Regulation No. 641

Adopted on 10 December 2019

**State Agency of Medicines Publicly Available Paid Service Price List**

Issued in accordance with

Article 5, Paragraph one

of the Law on Public Agencies

1. **This Regulation shall determine the price list of paid services provided by the State Agency of Medicines (hereinafter - price list) and the procedure for payment, fees and concessions.**

2. The State Agency of Medicines shall provide paid services in accordance with the price list (Annex).

3. The payment for services provided shall be made in one of the following ways:

3.1. At the State Agency of Medicines by using a payment card in a card terminal;

3.2. Via a payment service provider that is authorised to provide payment services in accordance with the Law on Payment Services and Electronic Money.

4. The receiver of service shall make payment for the service mentioned in Section 5 of the Annex to this Regulation once a year in the calendar year following adoption of decision regarding marketing authorisation or renewal of medicinal product based on an invoice issued by the Agency in accordance with data from the Medicinal Product Register of Latvia on January 1 of the relevant year.

5. The receiver of service shall make payment for the service mentioned in Sections 6, 13, 27, 28 and 31 of the Annex to this Regulation once a year based on an invoice issued by the Agency in accordance with data from the Medicinal Product Register and Pharmaceutical Activity Company Register of Latvia on January 1 of the relevant year.

6. The receiver of service shall make advance payment in full amount for the services mentioned in Sections 1, 2, 3, 4, 7, 8, 9, 10, 11 and 66 of the Annex to this Regulation by using a non-cash transaction.

7. If provision of a service is discontinued, the State Agency of Medicines shall charge a fee for the services provided until the discontinuation of service provision from the advance payment mentioned in Article 5 of this Regulation in accordance with the following procedure:

7.1. If primary expertise on application has been carried out determining compliance of marketing authorisation and renewal application with requirements of normative acts laying down procedure for marketing authorisation of medicinal products, for services mentioned in Sections 1, 2 and 3 of the Annex to this Regulation – 10 percent of the fee stated.

7.2. If primary expertise on application has been carried out determining compliance of marketing authorisation and renewal application with requirements of the normative acts determining procedure for marketing authorisation of medicinal products and if evaluation of additional data and documentation (expertise on documentation) for the services mentioned in Sections 1, 2 and 3 of the Annex to this Regulation has been initiated – 50 percent of the fee stated.

7.3. If evaluation of additional data and documentation (expertise on documentation) for the services mentioned in Sections 1, 2 and 3 of the Annex to this Regulation has been carried out – 90 percent of the fee stated.

7.4. For tasks carried out for Latvia as a reference member state in relation to the service mentioned in Section 4 of the Annex to this Regulation:

7.4.1. If primary expertise on application for marketing authorisation, renewal and variations to marketing authorisation has been carried out – 10 percent of the fee stated;

7.4.2. If primary expertise on application for marketing authorisation, renewal and variations to marketing authorisation has been carried out and evaluation of additional data and documentation of the application (expertise on documentation) has been initiated – 50 percent of fee stated;

7.4.3. If evaluation of the additional data and documentation of the application (expertise on documentation) has been carried out – 90 percent of the fee stated.

8. In the cases mentioned in Article 7 of this Regulation, the State Agency of Medicines shall refund the sum exceeding the actual costs until discontinuation of service within 30 calendar days after receipt of application from the receiver of services.

9. If travelling outside of Latvia is required for compliance evaluation, the applicant shall cover the costs of travel (transport) for the State Agency of Medicines to and from the company, costs of visa preparation, accommodation, health insurance and daily allowance related to the services mentioned in Sections 35, 36, 38, 39.2, 39.8 and 44 of the Annex to this Regulation.

10. The State Agency of Medicines shall apply a 100% discount to the annual post-authorisation maintenance fee for medicinal products authorised via national, mutual recognition or decentralised procedure and distributed in a pharmacy or healthcare institution in Latvia, if one of the following requirements are fulfilled:

10.1. The turnover did not exceed 3000 euros in the previous calendar year;

10.2. The amount sold in the previous year did not exceed 49 packagings.

11. The State Agency of Medicines shall apply a 100% discount to the annual fee for document and information maintenance for a general-type pharmacy, if one of the following requirements are fulfilled:

11.1. For a merchant who has received no more than two special permits (licences) for pharmaceutical activity and the turnover did not exceed 300 000 euros in the previous calendar year;

11.2. For a general-type pharmacy outside of city territory with a turnover that did not exceed 300 000 euros in the previous calendar year.

