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(Unofficial translation)

RESOLUTION OF THE COUNCIL OF MINISTERS OF THE REPUBLIC OF BELARUS
No. 570 dated October 8, 2021

On state registration of strategically important medicinal products

Amendments and additions:

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

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

Based on parts eighth, tenth and twenty-fifth of Article 10 of the Law of the Republic of Belarus No. 161-3 dated July 20, 2006 "On Circulation of Medicinal products" and subclause a) of clause 3 of the Rules for Marketing Authorisation and Expert Assessment of Medicinal Products, approved by Decision of the Eurasian Economic Commission Council No. 78 dated November 3, 2016 , the Council of Ministers of the Republic of Belarus RESOLVES:

1. Approve the Provision on the procedure and terms of state registration of strategically important medicinal products (attached).

2. Amend the Resolutions of the Council of Ministers of the Republic of Belarus in accordance with the Appendix.

3. the Ministry of Health shall within three months take measures to implement this Resolution.

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

First Deputy Prime Minister of the Republic of Belarus **N. Snopkov**

Appendix
to the Resolution
of the Council of Ministers
of the Republic of Belarus
No. 570 dated October 8, 2021

LIST
of amendments to the Resolutions of the Council of Ministers of the Republic of Belarus

1. In the Regulation on the Ministry of Health of the Republic of Belarus, approved by the Council of Ministers of the Republic of Belarus No. 1446 dated October 28, 2011:

in clause 8:

subclause 8.14 after the words "simplified procedure," add the words "state registration of strategically important medicines,";

subclause 8.14^1 shall be amended to read as follows:

"8.14^1. determines:

the procedure for conducting a complex of preliminary technical works related to the conduct of examinations, approbation of methods for quality control of a medicinal product and quality control of this medicinal product using such methods, other studies preceding the state registration

(confirmation of state registration) of medicinal products, conditional state registration (confirmation of conditional state registration) of medicinal products, state registration of medicinal products in a simplified manner, making changes to the registration dossier;

the procedure for conducting 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;

the procedure for technical support of maintaining the State Register of Medicinal Products of the Republic of Belarus;

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

a list of strategically important medicinal products;".

2. Excluded

3. In the Resolution of the Council of Ministers of the Republic of Belarus No. 254 dated April 1, 2015 "On state registration (confirmation of state registration) of medicinal products":

supplement the Resolution by adding clause 1^1 of the following content:

"1^1. Establish that the documents issued by the authorized bodies of foreign states (registration certificate, or a certificate of a pharmaceutical product issued in accordance with the format recommended by the World Health Organization, or another document on the registration of a medicinal product, a document certifying the production of a medicinal product under Good Manufacturing Practice, issued by an authorized by the authority of the country of manufacture of the medicinal product (for each participant in the manufacture of the medicinal product), a copy of the license issued by the authorized body of the country of manufacture and granting the right to manufacture the medicinal product), which expired (expires) from March 11, 2020 to December 31, 2021, shall be considered valid until July 1, 2022";

in the Provision on the procedure and conditions for state registration (confirmation of state registration) of medicinal products, approved by this Resolution:

part two of clause 1 shall be supplemented by the following indent:

"the state registration of strategically important medicinal products.";

clause 2 shall be amended to read as follows:

"2. The terms and their definitions in the meanings established by the Law of the Republic of Belarus "On Circulation of Medicinal Products" are used in this Provision, as well as the following terms and their definitions:

bulk product –a bulk medicinal product that has passed all stages of the technological process, with the exception of filling and (or) packaging processes.";

in clause 9:

the eleventh indent shall be supplemented with the words ", changing the packaging of bulk product";

the fourteenth indent after the word "product" shall be supplemented with the words "or the quantity of the medicinal product in the package of bulk product,";

in Appendix 1 to this Provision:

in clause 1:

after the second indent, add the clause with the following indent:

