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 26.10.2026 № 282)
Effective from 09.11.2026

Price List No. 1
for a set of examinations in the reference state, implemented 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 expert examinations in the reference state performed *during registration of* a medicinal product (original, biosimilar, combined (new combination)) - 1, 2 and 3.

Set of examinations in the reference state performed *during registration of* a medicinal product (reproduced, hybrid, combined (known combination), well-studied) - 1, 2 and 4.

Set of examinations in the reference state, performed *upon submission* of the medicinal product registration dossier with the requirements of the Eurasian Economic Union, *with benefit-risk reassessment* (original, biosimilar, combined (new combination)) – 1, 2 and 5.

Set of examinations in the reference state, performed *upon submission* of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union, *without benefit-risk reassessment* (original, biosimilar, combined (new combination)) – 1, 2 and 7.

Set of examinations in the reference state, performed *during the confirmation of registration (re-registration)* of a medicinal product – 1, 2, 7 and (if applicable) 10, 11+12 and/or 11+15.

Set of examinations in the reference state, performed *upon submission* of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union, *without benefit-risk reassessment* – 1, 2 and 8.

Set of examinations in the reference state, performed *upon submission* of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union, *submitted pursuant to* the Decree of the Board of the Ministry of Health of the Republic of Belarus – 1, 2 and 9.

Set of expert examinations in the reference state performed when insignificant changes are made to the registration dossier of a medicinal product of *IA/IANU types* - 1 and 10.

Set of examinations in the reference state, performed during making minor variations to the registration dossier of a medicinal product of *type IB* – 1, 11 and 12.

Set of examinations in the reference state, performed during making major variations to the registration dossier of a medicinal product of *type II* – 1, 11 and 13.

Set of examinations in the reference state, performed *during the expansion of registration* of a medicinal product – 1, 11 and 14.

Set of examinations in the reference state, performed during making unclassified variations to the registration dossier of a medicinal product of *type IB, 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, 11 and 15.

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	723,54	343,23
2	Examination of a medicinal product, in terms of assessing the fullness, completeness, and correctness of documents submitted in the registration dossier for a medicinal product, during registration of a medicinal product, during confirmation of registration (re-registration) of a medicinal product, and upon submission of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union	service	220,10	104,41
3	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier during registration of a medicinal product (original, biosimilar, combined (new combination)), for safety, efficacy, and quality	service	11 993,90	6 174,36
3.1	for the second and each subsequent dosage	service	788,41	405,87
3.2	for the second and each subsequent type of primary packaging	service	376,49	193,83
3.3	for a multi-component (2 or more active substances) medicinal product	service	752,98	387,65
4	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier during registration of a medicinal product (generic, hybrid, combined (known combination), well-studied), for safety, efficacy, and quality	service	8 999,38	4 491,03
4.1	for the second and each subsequent dosage	service	813,30	405,87
4.2	for the second and each subsequent type of primary packaging	service	388,38	193,83
4.3	for a multi-component (2 or more active substances) medicinal product	service	776,76	387,65

5	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier upon submission of the registration dossier for a medicinal product in complience with the requirements of the Eurasian Economic Union, with benefit-risk reassessment (original, biosimilar, combined (new combination)), for safety, efficacy, and quality	service	11 436,24	5 592,88
6	Examination of a medicinal product in terms of evaluation of documents and information submitted in the registration dossier, when bringing the registration dossier of a medicinal product in compliance with the requirements of the Eurasian Economic Union, with reassessment of "benefit-risk" (reproduced, hybrid, combined (known combination), well studied), for safety, efficacy and quality	service	7 992,32	3 908,67
7	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier during the confirmation of registration (re-registration) of a medicinal product, for safety, efficacy, and quality.	service	4 705,37	2 301,17
8	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier upon submission of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union, without benefit-risk reassessment, for safety, efficacy, and quality	service	5 770,85	2 822,27
9	Examination of a medicinal product, in terms of assessing the documents and information submitted by the applicant in the registration dossier upon submission of the registration dossier for a medicinal product for alignment with the requirements of the Eurasian Economic Union, submitted pursuant to the Decree of the Board of the Ministry of Health of the Republic of Belarus, for safety, efficacy, and quality	service	1 472,91	720,33
10	Examination of a medicinal product during making minor variations of type IA/IANU to the registration dossier	service	1 154,38	590,40
11	Examination of a medicinal product, in terms of assessing the fullness, completeness, and correctness of documents submitted in the registration dossier for a medicinal product, during making minor variations of type IB, major variations of type II, and the expansion of registration	service	109,26	53,44

12	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier for a medicinal product, during making minor variations of type IB, for safety, efficacy, and quality	service	1 847,12	903,34
13	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier for a medicinal product, for making major variations of type II, for safety, efficacy, and quality	service	3 015,52	1 474,75
14	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier for a medicinal product, during making variations for the expansion of registration, for safety, efficacy, and quality	service	7 539,96	3 687,46
15	Examination of a medicinal product, in terms of assessing the documents and information submitted in the registration dossier for a medicinal product, for making unclassified variations of type IB concerning only the documents of the administrative part of Module 1 of the RD	service	725,83	354,98

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 10, 11+12, 11+13, 11+14, 11+15 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 10, 11+12, 11+13, 11+14, 11+15 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 fees established by sub-items 2 and 7; 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 10, 11+12, 11+15 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 10, 11+12, 11+15 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 10 of this price list shall be charged.