12. The State Agency of Medicines shall apply a 100% discount to the fee for the services mentioned in Sections 39, 41, 42 of the Annex to this Regulation:

12.1. For expertise on application and documentation for distribution of specific tissues and cells from an establishment for tissue and cell procurement (including import and export) to a healthcare institution for immediate transplant in an identified recipient;

12.2. For expertise on application and documentation for import and expert of tissues and cells in emergency situations (to healthcare institutions);

12.3. In case of an non-routine/for-cause inspection at a healthcare institution in Latvia related to a biovigilance report received by the State Agency of Medicines (serious adverse effect or serious adverse event) from the State Blood Donor Centre, blood establishment, blood bank, tissue establishment, establishment for organ procurement and transplant centre or based on analysis of information entered into the EU rapid alert systems for blood (RAB) or tissues and cells (RATC), or on information from another EU member state.

13. The State Agency of Medicines shall apply a 90% discount to the fee for review of application for clinical trail with medicinal products and additional documentation for non-commercial research conducted by a non-profit organisation, independent group of experts, academic or scientific institutions, professional associations of doctors or an individual investigator in relation to the service mentioned in Section 43, 45 and 46 of the Annex to this Regulation.

14. The Cabinet of Ministers Regulation No. 873 of 17 September 2013 “Regulations Regarding the State Agency of Medicines Publicly Available Paid Service Pricelist” (“Latvijas Vēstnesis”, 2013, No. 184; 2014, No. 174; 2015, No. 253; 2017, No. 237; 2018, No. 112) is repealed.