"document (documents) confirming the right to be a marketing authorization holder or an applicant (if the marketing authorization holder does not manufacture a medicinal product), - contracts, license agreements confirming such a right, other documents;";

indents three-five and nine shall be excluded;

the eleventh indent shall be amended to read as follows:

"a copy of a valid document certifying the manufacture of the medicinal product under the Good Manufacturing Practices, issued by the authorized body of the country of manufacture of the medicinal product (for each participant in the production of the 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 medicinal product under the terms of Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the medicinal product (for each participant in the manufacture of the medicinal product);";

in clause 3:

the first indent of subclause 3.10 shall be supplemented with the words ", changing the packaging of bulk product";

in the first indent of subclause 3.13, the words "product or" shall be replaced by the words "product, or the quantity of the medicinal product in the packaging of bulk product, or";

in subclause 3.16:

the seventh indent shall be amended to read as follows:

"a copy of a valid document certifying the manufacture of the medicinal product under the Good Manufacturing Practices, issued by the authorized body of the country of manufacture of the medicinal product (for each participant in the production of the 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 medicinal product under the terms of Good Manufacturing Practice, issued by the authorized body of the country of manufacture of the medicinal product (for each participant in the manufacture of the medicinal product);";

indents eight to eleven should be excluded;

in subclause 3.17:

after the third indent, add the subclause with the following indent:

"document (documents) confirming the right to be a marketing authorization holder or an applicant (if the marketing authorization holder does not manufacture a medicinal product), - contracts, license agreements confirming such a right, other documents;";

indents four, sixth-eighth shall be excluded;

clause 5 of the Provision on the structure, formation and maintenance of the State Register of Medicinal Products of the Republic of Belarus, approved by this Resolution, shall be supplemented with the following part:

"Information about a registered medicinal product contains information on the type of packaging and the quantity in the package of bulk product (if available), the name of the manufacturer and the country of manufacture of bulk product (if available).".

APPROVED

Resolution
of the Council of Ministers of the
Republic of Belarus
No. 570 dated October 8, 2021

PROVISION
on the procedure and terms of state registration of strategically important medicinal products

1. This Provision determines the procedure and conditions for state registration (confirmation of state registration) of strategically important medicinal products, amendments to the registration dossier, as well as suspension and termination of registration certificates issued for strategically important medicinal products.

2. This Provision does not apply to the state registration (confirmation of state registration) of medicinal products in the manner determined by:

Provision on the procedure and conditions for the state registration (confirmation of state registration) of medicinal products, approved by the Resolution of the Council of Ministers of the Republic of Belarus No. 254 dated April 1, 2015;

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.

3. The terms and their definitions in the meanings established by the Law of the Republic of Belarus "On Circulation of Medicinal Products", international legal acts constituting the law of the Eurasian Economic Union in the sphere of circulation of medicines are used in this Provision, as well as the following terms and their definitions:

Traditional Chinese medicine medicinal product means a medicinal product produced using components of plant and (or) animal origin, minerals and other substances and registered by the State Administration of Traditional Chinese Medicine in the People's Republic of China;

strategically important medicinal products (hereinafter, unless otherwise specified, strategic medicinal products) that together meet the following criteria:

shall be intended for medical use in military operations, emergency situations and for organizing the provision of medical care to people affected by emergencies, to prevent emergencies, for prevention and treatment of diseases that pose a danger to others, as well as diseases and injuries resulting from exposure to adverse chemical, biological, radiation factors.

shall be registered at the time of submission of documents to perform the complex of preliminary technical works related to expert examinations to confirm compliance of the strategic medicinal product with safety, efficiency and quality requirements, as well as to determine the possibility of emergency use of the strategic medicinal product (hereinafter - complex of preliminary technical works) not more than three reproduced and (or) biosimilar medicinal products with the same international nonproprietary name, formulation and dosage, produced in the Republic of Belarus with fulfillment of all stages of the technological process, including the process of packaging, quality control, issuance of permission for release for sale;

emergency situation - a situation that has developed in a certain territory as a result of an industrial accident, other hazardous situation of a man-made nature, a catastrophe, a dangerous natural phenomenon, a natural or other disaster that has caused or may cause human casualties, harm to human health or the environment, significant material damage and violation of the living conditions of people, as well as the absence or threat of absence of strategic medicinal products on the territory of the Republic of Belarus.

