**Republic of Latvia**

**Cabinet Regulation No. 895**

Adopted 18 December 2024

Price list of the paid services of the State Agency of Medicines

Issued pursuant to [Article [5(1)](https://m.likumi.lv/ta/id/202272-publisko-agenturu-likums#p5) of the Public Agencies](https://m.likumi.lv/ta/id/202272-publisko-agenturu-likums) Law

1. This Regulation prescribes the price list (hereinafter – the price list), payment procedures, rates and reliefs for paid services provided by the State Agency of Medicines (hereinafter – the Agency).

2. The Agency shall provide paid services in accordance with the schedule of charges (Annex[https://m.likumi.lv/doc.php?id=357532 - piel](https://m.likumi.lv/doc.php?id=357532#piel)).

3. Payment for the services provided shall be made through a payment service provider entitled to provide payment services within the meaning [of the Law on Payment Services and Electronic Money.](https://m.likumi.lv/ta/id/206634-maksajumu-pakalpojumu-un-elektroniskas-naudas-likums)

4. The recipient of the service shall make the payment for the service referred to [in Clause 5](https://m.likumi.lv/doc.php?id=357532#p5) of [the Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation once a year in the calendar year following the taking of the decision on the registration or re-registration of medicinal products in accordance with the invoice issued by the Agency in accordance with the data of the Medicinal Product Register of Latvia on 1 January of the current year.

5. The recipient of the service shall pay for the service referred to in Clauses 13, 27, 28, 31 and 62 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation once a year in accordance with the invoice issued by the Agency in accordance with the data of the Medicinal Product Register of Latvia and the Register of Pharmaceutical Activity Undertakings as of 1 January of the current year.

6. The recipient of the service shall pay in full the prepayment for the services referred to in Clauses 1, 2, 3, 4, 7, 8, 9, 10, 11, 61 and 63 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation using non-cash payment.

7. Upon terminating the performance of the service, the Agency shall collect from the received prepayment referred to in Clauses 1, 2, 3 and 4 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation a fee for the works performed until the termination of the performance of the service, in accordance with the following procedures:

7.1. if a primary expert-examination of the application has been performed, in which conformity of the application for registration and re-registration of medicinal products with the requirements of laws and regulations, which determine the procedures for the registration of medicinal products for the services referred to in Clauses 1, 2 and 3 of [the Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation, has been determined – in the amount of 20 per cent of the determined fee;

7.2. if a primary expert-examination of the submission has been performed in which conformity of the application for registration and re-registration of medicinal products with the requirements of the laws and regulations governing the procedures for the registration of medicinal products has been determined, and evaluation of the data and documents attached to the submission (documentation expert-examination) has been commenced for the services referred to in Clauses 1, 2 and 3 of [the Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation – in the amount of 50 per cent of the determined fee;

7.3. if an assessment of the data and documents attached to the application (documentation expert-examination) has been carried out for the services referred to in Clauses 1, 2 and 3 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation – in the amount of 90 per cent of the determined fee;

7.4. For the tasks performed by Latvia as the reference Member State in accordance with the service referred to in Clause 4 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation:

7.4.1. if a primary expert-examination of the application has been performed for the registration, re-registration and changes in the registration documentation of medicinal products – in the amount of 20 per cent of the specified fee;

7.4.2. if a primary expert-examination of the submission has been performed for the registration, re-registration and changes in the registration documentation of medicinal products and the assessment of the data and documents attached to the submission (documentation expert-examination) has been commenced – in the amount of 50 per cent of the specified fee;

7.4.3. if an assessment of the data and documents attached to the application has been performed (documentation expert-examination) – in the amount of 90 per cent of the determined fee.

8. In the cases [referred to in Clause 7](https://m.likumi.lv/doc.php?id=357532#p7) of this Regulation, the Agency shall reimburse the remaining amount, which exceeds the actual costs incurred until the termination of the paid service, within 30 calendar days after receipt by the Agency of the application of the recipient of the service.

9. If the conformity assessment is related to a trip outside Latvia, the submitter of the documents shall cover the travel (transport) expenses of an official of the Agency to the company and back, expenses for visa processing, expenses for hotel (accommodation), health insurance expenses and daily allowance for the services referred to in Clauses 36, 38, Sub-clause 39.10 and Clause 44 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation.

10. The Agency shall apply a discount in the amount of 50 per cent of the specified amount for the service referred to in Sub-clause 5.1 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation for the second calendar year after the registration of the medicinal product.

11. The Agency shall apply a discount of 100 per cent of the annual fee for the maintenance of documentation and information to a general-type pharmacy if one of the following conditions is met:

11.1. a merchant or performer of economic activity to whom not more than two special permits (licences) for pharmaceutical activities have been issued and the turnover of a general-type pharmacy in the previous year has not exceeded *EUR* 300 000;

11.2. a general-type pharmacy outside the city, the turnover of which in the previous year has not exceeded *EUR* 300 000.

