holder of the registration certificate (applicant, manufacturer) and shall comply with the requirements of subclauses 1.25 and 1.26 of clause 1 of this Appendix
4.1.6	risk management plan	the risk management plan shall comply with the requirements of subclause 1.32 of clause 1 of this Appendix
4.2	in case of exclusion from the Summary of Product Characteristics (SmPC), instructions for medical use (leaflet) of the previously provided indication for medical use and (or) method of use (administration):	
4.2.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.2.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment being made and should be presented in the form of a table “old version and new version”

4.2.3	draft Summary of Product Characteristics (SmPC)	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements set forth in subclause 1.8 of clause 1 of this Appendix
4.2.4	draft instructions for medical use (leaflet)	draft instructions for medical use (leaflet) shall comply with the requirements established in subclause 1.9 of clause 1 of this Appendix
4.2.5	manufacturer's document confirming the need to exclude the previously provided indication for medical use and (or) method of use (administration)	the document shall contain information on the essence and reasonability of the amendment being made
4.3	when making amendments to the sections of Summary of Product Characteristics (SmPC), instructions for medical use (leaflet), including pharmacological and clinical sections:	
4.3.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.3.2	justification of the amendment made	the justification should contain information on the essence and reasonability of the amendment being made and should be presented in the form of a table "old version and new version"
4.3.3	draft Summary of Product Characteristics (SmPC)	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements set forth in subclause 1.8 of clause 1 of this Appendix
4.3.4	draft instructions for medical use (leaflet)	draft instructions for medical use (leaflet) shall comply with the requirements established in subclause 1.9 of clause 1 of this Appendix
4.4	when making amendments to the composition of a strategic medicinal product (replacement or introduction of an additional manufacturer of a pharmaceutical substance, introduction, exclusion or substitution of excipients), except for strategic medicinal products specified in subclause 4.25 of this clause:	
4.4.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.4.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version" (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table "old version and new version" is mandatory).
4.4.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.4.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.4.5	layouts of the primary and secondary packaging (intermediate packaging, if any) if the amendments affect this section of the registration dossier	Layouts of primary and secondary packaging (intermediate packaging, if any) shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.4.6	manufacturer's documents, including the pharmaceutical substance production scheme, structure confirmation methods, justification of impurities, declaration of validation of the manufacturing process and, if available, certificate of conformity with the European Pharmacopoeia monograph, in case of substitution or introduction	the documents shall comply with the requirements of subclause 1.11 of clause 1 of this Appendix

	of an additional manufacturer of the pharmaceutical substance included in the strategic product	
4.4.7	the quality control document for the pharmaceutical substance, if the amendment affects this section of the registration dossier	the quality control document for the pharmaceutical substance shall comply with the requirements of subclause 1.12 of clause 1 of this Appendix
4.4.8	documents containing information on materials of the primary packaging (components of the primary packaging) of the pharmaceutical substance, in case of replacement or introduction of an additional manufacturer of the pharmaceutical substance included in the strategic product	the documents shall comply with the requirements of subclause 1.13 of clause 1 of this Appendix
4.4.9	manufacturer's documents on stability study of the pharmaceutical substance in case of replacement or introduction of an additional manufacturer of the pharmaceutical substance included in the strategic product	the documents shall comply with the requirements of subclause 1.14 of clause 1 of this Appendix
4.4.10	manufacturer's document that includes information on the composition of the strategic product	the document shall comply with the requirements of subclause 1.15 of clause 1 of this Appendix
4.4.11	manufacturer's documents including a description of the new manufacturing process of the strategic medicinal product, quality control of intermediates, brief production scheme, production formula, volume of the industrial batches, report on validation of the manufacturing process in case the change of composition entails a change of the manufacturing process	the documents shall comply with the requirements of subclause 1.18 of clause 1 of this Appendix
4.4.12	draft of amendments to the quality normative document, if the amendments affect this section of the registration dossier	the draft of amendments to the quality normative document shall comply with the requirements of subclause 4.6.6 of this clause. In case the amendments affect more than half of the text of the regulatory document on quality or if there are more than three amendments in the regulatory document on quality, an updated draft of the regulatory document on quality, strategic medicinal product in a new edition shall be submitted in accordance with the requirements of subclause 1.19 of clause 1 of this Appendix
4.4.13	validation reports on quality control methods for the strategic medicinal product, if the amendments affect this section of the registration dossier.	validation reports on quality control methods for the strategic medicinal product shall comply with the requirements of subclause 1.21 of clause 1 of this Appendix
4.4.14	documents confirming the quality of one batch of a strategic medicinal product, pharmaceutical substance, excipients	the documents shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix. In the case of the use of new excipients, non-pharmacopoeial methods, methods of quality control, the document confirming the quality of one batch shall be accompanied by a description of methods, techniques of quality control of this excipient.
4.4.15	the manufacturer’s documents on the stability study of the strategic medicinal product, if the	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix

	amendments affect this section of the registration dossier.	
4.4.16	copies of reports on the results of a comparative bioavailability study of a strategic medicinal product with a new and previously registered composition	the documents shall be certified by the holder of the registration certificate (applicant, manufacturer) and shall comply with the requirements of subclause 1.27 or 1.28 of clause 1 of this Appendix. In case of replacement of the manufacturer of the pharmaceutical substance, copies of reports on the results of comparative bioavailability studies (in vitro studies) shall include the results of the test of comparative dissolution kinetics
4.4.17	other documents of the registration dossier affecting changes in the composition of the strategic medicinal product	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.5	making amendments to the “Composition” section of the registration dossier for a strategic medicinal product (if the amendments do not affect the actual composition of the strategic medicinal product):	
4.5.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.5.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).
4.5.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.5.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.5.5	manufacturer’s document that includes information on the composition of the strategic product	the document shall comply with the requirements of subclause 1.15 of clause 1 of this Appendix
4.5.6	draft of amendments to the quality normative document, if the amendments affect this section of the registration dossier	the draft of amendments to the quality normative document shall comply with the requirements of subclause 4.6.6 of this clause.
4.5.7	documents confirming the quality of one batch of a strategic medicinal product, pharmaceutical substance, excipients, if the amendments affect this section of the registration dossier	the documents shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix.
4.5.8	other documents in the registration dossier relating to the amendment of the “Composition” section of the registration dossier	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.6	when amendments are made to the regulatory document on the quality of the strategic medicinal product in case of changes in quality indicators, control methods, testing techniques:	
4.6.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.6.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet),

		formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).
4.6.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.6.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.6.5	layouts of the primary and secondary packaging (intermediate packaging, if any) if the amendments affect this section of the registration dossier	Layouts of primary and secondary packaging (intermediate packaging, if any) shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.6.6	draft on amendments to the regulatory document on quality and manufacturer's document on quality control of the strategic medicinal product (manufacturer’s document on quality control of the strategic medicinal product is required to be submitted if one of the participants of manufacture (finished, bulk or intermediate products) is foreign)	the draft on amendments to the regulatory document on quality shall be submitted in Belarusian or Russian in the form of the table “old version and new version” and shall contain: the title “AMENDMENTS TO THE REGULATORY DOCUMENT ON QUALITY”, a place for the stamp of approval, the words “Amendment No.”, after which, if necessary, the manufacturer shall indicate the next serial number of the amendment, the name of the strategic medicinal product, indication of the formulation, dosage, page numbers. Formatting of the text part shall comply with the requirements of subclause 1.19 of clause 1 of this Appendix. In case the amendments affect more than half of the text of the regulatory document on quality or in case there are more than three amendments to the regulatory document on quality, an updated draft of the regulatory document on quality of the strategic medicinal product shall be submitted in a new version in accordance with the requirements of subclause 1.19 of clause 1 of this Appendix. The manufacturer's document on quality control of the strategic medicinal product shall be submitted if the amendments made to the regulatory document on quality are related to changes in methods and (or) techniques of quality control and affect their reproducibility. Requirements to the manufacturer’s document on quality control of the strategic medicinal product are given in subclause 1.19 of clause 1 of this Appendix
4.6.7	validation reports on quality control methods for the strategic medicinal product, if the amendments affect this section of the registration dossier.	the documents shall comply with the requirements of subclause 1.21 of clause 1 of this Appendix
4.6.8	a document certifying the quality of one batch of a strategic product, if the amendments affect this section of the registration dossier.	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.6.9	documents confirming the quality of the reference materials used in quality control of the strategic product, if the amendments affect this section of the registration dossier.	the documents shall comply with the requirements of subclause 1.20 of clause 1 of this Appendix
4.7	when amendments are made to the quality indicators, control methods, test methods of a pharmaceutical substance that is part of a strategic medicinal product, if the documents of the manufacturer of this pharmaceutical substance are available in the registration dossier for the strategic medicinal product:	
4.7.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.7.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).