3^1. The list of strategic medicinal products shall be determined by the Ministry of Health.

4. The state registration (confirmation of state registration) of strategic medicinal products, amendments to the registration dossier are preceded by the complex of preliminary technical works.

The complex of preliminary technical works is carried out by the Republican Unitary Enterprise "Center for Examinations and Tests in Health Service" (hereinafter referred to as the Center) in the manner determined by the Ministry of Health, on the basis of agreements concluded for the performance of certain types of such works between the Center and the applicant.

In order to carry out the complex of preliminary technical works, the applicant submits to the Center the documents that make up the registration dossier of strategic medicinal products, according to the list approved by the Ministry of Health.

5. Based on the results of the implementation of the complex of preliminary technical works, the Center, depending on the type of procedure for state registration (confirmation of state registration) of strategic medicinal products, draws up:

report on the compliance (non-compliance) of the strategic medicinal product with the requirements of safety, efficiency and quality in the form established by the Ministry of Health;

report on the possibility (impossibility) of emergency use of a strategic medicinal product in the form established by the Ministry of Health.

6. State registration (confirmation of state registration)of strategic medicinal products is carried out:

under standard procedure;

conditionally;

conditionally for emergency use;

in a simplified manner.

In this respect, confirmation of conditional state registration of strategic medicinal products for emergency use is not carried out.

6[1]. Consideration of issues related to state registration (confirmation of state registration) of strategic medicinal products, amendments to the registration dossier, suspension, termination of validity of registration certificates issued for strategic medicinal products shall be carried out by the Commission for Medicinal Products of the Ministry of Health.

The Ministry of Health approves the Regulation on the Commission for Medicinal Products and determines its composition.

7. State registration of strategic medicinal products under standard procedure is carried out in relation to medicinal products included in the list of strategically important medicinal products determined by the Ministry of Health, except for the cases specified in clauses 8–11 of this Provision.

8. Conditional state registration (confirmation of conditional state registration) of strategic medicinal products is carried out subject to the following conditions in the aggregate:

categorization of strategic medicinal products as original medicinal products for the treatment, medical prevention, or diagnosis of life-threatening or seriously disabling diseases, or as medicines for the treatment of orphan (rare) diseases;

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

To make a decision on conditional state registration (confirmation of conditional state registration) of strategic medicinal products, the following are subject to assessment:

documents that make up the registration dossier, in terms of the completeness of information that allows assessing the compliance of a strategic medicinal product with safety, efficiency and quality requirements, with the exception of data on clinical studies (trials) of a strategic medicinal product, which may not be presented in full;

the ratio of benefits for the patient or public health resulting from conditional state registration, the availability of a strategic medicinal product and the risk associated with the lack of complete clinical data on the medicinal product (the “benefit-risk ratio”);

the possibility of obtaining complete clinical data on a strategic medicinal product after the completion of clinical trials, except in cases where the provision of complete clinical data is not possible.

The possibility of obtaining full clinical data on a strategic medicinal product is not evaluated if:

the indication(s) for medical use for which the strategic medicinal product is intended to be used is(are) so rare that the marketing authorization holder cannot reasonably expect to receive comprehensive evidence of the efficiency and safety of the strategic medicinal product;

with existing scientific research methods, complete information about the efficiency or safety of a strategic medicinal product cannot be provided;

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

9. When carrying out conditional state registration (confirmation of conditional state registration) of strategic medicinal products, the holder of the registration certificate:

continues current clinical studies or conducts new clinical studies in order to obtain full information to confirm a favorable benefit-risk ratio;

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

conducts post-registration studies on the safety of a strategic medicinal product;

takes other measures to ensure the safe and effective use of a strategic medicinal product in accordance with the requirements of the Guideline on good pharmacovigilance practices of the Eurasian Economic Union, approved by the Resolution of the Council of the Eurasian Economic Commission No. 87 dated November 3, 2016.

