APPROVED
Order of the Director of the
Republican Unitary Enterprise "Center for Examinations and Tests in Health Service"
dated January 21, 2022, No. 17
(as amended on 25.02.2026 № 46;
as amended on 30.06.2026 № 180)
Effective from 01.07.2026

Price List No. 4

for a set of preliminary technical works related to examinations preceding the state registration of pharmaceutical substances, making variations to the registration dossier of medicinal products previously registered in the Republic of Belarus, and obtaining permits for the import and (or) export of narcotic drugs, psychotropic substances, and their precursors restricted for movement across the State Border of the Republic of Belarus on non-economic grounds

Seq. No.	**Description of services**	Unit of measurement	Fee excluding VAT in US dollars
1	**Conducting a primary examination**		
1.1	Conducting primary expert examination of documentation for state registration of a domestically produced pharmaceutical substance	service	143,0
1.2	Conducting a primary examination of documentation for the state registration of a foreign-produced pharmaceutical substance, the registration certificate holder of which will be a legal entity of the Republic of Belarus holding a special permit (license) for pharmaceutical activities	service	143,0
1.3	Conducting a primary examination of documentation for the state registration of a foreign-produced pharmaceutical substance	service	143,0
1.4	Conducting primary expert examination of documentation for making changes to the marketing authorization dossier of a medicinal product	service	120,0
2	**Conducting specialized expert examination**		
2.1	Conducting specialized expert examination of documentation for state registration of a domestically produced pharmaceutical substance	service	701,0
2.1.1	Expert examination of documents by experts	service	556,0

2.1.2	Expert examination of documents by external experts	service	289,0
2.2	Conducting expert examination of documentation for state registration of a foreign-made pharmaceutical substance, where the marketing authorization holder shall be a legal entity of the Republic of Belarus holding a special permit (license) for pharmaceutical activities.	service	689,0
2.2.1	Expert examination of documents by experts	service	278,0
2.2.2	Expert examination of documents by external experts	service	145,0
2.3	Conducting specialized expert examination of documentation for state registration of foreign-made pharmaceutical substances	service	701,0
2.3.1	Expert examination of documents by experts	service	556,0
2.3.2	Expert examination of documents by external experts	service	289,0
2.4	Conducting expert examination of documentation for making changes to the registration dossier of a medicinal product		
2.4.1	Organization of activities for conducting expert examination of documentation for making changes to the registration dossier of a medicinal product	service	517,0
2.4.2	Conducting expert examination of documentation for adding a new indication and (or) a new route of administration to the summary of product characteristics, instructions for medical use of a medicinal product and (or) the package leaflet		
2.4.2.1	Expert examination of documents by experts	One expert examination of documents by one expert	552,0
2.4.2.2	Expert examination of documents by external experts	One expert examination of documents by one expert	271,0
2.4.3	Conducting expert examination of documentation for deleting a previously approved indication and (or) route of administration from the summary of product characteristics, instructions for medical use and (or) the package leaflet, as well as for making changes to the pharmacological and clinical sections of the summary of product characteristics, instructions for medical use and (or) the package leaflet		
2.4.3.1	Expert examination of documents by experts	One expert examination of	552,0

		documents by one expert	
2.4.3.2	Expert examination of documents by external experts	One expert examination of documents by one expert	271,0
2.4.4	Conducting expert examination of documentation for making changes to the sections of instructions for medical use of a medicinal product and (or) the package leaflet, excluding pharmacological and clinical sections	One expert examination of documents by one expert	147,0
2.4.5	Conducting expert examination of documentation for making changes to the composition of a medicinal product (replacement or introduction of an additional manufacturer of a pharmaceutical substance; introduction, exclusion or replacement of excipients)		
2.4.5.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	417,0
2.4.5.2	Pharmacological expert examination	One expert examination of documents by one expert	221,0
2.4.6	Conducting expert examination of documentation for making changes to the "Composition" section of the medicinal product registration dossier (provided that the changes do not affect the actual composition of the medicinal product)		
2.4.6.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	139,0
2.4.6.2	Pharmacological expert examination	One expert examination of documents by one expert	221,0