12. The Agency shall apply a discount in the amount of 100 per cent of the specified amount for the services referred to in Clauses 39, 41 and 42 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation, if:

12.1. an expert-examination of the application and documentation for the direct distribution of specific tissues and cells from the place of procurement of tissues and cells (including by importing or exporting) to medical treatment institutions for immediate transplantation to a known recipient;

12.2. an expert-examination of the submission and documentation for the import or export of tissues or cells in an emergency (tissue centres or medical treatment institutions);

12.3. a non-routine/unannounced inspection in a medical treatment institution in Latvia in relation to a biovigilance report (serious adverse reaction or serious adverse event) received from the Agency from the State Blood Donor Centre, the Blood Establishment, the Hospital Blood Bank, tissue centre, organ procurement and transplantation centre or on the basis of an analysis of information placed in the European Union Rapid Alert Systems (RAB or RATC) or information from another European Union Member State.

13. The Agency shall apply a discount in the amount of 90 per cent of the specified amount to non-commercial studies of a non-profit organisation, independent expert group, higher education or scientific institution, professional association of doctors or individual researcher regarding the service referred to in Clauses 43, 45, 46 and 47 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation.

14. Clauses 15 and 64 of the [Annex](https://m.likumi.lv/ta/id/357532#piel0) to this Regulation shall enter into force on 1 April 2025.

15. This Regulation shall enter into force on 1 January 2025.

16. Cabinet [Regulation No. 641 of 10 December 2019, Price List of Paid Services of the State Agency of Medicines (Latvijas](https://likumi.lv/ta/id/311501) Vēstnesis, 2019, No. 255; 2021, No 248; 2024, No 48), is repealed.