15. The Regulation shall enter into force on 1 January 2020.

Prime Minister Krišjānis Kariņš

Minister for Health Ilze Viņķele

Annex to   
Cabinet of Ministers

Regulation No.\_\_\_\_\_  
of \_\_\_\_\_\_\_\_\_ 2019

**State Agency of Medicines Publicly Available Paid Service Price List**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| No. | Type of Paid Service | Unit | Fee excluding VAT (*EUR*) | VAT (*EUR*) | Fee including VAT  (*EUR*) |
| **1.** | **Expertise on application and additional documentation for marketing authorisation of one medicinal product1** |  |  |  |  |
| 1.1. | Application for a new or known active substance (full marketing authorisation application) | 1 expertise on documentation | 4000.00 | 0.00 | 4000.00 |
| 1.2. | Application for a medicinal product with well-established use | 1 expertise on documentation | 4000.00 | 0.00 | 4000.00 |
| 1.3. | Application for marketing authorisation of a medicinal product containing an active substance used in an authorised medicinal product, but not in this combination (application for a fixed combination) | 1 expertise on documentation | 4000.00 | 0.00 | 4000.00 |
| 1.4. | Application for a biosimilar medicinal product | 1 expertise on documentation | 4000.00 | 0.00 | 4000.00 |
| 1.5. | Application for marketing authorisation where the marketing authorisation holder of the original medicinal product has given their approval for the marketing authorisation applicant to use pharmaceutical, non-clinical and clinical documentation included in the marketing authorisation documentation of the original medicinal product with an identical qualitative and quantitative active substance content and pharmaceutical form (Application with approval) | 1 expertise on documentation | 4000.00 | 0.00 | 4000.00 |
| 1.6. | Application for a generic medicinal product | 1 expertise on documentation | 2500.00 | 0.00 | 2500.00 |
| 1.7. | Mixed marketing authorisation application | 1 expertise on documentation | 2500.00 | 0.00 | 2500.00 |
| 1.8. | Application for expansion of marketing authorisation in accordance with Annex 1 of the European 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 (hereinafter – Commission Regulation No. 1234/2008) | 1 expertise on documentation | 1500.00 | 0.00 | 1500.00 |
| 1.9. | Application for a medicinal product with identical marketing authorisation documentation, but different names and one and the same or different marketing authorisation holder (repeat application, submitted simultaneously) | 1 expertise on documentation | 1500.00 | 0.00 | 1500.00 |
| 1.10. | Application for a homeopathic or anthroposophic medicinal product, 1 pharmaceutical form or 1 strength | 1 expertise on documentation | 560.00 | 0.00 | 560.00 |
| 1.11. | Application for a traditional-use herbal medicinal product (for herbal medicinal products to be authorised via the simplified marketing authorisation procedure), 1 pharmaceutical form or 1 strength | 1 expertise on documentation | 560.00 | 0.00 | 560.00 |
| 2. | **Additional fee for each additional medicinal product strength and/or pharmaceutical form, if submitted together with the initial marketing authorisation application1 (except Sections 1.10. and 1.11.)** |  |  |  |  |
| 2.1. | Marketing authorisation | 1 expertise on documentation | 1000.00 | 0.00 | 1000.00 |
| 2.2. | Renewal of marketing authorisation (including duplicate) | 1 expertise on documentation | 700.00 | 0.00 | 700.00 |
| 3. | **Expertise on application and additional documentation for renewal of marketing authorisation1** |  |  |  |  |
| 3.1. | For medicinal products authorised via national, mutual recognition, decentralised authorisation procedure | 1 expertise on documentation | 2000.00 | 0.00 | 2000.00 |
| 3.2. | For homeopathic and anthroposophic medicinal products, 1 pharmaceutical form or 1 strength | 1 expertise on documentation | 300.00 | 0.00 | 300.00 |
| 3.3. | For traditional-use herbal medicinal products, 1 pharmaceutical form or 1 strength | 1 expertise on documentation | 300.00 | 0.00 | 300.00 |
| **4.** | **Additional fee for performing tasks for Latvia as a reference member state in a mutual recognition or decentralised procedure1** |  |  |  |  |
| 4.1. | For marketing authorisation | 1 procedure number | 8500.00 | 0.00 | 8500.00 |
| 4.2. | For renewal of marketing authorisation | 1 procedure number | 4000.00 | 0.00 | 4000.00 |
| 4.3. | For repeat use mutual recognition procedure (RUP procedure) | 1 procedure number | 2500.00 | 0.00 | 2500.00 |
| 4.4. | For type II variation | 1 procedure number | 1000.00 | 0.00 | 1000.00 |
| 4.5. | For type IB variation | 1 procedure number | 500.00 | 0.00 | 500.00 |
| **5.** | **Annual post-authorisation maintenance fee1** |  |  |  |  |
| 5.1. | For medicinal products authorised via national, mutual recognition, decentralised procedure | 1 marketing  authorisation  number | 900.00 | 0.00 | 900.00 |