10. Conditional state registration of strategic medicinal products for emergency use is carried out when there is an urgent need for a strategic medicinal product, and therefore the use of other types of state registration procedures for strategic medicinal products that require a lot of time is inappropriate.

If there is a ground specified in part one of this clause, conditional state registration of strategic medicinal products for emergency use is carried out if they meet one of the following criteria:

a strategic medicinal product approved for emergency use by the competent authority of one of the following countries: the Commonwealth of Australia, the Republic of Austria, the Grand Duchy of Luxembourg, Hungary, the Hellenic Republic, Ireland, the Italian Republic, Canada, the Kingdom of Belgium, the Kingdom of Denmark, the Kingdom of Spain, the Kingdom of the Netherlands, the Kingdom of Sweden, Republic of Latvia, Republic of Lithuania, Portuguese Republic, Republic of Bulgaria, Republic of Cyprus, Republic of Malta, Republic of Poland, Republic of Slovenia, Republic of Croatia, Romania, Slovak Republic, Great Britain and Northern Ireland, United States of America, Federal Republic of Germany, Republic of Finland, French Republic, Swiss Confederation, Republic of Estonia, Japan;

the strategic medicinal product is included by the World Health Organization (hereinafter referred to as WHO) in the Emergency use listing (EUL);

a favorable ratio of the benefit to the patient or public health obtained from the conditional state registration of a strategic medicinal product for emergency use and the risk associated with the lack of complete clinical data on the medicinal product (the “benefit-risk ratio”) has been established, and (or) there is an approval of the strategic medicinal product for emergency use in one of the foreign countries (if available).

11. State registration (confirmation of state registration) of strategic medicinal products may be carried out in a simplified procedure if they meet one of the following criteria:

strategic medicinal products are registered by an authorized body of one of the following countries: the Commonwealth of Australia, the Republic of Austria, the Grand Duchy of Luxembourg, Hungary, the Hellenic Republic, Ireland, the Italian Republic, Canada, the Kingdom of Belgium, the Kingdom of Denmark, the Kingdom of Spain, the Kingdom of the Netherlands, the Kingdom of Sweden, Republic of Latvia, Republic of Lithuania, Portuguese Republic, Republic of Bulgaria, Republic of Cyprus, Republic of Malta, Republic of Poland, Republic of Slovenia, Republic of Croatia, Romania, Slovak Republic, Great Britain and Northern Ireland, United States of America, Federal Republic of Germany, Republic of Finland, French Republic, Swiss Confederation, Republic of Estonia, Japan;

strategic medicinal products are registered by the authorized body of the European Union under a centralized procedure;

strategic medicinal products are vaccines or medicinal products intended for the treatment of tuberculosis, hepatitis C, HIV infection and have undergone the World Health Organization (hereinafter referred to as WHO) prequalification program in accordance with the Joint Procedure between WHO/PQT and HPO for the Evaluation and Acceleration of State Registration of Pharmaceuticals and Vaccines Prequalified by WHO, dated May 16, 2018;

strategic medicinal products are medicines of traditional Chinese medicine.

State registration (confirmation of state registration) in a simplified procedure shall not be carried out in respect of strategic medicinal products which are homeopathic medicinal preparations, medicinal preparations based on medicinal plant raw materials, vitamin and mineral complexes, except for strategic medicinal products specified in indent five of part one of this clause.