4.7.3	draft on amendments to the quality control document for a pharmaceutical substance	the draft on amendments to the quality control document of a pharmaceutical substance may be presented in the form of a table “old version and new version” or in the form of an updated quality control document of a pharmaceutical substance and shall comply with the requirements of subclause 1.12 of clause 1 of this Appendix. There are no requirements for the design of the document on quality control of the pharmaceutical substance
4.7.4	validation reports on quality control methods for the strategic medicinal product, if the amendments affect this section of the registration dossier.	the documents shall be submitted in accordance with the requirements for quality control methodology validation reports specified in subclause 1.21 of clause 1 of this Appendix
4.7.5	a document certifying the quality of one batch of a strategic product, if the amendments affect this section of the registration dossier.	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.7.6	documents confirming the quality of the reference materials used in quality control of the strategic product, if the amendments affect this section of the registration dossier.	the documents shall comply with the requirements of subclause 1.20 of clause 1 of this Appendix
4.8	when the expiration date of a strategic medicinal product is changed:	
4.8.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.8.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).
4.8.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.8.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.8.5	layouts of the primary and secondary packaging (intermediate packaging, if any) if the amendments affect this section of the registration dossier	Layouts of primary and secondary packaging (intermediate packaging, if any) shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.8.6	a document certifying the quality of one batch of a strategic product	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.8.7	manufacturer's documents on stability studies of the strategic medicinal product	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix
4.8.8	other documents in the registration dossier related to changes in the expiration date of the strategic product	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.9	in case of change of expiration date of a pharmaceutical substance, which is a part of a strategic medicinal product, in case of availability of documents of the manufacturer of this pharmaceutical substance in the registration dossier for the strategic medicinal product:	
4.9.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.9.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s

		initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).
4.9.3	a document certifying the quality of one batch of a pharmaceutical substance	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.9.4	manufacturer's documents on stability studies of the pharmaceutical substance	the documents shall comply with the requirements of subclause 1.14 of clause 1 of this Appendix
4.9.5	other documents in the registration dossier related to changes in the expiration date of the pharmaceutical substance	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.10	when the storage conditions of the strategic medicinal product are changed:	
4.10.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.10.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).
4.10.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.10.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.10.5	layouts of the primary and secondary packaging (intermediate packaging, if any) if the amendments affect this section of the registration dossier	Layouts of primary and secondary packaging (intermediate packaging, if any) shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.10.6	a document certifying the quality of one batch of a strategic product, if the amendments affect this section of the registration dossier.	the document certifying the quality of one batch of a strategic product shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.10.7	manufacturer's documents on stability studies of the strategic medicinal product, if the amendments affect this section of the registration dossier	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix
4.10.8	other documents in the registration dossier related to changes in the storage conditions of the strategic product	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.11	in case of change of storage conditions of a pharmaceutical substance, which is a part of a strategic medicinal product, in case of availability of documents of the manufacturer of this pharmaceutical substance in the registration dossier for the strategic medicinal product:	
4.11.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.11.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet),

		formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).
4.11.3	a document certifying the quality of one batch of a pharmaceutical substance, if the amendments affect this section of the registration dossier.	the document certifying the quality of one batch of pharmaceutical substance shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.11.4	manufacturer's documents on stability studies of the pharmaceutical substance, if the amendments affect this section of the registration dossier	the documents shall comply with the requirements of subclause 1.14 of clause 1 of this Appendix
4.11.5	other documents in the registration dossier related to changes in the storage conditions of the pharmaceutical substance	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.12	when submitting an updated draft regulatory document on the quality of a strategic medicinal product in case of changes in quality indicators, control methods, testing techniques:	
4.12.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.12.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant’s initiative, it is allowed to formalize the amendment in the form of a table “old version and new version” (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table “old version and new version” is mandatory).
4.12.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.12.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.12.5	layouts of the primary and secondary packaging (intermediate packaging, if any) if the amendments affect this section of the registration dossier	Layouts of primary and secondary packaging (intermediate packaging, if any) shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.12.6	updated draft on amendments to the regulatory document on quality and manufacturer's document on quality control of the strategic medicinal product (manufacturer’s document on quality control of the strategic medicinal product is required to be submitted if one of the participants of manufacture (finished, bulk or intermediate products) is foreign)	the draft on amendments to the regulatory document on quality shall be submitted in Belarusian or Russian in the form of the table “old version and new version” and shall contain: the title “AMENDMENTS TO THE REGULATORY DOCUMENT ON QUALITY”, a place for the stamp of approval, the words “Amendment No.”, after which, if necessary, the manufacturer shall indicate the next serial number of the amendment, the name of the strategic medicinal product, indication of the formulation, dosage, page numbers. Formatting of the text part shall comply with the requirements of subclause 1.19 of clause 1 of this Appendix. In case the amendments affect more than half of the text of the regulatory document on quality or in case there are more than three amendments to the regulatory document on quality, an updated draft of the regulatory document on quality of the strategic medicinal product shall be submitted in a new version in accordance with the requirements of subclause 1.19 of clause 1 of this Appendix. The manufacturer's document on quality control of the strategic medicinal product shall be submitted if the amendments made to the regulatory document on quality are related to changes in methods and (or) techniques of quality control and affect their reproducibility. Requirements to the manufacturer’s document on quality control of the strategic medicinal product are given in subclause 1.19 of clause 1 of this Appendix
4.12.7	validation reports on quality control methods for	the document shall comply with the requirements of subclause 1.21 of clause 1 of this Appendix

	the strategic medicinal product, if the amendments affect this section of the registration dossier.	
4.12.8	a document certifying the quality of one batch of a strategic product, if the amendments affect this section of the registration dossier.	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.12.9	documents confirming the quality of the reference materials used in quality control of the strategic product, if the amendments affect this section of the registration dossier.	the documents shall comply with the requirements of subclause 1.20 of clause 1 of this Appendix
4.13	in case of change of material, type of primary packaging (packaging components, components of primary packaging) of a strategic medicinal product, change of primary packaging of bulk products or change of primary packaging of a pharmaceutical substance included in a strategic medicinal product, if there are documents of the manufacturer of this pharmaceutical substance in the registration dossier for the strategic medicinal product:	
4.13.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.13.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version" (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table "old version and new version" is mandatory).
4.13.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.13.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.13.5	layouts of the primary and secondary packaging (intermediate packaging, if any) if the amendments affect this section of the registration dossier	Layouts of primary and secondary packaging (intermediate packaging, if any) shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.13.6	documents on quality control of new materials (types) of primary packaging (packaging components, components of primary packaging) and documents confirming that new materials (types) of primary packaging (packaging components, components of primary packaging) of a strategic medicinal product, bulk product or pharmaceutical substance are suitable for use for packaging in the pharmaceutical industry.	the documents shall comply with the requirements of subclause 1.13 or 1.23 of clause 1 of this Appendix
4.13.7	the manufacturer's stability study documents for the strategic medicinal product, bulk product or pharmaceutical substance, if the amendments affect this section of the registration dossier.	the documents shall comply with the requirements of subclause 1.14 or 1.24 of clause 1 of this Appendix and shall be submitted for a strategic medicinal product manufactured using new materials (types) of primary packaging (packaging components, components of primary packaging), as well as for bulk products or a pharmaceutical substance in new primary packaging. The results of stability studies of a strategic medicinal product of domestic manufacture (including comparative data) shall be submitted for at least 3 months under long-term and accelerated studies for at least 2 batches, the volume of which is not less than the volume of the pilot batch, and shall include information containing the obligation