| 5.2. | For homeopathic and anthroposophic medicinal products | 1 marketing  authorisation  number | 250.00 | 0.00 | 250.00 |
| 5.3. | For traditional use herbal medical products | 1 marketing  authorisation  number | 250.00 | 0.00 | 250.00 |
| 6. | Annual pharmacovigilance fee for medicinal products authorised via national, mutual recognition, decentralised procedure (except homeopathic and traditional-use herbal medicinal products)1 | 1 marketing  authorisation  number | 60.00 | 0.00 | 60.00 |
| 7. | Expertise on periodic safety update report for medicinal products authorised via the national procedure with an identical active substance or identical active substances for one marketing authorisation holder1 | 1 report | 500.00 | 0.00 | 500.00 |
| **8.** | **Scientific consultation1** |  |  |  |  |
| 8.1. | Regarding issues related to marketing authorisation procedure, including changes in marketing authorisation procedures | 1 consultation | 2000.00 | 0.00 | 2000.00 |
| 8.2. | Regarding preclinical, clinical, pharmacovigilance and pharmaceutical issues prior to marketing authorisation | 1 consultation | 7000.00 | 0.00 | 7000.00 |
| 9. | Evaluation of pharmacologic, immunologic and metabolic properties of a product (for example, nutritional supplement, cosmetic product, biocide, medical device) in order to determine compliance with the definition of a medicinal product 1 | 1 application | 650.00 | 0.00 | 650.00 |
| 10. | Evaluation of draft post-authorisation safety study protocol, if study is being conducted to fulfil a marketing authorisation condition1 | 1 opinion | 500.00 | 0.00 | 500.00 |
| 11. | Evaluation of amendments to draft post-authorisation safety study protocol1 | 1 opinion | 200.00 | 0.00 | 200.00 |
| 12. | Notification of product marketing authorisation status1 | 1 notification | 41.00 | 0.00 | 41.00 |
| 13. | Annual maintenance fee for parallel imported medicinal products1 | 1 marketing authorisation number | 150.00 | 0.00 | 150.00 |
| 14. | Expertise on application and additional documentation to receive permit for distribution of parallel imported medicinal products in Latvia1 | 1 expertise on documentation | 302.00 | 0.00 | 302.00 |
| **15.** | **Expertise on application and documentation for distribution of unauthorised, individually supplied medicinal products (in the case mentioned in Section 10, Paragraph 7(a) of the Pharmaceutical Law)1** |  |  |  |  |
| 15.1 | First record of medicinal product in documentation | 1 expertise on documentation | 0.71 | 0.00 | 0.71 |
| 15.2 | Each following record of medicinal product in documentation | 1 expertise on documentation | 0.71 | 0.00 | 0.71 |
| **16.** | **Expertise on application and documentation for distribution of unauthorised, individually supplied medicinal products (in the cases described in Section 10, Paragraphs 7(b) and 7(c) of the Pharmaceutical Law)1** |  |  |  |  |
| 16.1 | First record of medicinal product in documentation | 1 expertise on documentation | 21.00 | 0.00 | 21.00 |
| 16.2 | Each following record of medicinal product in documentation | 1 expertise on documentation | 7.00 | 0.00 | 7.00 |
| **17.** | **Expertise on application and documentation for import of medicinal product samples1** |  |  |  |  |
| 17.1 | Up to 5 records of medicinal products | 1 expertise on documentation | 10.00 | 0.00 | 10.00 |
| 17.2 | Each following record of medicinal product | 1 expertise on documentation | 2.00 | 0.00 | 2.00 |
| **18.** | **Issuance of medicinal product turnover data1** |  |  |  |  |
| **18.1** | **Standard report of medicinal product turnover data (indicating the Anatomical Therapeutic Chemical (ATC) classification code, international non-proprietary name (INN), pharmaceutical form, strength or concentration, number inside packaging, number of packagings sold, turnover in euros)** |  |  |  |  |
| 18.1.1. | Quarter according to month | 1 report | 497.00 | 0.00 | 497.00 |
| 18.1.2. | 6 months | 1 report | 852.00 | 0.00 | 852.00 |
| 18.1.3. | Year | 1 report | 1419.00 | 0.00 | 1419.00 |
| **18.2.** | **Expanded report of medicinal product turnover data (includes the information in standard report, as well as the consumer group or medicinal product affiliation to classification group)** |  |  |  |  |
| 18.2.1. | Quarter according to month | 1 report | 603.00 | 0.00 | 603.00 |
| 18.2.2. | 6 months | 1 report | 993.00 | 0.00 | 993.00 |
| 18.2.3. | Year | 1 report | 1774.00 | 0.00 | 1774.00 |
| **18.3.** | **Full report of medicinal product turnover data (includes the information in standard report, as well as the consumer group and medicinal product affiliation to classification group)** |  |  |  |  |
| 18.3.1. | Quarter according to month | 1 report | 674.00 | 0.00 | 674.00 |