Prime Minister *E. Siliņa*

Minister for Health *H. Abu Meri*

Annex
the Cabinet of Ministers
18 December 2024
Regulation No. 895

Price list of the paid services of the State Agency of Medicines

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| --- | --- | --- | --- | --- | --- |
| No.p.m. | Type of fee-based service | Unit of measurement | Price excluding VAT (EUR) | VAT (in*euros)* | Price including VAT (*EUR*) |
| 1. | Expertise of application for registration of medicinal products and accompanying documentation for one medicinal product1 |
| 1.1. | Application for a medicinal product with a new or known active substance (complete application for registration of a medicinal product) | 1 documentation expertise | 4000,00 | 0,00 | 4000,00 |
| 1.2. | Application for well-established medicinal use | 1 documentation expertise | 4000,00 | 0,00 | 4000,00 |
| 1.3. | Application for authorisation of a medicinal product containing active substances used in the composition of an authorised medicinal product but not previously used in that combination for therapeutic purposes (application for a fixed combination) | 1 documentation expertise | 4000,00 | 0,00 | 4000,00 |
| 1.4. | Application for a similar biological medicinal product | 1 documentation expertise | 4000,00 | 0,00 | 4000,00 |
| 1.5. | Application for registration in which the marketing authorisation holder of the original medicinal product has agreed that the applicant for registration of the medicinal product shall use the pharmaceutical, non-clinical and clinical documentation included in the registration dossier of the original medicinal product containing the same qualitative and quantitative composition of active substances and the same pharmaceutical form (application with consent) | 1 documentation expertise | 4000,00 | 0,00 | 4000,00 |
| 1.6. | application for a generic medicinal product | 1 documentation expertise | 2500,00 | 0,00 | 2500,00 |
| 1.7. | mixed application for registration | 1 documentation expertise | 2500,00 | 0,00 | 2500,00 |
| 1.8. | Application for extension of registration of a medicinal product in accordance with Annex 1 to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products | 1 documentation expertise | 1500,00 | 0,00 | 1500,00 |
| 1.9. | Application for a medicinal product with an identical registration dossier but with different product names and the same or different marketing authorisation holder (multiple submission at the same time) | 1 documentation expertise | 1500,00 | 0,00 | 1500,00 |
| 1.10. | Application for homeopathic or anthroposophic medicinal products per pharmaceutical form or per strength | 1 documentation expertise | 560,00 | 0,00 | 560,00 |
| 1.11. | Application for traditional herbal medicinal products (herbal medicinal products to be registered under the simplified authorisation procedure) per pharmaceutical form or per pharmaceutical strength | 1 documentation expertise | 560,00 | 0,00 | 560,00 |
| 2. | Expertise of the submission and documentation for each additionally submitted strength and/or pharmaceutical form of one medicinal product, if submitted at the same time as the initial application for registrationof the medicinal product 1 (except 1.10 and 1.11) |
| 2.1. | for the authorisation of medicinal products | 1 documentation expertise | 1000,00 | 0,00 | 1000,00 |
| 2.2. | for the re-registration of a medicinal product (including a duplicate) | 1 documentation expertise | 700,00 | 0,00 | 700,00 |
| 3. | Expertise of application and attached documentation for re-registration of medicinal products1 |
| 3.1.  | for medicinal products authorised through the national, mutual recognition, decentralised authorisation procedure | 1 documentation expertise | 2000,00 | 0,00 | 2000,00 |
| 3.2. | homeopathic and anthroposophic medicinal products per pharmaceutical form or per strength | 1 documentation expertise | 300,00 | 0,00 | 300,00 |
| 3.3.  | for traditional herbal medicinal products, one pharmaceutical form or one strength; | 1 documentation expertise | 300,00 | 0,00 | 300,00 |
| 4.  | Ensuring the functioning of the mutual recognition or decentralised procedure if Latvia is the reference Member State (in addition to Clauses [1](https://m.likumi.lv/ta/id/357532#p1) and [3](https://m.likumi.lv/ta/id/357532#p3) of this Regulation)1 |
| 4.1.  | Registration of medicinal products | 1 procedure number | 8500,00 | 0,00 | 8500,00 |
| 4.2. | re-registration of medicinal products | 1 procedure number | 4000,00 | 0,00 | 4000,00 |
| 4.3. | Repeated mutual recognition procedure (RUP procedure) | 1 procedure number | 2500,00 | 0,00 | 2500,00 |
| 4.4.  | Type II variations | 1 procedure number | 1000,00 | 0,00 | 1000,00 |
| 4.5. | Type IB variations | 1 procedure number | 500,00 | 0,00 | 500,00 |
| 4.6. | Type IA variations | 1 procedure number | 513,81 | 0,00 | 513,81 |
| 5.  | Annual fee for post-authorisation maintenanceof the medicinal product 1 |
| 5.1.  | for medicinal products authorised through the national, mutual recognition, decentralised authorisation procedure | 1 registration number | 850,00 | 0,00 | 850,00 |
| 5.2. | homeopathic and anthroposophic medicinal products | 1 registration number | 250,00 | 0,00 | 250,00 |