		to continue long-term studies for the entire proposed expiration date and accelerated studies for 6 months and the obligation to conduct stability studies under long-term studies. The information shall include a statement that the Ministry of Health will be informed immediately if stability problems are discovered with the medicinal product
4.13.8	other documents in the registration dossier concerning a change in the material, type of primary packaging (packaging accessories, primary packaging components) of a strategic medicinal product, a change in the primary packaging of bulk products or a change in the primary packaging of a pharmaceutical substance.	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.14	when changes are made to the manufacturing process of a strategic medicinal product:	
4.14.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.14.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version".
4.14.3	reports on physicochemical and biological studies to confirm the comparability of the strategic medicinal product manufactured using the new and previously approved manufacturing processes (for a biosimilar strategic medicinal product), if the amendments affect this section of the registration dossier.	the documents shall be submitted in the form of copies of documents certified by the holder of the registration certificate (applicant, manufacturer) and, in case they are drawn up in a foreign language, shall be accompanied by a translation into Belarusian or Russian certified by the holder of the registration certificate (applicant, manufacturer). The documents shall comply with Good Clinical Practice for biological medicinal products of the Eurasian Economic Union and shall be submitted, including in the event that a change in the manufacturing process affects the pharmaceutical substance
4.14.4	manufacturer's documents, including a description of the new manufacturing process of the strategic medicinal product, quality control of intermediates, brief production scheme, production formula, volume of industrial batches	the documents shall comply with the requirements of subclause 1.18 of clause 1 of this Appendix
4.14.5	validation report for a new manufacturing process for a strategic medicinal product, if the amendments affect this section of the registration dossier.	the document shall comply with the requirements of subclause 1.18 of clause 1 of this Appendix
4.14.6	document confirming the quality of one batch of a strategic medicinal product	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.14.7	the manufacturer's stability study documents for the strategic medicinal product	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix and shall be submitted for a strategic medicinal product manufactured using new manufacturing process. The results of stability studies of a strategic medicinal product of domestic manufacture (including comparative data) shall be submitted for at least 3 months under long-term and accelerated studies for at least 2 batches, the volume of which is not less than the volume of the pilot batch, and shall include information containing the obligation to continue long-term studies for the entire proposed expiration date and accelerated studies for 6 months and the obligation to conduct stability studies under long-term studies. The information shall include a statement that the Ministry of Health will be informed immediately if stability problems are discovered with the medicinal product
4.14.8	copies of reports on preclinical (non-clinical) studies and clinical studies (trials) to confirm the	the documents are certified by the holder of the registration certificate (applicant, manufacturer) and submitted in accordance with the Good Clinical Practice for biological medicinal products of the Eurasian Economic Union

	comparability of a strategic medicinal product manufactured using a new and previously approved manufacturing process (if there is no convincing evidence of comparability based on reports on physicochemical and biological studies), - for a biotechnological strategic medicinal product.	
4.14.9	copies of reports on the results of comparative bioavailability studies of a strategic medicinal product manufactured using new and previously approved manufacturing processes (except for a strategic biotech medicinal product)	the documents shall be certified by the holder (applicant, manufacturer) and shall comply with the requirements of subclause 1.27 or 1.28 of clause 1 of this Appendix. In case of changes in the previously approved manufacturing process that may affect bioavailability, in vivo bioequivalence studies shall be conducted, unless other justifications are provided
4.14.10	strategic medicinal product risk management plan for a biotech medicinal product	the strategic medicinal product risk management plan for a biotechnological medicinal product shall comply with the requirements of subclause 1.32 of clause 1 of this Appendix
4.14.11	other documents in the registration dossier relating to changes in the manufacturing process of the strategic medicinal product	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.15	when changes are made to the manufacturing process of a pharmaceutical substance that is part of a strategic medicinal product, if the documents of the manufacturer of this pharmaceutical substance are available in the registration dossier for the strategic medicinal product:	
4.15.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.15.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version".
4.15.3	manufacturer's documents including the pharmaceutical substance production scheme, structure confirmation methods, justification of impurities, declaration of validation of the manufacturing process and, if available, certificate of conformity to the monograph of European Pharmacopoeia	the documents shall be submitted for a pharmaceutical substance manufactured using a modified manufacturing process and shall comply with the requirements of subclause 1.11 of clause 1 of this Appendix.
4.15.4	document confirming the quality of one batch of a pharmaceutical substance	the document shall be submitted for a pharmaceutical substance manufactured using a modified manufacturing process and shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix.
4.15.5	the manufacturer's stability study documents for the pharmaceutical substance	the documents shall be submitted for a pharmaceutical substance manufactured using a modified manufacturing process and shall comply with the requirements of subclause 1.14 of clause 1 of this Appendix.
4.15.6	other documents in the registration dossier relating to changes in the manufacturing process of the pharmaceutical substance	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.16	when changes are made to the layout design of primary, and/or secondary, and/or intermediate packaging of a strategic medicinal product (if any) or when additional layouts of primary, and/or secondary, and/or intermediate packaging with a different design are introduced (if any):	
4.16.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.16.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version".

4.16.3	layouts of primary and secondary packaging (intermediate packaging, if any)	the documents shall be submitted with a new labeling in Belarusian or Russian or in a foreign language with a sticker in Belarusian or Russian and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.17	when adding a dosage of a strategic medicinal product, provided that the indications for medical use are the same:	
4.17.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.17.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version".
4.17.3	document confirming the registration of the medicinal product in the country of the registration certificate holder (country of manufacturer) (registration certificate or certificate of pharmaceutical product according to the format recommended by WHO, issued by the authorized body of the country of the registration certificate holder (country of manufacturer) for the strategic medicinal product, or information from the official website of the regulatory body on the global network Internet, confirming the registration of the strategic medicinal product (for strategic medicinal product).	the documents shall comply with the requirements of subclause 1.4 of clause 1 of this Appendix
4.17.4	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.17.5	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.17.6	layouts of the primary and secondary packaging (intermediate packaging, if any)	the documents shall be submitted for the added dosage of the strategic medicinal product in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.17.7	manufacturer's document that includes information on the composition of the strategic medicinal product	the document shall be submitted for the added dosage of the strategic medicinal product and comply with the requirements of subclause 1.15 of clause 1 of this Appendix
4.17.8	the pharmaceutical development document, if the amendments affect this section of the registration dossier	the document shall be submitted for the added dosage of the strategic medicinal product and comply with the requirements of subclause 1.16 of clause 1 of this Appendix
4.17.9	reports on physicochemical and biological studies to confirm comparability with the original (reference) medicinal product (for a biosimilar strategic medicinal product), if the amendments affect this section of the registration dossier	the documents shall be submitted for the added dosage of the strategic medicinal product and comply with the requirements of subclause 1.17 of clause 1 of this Appendix
4.17.10	manufacturer's documents including a description of the manufacturing process of the strategic	the documents shall be submitted for the added dosage of the strategic medicinal product and comply with the requirements of subclause 1.18 of clause 1 of this Appendix