| 18.3.2. | 6 months | 1 report | 1135.00 | 0.00 | 1135.00 |
| 18.3.3. | Year | 1 report | 1987.00 | 0.00 | 1987.00 |
| 18.4. | **Individual report of medicinal product turnover data** | 1 indicator | 14.00 | 0.00 | 14.00 |
| **19.** | **Expertise on application and documentation for receipt of permit for distribution of a medicinal product authorised in a European Economic Area country, but not authorised in the Republic of Latvia1** |  |  |  |  |
| 19.1. | Expertise on application for permit | 1 expertise on documentation | 710.00 | 0.00 | 710.00 |
| 19.2. | Expertise on application for amendments to documentation | 1 expertise on documentation | 71.00 | 0.00 | 71.00 |
| 20. | Expertise on application and documentation for registration of precursoroperators1 | 1 expertise on documentation | 171.00 | 0.00 | 171.00 |
| 21. | Expertise on application and documentation for receipt of licence for work with precursors1 | 1 expertise on documentation | 190.00 | 0.00 | 190.00 |
| 22. | Expertise on application and documentation for use of plants included in lists I, II and III of narcotic, psychotropic substances and precursors controlled in Latvia, their substances and medicinal products in medical and veterinary medical scientific research, determining physical and chemical properties, as well as training1 | 1 expertise on documentation | 71.00 | 0.00 | 71.00 |
| 23. | Expertise on documentation for variations to precursor operation registration1 | 1 expertise on documentation | 71.00 | 0.00 | 71.00 |
| 24. | Expertise on documentation for variations to licence for work with precursors1 | 1 expertise on documentation | 90.00 | 0.00 | 90.00 |
| 25. | Expertise on application and documentation for purchase of medicinal products (to ensure own operation) 1 | 1 expertise on documentation | 25.00 | 0.00 | 25.00 |
| 26. | Expertise on application and documentation for use of list I, II and III narcotic, psychotropic substances and precursors controlled in Latvia in manufacturing 1 | 1 expertise on documentation | 71.00 | 0.00 | 71.00 |
| 27. | Annual fee for maintenance of documentation and information for general-type pharmacy1 | 1 pharmacy | 200.00 | 0.00 | 200.00 |
| 28. | Annual fee for maintenance of documentation and information for medicinal product wholesaler1 | 1 wholesaler | 700.00 | 0.00 | 700.00 |
| 29. | Processing of application data submitted by merchant in information systems and review related to approval of pharmaceutical activity site (address)1 | 1 expertise on pharmaceutical activity site (address) | 72 .00 | 0.00 | 72 .00 |
| **30.** | **Evaluation of compliance of application and documentation submitted by a pharmaceutical activity company1** |  |  |  |  |
| 30.1. | Expertise on documentation for evaluation of complete or partial manufacturing or import process | 1 expertise on documentation | 600.00 | 0.00 | 600.00 |
| 30.2. | Partial expertise on application and documentation of a medicinal product manufacturing process or active substance manufacturing company (applicable also to manufacturing of advanced therapy medicinal products, based on unconventional process) | 1 expertise on documentation | 450.00 | 0.00 | 450.00 |
| 30.3. | Expertise on application and documentation of a company that only prepacks ethyl alcohol | 1 expertise on documentation | 300.00 | 0.00 | 300.00 |
| 31. | Annual fee for maintenance of documentation and information for pharmaceutical activity of a company registered in a European Union member state or European Economic Area country for wholesale distribution, manufacturing or import of medicinal products1 | 1 (investigational) medicinal product manufacturing or import company or wholesaler | 500.00 | 0.00 | 500.00 |
| **32.** | Expertise on documentation (applicable also to amendments to submitted information) of a merchant, that manufactures, imports or distributes active substances, for receipt of authorisation, processing of information in information systems and publishing in the public register1 |  |  |  |  |
| 32.1. | First (one) manufactured, imported or distributed active substance | 1 expertise on documentation | 100.00 | 0.00 | 100.00 |
| 32.2. | Each following manufactured, imported or distributed active substance | 1 expertise on documentation | 20.00 | 0.00 | 20.00 |
| **33.** | Expertise on documentation of a merchant that acts as a broker of medicinal products, processing of information in information systems and publishing in the public register1 |  |  |  |  |
| 33.1. | Expertise on documentation | 1 expertise on documentation | 70.00 | 0.00 | 70.00 |
| 33.2. | Expertise on documentation regarding amendments to the information submitted for authorisation | 1 expertise on documentation | 20.00 | 0.00 | 20.00 |