| 5.3. | traditional herbal medicinal products | 1 registration number | 250,00 | 0,00 | 250,00 |
| 6. | Issuance of a paper document or a duplicate of a document on request1 | page 1 | 1,50 | 0,00 | 1,50 |
| 7.  | Expertise of periodic safety update reports for nationally authorised medicinal products with the same active substance or the same active substances per marketing authorisation holder1 | 1 report | 500,00 | 0,00 | 500,00 |
| 8.  | Scientific advice1 |
| 8.1. | on issues relating to the procedures for the authorisation of medicinal products, including changes to the procedures for the authorisation of medicinal products; on matters concerning the classification, clinical evaluation and performance evaluation of medical devices and *in vitro* diagnostic medical devices; on pre-clinical, clinical and investigational medicinal product quality issues in clinical trials | 1 consultation | 2000,00 | 0,00 | 2000,00 |
| 8.2. | on pre-clinical, clinical, pharmacovigilance and pharmaceutical issues prior to the authorisation procedure for a medicinal product | 1 consultation | 7000,00 | 0,00 | 7000,00 |
| 9. | Assessment of the pharmacological, immunological and metabolic properties of the product (e.g. food supplement, cosmetic product, biocidal product, medical device) to determine its compliance with the definition of medicinal product1 | 1 submission | 650,00 | 0,00 | 650,00 |
| 10. | Evaluation of the draft protocol for the post-authorisation safety study, if the study is conducted in order to fulfil the condition regarding the marketing authorisation of the medicinal product1 | 1 opinion | 500,00 | 0,00 | 500,00 |
| 11. | Consideration of an amendment to the protocol of a post-authorisation safety study1 | 1 opinion | 200,00 | 0,00 | 200,00 |
| 12. | Notification of product registration status1 | 1 notification | 41,00 | 0,00 | 41,00 |
| 13. | Annual fee for the maintenance of medicinal products imported in parallel1 | 1 registration number | 150,00 | 0,00 | 150,00 |
| 14. | Expertise of application and documentation for granting of a permit for distribution of parallel-imported medicinal products in Latvia1 | 1 documentation expertise | 302,00 | 0,00 | 302,00 |
| 15.  | Expertise of the application and documentation for the distribution of individually granted unregistered medicinal products, if the medicinal product is necessary for the treatment of a specific patient or animal1 |
| 15.1. | first product entry in the document | 1 documentation expertise | 11,98 | 0,00 | 11,98 |
| 15.2. | each subsequent product entry in the document | 1 documentation expertise | 6,98 | 0,00 | 6,98 |
| 16. | An expertise of the application and documentation for the distribution of individually granted unregistered medicinal products, if the medicinal product is necessary for the treatment of a specific disease or performance of medical manipulation in a specific medical treatment institution or social care institution, or for the treatment or performance of manipulation of a specific animal disease, or if the medicinal product is necessary for the provision of medical assistance in case of disaster, natural disaster or epidemic1 |
| 16.1. | first product entry in the document | 1 documentation expertise | 21,00 | 0,00 | 21,00 |
| 16.2. | each subsequent product entry in the document | 1 documentation expertise | 7,00 | 0,00 | 7,00 |
| 17.  | Examination of application and documentation for import of samples of medicinal products1 |
| 17.1.  | up to five drug records | 1 documentation expertise | 10,00 | 0,00 | 10,00 |
| 17.2.  | each subsequent drug entry | 1 documentation expertise | 2,00 | 0,00 | 2,00 |
| 18.  | Provision of data on the sale of medicinal products1 |
| 18.1.  | Standard overview of product sales data (the overview indicates the anatomical therapeutic chemical classification code (ATC code), International Nonproprietary Name (INN) of the medicinal product, form, strength or concentration, number of packages, number of packages sold, turnover in *euros)* |
| 18.1.1. | Quarterly breakdown by month | 1 overview | 497,00 | 0,00 | 497,00 |
| 18.1.2. | half-year | 1 overview | 852,00 | 0,00 | 852,00 |
| 18.1.3.  | year | 1 overview | 1419,00 | 0,00 | 1419,00 |
| 18.2. | Extended overview of product sales data (includes information included in the standard overview and additionally indicates the recipient group or the classification group of the product) |
| 18.2.1. | Quarterly breakdown by month | 1 overview | 603,00 | 0,00 | 603,00 |
| 18.2.2. | half-year | 1 overview | 993,00 | 0,00 | 993,00 |
| 18.2.3. | year | 1 overview | 1774,00 | 0,00 | 1774,00 |
| 18.3. | a full overview of the marketing data (includes the information included in the standard overview, indicates the group of the recipient of the medicinal product and the classification group of the medicinal product) |
| 18.3.1. | Quarterly breakdown by month | 1 overview | 674,00 | 0,00 | 674,00 |
| 18.3.2. | half-year | 1 overview | 1135,00 | 0,00 | 1135,00 |
| 18.3.3. | year | 1 overview | 1987,00 | 0,00 | 1987,00 |
| 18.4. | Individual review of drug sales data | 1 parameter | 14,00 | 0,00 | 14,00 |
| 19.  | Expertise of the application and documentation for the receipt of a distribution permit for medicinal products registered in a state of the European Economic Area but not registered in the Republic of Latvia1 |