	medicinal product, quality control of intermediates, brief production scheme, production formula, volume of the industrial batches, report on validation of the manufacturing process (for domestically manufactured strategic medicinal products that do not belong to non-standard products or processes, it is allowed to submit a manufacturing process validation plan and a guarantee obligation to provide a validation report instead of a manufacturing process validation report).	
4.17.11	draft of amendments to the quality normative document, if the amendments affect this section of the registration dossier	the project on amendments to the normative document on quality shall comply with the requirements of subclause 4.6.6 of this clause
4.17.12	validation reports on quality control methods for the strategic medicinal product, if the amendments affect this section of the registration dossier	the documents shall be submitted for the added dosage of the strategic medicinal product and comply with the requirements of subclause 1.21 of clause 1 of this Appendix
4.17.13	documents confirming the quality of one batch of a strategic medicinal product	documents confirming the quality of one batch of a strategic medicinal product shall be submitted for the added dosage of the strategic medicinal product and shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.17.14	the manufacturer's stability study documents for the strategic medicinal product	the documents shall be submitted for the added dosage of the strategic medicinal product and comply with the requirements of subclause 1.24 of clause 1 of this Appendix
4.17.15	other documents of the registration dossier related to the addition of a dosage of a strategic medicinal product	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.18	when changing the number of doses in primary, and/or secondary, and/or intermediate packaging of a strategic medicinal product or the quantity of a strategic medicinal product in a bulk product packaging:	
4.18.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.18.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version" (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table "old version and new version" is mandatory).
4.18.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.18.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.18.5	layouts of the primary and secondary packaging (intermediate packaging, if any)	the documents shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.18.6	draft of amendments to the quality normative document, if the amendments affect this section of	the project on amendments to the normative document on quality shall comply with the requirements of subclause 4.6.6 of this clause

	the registration dossier	
4.18.7	document confirming the quality of one batch of a strategic medicinal product, if the amendments affect this section of the registration dossier	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.18.8	the manufacturer's stability study documents for the strategic medicinal product, if the amendments affect this section of the registration dossier	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix and shall be submitted for a strategic medicinal product manufactured using new manufacturing process. The results of stability studies of a strategic medicinal product of domestic manufacture (including comparative data) shall be submitted for at least 3 months under long-term and accelerated studies for at least 2 batches, the volume of which is not less than the volume of the pilot batch, and shall include information containing the obligation to continue long-term studies for the entire proposed expiration date and accelerated studies for 6 months and the obligation to conduct stability studies under long-term studies. The information shall include a statement that the Ministry of Health will be informed immediately if stability problems are discovered with the medicinal product
4.19	when changing the name of the strategic medicinal product, name of the formulation, method of indicating the dosage of the strategic medicinal product, or changing the name of the pharmaceutical substance that is a part of the strategic medicinal product, if the documents of the manufacturer of this pharmaceutical substance are available in the registration dossier for the strategic medicinal product:	
4.19.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.19.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version" (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table "old version and new version" is mandatory).
4.19.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.19.4	draft instructions for medical use (leaflet) (of the strategic medicinal product), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.19.5	layouts of the primary and secondary packaging (intermediate packaging, if any) of the strategic medicinal product	the documents shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.19.6	draft of amendments to the quality normative document, if the amendments affect this section of the registration dossier	the project on amendments to the normative document on quality shall comply with the requirements of subclause 4.6.6 of this clause
4.19.7	document confirming the quality of one batch of a strategic medicinal product, pharmaceutical substance, if the amendments affect this section of the registration dossier	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.19.8	other documents of the registration dossier concerning changes in the name of the strategic product, name of the formulation, method of dosage indication or name of the pharmaceutical substance	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix

4.20	in case of reorganization and (or) change of name and (or) address without changing the actual location of the manufacturer of the strategic medicinal product:	
4.20.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.20.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version".
4.20.3	notarized copy of the document confirming reorganization and (or) change of name and (or) address without changing the actual location of the manufacturer of the strategic medicinal product, applicant and (or) holder of the registration certificate	document drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian (the accuracy of the translation or the authenticity of the translator's signature shall be notarized). Documents shall be legalized or apostilled, unless otherwise stipulated by international treaties of the Republic of Belarus.
4.20.4	draft of amendments to the quality normative document, if the amendments affect this section of the registration dossier	the project on amendments to the normative document on quality shall comply with the requirements of subclause 4.6.6 of this clause
4.20.5	document confirming the quality of one batch of a strategic medicinal product, if the amendments affect this section of the registration dossier	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.20.6	documents of the registration dossier concerning reorganization and (or) change of name and (or) address without changing the actual location of the manufacturer of the strategic medicinal product, applicant and (or) holder of the registration certificate	draft Summary of Product Characteristics (SmPC), instructions for medical use (leaflet), layouts of the package of the strategic medicinal product, manufacturer's document including information on the composition of the strategic medicinal product in accordance with subclauses 1.8, 1.9, 1.10, 1.15 of clause 1 of this Appendix shall be submitted if the amendments affect these sections of the registration dossier. If other documents are submitted, they shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.21	in case of reorganization and (or) change of name and (or) address without changing the actual location of the manufacturer of the pharmaceutical substance that is part of the strategic medicinal product, if the documents of the manufacturer of this pharmaceutical substance are available in the registration dossier for the strategic medicinal product:	
4.21.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.21.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version".
4.21.3	copy of the document confirming reorganization and (or) change of name and (or) address without changing the actual location of the pharmaceutical substance manufacturer, in case the documents of the pharmaceutical substance manufacturer are available in the registration dossier for the strategic medicinal product	the copy of the document shall be certified by the holder of the registration certificate (applicant). A document drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian, the accuracy of the translation shall be certified by the holder of the registration certificate (applicant).
4.21.4	document confirming the quality of one batch of a strategic medicinal product, if the amendments affect this section of the registration dossier	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.21.5	manufacturer's document that includes information on the composition of the strategic product, if the amendments affect this section of	the document shall comply with the requirements of subclause 1.15 of clause 1 of this Appendix

	the registration dossier	
4.21.6	other documents of the registration dossier concerning the reorganization and (or) change of name and (or) address without changing the actual location of the pharmaceutical substance manufacturer	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.22	when there is a change of the manufacturer, country of manufacture of a strategic medicinal product (replacement or addition of a new manufacturing site for part or all of the manufacturing processes):	
4.22.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.22.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version".
4.22.3	original or copy of the document confirming the registration of the strategic medicinal product in the country of the registration certificate holder (country of manufacturer) (registration certificate or certificate of pharmaceutical product according to the format recommended by the World Health Organization) issued by the authorized body of the country of the registration certificate holder (country of manufacturer)	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 according to the format recommended by the World Health Organization) issued by the authorized body of the country of the registration certificate holder (country of manufacturer). The document shall contain information about the new manufacturer (new manufacturing site). Copies of documents issued by the authorized body of the country of the holder of the registration certificate (country of the manufacturer) shall be notarized. Documents shall be submitted with a translation into Belarusian or Russian (the accuracy of the translation or the authenticity of the translator's signature shall be notarized). The documents shall be legalized or apostilled, unless otherwise provided for by international treaties of the Republic of Belarus (for a strategic medicinal product of foreign manufacture).
4.22.4	copy of the license issued by the authorized body of the country of manufacture and granting the right to manufacture the medicinal product, or information from the official website of the regulatory body on the global network Internet, confirming the existence of a valid license (for strategic medicinal product of foreign manufacture)	a copy of the license shall be notarized. The document shall be accompanied by a translation into Belarusian or Russian (the accuracy of the translation or authenticity of the translator's signature shall be notarized). Documents shall be legalized or apostilled, unless otherwise provided for by international treaties of the Republic of Belarus. Information from the official website of the regulatory body on the global network Internet shall be produced in the form of a printout of a graphic image of the screen (screenshot) of the Internet page of the official website of the regulatory body on the global network Internet and accompanied by a translation into Belarusian or Russian (the accuracy of the translation or authenticity of the translator's signature shall be notarized). The time of manufacture of the printout should not be more than 3 months from the date of submission of documents
4.22.5	document certifying the manufacture of the strategic medicinal product under Good Manufacturing Practice conditions, issued by the authorized body of the country of manufacture of the strategic medicinal product (for each participant in the manufacture of the strategic medicinal product), or a printout of a graphic image of the screen (screenshot) of the website of the official website of the regulatory body of the country of manufacture of the strategic medicinal product in the global network Internet, containing information on the valid document certifying the manufacture of the strategic medicinal product under Good Manufacturing Practice conditions	the documents shall comply with the requirements of subclause 1.6 of clause 1 of this Appendix