| 34. | Evaluation of compliance of education and professional expertise of the qualified person of a medicinal product manufacturing or import company with the requirements laid down in normative acts regarding manufacturing of medicinal products (if documents are not submitted for receipt (renewal) of special permit for pharmaceutical activity)1 | 1 person for medicinal product manufacturing | 100.00 | 0.00 | 100.00 |
| 35. | Good manufacturing practice inspection at a medicinal product or active substance, or excipient manufacturing or import company or laboratory in Latvia carrying out quality control of medicinal products or materials under contract1 |  |  |  |  |
| 35.1 | First day of inspection | 1 day | 2000.00 | 0.00 | 2000.00 |
| 35.2. | Each following day of inspection | 1 day | 1000.00 | 0.00 | 1000.00 |
| 36. | Good manufacturing practice inspection in a country outside of the European Economic Area at a medicinal product or active substance, or excipient manufacturing company or laboratory carrying out quality control under contract1 |  |  |  |  |
| 36.1 | First day of inspection | 1 day | 3000.00 | 0.00 | 3000.00 |
| 36.2. | Each following day of inspection | 1 day | 1500.00 | 0.00 | 1500.00 |
| 37. | Good manufacturing practice inspection for an advanced therapy medicinal product, based on unconventional process, at a manufacturing company or laboratory in Latvia carrying out quality control under contract1 |  |  |  |  |
| 37.1. | First day of inspection | 1 day | 1000.00 | 0.00 | 1000.00 |
| 37.2. | Each following day of inspection | 1 day | 500.00 | 0.00 | 500.00 |
| 38. | Good distribution practice inspection of a medicinal product wholesaler or distributor, importer or distributor of active substances or broker of medicinal products1 |  |  |  |  |
| 38.1. | First day of inspection | 1 day | 1000.00 | 0.00 | 1000.00 |
| 38.2. | Each following day of inspection | 1 day | 500.00 | 0.00 | 500.00 |
| 39. | Compliance evaluation and compliance surveillance of establishments for procurement, testing, processing, storage and distribution of human blood and blood components and establishments for utilisation of human tissues, cells and organs1 |  |  |  |  |
| 39.1. | Compliance evaluation of a blood donor centre, establishment for utilisation of tissues, cells and organs | 1 expertise on documentation | 200.00 | 0.00 | 200.00 |
| 39.2. | Compliance evaluation or compliance surveillance inspection of a blood donor centre, an establishment for utilisation of organs at a healthcare institution | 1 centre | 500.00 | 0.00 | 500.00 |
| 39.3. | Compliance evaluation of a blood establishment | 1 expertise on documentation | 150.00 | 0.00 | 150.00 |
| 39.4. | Compliance evaluation inspection or compliance surveillance inspection of a blood establishment at a healthcare institution | 1 site of operation | 400.00 | 0.00 | 400.00 |
| 39.5 | Compliance evaluation of a blood bank | 1 expertise on documentation | 100.00 | 0.00 | 100.00 |
| 39.6 | Compliance evaluation or compliance surveillance inspection of a blood bank at a healthcare institution | 1 site of operation | 250.00 | 0.00 | 250.00 |
| 39.7. | Evaluation of changes in operation and standard operation procedures of establishments for utilisation of blood, tissues, cells and organs (if a new compliance evaluation is not required) | 1 expertise on documentation | 75.00 | 0.00 | 75.00 |
| 39.8 | Compliance evaluation or compliance surveillance inspection of an establishment for utilisation of tissues, cells in a country not within the European Economic Area | 1 tissue establishment/ related institution | 3000.00 | 0.00 | 3000.00 |
| **40.** | **Compliance evaluation and compliance surveillance of an establishment for utilisation of tissues, cells, organs and bodies of deceased human beings for the implementation of an accredited medical studies program and a professional development program for medical practitioners at a higher education institution1** |  |  |  |  |
| 40.1. | Compliance evaluation of an establishment for utilisation of tissues, cells, organs and bodies of deceased human beings | 1 expertise on documentation | 100.00 | 0.00 | 100.00 |
| 40.2. | Compliance evaluation or compliance surveillance inspection of an establishment for utilisation of tissues, cells, organs and bodies of deceased human beings at a higher education institution | 1 site of operation | 250.00 | 0.00 | 250.00 |
| 40.3. | Evaluation of documentation on changes in operation and standard operation procedures of an establishment for utilisation of tissues, cells, organs and bodies of deceased human beings (if new compliance evaluation is not required) | 1 expertise on documentation | 75.00 | 0.00 | 75.00 |
| 41. | Expertise on application and documentation for direct distribution of specific tissues and cells from an establishment for tissue and cell procurement (including import and export) to healthcare institutions for immediate transplant in an identified recipient1 | 1 expertise on documentation | 50.00 | 0.00 | 50.00 |