2.4.7	Conducting expert examination of documentation for making changes to the quality control specification (including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product containing this pharmaceutical substance) upon changes in quality attributes, control methods, or testing procedures		
2.4.7.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	278,0
2.4.7.2	Pharmacological expert examination	One expert examination of documents by one expert	221,0
2.4.7.3	Chemical and pharmaceutical expert examination by external experts	One expert examination of documents by one expert	145,0
2.4.8	Conducting expert examination of documentation for changing the shelf life of a medicinal product (including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product containing this pharmaceutical substance)		
2.4.8.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	208,0
2.4.8.2	Pharmacological expert examination	One expert examination of documents by one expert	221,0
2.4.9	Conducting expert examination of documentation for changing the storage conditions of a medicinal product (including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product containing this pharmaceutical substance)		
2.4.9.1	Chemical and pharmaceutical expert examination	One expert examination of documents	208,0

		by one expert	
2.4.9.2	Pharmacological expert examination	One expert examination of documents by one expert	221,0
2.4.10	Conducting expert examination of documentation for making changes to the registration dossier upon submission of an updated draft quality control specification (including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product containing this pharmaceutical substance) in the event of changes in quality attributes, control methods, or testing procedures		
2.4.10.1	Expert examination of documents by experts	One expert examination of documents by one expert	441,0
2.4.10.2	Expert examination of documents by external experts	One expert examination of documents by one expert	217,0
2.4.11	Conducting expert examination of documentation for changing the material, type of primary packaging, or packaging components of a medicinal product (including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product containing this pharmaceutical substance)		
2.4.11.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	77,0
2.4.11.2	Pharmacological expert examination	One expert examination of documents by one expert	82,0
2.4.12	Conducting expert examination of documentation for making changes to the manufacturing process of a medicinal product (including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product containing this pharmaceutical		

	substance)		
2.4.12.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	278,0
2.4.12.2	Pharmacological expert examination	One expert examination of documents by one expert	221,0
2.4.13	Conducting expert examination of documentation for making changes to the design of mock-ups for primary and (or) secondary and (or) intermediate packaging of a medicinal product (if any), or introduction of additional mock-ups for primary and (or) secondary and (or) intermediate packaging with different design (if any).	One expert examination of documents by one expert	74,0
2.4.14	Conducting expert examination of documentation for changing the number of doses in the primary and (or) secondary and (or) intermediate packaging of a medicinal product, or the quantity of a pharmaceutical substance in the packaging of a pharmaceutical substance		
2.4.14.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	69,0
2.4.14.2	Pharmacological expert examination	One expert examination of documents by one expert	74,0
2.4.15	Conducting expert examination of documentation for changing the name of a medicinal product, the name of a dosage form, or the method of dosage indication (for a medicinal product)		
2.4.15.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	139,0
2.4.15.2	Pharmacological expert examination	One expert examination	147,0

		of documents by one expert	
2.4.16	Conducting expert examination of documentation for reorganization and (or) change of name and (or) address without changing the actual location of the medicinal product manufacturer, the applicant and (or) the marketing authorization holder, including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product		
2.4.16.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	139,0
2.4.16.2	Pharmacological expert examination	One expert examination of documents by one expert	147,0
2.4.17	Conducting expert examination of documentation for changing the manufacturer or the country of manufacture (replacement or addition of a new manufacturing site for some or all manufacturing processes — for medicinal products; replacement or addition of a new manufacturing site for some manufacturing processes — for pharmaceutical substances), including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product		
2.4.17.1	Chemical and pharmaceutical expert examination	One expert examination of documents by one expert	278,0
2.4.17.2	Pharmacological expert examination	One expert examination of documents by one expert	270,0
2.4.18	Conducting expert examination of documentation for changing the applicant and (or) the marketing authorization holder of a medicinal product.		
2.4.18.1	Chemical and pharmaceutical expert examination	One expert examination of	139,0

		documents by one expert	
2.4.18.2	Pharmacological expert examination	One expert examination of documents by one expert	74,0
2.4.19	Conducting expert examination of documentation for changing the format of the certificate of analysis/quality certificate (certificate design) for a medicinal product.	One expert examination of documents by one expert	74,0
3	Conducting expert examination of documentation on the possibility of issuing permits for the import and (or) export of narcotic drugs, psychotropic substances and their precursors restricted for movement across the State Border of the Republic of Belarus on non-economic grounds.	service	154,0