| 19.1. | Expertise of the application for the granting of a permit | 1 documentation expertise | 710,00 | 0,00 | 710,00 |
| 19.2. | Expertise of an application for changes in documentation | 1 documentation expertise | 71,00 | 0,00 | 71,00 |
| 20. | Submission and Documentation Expertise for Registration of Precursor Operators1 | 1 documentation expertise | 171,00 | 0,00 | 171,00 |
| 21. | Expertise of application and documentation for obtaining a licence to work with precursors1 | 1 documentation expertise | 190,00 | 0,00 | 190,00 |
| 22. | Expert-examination of the application and documentation for the use of plants, their substances and medicinal products included in Lists I, II and III of narcotic substances, psychotropic substances and precursors to be controlled in Latvia for medical and veterinary medical scientific research, determination of physical and chemical properties, as well as for training1 | 1 documentation expertise | 71,00 | 0,00 | 71,00 |
| 23. | Documentation expertise for changes to the registration of precursor operators1 | 1 documentation expertise | 71,00 | 0,00 | 71,00 |
| 24. | Documentation expertise for changes to the licence to work with precursors1 | 1 documentation expertise | 90,00 | 0,00 | 90,00 |
| 25. | Expert-examination of the application and documentation for the acquisition of medicinal products (also for ship agents) for ensuring their operation1 | 1 documentation expertise | 25,00 | 0,00 | 25,00 |
| 26.  | Expert-examination of the application and documentation for the use of narcotic substances, psychotropic substances and precursors in industry in Lists II and III to be controlled in Latvia1 | 1 documentation expertise | 71,00 | 0,00 | 71,00 |
| 27.  | Annual fee for maintenance of documentation and information for a general pharmacy1 | 1 pharmacy | 200,00 | 0,00 | 200,00 |
| 28.  | Annual fee for maintenance of documentation and information for a medicinal product wholesaler1 | 1 wholesaler | 700,00 | 0,00 | 700,00 |
| 29.  | Processing of the submission data of a merchant in information systems and examination of the approval of the location (address) of pharmaceutical activity1 | 1 pharmaceutical site (address) expert-examination | 72,00 | 0,00 | 72,00 |
| 30.  | Conformity assessment of a pharmaceutical activity company's application and documentation1 |
| 30.1. | Documentation expertise to assess the whole or part of the manufacturing or import process | 1 documentation expertise | 600,00 | 0,00 | 600,00 |
| 30.2. | Partial assessment of the application and documentation of the manufacturing process of the medicinal product or of the active substance manufacturing company (applies also to the manufacturing of advanced therapy medicinal products on the basis of an unusual process) | 1 documentation expertise | 450,00 | 0,00 | 450,00 |
| 30.3. | Examination of the application and documentation of the undertaking which only pre-packages the ethyl alcohol | 1 documentation expertise | 300,00 | 0,00 | 300,00 |
| 31. | Annual fee for the maintenance of documentation and information for pharmaceutical activities of an undertaking registered in a Member State of the European Union or a State of the European Economic Area for the wholesale distribution of medicinal products, the manufacture or importation of medicinal products1 | 1 medicine (research medicine) manufacturing or importing company or medicine wholesaler | 500,00 | 0,00 | 500,00 |
| 32. | Expertise of a dossier of a merchant or economic operator who manufactures, imports or distributes an active substance (applies also to changes in the information provided) for the receipt of a registration certificate, processing of information in information systems and publication in the public register1 |
| 32.1.  | first active substance produced, imported or distributed  | 1 documentation expertise | 100,00 | 0,00 | 100,00 |
| 32.2.  | each subsequent active substance manufactured, imported or distributed  | 1 documentation expertise | 20,00 | 0,00 | 20,00 |
| 33.  | Expert-examination of documentation, processing of information in information systems and publication in the public register of a merchant or performer of economic activity who performs intermediation transactions with medicinal products1 |
| 33.1. | Documentation expertise | 1 documentation expertise | 70,00 | 0,00 | 70,00 |
| 33.2. | Documentation expertise on changes to the information submitted for registration | 1 documentation expertise | 20,00 | 0,00 | 20,00 |
| 34.  | Assessment of the conformity of the education and professional experience of a qualified person of a medicinal product manufacturing or importing undertaking with the requirements laid down in the laws and regulations regarding the manufacture of medicinal products (if documents are not submitted in order to receive (re-registered) a special permit for pharmaceutical activity)1 | 1 person manufacturing medicinal products | 100,00 | 0,00 | 100,00 |
| 35. | Verification of the provision of good manufacturing practice in an undertaking or laboratory manufacturing or importing medicinal products or active substances or excipients in Latvia, which performs quality control of medicinal products or raw materials on the basis of a contract1 |