	issued by an authorized body of the country of manufacture of the strategic medicinal product (for each participant in the manufacture of the strategic medicinal product) (for strategic medicinal product of foreign manufacture)	
4.22.6	manufacturer's document that includes information on the composition of the strategic product	the document shall comply with the requirements of subclause 1.15 of clause 1 of this Appendix
4.22.7	manufacturer's documents, including a description of the manufacturing process of the strategic medicinal product, quality control of intermediates, brief production scheme, production formula, volume of industrial batches	the documents shall comply with the requirements of subclause 1.18 of clause 1 of this Appendix
4.22.8	validation reports on the manufacturing process of the strategic medicinal product, if the amendments affect this section of the registration dossier	the document shall comply with the requirements of subclause 1.18 of clause 1 of this Appendix
4.22.9	document confirming the quality of one batch of a strategic medicinal product	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.22.10	the manufacturer's stability study documents for the strategic medicinal product	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix and shall be submitted for a strategic medicinal product manufactured using new manufacturing process. The results of stability studies of a strategic medicinal product of domestic manufacture (including comparative data) shall be submitted for at least 3 months under long-term and accelerated studies for at least 2 batches, the volume of which is not less than the volume of the pilot batch, and shall include information containing the obligation to continue long-term studies for the entire proposed expiration date and accelerated studies for 6 months and the obligation to conduct stability studies under long-term studies. The information shall include a statement that the Ministry of Health will be informed immediately if stability problems are discovered with the medicinal product
4.22.11	copies of reports on the results of comparative bioavailability studies of the strategic medicinal product manufactured at the new and previously approved manufacturing sites	the documents shall be certified by the holder (applicant, manufacturer) and shall comply with the requirements of subclause 1.27 or 1.28 of clause 1 of this Appendix. For reproduced medicinal products, copies of reports on biopharmaceutical studies (in vitro studies (including comparative dissolution kinetics test) and results establishing correlation of results obtained under in vitro and in vivo conditions) shall be provided
4.22.12	other documents of the registration dossier concerning changes of the manufacturer (country of manufacturer) of the strategic medicinal product	the document shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.23	in case of change of manufacturer, country of manufacture of a pharmaceutical substance (replacement or addition of a new manufacturing site for part or all manufacturing processes), which is a part of a strategic medicinal product, in case of availability of documents of the manufacturer of this pharmaceutical substance in the registration dossier for the strategic medicinal product:	
4.23.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.23.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version". If a new manufacturing site is added for all manufacturing processes, the justification for the change shall include confirmation that the new manufacturing site is within the same pharmaceutical company group as the previously approved site

4.23.3	copy of the document certifying the manufacture of the pharmaceutical substance under conditions of Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the pharmaceutical substance (for each participant in the manufacture of the pharmaceutical substance)	the copy of the document shall be certified by the holder of the registration certificate (applicant). A document drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian, the accuracy of the translation shall be certified by the holder of the registration certificate (applicant).
4.23.4	manufacturer's documents including the pharmaceutical substance production scheme, structure confirmation methods, justification of impurities, declaration of validation of the manufacturing process and, if available, certificate of conformity to the monograph of European Pharmacopoeia, if the amendments affect this section of the registration dossier	the documents shall be submitted for a pharmaceutical substance manufactured using a modified manufacturing process and shall comply with the requirements of subclause 1.11 of clause 1 of this Appendix.
4.23.5	document confirming the quality of one batch of a pharmaceutical substance	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.23.6	the manufacturer's stability study documents for the pharmaceutical substance, if the amendments affect this section of the registration dossier	the documents shall comply with the requirements of subclause 1.14 of clause 1 of this Appendix.
4.23.7	document confirming the quality of one batch of the strategic medicinal product, if the amendments affect this section of the registration dossier	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.23.8	the manufacturer's stability study documents for the strategic medicinal product, if the amendments affect this section of the registration dossier	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix.
4.23.9	other documents in the registration dossier related to changes in the storage conditions of the pharmaceutical substance	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.24	in case of change of the applicant and (or) the holder of the registration certificate:	
4.24.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.24.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version" (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table "old version and new version" is mandatory).
4.24.3	document (documents) confirming the right to be the holder of the registration certificate or applicant (if the holder of the registration certificate does not manufacture the medicinal product) - contract, license agreement confirming such right, other document	copies of the contract, license agreement shall be certified by one of the parties to the contract, license agreement. A contract or license agreement drawn up in a foreign language shall be accompanied by a translation into Belarusian or Russian certified by one of the parties to the contract or license agreement. Other documents (including an extract from the Trade Register of the country of the holder of the registration certificate or the applicant, a document confirming that the applicant is a member of an association which also includes a medicinal product manufacturer, annual financial report of the holder of the registration certificate or the applicant) shall be submitted in the form of originals or notarized copies of other documents. Other documents drawn up in a foreign language shall be accompanied by a translation into

		Belarusian or Russian (the accuracy of the translation or authenticity of the translator's signature shall be notarized). Documents shall be legalized or apostilled, unless otherwise provided for by international treaties of the Republic of Belarus.
4.24.4	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.24.5	draft instructions for medical use (leaflet) (of the strategic medicinal product), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.24.6	layouts of the primary and secondary packaging (intermediate packaging, if any) of the strategic medicinal product	the documents shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.24.7	draft of amendments to the quality normative document, if the amendments affect this section of the registration dossier	the project on amendments to the normative document on quality shall comply with the requirements of subclause 4.6.6 of this clause
4.24.8	document confirming the quality of one batch of a strategic medicinal product, if the amendments affect this section of the registration dossier	the document shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix
4.24.9	other documents of the registration dossier concerning changes of the applicant and (or) the holder of the registration certificate	the documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix
4.25	when changes are made to the composition of a domestically produced strategic medicinal product (replacement or introduction of an additional pharmaceutical substance manufacturer, introduction, exclusion or replacement of excipients):	
4.25.1	application	the application shall be executed in accordance with subclause 4.1.1 of this clause
4.25.2	justification of the amendment made	the justification shall contain information on the essence and reasonability of the amendment. At the applicant's initiative, it is allowed to formalize the amendment in the form of a table "old version and new version" (if the amendment affects the Summary of Product Characteristics (SmPC) and instructions for medical use (leaflet), formalization of amendments to these documents in the form of a table "old version and new version" is mandatory).
4.25.3	draft Summary of Product Characteristics (SmPC), if the amendments affect this section of the registration dossier	the draft Summary of Product Characteristics (SmPC) shall comply with the requirements of subclause 1.8 of clause 1 of this Appendix
4.25.4	draft instructions for medical use (leaflet), if the amendments affect this section of the registration dossier	draft instructions for medical use (leaflet) shall comply with the requirements of subclause 1.9 of clause 1 of this Appendix
4.25.5	layouts of the primary and secondary packaging (intermediate packaging, if any), if the amendments affect this section of the registration dossier	the layouts of the primary and secondary packaging (intermediate packaging, if any) shall be submitted in the Belarusian or Russian language or in a foreign language with a sticker in the Belarusian or Russian language and shall comply with the requirements of subclause 1.10 of clause 1 of this Appendix
4.25.6	manufacturer's documents including the scheme of production of the pharmaceutical substance, methods of structure confirmation, justification of	documents shall comply with the requirements of subclause 1.11 of clause 1 of this Appendix. In this case, in the absence of a pharmacopoeial article (monograph) on the pharmaceutical substance in the State Pharmacopoeia of the Republic of Belarus, the Pharmacopoeia of the Eurasian Economic Union, the European