Note:

1. The fees of this price list are effective within the territory of the Republic of Belarus and shall apply to the services rendered by the Republican Unitary Enterprise "Centre for Examinations and Tests in Health Service" for the performance of a set of preliminary technical activities related to expert examinations preceding the state registration of pharmaceutical substances, making changes to the registration dossier of medicinal products, and obtaining permits for the import and (or) export of narcotic drugs, psychotropic substances and their precursors restricted for movement across the State Border of the Republic of Belarus on non-economic grounds, for non-resident applicants of the Republic of Belarus.

2. The fees of this price list are differentiated by groups of medicinal products and the complexity of the expert examination of the documentation submitted for consideration.

3. The costs of chemical, toxicological, clinical (medical) trials, bioequivalence and other studies, materials, support activities and services required for the set of activities preceding the state registration of pharmaceutical substances or making changes to the registration dossier of

medicinal products, in accordance with the attached work descriptions, shall be paid by the applicant additionally at the fees approved in the established manner.

4. State duty to the Republican budget for the state registration of pharmaceutical substances shall be charged additionally in the manner and in accordance with the current legislation of the Republic of Belarus.

5. In case of conducting expert examination of documentation for making changes to the registration dossier of a medicinal product (pharmaceutical substance), an additional fee in the amount of 10% of the fee provided for in sub-clauses 2.4.13, 2.4.14, 2.4.15, 2.4.16, 2.4.17 of clause 2 of the price list shall be charged for the second and each subsequent pack size or dosage.

6. In case of conducting expert examination of documentation for a medicinal product or a pharmaceutical substance related to a change in the name of the medicinal product/pharmaceutical substance or the name of the manufacturer, a change of the manufacturer (country of manufacture), or registration for other plants of the same company, an additional fee in the amount of 10% of the fee provided for in sub-clauses of the price list shall be charged for the second and each subsequent pack size or dosage.

7. Payments by non-residents for the performance of a set of preliminary technical activities related to expert examinations preceding the state registration of pharmaceutical substances, making changes to the registration dossier of medicinal products, and obtaining permits for the import and (or) export of narcotic drugs, psychotropic substances and their precursors restricted for movement across the State Border of the Republic of Belarus on non-economic grounds, shall be performed in accordance with the current currency legislation of the Republic of Belarus.

8. By order of the Ministry of Health of the Republic of Belarus, the performance of a set of preliminary technical activities related to expert examinations preceding the state registration of pharmaceutical substances, making changes to the registration dossier of medicinal products, and obtaining permits for the import and (or) export of narcotic drugs, psychotropic substances and their precursors restricted for movement across the State Border of the Republic of Belarus on non-economic grounds, and certain names of medicinal products, may be performed without charging a fee.

9. In case of conducting expert examination of documentation for making

changes to the registration dossier (including cases where documentation of the pharmaceutical substance manufacturer is included in the registration dossier of the medicinal product containing this pharmaceutical substance) 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 10% of the fee provided for in sub-clauses 2.4.7, 2.4.9, 2.4.11, 2.4.14 of clause 2 of the price list shall be charged.

10. In case of conducting an accelerated procedure for the expert examination of documentation for making changes to the registration dossier of a medicinal product (pharmaceutical substance), a coefficient of 2 shall be applied to the fees provided for in clause 1.4 and sub-clauses 2.4.1, 2.4.3, 2.4.4, 2.4.6, 2.4.8, 2.4.9, 2.4.11, 2.4.13, 2.4.14, 2.4.15, 2.4.16, 2.4.18 of the price list.

11. 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 5% of the rates provided for in items 1.4, 2.4.1 and 2.4.4 of this price list shall be charged.