12. For state registration (confirmation of state registration) of strategic medicinal products, the applicant shall submit to the Ministry of Health an application and the Center’s report on:

compliance (non-compliance) of a strategic medicinal product with safety, efficiency and quality requirements - based on the results of the complex of preliminary technical works preceding state registration (confirmation of state registration) of a strategic medicinal product carried out under the standard procedure, conditionally, under a simplified procedure, introduction of amendments to

the registration dossier of a strategic medicinal product registered under the standard procedure, conditionally, under a simplified procedure;

the possibility (impossibility) of emergency use of a strategic medicinal product - based on the results of the complex of preliminary technical 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.

In case of simultaneous introduction of several amendments to the registration dossier, the applicant shall submit an application and the Center's report on compliance (non-compliance) of the strategic medicinal product with the safety, efficiency and quality requirements or on the possibility (impossibility) of emergency use of the strategic medicinal product for each amendment made separately.

To make a decision on the possibility (impossibility) of state registration (confirmation of state registration) of strategic medicinal products, the Center, with the written consent of the holder of the registration certificate, provides the Ministry of Health with access to the documents that make up the registration dossier.

13. Based on the results of consideration of the documents submitted by the applicant, the Ministry of Health, taking into account the recommendations of the Commission for Medicinal Products of the Ministry of Health, takes one of the following decisions:

on the refusal to accept the application, indicating the reasons for the refusal;

on state registration (confirmation of state registration) of a strategic medicinal product under standard procedure;

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

on conditional state registration of a strategic medicinal product for emergency use with indication of obligations imposed on the holder of the registration certificate;

on the state registration (confirmation of state registration) of a strategic medicinal product in a simplified manner;

on amendments to the registration dossier;

on the refusal of state registration (confirmation of state registration) of a strategic medicinal product under standard procedure indicating the reasons for the refusal;

on the refusal of conditional state registration (confirmation of conditional state registration) of a strategic medicinal product, indicating the reasons for the refusal;

on the refusal of conditional state registration of a strategic medicinal product for emergency use, indicating the reasons for the refusal;

on the refusal to state registration of a strategic medicinal product in a simplified manner, indicating the reasons for the refusal;

on refusal to make amendments in the registration dossier with indication of the reasons for refusal.

Decisions specified in part one of this clause shall be formalized by the order of the Ministry of Health.

14. The Ministry of Health may deny state registration (confirmation of state registration) of a strategic medicinal product, making amendments in the registration dossier, to an applicant in cases stipulated by Article 25 of Law of the Republic of Belarus No 433-З dated October 28, 2008 "On Principles of Administrative Procedures" and part twenty-two of Article 10 of Law of the Republic of Belarus "On Circulation of Medicinal Products".

15. The applicant is notified in writing by the Ministry of Health of the decision taken in accordance with clause 13 of this Provision no later than five working days from the date of its adoption, and in the event of a decision on state registration (confirmation of state registration) of a strategic medicinal product, also of the obligation to pay the state fee in accordance with the law.

16. After receiving a written notification of the state registration (confirmation of state registration) of a strategic medicinal product, the applicant or the holder of the registration certificate shall pay the state fee in accordance with the law.

17. Based on the results of the state registration (confirmation of state registration) of a strategic medicinal product, after confirmation of payment of the state fee to the republican budget in the manner prescribed by the Tax Code of the Republic of Belarus, the holder of the registration certificate is issued by the Ministry of Health:

within five working days - registration certificate;

within fifteen working days - the documents specified in part eighteen of Article 10 of the Law of the Republic of Belarus "On Circulation of Medicinal Products".

18. The Ministry of Health issues a registration certificate:

on state registration (confirmation of state registration) of a strategically important medicinal product under the standard procedure or in a simplified manner in accordance with the form in accordance with Appendix 1;

on conditional state registration (confirmation of conditional state registration) of a strategically important medicinal product according to the form in accordance with Appendix 2;

on conditional state registration of a strategically important medicinal product for emergency use according to the form in accordance with Appendix 3.

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

simultaneously in several formulations, a registration certificate is issued for each formulation;

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

simultaneously in the same formulation, but with different dosages, one registration certificate is issued;

in one formulation, but having different tastes (flavoring additives), different registration certificates are issued.