	impurities, declaration of validation of the manufacturing process and, if available, certificate of conformity to the European Pharmacopoeia monograph, in case of replacement or introduction of an additional manufacturer of the pharmaceutical substance included in the strategic medicinal product	Pharmacopoeia, the British Pharmacopoeia or the U.S. Pharmacopoeia, the documents of the manufacturer of the pharmaceutical substance shall include the following information: on the brief scheme of synthesis (stages of manufacture); validation of the process of manufacture of the pharmaceutical substance (in the form of a declaration); on the methods of validation of the structure of the pharmaceutical substance; on the justification of impurities in the pharmaceutical substance. In the case of Certification of Suitability (CEP), this certificate shall be submitted; additional information concerning the manufacture of the pharmaceutical substance is not required. In case of confirmation in the documents of the pharmaceutical substance manufacturer of compliance of the quality of the pharmaceutical substance with the requirements of the State Pharmacopoeia of the Republic of Belarus, the Pharmacopoeia of the Eurasian Economic Union, the European Pharmacopoeia, the British Pharmacopoeia or the U.S. Pharmacopoeia, the following information shall be submitted: on validation of the pharmaceutical substance manufacturing process (in the form of a declaration); on justification of impurities in the pharmaceutical substance
4.25.7	the quality control document for the pharmaceutical substance, if the amendments affect this section of the registration dossier	the quality control document for the pharmaceutical substance shall comply with the requirements of subclause 1.12 of clause 1 of this Appendix.
4.25.8	documents containing information on materials of the primary packaging (components of the primary packaging) of the pharmaceutical substance, in case of replacement or introduction of an additional manufacturer of the pharmaceutical substance included in the strategic medicinal product	documents shall comply with the requirements of subclause 1.13 of clause 1 of this Appendix.
4.25.9	manufacturer’s documents on the study of stability of the pharmaceutical substance in case of replacement or introduction of an additional manufacturer of the pharmaceutical substance included in the strategic medicinal product	documents shall comply with the requirements of subclause 1.14 of clause 1 of this Appendix.
4.25.10	manufacturer's document that includes information on the composition of the strategic medicinal product	document shall comply with the requirements of subclause 1.16 of clause 1 of this Appendix.
4.25.11	manufacturer’s documents including a description of the new manufacturing process of the strategic medicinal product, quality control of intermediates, brief production scheme, production formula, volume of the industrial batch, report on validation of the manufacturing process in case the change of composition entails a change of the manufacturing process	documents shall comply with the requirements of subclause 1.18 of clause 1 of this Appendix.
4.25.12	draft on amendments to the quality normative document, if the amendments affect this section of	the draft on amendments to the regulatory document on quality shall comply with the requirements of subclause 4.6.6 of this clause. If the amendments affect more than half of the text of the regulatory document on quality or if there are more

	the registration dossier	than three amendments in the regulatory document on quality, an updated draft of the regulatory document on quality of the strategic medicinal product in a new edition shall be submitted in accordance with the requirements of subclause 1.19 of clause 1 of this Appendix.
4.25.13	validation reports on quality control methods for the strategic medicinal product, if the amendments affect this section of the registration dossier.	the validation reports on quality control methods for the strategic medicinal product shall comply with the requirements of subclause 1.21 of clause 1 of this Appendix
4.25.14	a document certifying the quality of one batch of a strategic product, pharmaceutical substance, excipients	the documents shall comply with the requirements of subclause 1.22 of clause 1 of this Appendix. If new excipients, non-pharmacopoeial methods, methods of quality control are used, the document confirming the quality of one batch shall be accompanied by a description of methods, methods of quality control of this excipient
4.25.15	the manufacturer's stability study documents for the strategic medicinal product	the documents shall comply with the requirements of subclause 1.24 of clause 1 of this Appendix and shall be submitted for a strategic medicinal product manufactured using new manufacturing process. The results of stability studies of a strategic medicinal product of domestic manufacture (including comparative data) shall be submitted for at least 3 months under long-term and accelerated studies for at least 2 batches, the volume of which is not less than the volume of the pilot batch, and shall include information containing the obligation to continue long-term studies for the entire proposed expiration date and accelerated studies for 6 months and the obligation to conduct stability studies under long-term studies. The information shall include a statement that the Ministry of Health will be informed immediately if stability problems are discovered with the medicinal product
4.25.16	copies of reports on the results of comparative bioavailability studies of the strategic medicinal product with new previously registered formulation	the documents shall be certified by the holder of the registration certificate (applicant, manufacturer) and shall comply with the requirements of subclause 1.27 or 1.28 of clause 1 of this Appendix. In case of replacement of the manufacturer of the pharmaceutical substance, copies of reports on the results of comparative bioavailability studies (in vitro studies) shall include the results of the test of comparative dissolution kinetics
4.25.17	other documents of the registration dossier affecting changes in the composition of the strategic medicinal product	documents shall comply with the requirements of subclause 1.34 of clause 1 of this Appendix.

APPROVED

Decree
of the Ministry of Health
of the Republic of Belarus
№ 126 dated 21.12.2021

INSTRUCTION
on the procedure for conducting a complex of preliminary technical works related to expert examinations to confirm compliance of a strategically important medicinal product with safety, efficiency and quality requirements, to determine the possibility of emergency use of a strategically important medicinal product

1. This Instruction determine the procedure for the Republican Unitary Enterprise "Center for Examinations and Tests in Health Service" (hereinafter, unless otherwise specified, the Center) to carry out a complex of preliminary technical works related to the conduct of expert examinations to confirm the compliance of a strategically important medicinal product (hereinafter, unless otherwise specified - strategic medicinal product) to the requirements of safety, efficiency and quality, as well as to determine the possibility of emergency use of a strategic medicinal product (hereinafter, unless otherwise specified - a complex of preliminary works).

A complex of preliminary works precedes:

state registration (confirmation of state registration) of a strategic medicinal product, carried out according to the standard procedure, conditionally, in a simplified procedure;

conditional state registration of a strategic medicinal product for emergency use;

amendments to the registration dossier of a strategic medicinal product registered under the standard procedure, conditionally, under the simplified procedure, conditionally for emergency use.

2. This Instruction shall not apply to the complex of preliminary works preceding:

state registration of medicinal products in accordance with the Regulations on the Procedure and Conditions of State Registration (Confirmation of State Registration) of Medicinal Products approved by Resolution of the Council of Ministers of the Republic of Belarus No. 254 dated April 1, 2015;

state registration of medicinal products in a simplified procedure in accordance with the Regulation on the Simplified Procedure for State Registration of Medicinal Products approved by Resolution of the Council of Ministers of the Republic of Belarus No. 191 dated April 1, 2020.

3. Within this Instruction the terms and their definitions are used in the meanings established by the Law of the Republic of Belarus No. 161-3 dated July 20, 2006 "On Medicine Circulation", the Regulations on the Procedure and Conditions of State Registration of Strategically Important Medicinal Products.

4. The complex of preliminary works preceding the state registration (confirmation of state registration) of a strategic medicinal product under the standard procedure and conditional state registration (confirmation of conditional state registration) of a strategic medicinal product, introduction of amendments to the registration dossier of a strategic medicinal product registered under the standard procedure and conditionally, shall be carried out on the basis of contracts concluded for performance of certain types of works between the Center and the applicant.

The total period of the preliminary works package shall not exceed 180 calendar days. This term may be extended up to 360 calendar days by agreement of the parties.

To carry out the complex of preliminary works, the applicant shall submit to the Center the documents constituting the registration dossier of a strategic medicinal product (hereinafter referred to as documents) on paper (except for the documents submitted on electronic medium) and their copies in singlicate (except for the documents submitted on electronic medium).

The complex of preliminary works includes:

4.1. initial examination of documents, which includes:

verification of completeness and correctness of the documents;

assessment of compliance of the trade name of the strategic medicinal product with the criteria established by Resolution of the Ministry of Health of the Republic of Belarus No. 78 dated September 24, 2020 “On Criteria for Trade Names of Medicinal Products”.

The primary expert examination of documents shall be conducted by an expert, who is an employee of the Center (hereinafter referred to as the Center’s expert), on the basis of an agreement concluded between the Center and the applicant, within a period not exceeding 5 calendar days from the date of receipt of documents, subject to receipt of funds to the settlement account of the Center.

Based on the results of the initial expert examination of the documents, an expert report shall be issued, which shall contain the following conclusions:

on compliance (non-compliance) of the submitted documents with the requirements of the legislation;

compliance (non-compliance) of the trade name of the strategic medicinal product with the established criteria.

The expert report specified in part three of this subclause shall be sent to the applicant in writing and (or) electronically within 5 business days from the date of its signing.