| 42. | Expertise on application and documentation for emergency import or export of tissues or cells (for tissue establishments or healthcare institutions)1 | 1 expertise on documentation | 50.00 | 0.00 | 50.00 |
| 43. | Review of clinical trial application and additional documentation1 | 1 expertise on documentation | 2100.00 | 0.00 | 2100.00 |
| 44. | Good clinical practice compliance evaluation at a clinical trial site in relation to a marketing authorisation application for a medicinal product1 |  |  |  |  |
| 44.1 | One site | 1 clinical trial site/related institution | 3700.00 | 0.00 | 3700.00 |
| 44.2. | Each following site | 1 clinical trial site | 2000.00 | 0.00 | 2000.00 |
| 45. | Substantial amendments to clinical trial documentation for medicinal products1 |  |  |  |  |
| 45.1. | Review of substantial amendment to protocol | 1 amendment | 300.00 | 0.00 | 300.00 |
| 45.2. | Review of substantial amendment to investigator’s brochure | 1 amendment | 300.00 | 0.00 | 300.00 |
| 45.3 | Review of substantial amendment to investigational medicinal product master file | 1 amendment | 300.00 | 0.00 | 300.00 |
| 45.4 | Review of substantial amendment to patient documentation | 1 amendment | 300.00 | 0.00 | 300.00 |
| 45.5. | Review of a substantial administrative amendment | 1 amendment | 150.00 | 0.00 | 150.00 |
| 46. | Review of application and additional documentation for a medicinal product observational study requested by medicinal product manufacturer (its representative)1 | 1 expertise on documentation | 300.00 | 0.00 | 300.00 |
| 47. | Issuance of scientific opinion regarding clinical trial documentation submitted as part of the voluntary harmonisation procedure, if the clinical trial application is not submitted after completion of procedure (Section 44 of this Annex)1 | 1 opinion | 1500.00 | 0.00 | 1500.00 |
| **48.** | **Quality control of medicinal products1** |  |  |  |  |
| **48.1.** | **Identification of medicinal product** |  |  |  |  |
| 48.1.1. | Using a chemical reaction | 1 test | 18.00 | 0.00 | 18.00 |
| 48.1.2. | Using instrumental methods and thin layer chromatography (TLC) | 1 test | 46.00 | 0.00 | 46.00 |
| 48.2. | Determination of clarity | 1 test | 8.00 | 0.00 | 8.00 |
| 48.3. | Determination of colour compliance | 1 test | 8.00 | 0.00 | 8.00 |
| 48.4. | Determination of solubility | 1 test | 8.00 | 0.00 | 8.00 |
| 48.5. | Determination of pH | 1 test | 15.00 | 0.00 | 15.00 |
| 48.6. | Determination of density | 1 test | 17.00 | 0.00 | 17.00 |
| 48.7. | Determination of refractive index | 1 test | 8.00 | 0.00 | 8.00 |
| 48.8. | Determination of melting point (temperature) | 1 test | 19.00 | 0.00 | 19.00 |
| 48.9. | Determination of optical rotation | 1 test | 21.00 | 0.00 | 21.00 |
| **48.10.** | **Determination of particulate contamination** | 1 test |  |  |  |
| 48.10.1. | Visually | 1 test | 14.00 | 0.00 | 14.00 |
| 48.10.2. | Instrumentally | 1 test | 21.00 | 0.00 | 21.00 |
| **48.11.** | **Determination of impurities** | 1 test |  |  |  |
| 48.11.1. | Using limiting test methods | 1 test | 15.00 | 0.00 | 15.00 |
| 48.11.2. | Using thin layer chromatography (TLC) | 1 test | 59.00 | 0.00 | 59.00 |
| 48.12. | Determination of nominal volume | 1 test | 3.00 | 0.00 | 3.00 |
| 48.13. | Determination of average mass and deviations from average mass | 1 test | 9.00 | 0.00 | 9.00 |
| 48.14. | Determination of amount of sulphated ash | 1 test | 18.00 | 0.00 | 18.00 |
| 48.15. | Determination of heavy metal content | 1 test | 18.00 | 0.00 | 18.00 |
| 48.16. | Determination of loss of mass on drying | 1 test | 13.00 | 0.00 | 13.00 |
| 48.17. | Determination of water content | 1 test | 20.00 | 0.00 | 20.00 |
| 48.18. | Determination of disintegration | 1 test | 19.00 | 0.00 | 19.00 |
| 48.19. | Determination of friability | 1 test | 8.00 | 0.00 | 8.00 |
| 48.20. | Dissolution test (without further relevant quantitative analysis) | 1 test | 59.00 | 0.00 | 59.00 |
| 48.21. | Determining hardness of solid pharmaceutical forms | 1 test | 10.00 | 0.00 | 10.00 |
| 48.22. | Determination of size of solid pharmaceutical forms | 1 test | 10.00 | 0.00 | 10.00 |
| 48.23. | Determination of osmolality | 1 test | 9.00 | 0.00 | 9.00 |
| 48.24. | Determination of viscosity | 1 test | 28.00 | 0.00 | 28.00 |
| **48.25.** | **Determination of uniformity of active substance content** |  |  |  |  |
| 48.25.1. | Using titration | 1 test | 123.00 | 0.00 | 123.00 |
| 48.25.2. | Using spectrophotometry | 1 test | 136.00 | 0.00 | 136.00 |
| 48.25.3. | Using polarimetry | 1 test | 87.00 | 0.00 | 87.00 |
| 48.25.4. | Using high performance liquid chromatography (HPLC) | 1 test | 199.00 | 0.00 | 199.00 |
| 48.25.5. | Using gas chromatography (GC) | 1 test | 139.00 | 0.00 | 139.00 |