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

18[1]. If amendments made to the registration dossier simultaneously entail changes in the information contained in the State Register of Medicinal Products of the Republic of Belarus (hereinafter referred to as the State Register), as well as information contained in the previously issued registration certificate and (or) its appendix, the Ministry of Health shall issue a new registration certificate with its appendix. The validity period of such registration certificate shall be set within the validity period of the registration certificate issued upon state registration (confirmation of state registration) of the strategic medicinal product.

The decision to issue a new registration certificate with its appendix shall be formalized by an order of the Ministry of Health.

Based on the decisions of the Ministry of Health on state registration (confirmation of state registration) of a strategic medicinal product, amendments to the registration dossier, issuance of a new registration certificate with its appendix, the Center shall include relevant information into the State Register within five working days.

19. The form of the registration certificate, including its appendix, is a document with a certain degree of protection.

20. State registration (confirmation of state registration) of strategic medicinal products, introduction of amendments to the registration dossier shall be carried out within the terms stipulated in subclauses 9.4.3, 9.4.13-9.4.19 of clause 9.4 of the Unified List of Administrative Procedures carried out in relation to business entities, approved by Resolution of the Council of Ministers of the Republic of Belarus No. 548 dated September 24, 2021.

21. The Ministry of Health may decide to suspend the validity of the registration certificate issued in accordance with clause 18 of this Provision for a period not exceeding six months in the cases stipulated in part twenty-third of Article 10 of the Law of the Republic of Belarus "On Circulation of Medicinal Products".

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

22. The Center, based on the decision of the Ministry of Health to suspend the registration certificate, shall include this information into the State Register within five working days from the date of the decision.

23. For the period of suspension of the registration certificate, its validity shall not be prolonged, except for cases when the court decision recognizes the suspension of its validity as unlawful.

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

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

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

Written notification on elimination of the circumstances that led to suspension of the registration certificate with attachment of supporting documents shall be submitted to the Ministry of Health not later than 30 calendar days before the expiration of the established period of suspension.

26. The Ministry of Health shall take a decision, formalized by the order of the Ministry of Health, on renewal of the registration certificate, indicating the date of renewal.

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

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

27. The Ministry of Health shall take a decision, formalized by an order of the Ministry of Health, to terminate the validity of the registration certificate in the cases provided for in part twenty-four of Article 10 of the Law of the Republic of Belarus “On Circulation of Medicinal Products”, except for the case provided for in the indent two of the said part.

The Center shall include this information into the State Register within five working days from the date of the decision of the Ministry of Health to terminate the validity of the registration certificate.

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

28. Upon expiration of the term of validity of the registration certificate for a strategic medicinal product that has not undergone the procedure of confirmation of state registration, information on the date of termination of validity of the registration certificate shall be entered into the State Register.

Appendix 1
to the Provision on the procedure
and terms of state registration of
strategically important medicinal
products (as amended by Resolution of
the Council of Ministers of the Republic
of Belarus No. 441 dated 06.07.2023)

Form

MINISTRY OF HEATH
OF THE REPUBLIC OF BELARUS

REGISTRATION CERTIFICATE
of the state registration of a strategically important medicinal product under standard procedure or in a simplified manner
No. _____

This registration certificate is issued to _____
(name of the holder

_____
of the registration certificate indicating the country of the holder, his location)

_____
and is a confirmation that the Ministry of Health has registered

_____
(trade name of a strategically important medicinal product)

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

This registration certificate does not guarantee the purchase of this strategically important medicinal product.

Information on a strategically important medicinal product is presented according to the Appendix on __ pages in __ copies.

Date of state registration
(confirmation of state registration)
__ _____ 20__.

Valid until
__ _____ 20__

Minister of Health (Deputy Minister) _____ _____
(signature) (initials (initial of first name), surname)
L.S.