If the expert report specified in part three of this subclause contains conclusions on non-compliance of the submitted documents with the requirements of the legislation and (or) non-compliance of the trade name of the strategic medicinal product with the established criteria, the documents shall be returned to the applicant and the complex of preliminary works shall be terminated.

In case of a positive result of the primary expert examination, the documents shall be sent for specialized expert examination;

4.2. specialized expert examination, which is an evaluation of documents in order to confirm the compliance of the strategic medicinal product with safety, efficiency and quality requirements, taking into account its chemical-pharmaceutical and clinical-pharmacological features (hereinafter referred to as specialized expert examination).

The specialized expert examination shall be conducted on the basis of the contract concluded between the Center and the applicant within a period not exceeding 60 calendar days from the date of receipt of funds to the settlement account of the Center.

The specialized expert examination shall be carried out by:

the Center’s experts included in the expert groups of the Commission for Medicinal Products of the Ministry of Health (hereinafter referred to as the Commission);

experts who are not experts of the Center and included in the expert groups of the Commission, in cases of:

state registration (confirmation of state registration) of a strategic medicinal product under the standard procedure and conditional state registration (confirmation of conditional state

registration) of a strategic medicinal product in respect of a strategic medicinal product with a new active substance not previously registered in the Republic of Belarus;

state registration (confirmation of state registration) of a strategic medicinal product under the standard procedure, conditional state registration (confirmation of conditional state registration), amendments to the registration dossier of a strategic medicinal product which is a biological medicinal product;

on the recommendation of the expert (experts) of the Center with justification reflected in the expert report specified in part four of this subclause;

the applicant's disagreement with the remarks of the expert (experts) of the Center upon his written request;

decisions of the Commission;

experts appointed by the Ministry of Health and having special knowledge in the field of clinical application of a strategic medicinal product, provided that they are not members of the expert groups of the Commission (only in case of conditional state registration (confirmation of conditional state registration) of a strategic medicinal product).

Based on the results of the specialized expert examination, each expert shall draw up an expert report.

If there are any remarks in the expert reports specified in part four of this subclause, the Center shall send them to the applicant (without specifying the experts) in writing and (or) electronically within 5 working days from the date of their signing.

Upon compliance with remarks, the applicant shall submit to the Center the documents and (or) materials confirming the compliance with remarks, in accordance with the requirements to the documents (in written and (or) electronic form) within a period not exceeding 40 calendar days from the date of receipt of these remarks. The specified period may be extended for up to 90 calendar days on the basis of a reasonable written request of the applicant. The specified term shall not be counted as the term of the preliminary works.

The Center shall review the documents and (or) materials submitted by the applicant within a period not exceeding 30 calendar days from the date of their submission. Subsequent remarks shall be allowed only in case of additional questions concerning the documents and (or) materials submitted by the applicant in response to the previous remarks;

4.3. approbation of quality control methods for a strategic medicinal product and quality control of this strategic medicinal product using such methods (hereinafter, unless otherwise specified - approbation and quality control), which shall be carried out during a set of preliminary works preceding the state registration of a strategic medicinal product under the standard procedure, introduction of amendments to the registration dossier of a strategic medicinal product registered under the standard procedure, on the basis of an agreement concluded between the Center and the applicant. For quality indicators involving multilevel testing and evaluation of results, in case of doubtful or negative results on the first level requiring testing on the following levels, the period of approbation and quality control works may be extended up to 120 calendar days on the basis of an additional agreement to the previously concluded contract.

Approbation and quality control are not carried out for:

narcotic drugs and psychotropic substances;

radiopharmaceutical strategic medicinal products;

orphan (rare) strategic medicinal products;

strategic medicinal products, the approbation of quality control methods of which was carried out as part of a set of preliminary technical works preceding the issuance of an

authorization to conduct clinical trials (studies), provided that the quality control methods have not been changed.

Samples of strategic medicinal products and reference materials, as well as test strains of microorganisms, cell cultures, diagnostic test systems, chromatographic columns, specific expendables and reagents of the manufacturer of the strategic medicinal product required for approbation and quality control shall be submitted to the Center by the applicant. Remains of reference materials, specific expendables, chromatographic columns after testing shall be returned to the applicant upon his application.

If the Center does not have the technical capability, approbation and quality control shall be carried out by testing laboratories of state institutions "Republican Scientific and Practical Center of Epidemiology and Microbiology" and "Republican Scientific and Practical Center of Transfusiology and Medical Biotechnology" (hereinafter referred to as testing laboratories) accredited in the National Accreditation System of the Republic of Belarus for testing of medicinal products on the basis of contracts concluded with the Center, taking into account their technical equipment.

In the absence of technical capability of the Center and testing laboratories to conduct approbation and quality control, as well as in case of impossibility for the applicant to submit samples of the strategic medicinal products, test strains of microorganisms, cell cultures, diagnostic test systems, reference materials, chromatographic columns, specific expendables and reagents of the manufacturer of the strategic medicinal product, approbation and quality control shall be carried out at the address of the manufacturer of the strategic medicinal product that performs quality control, with participation of the Center's employees and testing laboratories (if necessary). In case the Center's and testing laboratories' employees cannot participate in the approbation and quality control at the address of the manufacturer of the strategic medicinal product due to objective reasons beyond the control of the Center and testing laboratories, these tests may be carried out taking into account the submitted documentation and materials of the manufacturer using means of remote interaction, including by means of audio and video communication, video recording.

If the applicant provides documentary confirmation that the cost of strategic medicinal product samples required for validation and quality control exceeds 1000 monetary units equivalent to 1000 US dollars at the exchange rate of the National Bank of the Republic of Belarus set as of the date of submission of documents by the applicant for initial examination, validation and quality control shall be carried out according to separate indicators of the regulatory document on quality used to confirm the authenticity (identification), quantitative content of the active ingredients, and the content of the related impurities.

Upon completion of approbation and quality control of the strategic medicinal product, the Center and (or) testing laboratories shall draw up the act(s) of approbation and protocol(s) of testing of the strategic medicinal product, which shall be sent to the applicant in writing and (or) electronically within a period not exceeding 5 working days from the date of their signing. Based on the results of approbation and quality control of the strategic medicinal product using remote interaction means or at the address of the manufacturer responsible for quality control, the applicant shall issue test results signed (certified) by the manufacturer responsible for quality control of the strategic medicinal product. The Center and testing laboratories (if necessary) shall draw up an approbation act, which shall be sent to the applicant in writing and (or) electronically within a period not exceeding 5 working days from the date of its signing. If there are remarks in the approbation act(s), the applicant shall comply with remarks within a period not exceeding 60

calendar days from the date of receipt by the applicant of the protocol(s) of testing of the strategic medicinal product and (or) the approbation act(s). The said period may be extended for up to 90 calendar days on the basis of a reasonable written request of the applicant. The specified period shall not be counted against the period for conducting a set of preliminary works.

Confirmation of compliance by the applicant with remarks specified in the act(s) of approbation, which do not require reapproval, shall be carried out by the Center and (or) testing laboratories and shall be formalized by the act(s) of approbation within a period not exceeding 15 calendar days from the date of submission of documents and materials confirming the compliance with remarks.

In order to confirm the applicant's compliance with remarks that require repeated approbation, the Center and (or) testing laboratories shall conduct approbation and quality control again within a period not exceeding 90 calendar days from the date of receipt of documents and materials necessary to confirm the compliance with remarks. The results shall be formalized by the act(s) of approbation and protocol(s) of testing of the strategic medicinal product.

Subsequent remarks shall be sent to the applicant only in case of additional questions concerning the information (materials) submitted by him in response to the previous remarks.

5. The complex of preliminary works preceding the conditional state registration of a strategic medicinal product for emergency use shall be carried out on the basis of an agreement concluded between the Center and the applicant within a period not exceeding 15 working days from the date of submission of documents, subject to receipt of funds to the settlement account of the Center.

