



Registration of strategically important drugs for circulation on the market of the Republic of Belarus

ADOPTED by Decision of the Council of the Eurasian Economic Commission No 78 of 3 November 2016



Point 3 «GENERAL PROVISIONS» RULES of authorization and assessment of medicinal products for human use

3. The requirements of these Rules **do not apply to:**

- a) medicinal products intended for use during warfare, **emergencies**, for prevention and treatment of diseases and injuries due to release of chemical, biological, radiation hazards, and developed under the order of the Member States competent authorities for safety and defense and whose **circulation is regulated by the Member States legislation;**

RESOLUTION OF THE COUNCIL OF MINISTERS OF THE REPUBLIC OF BELARUS
October 8, 2021 No. 570 «On state registration of strategically important medicinal products» the following definition of emergency situation is given

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.**



strategically important medicinal products (hereinafter, unless otherwise specified, strategic medicinal products) - medicinal products 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.

The list of strategically important medicinal products is determined by the Ministry of Health:

Web site rceth.by



MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
"CENTER FOR EXAMINATIONS AND TESTS IN HEALTH SERVICE"
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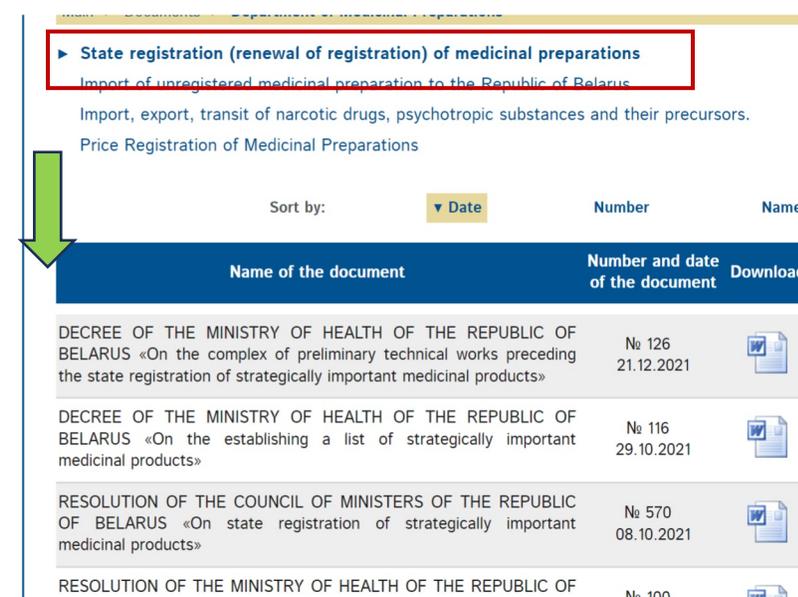
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Department of Medicinal Preparations
Department of Medical Equipment
Republican Clinical and Pharmacological Laboratory
Laboratory of Pharmacopoeial and Pharmaceutical Analysis
Republican Control and Analytical Laboratory

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▶ State registration (renewal of registration) of medicinal preparations

- Department of Medicinal Preparations
- Department of Medical Equipment
- Republican Clinical and Pharmacological Laboratory
- Laboratory of Pharmacopoeial and Pharmaceutical Analysis
- Republican Control and Analytical Laboratory



▶ State registration (renewal of registration) of medicinal preparations
Import of unregistered medicinal preparation to the Republic of Belarus
Import, export, transit of narcotic drugs, psychotropic substances and their precursors.
Price Registration of Medicinal Preparations

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Types of procedures for state registration of strategically important medicinal products



RESOLUTION OF THE COUNCIL OF MINISTERS OF THE REPUBLIC OF BELARUS No. 570 :

1) **under operating procedure** (duration - 180 days)

Validity REGISTRATION CERTIFICATE **5 years**

2) **conditional** (duration - 180 days)

Validity REGISTRATION CERTIFICATE **1 year**

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.

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 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

3) **conditional for emergency use** (duration **15 days**);

Validity REGISTRATION CERTIFICATE **1 year**

4) **in a simplified manner** (duration **30 days**)

Validity REGISTRATION CERTIFICATE **5 years**

The medicinal product is registered by **authorized bodies of foreign countries**: the Commonwealth of Australia, the Republic of Austria, the United States of America, Canada, the Swiss Confederation, Japan, the United Kingdom of Great Britain and Northern Ireland, the Federal Republic of Germany, the Kingdom of Denmark, the Kingdom of the Netherlands, the Kingdom of Sweden, the Kingdom of Spain, the Portuguese Republic ;

2. The medicinal product is registered by the **authorized body of the European Union under a centralized procedure**, for use on the territory of the states: the Commonwealth of Australia, the Republic of Austria, the United States of America, Canada, the Swiss Confederation, Japan, the United Kingdom of Great Britain and Northern Ireland, the Federal Republic of Germany, the Kingdom of Denmark, Kingdom of the Netherlands, Kingdom of Sweden, Kingdom of Spain, Portuguese Republic;

3. strategic drugs **are vaccines or medicines, intended for the treatment of tuberculosis, hepatitis C, HIV infection, and have undergone prequalification program of the World Health Organization (hereinafter - WHO)**



Special features requirements for registration dossier documents when registering strategically important medicinal products



DECREE OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS «On the complex of **preliminary technical works preceding the state registration of strategically important medicinal products**» №126 21.12.2021

- Registration dossier documents are submitted in paper form, some documents may be submitted in the form of electronic copies;
- **No GMP inspection** is required for compliance with the EAEU GMP requirements or national requirements. **GMP certificate issued in the country of production is accepted;**
- Approbation of methods for quality control of a strategic drug and quality control of this strategic drug is required **only** for state registration of a strategic drug according to the **operating procedure** ;
Approbation of quality control methods is **not required** during registration on **conditional, conditional for emergency use and in a simplified manner types of procedures** for state registration of strategically important medicinal products;
- Part of the registration dossier **documents can be presented in English**: documents 4.5 modules, master file of the pharmacovigilance system. The listed documents can be submitted **in the form of electronic copies and on electronic media;**
- Registration of **primary and secondary packaging in foreign languages with a sticker in Russian (Belarusian) is allowed.**



Indicators of registration of strategically important drugs as of 09/ 2023



Applications submitted TOTAL for 2022 – 2023 : **161** applications

2022 year: 65 applications

- **under operating procedure** 44 applications
- **in a simplified manner** 19 applications
- **conditional for emergency use** 3 applications

2023 year : 96 applications

- **under operating procedure** 80 applications
- **in a simplified manner** 16 applications

Issued as of **09/ 2023** - **43** REGISTRATION CERTIFICATE (**RC**)

21 RC– **under operating procedure**

17 RC **in a simplified manner**

3 RC – **conditional registration;**

2 RC **conditional for emergency use**





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