| 48.25.6. | Using atomic absorption spectrometry (AAS) | 1 test | 199.00 | 0.00 | 199.00 |
| **48.26.** | **Determining quantitative composition** |  |  |  |  |
| 48.26.1. | Using titration | 1 test | 50.00 | 0.00 | 50.00 |
| 48.26.2. | Using spectrophotometry | 1 test | 76.00 | 0.00 | 76.00 |
| 48.26.3. | Using polarimetry | 1 test | 36.00 | 0.00 | 36.00 |
| 48.26.4. | Using high performance liquid chromatography (HPLC) | 1 test | 139.00 | 0.00 | 139.00 |
| 48.26.5. | Using gas chromatography (GC) | 1 test | 81.00 | 0.00 | 81.00 |
| 48.26.6. | Using atomic absorption spectrometry (AAS) | 1 test | 128.00 | 0.00 | 128.00 |
| 48.27 | Determining electrical conduction | 1 test | 15.00 | 0.00 | 15.00 |
| 48.28 | Determining other solvents | 1 test | 81.00 | 0.00 | 81.00 |
| 49. | Translation and formatting of medicinal product quality control analysis protocol in English | 1 protocol | 27.27 | 5.73 | 33.00 |
| **50.** | **Quality control of medicinal plants1** |  |  |  |  |
| **50.1.** | **Identification** |  |  |  |  |
| 50.1.1. | External characteristics (of a medicinal plant) | 1 test | 4.00 | 0.00 | 4.00 |
| 50.1.2. | Microscopy (of a medicinal plant) | 1 test | 16.00 | 0.00 | 16.00 |
| 50.2. | Determining particulate contamination of a medicinal plant | 1 test | 14.00 | 0.00 | 14.00 |
| **50.3.** | **Determining quantitative contents** |  |  |  |  |
| 50.3.1. | Content of extractive substances in a medicinal plant | 1 analysis | 55.00 | 0.00 | 55.00 |
| 50.3.2. | Content of essential oils in a medicinal plant | 1 analysis | 55.00 | 0.00 | 55.00 |
| 51. | Quality control of purified water (in pharmacies)1 | 1 sample | 40.00 | 0.00 | 40.00 |
| 52. | Preparation of volumetric solutions, indicators and reactants for pharmacies 1 | 1 name | 7.00 | 0.00 | 7.00 |
| 53. | Travel for compliance evaluation in Latvia or selection of purified water samples from a pharmacy | 1 journey | 16.53 | 3.47 | 20.00 |
| 54. | Quantitative and qualitative analysis of pharmacy’s extemporaneous preparation1 | 1 analysis | 75.00 | 0.00 | 75.00 |
| 55. | Issuance of expert opinion upon official request1 | 1 protocol | 85.00 | 0.00 | 85.00 |
| 56. | Issuance of Certificate of Free Sale for a medical device1 | 1 certificate | 55.50 | 0.00 | 55.50 |
| 57. | Expertise on documentation for a clinical trial with medical devices and a performance study of *in vitro* diagnostic medical devices1 | 1 expertise on documentation | 1500.00 | 0.00 | 1500.00 |
| 58. | Expertise on documentation for substantial amendments to a clinical trial with medical devices and a performance study of *in vitro* diagnostic medical devices1 | 1 expertise on documentation | 900.00 | 0.00 | 900.00 |
| 59. | Resumption of a clinical trial with medical devices and a performance study of *in vitro* diagnostic medical devices after clinical trial suspension1 | 1 expertise on documentation | 900.00 | 0.00 | 900.00 |
| 60. | Issuance of product certificate1 | 1 certificate | 100.00 | 0.00 | 100.00 |
| 61. | Issuance of abridged certificate (Pharmaceutical Product Certificate or Certificate of Free Sale)1 | 1 certificate | 55.00 | 0.00 | 55.00 |
| 62. | Issuance of paper format document or duplicate upon request1 | 1 page | 1.50 | 0.00 | 1.50 |
| 63. | Expertise on application and documentation and issuance of authorisation for import and export of psychotropic, narcotic substances and medicinal products and precursors1 | 1 expertise on documentation | 45.00 | 0.00 | 45.00 |
| 64. | Expertise on application and documentation regarding medical and economic cost-effectiveness of medicinal products or cost-effectiveness of medical devices1 | 1 application | 1200.00 | 0.00 | 1200.00 |
| 65. | Annual fee for ensuring operation of a medical device vigilance system1 | | | | |
| 65.1. | For ensuring operation of a medical device vigilance system for class I medical devices and other (remaining) *in vitro* diagnostic medical devices1 | 1 manufacturer or 1 authorised representative  or  1 distributor | 105.20 | 0.00 | 105.20 |
| 65.2. | For ensuring operation of a medical device vigilance system for class IIa, IIb and III (including class I) medical devices, list A, list B and self-testing (including other (remaining)) *in vitro* diagnostic medical devices1 | 1 manufacturer or 1 authorised representative  or  1 distributor | 210.90 | 0.00 | 210.90 |
| 66. | Expertise on application and documentation for market release or commissioning of specific medical devices or in vitro diagnostic medical devices which have not undergone the compliance evaluation procedures stipulated by normative acts and do not have a CE mark1 | 1 expertise on documentation | 528.60 | 0.00 | 528.60 |

Notes:

1 Value added tax not applicable in accordance with Section 3, Paragraph eight of the Value Added Tax Law.