APPROVED
Order of the Director
of the Republican Unitary Enterprise "Center for Examinations
and Tests in Health Service"
27.05.2026 № 134
(as amended on 30.06.2026 № 178)
Effective from 01.07.2026

Price List No. 2
for a set of examinations in the state of recognition, performed during registration (confirmation of registration) and other procedures related to the registration of medicinal products within the framework of the Eurasian Economic Union

Set of examinations in the state of recognition performed *during the registration of* a medicinal product - 1 and 2.

Set of examinations in the state of recognition, performed *during the confirmation of registration (re-registration)* of a medicinal product – 1, 3 and (if applicable) 5, 6 and/or 10.

Set of examinations in the state of recognition, performed *upon submission* of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union – 1 and 4.

Set of examinations in the state of recognition, performed during making minor variations of *type IA/IANU* to the registration dossier of a medicinal product – 1 and 5.

Set of examinations in the state of recognition, performed during making minor variations of *type IB* to the registration dossier of a medicinal product – 1 and 6.

Set of examinations in the state of recognition, performed during making major variations of *type II* to the registration dossier of a medicinal product – 1 and 7.

Set of examinations in the state of recognition, performed *during the expansion of registration* of a medicinal product – 1 and 8.

Set of examinations in the state of recognition, performed *during the registration* of a medicinal product *upon the initiative* of the member state's authorized body – 9.

Set of examinations in the state of recognition, performed during making unclassified variations of *type IB to the registration dossier of a medicinal product, concerning the administrative part of Module 1 of the RD* (Sections 1.2.3., 1.2.4., 1.3.4., 1.4.1., 1.6.1., 1.6.2., 1.6.6., 1.6.7., 1.6.8., 1.6.9., 1.11.) – 1 and 10.

Seq. No.	Description of works (services)	Unit of measurement	Fee excluding VAT, BYN	Fee excluding VAT, USD
1	Organization of work for Set of expert examinations performed during registration, confirmation of registration (re-registration), bringing the registration dossier of a medicinal product in compliance with the requirements of the Eurasian Economic Union, during amendments to the registration dossier of a medicinal product, during expansion of registration of a medicinal product	service	757,81	370,16

2	Examination of a medicinal product during registration	service	5 082,83	2 465,59
3	Examination of a medicinal product during the confirmation of registration (re-registration)	service	3 072,87	1 524,78
4	Examination of a medicinal product upon submission of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union	service	4 022,70	2 013,72
5	Examination of a medicinal product during making minor variations of type IA/IANU	service	778,51	375,26
6	Examination of a medicinal product during making minor variations of type IB	service	1 245,21	601,15
7	Examination of a medicinal product during making major variations of type II	service	1 971,49	952,52
8	Examination of a medicinal product during the expansion of registration	service	3 833,03	1 858,94
9	Technical support works, performed during the registration of a medicinal product upon the initiative of the member state's authorized body	service	239,76	116,70
10	Examination of a medicinal product during making unclassified variations of type IB concerning the administrative part of Module 1 of the RD	service	405,28	196,72

Note:

1. The fees of this price list are effective within the territory of the Republic of Belarus.

2. Settlements with non-residents of the Republic of Belarus for services (works) rendered (performed) in accordance with this price list shall be carried out in accordance with the legislation of the Republic of Belarus on currency regulation.

3. State duty to the Republican budget for registration, confirmation of registration (re-registration) of a medicinal product is charged additionally in the manner and in accordance with the current legislation of the Republic of Belarus.

4. The cost of services (works) under this price list shall be recalculated into the currency selected for payment at the exchange rate of the National Bank of the Republic of Belarus on the date of the Service Agreement.

5. The cost of chemical, toxicological, clinical trials, bioequivalence and other studies, materials, auxiliary works and services required for registration (confirmation of registration) and other procedures related to the registration of a medicinal product within the framework of the Eurasian Economic Union shall be paid by the applicant additionally at the fees approved in accordance with the established procedure.

6. Upon submission of a grouped application for variations to the registration dossier, the fee for the organization of works for a set of examinations shall be charged once at the rate of 100% of the fee established by sub-item 1; the fee for the examination of a medicinal product shall be charged at the rate of 100% of the fee for each type of examination established by sub-items 5, 6, 7, 8, 10 of this price list, and the fee for the examination of documents for each subsequent variation in the same group shall be additionally charged at the rate of 20% of the fee provided for by sub-items 5, 6, 7, 8, 10 of this price list.

7. Upon submission of an application for confirmation of registration (re-registration) of a medicinal product with type I variations to the registration dossier, the fee for the organization of works for a set of

examinations shall be charged once at the rate of 100% of the fee established by sub-item 1; the fee for the examination in terms of confirmation of registration (re-registration) of a medicinal product shall be charged at the rate of 100% of the fee established by sub-item 3; the fee for the examination in terms of making variations to the registration dossier of a medicinal product shall be charged at the rate of 100% of the fee for each type of examination established by sub-items 5, 6, 10 of this price list, and the fee for the examination of documents for each subsequent variation in the same group shall be additionally charged at the rate of 20% of the fee provided for by sub-items 5, 6, 10 of this price list.

8. For residents of the Republic of Belarus, when performing a set of examinations during registration (confirmation of registration) and other procedures related to the registration of a foreign-made medicinal product within the framework of the Eurasian Economic Union, a coefficient of 1,3 shall be applied to the fees of this price list when charging.

9. By order of the Ministry of Health of the Republic of Belarus, the set of examinations performed during registration (confirmation of registration) and other procedures related to the registration of a medicinal product within the framework of the Eurasian Economic Union, for specific names of medicinal products, may be performed without charge.

10. 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 and 5 of this price list shall be charged.