| 35.1. | first day of inspection | 1 day | 2995,41 | 0,00 | 2995,41 |
| 35.2. | each subsequent day of inspection; | 1 day | 1478,44 | 0,00 | 1478,44 |
| 36. | Verification of the provision of good manufacturing practice in a country which is not a member of the European Economic Area, in an establishment for the manufacture of medicinal products or active substances or excipients or in a laboratory carrying out quality control on the basis of a contract(1) |
| 36.1. | first day of inspection | 1 day | 5997,06 | 0,00 | 5997,06 |
| 36.2. | each subsequent day of inspection; | 1 day | 2136,89 | 0,00 | 2136,89 |
| 37.  | Verification of the provision of good manufacturing practice for the manufacture of advanced therapy medicinal products on the basis of an unusual process in a manufacturing establishment or laboratory in Latvia that performs quality control of medicinal products or their raw materials on the basis of a contract1 |
| 37.1. | first day of inspection | 1 day | 1000,00 | 0,00 | 1000,00 |
| 37.2. | each subsequent day of inspection; | 1 day | 500,00 | 0,00 | 500,00 |
| 38.  | Verification of the provision of good distribution practices at a medicinal product wholesaler or manufacturer, importer and distributor of active substances or broker 1 |
| 38.1. | first day of inspection | 1 day | 1498,51 | 0,00 | 1498,51 |
| 38.2. | each subsequent day of inspection; | 1 day | 1000,09 | 0,00 | 1000,09 |
| 39. | Conformity assessment of the site of collection, testing, processing, storage and distribution of human blood and blood components and of the site of use of tissues, cells and organs and monitoring of compliance of activities1 |
| 39.1. | Conformity assessment of blood donor centre, tissue, cell application site, organ application site | 1 documentation expertise | 499,24 | 0,00 | 499,24 |
| 39.2. | Verification of conformity assessment or supervision of conformity of operation of a blood donor centre in a medical treatment institution | 1 place of activity | 1499,21 | 0,00 | 1499,21 |
| 39.3. | Conformity assessment of the blood establishment | 1 documentation expertise | 499,24 | 0,00 | 499,24 |
| 39.4.  | Verification of conformity of the blood establishment or verification of conformity of activities in a medical treatment institution | 1 place of activity | 596,77 | 0,00 | 596,77 |
| 39.5. | conformity assessment of hospital blood bank | 1 documentation expertise | 369,21 | 0,00 | 369,21 |
| 39.6. | Verification of conformity assessment or conformity monitoring of activities of the hospital blood bank in a medical treatment institution | 1 place of activity | 369,21 | 0,00 | 369,21 |
| 39.7. | Evaluation of documentation of changes to standard procedures for blood, tissues, cells and organs at the site of application (if no new conformity assessment is required) | 1 documentation expertise | 195,43 | 0,00 | 195,43 |
| 39.8. | human tissues, cells and organs site compliance assessment and performance compliance monitoring | 1 place of activity | 759,29 | 0,00 | 759,29 |
| 39.9. | each subsequent site of activity (the National Blood Donor Centre or the site of use of human tissues, cells and organs) | 1 place of activity | 499,24 | 0,00 | 499,24 |
| 39.10. | Conformity assessment of tissues, cells and blood application sites or verification of compliance monitoring of activities in a non-European Economic Area country | 1 tissue or blood establishment/associated institution | 4993,77 | 0,00 | 4993,77 |
| 40. | Conformity Assessment of the Place of Use of Tissues, Cells, Organs and Dead Human Body and Supervision of Conformity of Activities for Implementation of Accredited Medical Studies and Professional Improvement Programme for Medical Practitioners in an Institution of Higher Education1 |
| 40.1. | Conformity assessment of tissues, cells, organs and the location of use of the deceased human body | 1 documentation expertise | 195,43 | 0,00 | 195,43 |
| 40.2. | Examination of the conformity assessment or supervision of the operation of a place of use of tissues, cells, organs and the body of a deceased person in a higher education institution | 1 place of activity | 369,21 | 0,00 | 369,21 |
| 40.3. | Evaluation of documentation of changes to standard procedures for the operation and functioning of tissues, cells, organs and the site of application of the deceased human body (if no new conformity assessment is required) | 1 documentation expertise | 152,10 | 0,00 | 152,10 |
| 41.  | Examination of application and documentation for direct distribution of specific tissues and cells from the place of procurement of tissues and cells (including import or export) to medical institutions for immediate transplantation to a known recipient1 | 1 documentation expertise | 50,00 | 0,00 | 50,00 |
| 42. | Expertise of application and documentation for import or export of tissues or cells in case of emergency (tissue centres or medical treatment institutions)1 | 1 documentation expertise | 50,00 | 0,00 | 50,00 |
| 43. | Examination of an Application for a Clinical Trial of Medicinal Products and the Documentation Accompanying it¹ |