The complex of preliminary works includes:

verification of completeness and correctness of documents;

assessment of compliance of the trade name of the strategic medicinal product with the criteria established by Resolution of the Ministry of Health of the Republic of Belarus No. 78 dated September 24, 2020;

examination of documents.

The examination of documents shall be carried out by the Commission, which shall include experts determined by the order of the Ministry of Health, within a period not exceeding 10 working days. The Commission shall be established for the examination of each strategic medicinal product.

Based on the results of expert examination of documents, the commission shall issue an expert report on the possibility (impossibility) of conditional state registration of a strategic medicinal product for emergency use. The expert report shall be signed by all members of the commission.

If there are remarks in the expert report, the Center shall send them to the applicant in writing and (or) electronically within 1 working day from the date of their signing.

In case of compliance with remarks, the applicant shall submit to the Center documents and (or) materials confirming the compliance with remarks in written and (or) electronic form within a period not exceeding 10 working days from the date of their receipt. The specified term shall not be counted as the term of the preliminary works.

The Commission shall consider the documents and (or) materials submitted by the applicant within a period not exceeding 5 working days from the date of their submission and issue an expert report.

5^1. The complex of preliminary works preceding the introduction of amendments to the registration dossier of a strategic medicinal product registered under the procedure of conditional

state registration for emergency use shall be carried out on the basis of an agreement concluded between the Center and the applicant within a period not exceeding 15 working days from the date of submission of documents, subject to receipt of funds to the settlement account of the Center.

The complex of preliminary works shall include:

verification of the completeness and correctness of the documents;

examination of the documents.

Expert examination of the documents shall be conducted by the Center's experts included in the expert groups of the Commission or by the experts of the Commission determined by the order of the Ministry of Health, who conducted conditional state registration of a strategic medicinal product for emergency use, within a period not exceeding 10 working days.

Based on the results of expert examination of documents, each expert shall draw up an expert report.

If there are any remarks in the expert report, the Center shall send them to the applicant in writing and (or) electronically within 1 working day from the date of their signing.

In case of compliance with remarks, the applicant shall submit to the Center documents and (or) materials confirming the compliance with remarks in written and (or) electronic form within a period not exceeding 10 working days from the date of their receipt. The specified term shall not be counted as the term of the preliminary works.

Experts shall review the documents and (or) materials submitted by the applicant within a period not exceeding 5 working days from the date of their submission and issue an expert report.

6. The complex of preliminary works preceding the state registration (confirmation of state registration) of a strategic medicinal product under the simplified procedure, introduction of amendments to the registration dossier of a strategic medicinal product registered under the procedure of state registration under the simplified procedure shall be carried out on the basis of an agreement concluded between the Center and the applicant within a period not exceeding 30 business days from the date of submission of documents by the applicant and subject to receipt of funds to the settlement account of the Center.

The complex of preliminary works includes:

verification of completeness and correctness of documents;

assessment of compliance of the trade name of the strategic medicinal product with the criteria established by Resolution of the Ministry of Health of the Republic of Belarus No. 78 dated September 24, 2020;

examination of the documents, which shall be conducted by experts determined by the Center within a period not exceeding 15 working days. Expert examination of the documents specified in subclause 3.16 of clause 3 of the Appendix to the Decision approving the present Instruction shall be carried out in case of necessity to clarify (confirm) the information in the documents specified in subclauses 3.1-3.15 of clause 3 of the Appendix to the Decision approving the present Instruction.

Based on the results of the examination of documents, each expert shall issue an expert report.

If there are remarks in the expert reports, the Center shall send them to the applicant in writing and (or) electronically within 2 working days from the date of their signing.

In case of compliance with remarks, the applicant shall submit to the Center documents and (or) materials confirming the compliance with remarks in written and (or) electronic form within a

period not exceeding 30 calendar days from the date of their receipt. The specified term shall not be counted as the term of the preliminary works.

Experts shall review the documents and (or) materials submitted by the applicant within a period not exceeding 10 working days from the date of their submission, and draw up expert reports.

7. Based on the results of the preliminary work package, the Center shall issue:

report on compliance (non-compliance) of a strategic medicinal product with safety, efficiency and quality requirements in the form according to Appendix 1 - based on the results of the complex of preliminary works preceding state registration (confirmation of state registration) of a strategic medicinal product carried out under the standard procedure, conditionally, in a simplified procedure, introduction of amendments to the registration dossier of a strategic medicinal product registered under the standard procedure, conditionally, in a simplified procedure;

report on the possibility (impossibility) of emergency use of a strategic medicinal product in the form according to Appendix 2 - based on the results of the complex of preliminary works preceding conditional state registration of a strategic medicinal product for emergency use, introduction of amendments to the registration dossier of a strategic medicinal product registered conditionally for emergency use.

The reports specified in the first part of this clause shall be drawn up in two copies, signed by the authorized official and sealed with the Center's seal. One copy of the report shall be sent to the applicant within 5 working days from the date of its signing, the second copy shall be kept at the Center.

The validity term of the report:

on compliance (non-compliance) of the strategic medicinal product with safety, efficiency and quality requirements - 6 months from the date of its issuance;

on the possibility (impossibility) of emergency use of the strategic medicinal product - 1 month from the date of its issuance.

8. At the initiative of the applicant, the complex of preliminary works may be terminated and the report specified in part one of clause 7 of this Instruction shall not be issued by the Center in this case.

Appendix 1
to the Instruction on the procedure for conducting a complex of preliminary technical works related to expert examinations to confirm compliance of a strategically important medicinal product with safety, efficiency and quality requirements, to determine the possibility of emergency use of a strategically important medicinal product (as amended by Resolution of the Ministry of Health of the Republic of Belarus No. 163 of 06.10.2023)

Form

REPUBLICAN UNITARY ENTERPRISE
"CENTER FOR EXAMINATIONS AND TESTS IN HEALTH SERVICE"

REPORT
on compliance (non-compliance) of a strategically important medicinal product with safety, efficiency and quality requirements

___ _____ 20__ Minsk

This report has been prepared based on the results of the complex of preliminary technical works preceding the state registration (confirmation of state registration) of a strategically important medicinal product, introduction of amendments to the registration dossier of a strategically important medicinal product (specify as appropriate):

□ state registration of a strategically important medicinal product carried out:
□ according to the standard procedure
□ conditionally
□ in a simplified procedure;
□ confirmation of state registration of a strategically important medicinal product carried out:
□ according to the standard procedure
□ conditionally
□ in a simplified procedure;
□ introduction of amendments to the registration dossier of a strategically important medicinal product registered:
□ according to the standard procedure
□ conditionally
□ under simplified procedure

_____
(trade name of a strategically important medicinal product, formulation,

_____
name and country of the marketing authorization holder,

_____
name and country of manufacturer(s)

_____
(meets (does not meet) the requirements

_____
of safety, efficiency and quality)

This report is valid for 6 months from the date of issue.

(employee position of an authorized official)	(signature)	(initials (initial of the first name), surname)

L.S.

Appendix 2
to the Instruction on the procedure for conducting a complex of preliminary technical works related to expert examinations to confirm compliance of a strategically important medicinal product with safety, efficiency and quality requirements, to determine the possibility of emergency use of a strategically important medicinal product (as amended by Resolution of the Ministry of Health of the Republic of Belarus No. 163 of 06.10.2023)

Form

REPUBLICAN UNITARY ENTERPRISE
"CENTER FOR EXAMINATIONS AND TESTS IN HEALTH SERVICE"

REPORT
on the possibility (impossibility) of emergency use of a strategically important medicinal product

___ _____ 20__ Minsk

This report has been prepared based on the results of a complex of preliminary technical works preceding conditional state registration of a strategically important medicinal product for emergency use, amendments to the registration dossier of a strategically important medicinal product registered conditionally for emergency use.

(trade name of a strategically important medicinal product,

formulation, name and country of the marketing authorization holder,

name and country of manufacturer(s)

(possible (impossible) emergency use

of a strategically important medicinal product)

This report is valid for 1 month from the date of issue.

(employee position of an authorized official)	(signature)	(initials (initial of the first name), surname)

L.S.