APPROVED
Order of the Director
of the Republican Unitary Enterprise "Center for Examinations
and Tests in Health Service"
25.02.2026 № 47
(as amended on 30.06.2026 № 179)
Effective from 01.07.2026

Price List No. 5
for the performance of a set of preliminary technical activities related to expert examinations for confirming the compliance of strategically important medicinal products with the requirements for safety, efficacy, and quality, preceding the state registration (re-registration) under the standard procedure, conditional state registration (re-registration), conditional state registration for emergency use, state registration (re-registration) under the simplified procedure, and making changes to the registration dossiers of strategically important medicinal products

Seq. No.	Description of works (services)	Unit of measurement	Fee excluding VAT, BYN
1	Set of preliminary technical activities preceding the state registration of a strategically important medicinal product under the standard procedure (conditional state registration of a strategically important medicinal product)		
1.1	Conducting primary expert examination of documents for state registration of a strategically important medicinal product under the standard procedure (conditional state registration of a strategically important medicinal product)	service	356,0
1.2	Conducting specialized expert examination of documents for state registration of a strategically important medicinal product under the standard procedure (conditional state registration of a strategically important medicinal product)	service	10 720,0
2	Set of preliminary technical activities preceding the re-registration of a strategically important medicinal product under the standard procedure (confirmation of conditional state registration of a strategically important medicinal product)		
2.1	Conducting primary expert examination of documents for the re-registration of a strategically important medicinal product under the standard procedure (confirmation of conditional state registration of a strategically important medicinal product)	service	254,0
2.2	Conducting specialized expert examination of documents for the re-registration of a strategically important medicinal product under the standard procedure (confirmation of conditional state registration of a strategically important medicinal product)	service	4 233,0
3	Set of preliminary technical activities preceding the state registration (re-registration) of a strategically important medicinal product under the simplified procedure	service	4 053,0
4	Set of preliminary technical activities related to the expert examination of documents for conditional state registration of a strategically important medicinal product for	service	1 353,0

	emergency use		
5	A set of preliminary technical works preceding amendments to the registration dossier of a strategically important medicinal product registered under the standard procedure, conditionally, under simplified procedure or conditionally for emergency use		
5.1	Conducting primary expert examination of documents for making changes to the registration dossier of a strategically important medicinal product registered under the standard procedure, conditionally, under the simplified procedure or conditionally for emergency use	service	335,0
5.2	Conducting specialized expert examination of documents for making changes to the registration dossier of a strategically important medicinal product registered under the standard procedure, conditionally, under the simplified procedure or conditionally for emergency use	service	1 851,0

Note:

1. The fees of this price list are effective within the territory of the Republic of Belarus and shall apply to the services for the performance of a set of preliminary technical activities related to expert examinations to confirm the compliance of a strategically important medicinal product with the requirements for safety, efficacy and quality (hereinafter — SPTA), preceding the state registration (re-registration) under the standard procedure, conditional state registration (confirmation of conditional state registration), conditional state registration for emergency use, state registration (re-registration) under the simplified procedure, and making changes to the registration dossiers of strategically important medicinal products, carried out by the Republican Unitary Enterprise "Centre for Examinations and Tests in Health Service".

2. The cost of services under this price list shall be converted into the payment currency selected for payment at the exchange rate of the National Bank of the Republic of Belarus as of the date of the service agreement.

3. The costs of chemical, toxicological, clinical (medical) trials, bioequivalence and other studies, materials, support activities and services required for performing the SPTA preceding the state registration (re-registration) under the standard procedure, conditional state registration (confirmation of conditional state registration), conditional state registration for emergency use, state registration (re-registration) under the simplified procedure, or making changes to the registration dossier of a strategically important medicinal product, shall be paid by the applicant additionally at the fees approved in the established manner, in accordance with the work descriptions.

4. State duty to the Republican budget for the state registration (re-registration) under the standard procedure, conditional state registration (confirmation of conditional state registration), conditional state registration for emergency use, or state registration (re-registration) under the simplified procedure shall be charged additionally in the manner and in accordance with the current legislation of the Republic of Belarus.

5. Upon the applicant’s request, the expert examination of documents for making changes to the registration dossier of a strategically important medicinal product under clauses 4.2, 4.3, 4.5, 4.8, 4.9, 4.10, 4.11, 4.13, 4.16, 4.18, 4.19, 4.20, 4.21, 4.24 of Annex 1 to the Resolution of the Ministry of Health of the Republic of Belarus No. 126 dated December 21, 2021 "On the List of Strategically Important Medicinal Products and the Set of Preliminary Technical Activities Preceding Their State Registration," may be carried out under the accelerated procedure. In case of conducting an accelerated expert examination of documents, a coefficient of 2 shall be applied to the fees set forth in clause 5 of this price list.

6. Upon the applicant’s request to correct only technical errors (clerical errors) when making changes to the registration dossier of a strategically important medicinal product, where the submission of

a full set of documents is not required under the legislation of the Republic of Belarus, a fee in the amount of 50% of the fee set forth in clause 5 of this price list shall be charged.

7. In case of performing the SPTA preceding the state registration (re-registration) under the standard procedure, conditional state registration (confirmation of conditional state registration), conditional state registration for emergency use, state registration (re-registration) under the simplified procedure, or making changes to the registration dossiers of a foreign-made strategically important medicinal product, a coefficient of 2 shall be applied to the fees provided for in this price list.

8. By order of the Ministry of Health of the Republic of Belarus, the performance of the SPTA preceding the state registration (re-registration) under the standard procedure, conditional state registration (confirmation of conditional state registration), conditional state registration for emergency use, state registration (re-registration) under the simplified procedure, or making changes to the registration dossier of a strategically important medicinal product, performed by the Republican Unitary Enterprise "Centre for Examinations and Tests in Health Service," and certain names of strategically important medicinal products, may be performed without charging a fee.

9. If it is necessary to amend the registration dossier of a medicinal product solely to change, in the Summary of Product Characteristics and the package leaflet, the details of the organisation in the territory of the Republic of Belarus to which suspected adverse reactions to the medicinal product should be reported (the SPC section "4.8. Undesirable effects. Reporting of suspected adverse reactions" and the package leaflet section "Reporting of adverse reactions"), a fee of 4% of the rates provided for in items 5.1 and 5.2 of this price list shall be charged.