| 43.1. | Examination of an application for a clinical trial of a medicinal product and of the documentation attached to it in Parts I and II | 1 documentation expertise | 4000,54 | 0,00 | 4000,54 |
| 43.2. | Examination of an application for a clinical trial of a medicinal product and of the documentation attached to it under Part I | 1 documentation expertise | 2500,85 | 0,00 | 2500,85 |
| 43.3. | Examination of an application for a clinical trial of a medicinal product and of the documentation attached to it in Part II | 1 documentation expertise | 1499,64 | 0,00 | 1499,64 |
| 43.4. | Examination of the application for a low-intervention clinical trial and the accompanying documentation in Parts I and II | 1 documentation expertise | 2200,89 | 0,00 | 2200,89 |
| 43.5. | Examination of the low-intervention clinical trial application and the accompanying Part I dossier | 1 documentation expertise | 1200,07 | 0,00 | 1200,07 |
| 43.6. | Examination of the low-intervention clinical trial application and the accompanying Part II dossier | 1 documentation expertise | 999,81 | 0,00 | 999,81 |
| 43.7. | Examination of an application for a clinical trial of a medicinal product and of the dossier in Parts I and II attached thereto, where Latvia is the reporting Member State | 1 documentation expertise | 4000,54 | 0,00 | 4000,54 |
| 44. | Assessment of compliance with good clinical practice in a clinical trial centre in relation to an application for registration of a medicinal product1 |
| 44.1.  | one centre | 1 clinical trial centre/associated institution | 3700,00 | 0,00 | 3700,00 |
| 44.2. | every next centre | 1 clinical trial centre | 2000,00 | 0,00 | 2000,00 |
| 45.  | Substantial Amendments to the Documentation of Part I of the Clinical Trial of Medicinal Products1 |
| 45.1.  | Consideration of a substantial amendment to the protocol or a substantial amendment to the researcher's brochure | 1 amendment | 499,96 | 0,00 | 499,96 |
| 45.2.  | Consideration of a substantial amendment to the protocol or a substantial amendment to the investigator’s brochure if Latvia is the reporting Member State | 1 amendment | 590,58 | 0,00 | 590,58 |
| 45.3.  | Consideration of a substantial amendment of the investigational medicinal product dossier | 1 amendment | 262,38 | 0,00 | 262,38 |
| 46. | Substantial Amendments to the Documentation of Part II of the Clinical Trial of Medicinal Products1 |
| 46.1. | Consideration of an amendment to the informed consent | 1 amendment | 400,00 | 0,00 | 400,00 |
| 46.2.  | Consideration of an amendment to the documentation related to the clinical trial site | 1 amendment | 400,00 | 0,00 | 400,00 |
| 47. | Review of the annual safety report for investigational medicinal products if Latvia is the safety the reporting Member State1 | 1 report | 526,54 | 0,00 | 526,54 |
| 48. | Quality control of medicines1 |
| 48.1. | Determination of the identity of a medicinal product |
| 48.1.1. | using a chemical reaction | 1 analysis | 30,17 | 0,00 | 30,17 |
| 48.1.2. | using instrumental methods and thin-layer chromatography (PSC) | 1 analysis | 80,05 | 0,00 | 80,05 |
| 48.2. | Determination of clarity | 1 analysis | 19,77 | 0,00 | 19,77 |
| 48.3. | Colour matching determination | 1 analysis | 19,77 | 0,00 | 19,77 |
| 48.4. | determination of solubility | 1 analysis | 19,77 | 0,00 | 19,77 |
| 48.5. | Determination of pH | 1 analysis | 30,17 | 0,00 | 30,17 |
| 48.6. | determination of density | 1 analysis | 60,22 | 0,00 | 60,22 |
| 48.7. | determination of the refractive index | 1 analysis | 39,82 | 0,00 | 39,82 |
| 48.8. | determination of melting point | 1 analysis | 39,82 | 0,00 | 39,82 |
| 48.9. | determination of optical rotation | 1 analysis | 49,86 | 0,00 | 49,86 |
| 48.10. | Determination of mechanical impurities |
| 48.10.1. | visually | 1 analysis | 30,17 | 0,00 | 30,17 |
| 48.10.2. | instrumental | 1 analysis | 54,96 | 0,00 | 54,96 |
| 48.11. | Determination of impurities |
| 48.11.1. | using limit test methods | 1 analysis | 49,86 | 0,00 | 49,86 |
| 48.11.2. | by thin-layer chromatography (PSC) | 1 analysis | 100,03 | 0,00 | 100,03 |
| 48.12. | determination of nominal volume | 1 analysis | 24,61 | 0,00 | 24,61 |
| 48.13. | determination of average mass and deviation from average mass | 1 analysis | 24,61 | 0,00 | 24,61 |
| 48.14. | determination of sulphate ash | 1 analysis | 39,82 | 0,00 | 39,82 |
| 48.15. | determination of heavy metal content | 1 analysis | 45,48 | 0,00 | 45,48 |
| 48.16. | determination of loss in mass by drying | 1 analysis | 39,82 | 0,00 | 39,82 |
| 48.17. | determination of water quantity | 1 analysis | 69,80 | 0,00 | 69,80 |
| 48.18. | Detection of disintegration | 1 analysis | 39,82 | 0,00 | 39,82 |
| 48.19. | determination of litterfall | 1 analysis | 24,60 | 0,00 | 24,60 |
| 48.20. | determination of dissolution (without further relevant quantitative analysis) | 1 analysis | 60,22 | 0,00 | 60,22 |
| 48.21. | Determination of hardness of solid pharmaceutical forms | 1 analysis | 24,57 | 0,00 | 24,57 |
| 48.22. | sizing of solid pharmaceutical forms | 1 analysis | 24,57 | 0,00 | 24,57 |
| 48.23. | determination of osmolality | 1 analysis | 45,35 | 0,00 | 45,35 |
| 48.24. | determination of viscosity | 1 analysis | 60,22 | 0,00 | 60,22 |