Appendix
to the registration certificate
of state registration (confirmation of state registration) of a strategically important medicinal product under standard procedure or in a simplified manner
No. _____

INFORMATION
about a strategically important medicinal product

1.Trade name of a strategically important medicinal product

_____

2. International nonproprietary name of a strategically important medicinal product (in case of absence of the international nonproprietary name, the common (grouping) name, scientific (chemical) name shall be indicated)

3. Formulation _____

4. Dosage (dosages) _____

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

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

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

7. Participants in the manufacture of a strategically important medicinal product:

_____

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

_____

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

_____

(name of the manufacturer filling strategically important medicinal product, location of manufacturing site(s))

_____

(name of the manufacturer packaging strategically important medicinal product, location of manufacturing site(s))

_____

(name of the manufacturer responsible for quality control of the strategically important medicinal product, location of manufacturing site(s))

_____

(name of the manufacturing participant issuing authorization for the release of a batch of a strategically important medicinal product, location of manufacturing site(s))

_____

(names of other participants in the manufacture of a strategically important medicinal product (pharmaceutical substance), location of manufacturing sites (if any) with indication of the type of work)

8. Expiration date of a strategically important medicinal product _____

9. Storage conditions _____

10. A strategically important medicinal product is being sold (underline as appropriate):
by a doctor's prescription;
without a doctor's prescription;
for the provision of medical care in hospitals.

11. Is (is not) a narcotic drug (underline as appropriate).

12. Is (is not) a psychotropic substance (underline as appropriate).

13. Included (not included) in the list “A” (underline as appropriate).

Date of state registration
(confirmation of state registration)
__ _____ 20__.

Valid until
__ _____ 20__

Date of amendments
to the registration dossier
__ _____ 20__.

Valid until
__ _____ 20__

Minister of Health (Deputy Minister) _____ _____

(signature) (initials (initial of first name), surname)

L.S.

Appendix 2
to the Provision on the procedure and terms of state registration of strategically important medicinal products (as amended by Resolution of the Council of Ministers of the Republic of Belarus No. 441 dated 06.07.2023)

Form

MINISTRY OF HEATH
OF THE REPUBLIC OF BELARUS

REGISTRATION CERTIFICATE
of conditional state registration of a strategically important medicinal product
No. _____

This registration certificate is issued to _____
(name of the holder

_____
of the registration certificate indicating the country of the holder, his location)

_____
and is a confirmation that the Ministry of Health has registered

_____
(trade name of a strategically important medicinal product)

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

This registration certificate does not guarantee the purchase of this strategically important medicinal product.

Information on a strategically important medicinal product is presented according to the Appendix on __ pages in __ copies.

Date of conditional state registration (confirmation of conditional state registration) __ _____ 20__.

Valid until __ _____ 20__

Minister of Health (Deputy Minister) _____ _____

(signature) (initials (initial of first name), surname)

L.S.

Appendix
to the registration certificate
of conditional state registration
(confirmation of conditional state
registration) of a strategically important
medicinal product
No. _____

INFORMATION
about a strategically important medicinal product

1.Trade name of a strategically important medicinal product

_____

2. International nonproprietary name of a strategically important medicinal product (in case of absence of the international nonproprietary name, the common (grouping) name, scientific (chemical) name shall be indicated)

3. Formulation _____

4. Dosage (dosages) _____

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

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

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

7. Participants in the manufacture of a strategically important medicinal product:

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

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

_____
(name of the manufacturer filling strategically important medicinal product, location of manufacturing site(s))

_____
(name of the manufacturer packaging strategically important medicinal product, location of manufacturing site(s))

_____
(name of the manufacturer responsible for quality control of the strategically important medicinal product, location of manufacturing site(s))

_____
(name of the manufacturing participant issuing authorization for the release of a batch of a strategically important medicinal product, location of manufacturing site(s))

_____
(names of other participants in the manufacture of a strategically important medicinal product (pharmaceutical substance), location of manufacturing sites (if any) with indication of the type of work)

8. Expiration date of a strategically important medicinal product _____

9. Storage conditions _____

10. A strategically important medicinal product is being sold (underline as appropriate):
by a doctor's prescription;
without a doctor's prescription;
for the provision of medical care in hospitals.

11. Is (is not) a narcotic drug (underline as appropriate).

12. Is (is not) a psychotropic substance (underline as appropriate).

13. Included (not included) in the list “A” (underline as appropriate).

14. Obligations established upon conditional state registration (confirmation of conditional state registration) of a strategically important medicinal product,
_____

Date of conditional state registration (confirmation of conditional state registration) __ _____ 20__.

Valid until __ _____ 20__

Date of amendments to the registration dossier __ _____ 20__.

Valid until __ _____ 20__

Minister of Health (Deputy Minister) _____ _____

(signature) L.S.

(initials (initial of first name), surname)

Appendix 3
to the Provision on the procedure and terms of state registration of strategically important medicinal products (as amended by Resolution of the Council of Ministers of the Republic of Belarus No. 441 dated 06.07.2023)

Form

MINISTRY OF HEATH
OF THE REPUBLIC OF BELARUS

REGISTRATION CERTIFICATE
of conditional state registration of a strategically important medicinal product for emergency use
No. _____

This registration certificate is issued to _____
(name of the holder

_____
of the registration certificate indicating the country of the holder, his location)

_____
and is a confirmation that the Ministry of Health has registered

_____
(trade name of a strategically important medicinal product)

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

This registration certificate does not guarantee the purchase of this strategically important medicinal product.

Information on a strategically important medicinal product is presented according to the Appendix on __ pages in __ copies.

Date of conditional state registration
for emergency use
__ _____ 20__.

Valid until
__ _____ 20__

Valid until
__ _____ 20__

Date of amendments
to the registration dossier
__ _____ 20__.

Minister of Health (Deputy Minister) _____ _____

(signature) (initials (initial of first name), surname)

L.S.

Appendix
to the registration certificate
of conditional state registration of a
strategically important medicinal product
for emergency use
No. _____

INFORMATION
about a strategically important medicinal product

1.Trade name of a strategically important medicinal product

_____

2. International nonproprietary name of a strategically important medicinal product (in case of absence of the international nonproprietary name, the common (grouping) name, scientific (chemical) name shall be indicated)

3. Formulation _____

4. Dosage (dosages) _____

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

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

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

7. Participants in the manufacture of a strategically important medicinal product:

_____

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

_____

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

_____

(name of the manufacturer filling strategically important medicinal product, location of manufacturing site(s))

_____

(name of the manufacturer packaging strategically important medicinal product, location of manufacturing site(s))

_____

(name of the manufacturer responsible for quality control of the strategically important medicinal product, location of manufacturing site(s))

_____

(name of the manufacturing participant issuing authorization for the release of a batch of a strategically important medicinal product, location of manufacturing site(s))

_____

(names of other participants in the manufacture of a strategically important medicinal product (pharmaceutical substance), location of manufacturing sites (if any) with indication of the type of work)

8. Expiration date of a strategically important medicinal product _____

9. Storage conditions _____

10. A strategically important medicinal product is being sold (underline as appropriate):

by a doctor's prescription;

without a doctor's prescription;

for the provision of medical care in hospitals.

11. Is (is not) a narcotic drug (underline as appropriate).

12. Is (is not) a psychotropic substance (underline as appropriate).

13. Included (not included) in the list "A" (underline as appropriate).

14. Obligations established upon conditional state registration of a strategically important medicinal product for emergency use,

_____

Date of conditional state registration for emergency use __ _____ 20__.

Valid until __ _____ 20__

Date of amendments to the registration dossier __ _____ 20__.

Valid until __ _____ 20__

Minister of Health (Deputy Minister) _____ _____

(signature) L.S.

(initials (initial of first name), surname)