| 48.25. | determination of the homogeneity of the active substance content |
| 48.25.1. | by titration | 1 analysis | 149,66 | 0,00 | 149,66 |
| 48.25.2. | using spectrophotometry | 1 analysis | 149,66 | 0,00 | 149,66 |
| 48.25.3. | using polarimetry | 1 analysis | 100,03 | 0,00 | 100,03 |
| 48.25.4. | using high-performance liquid chromatography (HPLC) | 1 analysis | 500,11 | 0,00 | 500,11 |
| 48.25.5. | by gas chromatography (GH) | 1 analysis | 500,11 | 0,00 | 500,11 |
| 48.26. | Quantification |
| 48.26.1. | by titration | 1 analysis | 100,03 | 0,00 | 100,03 |
| 48.26.2. | using spectrophotometry | 1 analysis | 100,03 | 0,00 | 100,03 |
| 48.26.3. | using polarimetry | 1 analysis | 100,03 | 0,00 | 100,03 |
| 48.26.4. | using high-performance liquid chromatography (HPLC) | 1 analysis | 500,11 | 0,00 | 500,11 |
| 48.26.5. | by gas chromatography (GH) | 1 analysis | 500,11 | 0,00 | 500,11 |
| 48.27. | determination of electrical conductivity | 1 analysis | 30,17 | 0,00 | 30,17 |
| 48.28. | determination of residual solvents | 1 analysis | 500,11 | 0,00 | 500,11 |
| 49. | Translation and presentation of the protocol for the analysis of the quality control of medicinal products in English | protocol 1 | 39,82 | 8,36 | 48,18 |
| 50. | Quality control of Medicinal Plant Drones1 |
| 50.1. | determination of identity by means of external signs (medicinal herbal drones) or determination of identity by microscopy (medicinal herbal drones) or determination of impurities in medicinal herbal drones | 1 analysis | 30,17 | 0,00 | 30,17 |
| 50.2. | Quantification: the content of extractive substances in medicinal herbs or the content of essential substances in medicinal herbs | 1 analysis | 69,80 | 0,00 | 69,80 |
| 51. | Purified water quality control (pharmacies)1 | 1 sample | 80,05 | 0,00 | 80,05 |
| 52. | Preparation of titrated solutions, indicators and reagents for pharmacies (50 ml)1 | 1 name | 19,77 | 0,00 | 19,77 |
| 53. | Execution of expert opinion upon official request1 | 1 opinion | 85,00 | 0,00 | 85,00 |
| 54. | Issuance of a certificate of free sale of a medical device1 | 1 certificate | 185,41 | 0,00 | 185,41 |
| 55. | Expertise of medical device clinical investigation and *in vitro* diagnostic medical device performance study documentation1 | 1 documentation expertise | 1500,00 | 0,00 | 1500,00 |
| 56. | Expertise of documentation of significant changes *in the clinical investigation of medical devices and in vitro* diagnostic medical device performance study1 | 1 documentation expertise | 900,00 | 0,00 | 900,00 |
| 57. | Renewal of the clinical investigation of medical devices and *of the performance study of in vitro* diagnostic medical devices after suspension of the clinical investigation1 | 1 documentation expertise | 900,00 | 0,00 | 900,00 |
| 58. | Issuance of a product certificate1 | 1 certificate | 185,46 | 0,00 | 185,46 |
| 59. | Issuance of an abbreviated product certificate (pharmaceutical product certificate or free trade certificate)1 | 1 certificate | 99,60 | 0,00 | 99,60 |
| 60. | Expert-examination of the application and documentation and issuance of a permit for the import and export of psychotropics, narcotic substances and medicinal products and precursors1 | 1 documentation expertise | 45,00 | 0,00 | 45,00 |
| 61. | Expertise on the therapeutic and cost-effectiveness of medicinal products or on the cost-effectiveness of medical devices for one diagnosis or group of similar diagnoses, one (single) patient group and one (single) comparator 1 | 1 documentation expertise | 1200,00 | 0,00 | 1200,00 |
| 62. | Annual fee for the operation of the vigilance system for medical devices1 |
| 62.1. | on ensuring the operation of the vigilance system for Class I medical devices and other (other) and Class A *in vitro* diagnostic medical devices | 1 manufacturer or1 authorised representative, or1 distributor | 105,20 | 0,00 | 105,20 |
| 62.2. | on the operation of the vigilance system for Classes IIa, IIb and III (including Class I) medical devices, List A, List B and self-tests (including other (other)), Class B, Class C and Class D (including Class A) *in vitro* diagnostic medical devices | 1 manufacturer or1 authorised representative, or1 distributor | 201,90 | 0,00 | 201,90 |
| 63. | Examination of the application and documentation for placing on the market or putting into service of individual medical devices or *in vitro* diagnostic medical devices which have not undergone the conformity assessment procedures provided for in regulatory enactments and which have not been CE marked1 | 1 documentation expertise | 528,60 | 0,00 | 528,60 |
| 64. | Expertise of the application and documentation for the supply of medicinal products to another European Union Member State or for the export of medicinal products1 |   |   |   |   |
| 64.1 | first product entry in the document | 1 documentation expertise | 43,50 | 0,00 | 43,50 |
| 64.2. | each subsequent product entry in the document  | 1 documentation expertise | 20,38 | 0,00 | 20,38 |

Note:

1 Value added tax shall not be applied in accordance with [Section[3,](https://m.likumi.lv/ta/id/253451-pievienotas-vertibas-nodokla-likums#p3) Paragraph eight of the Value Added Tax Law.](https://m.likumi.lv/ta/id/253451-pievienotas-vertibas-nodokla-likums)