**Price list for Marketing Authorisation of Veterinary Medicinal Products in Latvia**

The English language text below is provided by the Food and Veterinary Service for information only. Only the original Latvian text of the Cabinet Regulation No. 681, adopted on December 17, 2019, is authentic.

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| **No.** | **Type of service** | **Measurement** | **Price with VAT(*euro*)** |
| **I The authorisation, renewal and post-marketing authorisation surveillance of veterinary medicinal products** |
| **1. NATIONAL REGISTRATION PROCEDURE** |
| **1.1.** | **Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with a national registration procedure:** |
| 1.1.1. | basic pharmaceutical form and strength | application | 750.00 |
| 1.1.1.1. | each additional pharmaceutical form (if submitted simultaneously) | application | 320.00 |
| 1.1.1.2. | each additional strength (if submitted simultaneously) | application | 235.00 |
| 1.1.2. | homeopathic veterinary medicinal product | application | 160.00 |
| **1.2.** | **Application and attached documentation expertise for renewal of veterinary medicinal products authorized in accordance with a national registration procedure:** |
| 1.2.1. | single pharmaceutical form and strength | application | 320.00 |
| 1.2.1.1. | each additional pharmaceutical form (if submitted simultaneously) | application | 160.00 |
| 1.2.1.2. | each additional strength (if submitted simultaneously) | application | 96.00 |
| 1.2.2. | homeopathic veterinary medicinal product | application | 96.00 |
| **2. MUTUAL REGISTRATION PROCEDURE** |
| **2.1.** | **Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with mutual recognition procedure:** |
| 2.1.1. | basic pharmaceutical form and strength | application | 1565.00 |
| 2.1.2. | each additional pharmaceutical form (if submitted simultaneously) | application | 785.00 |
| 2.1.3. | each additional strength, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously | application | 525.00 |
| 2.1.4. | for reference procedure (additionally to sections 2.1.1., 2.1.2. and 2.1.3.) | procedure number | 1955.00  |
| **2.2.** | **Application and attached documentation expertise for renewal of veterinary medicinal products:** |
| 2.2.1. | basic pharmaceutical form and strength | application | 1045.00 |
| 2.2.2. | each additional pharmaceutical form (if submitted simultaneously) | application | 655.00 |
| 2.2.3. | each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously | application | 265.00 |
| 2.2.4. | for reference procedure (additionally to sections 2.2.1.,2.2.2. and 2.2.3.) | procedure number | 1955.00  |
| **3. DECENTRALIZED REGISTRATION PROCEDURE** |
| **3.1.** | **Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with decentralized procedure:** |
| 3.1.1. | basic pharmaceutical form and strength | application | 1565.00 |
| 3.1.2. | each additional pharmaceutical form (if submitted simultaneously) | application | 785.00 |
| 3.1.3. | each additional strength, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously | application | 525.00 |
| 3.1.4. | for reference procedure (additionally to sections 3.1.1., 3.1.2. and 3.1.3.) | procedure number | 1955.00  |
| **3.2.** | **Application and attached documentation expertise for renewal of veterinary medicinal products:** |
| 3.2.1. | basic pharmaceutical form and strength | application | 1045.00 |
| 3.2.2. | each additional pharmaceutical form (if submitted simultaneously) | application | 655.00 |
| 3.2.3. | each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously | application | 265.00 |
| 3.2.4. | for reference procedure (additionally to sections 3.2.1.,3.2.2. and 3.2.3.) | procedure number | 1955.00  |
| **4. Issuing of marketing authorisation and export certificates** |
| 4.1. | Issuing of marketing authorisation certificate in paper form | certificate | 15.00 |
| 4.2. | Issuing of veterinary medicinal product export certificate | certificate | 140.00 |
| 4.3. | Issuing of veterinary medicinal product export (limited) certificate (free sale certificate or statement of licensing status of veterinary medicinal product) | certificate | 41.50 |
| **5. POST-MARKETING AUTHORISATION SURVEILLANCE (each registered pharmaceutical form and strength)** |
| **5.1.** | **Annual fee or:** | marketing authorisation number | **235.00** |
| 5.1.1. | annual fee, if total annual turnover of veterinary medicinal product distributed in Latvia for the previous calendar year exceeded 2000.00 euro | marketing authorisation number | 235.00 |
| 5.1.2. | annual fee, if total annual turnover of veterinary medicinal product distributed in Latvia for the previous calendar year exceeded from 1000.01 until 2000.00 euro | marketing authorisation number | 100.00 |
| **5.2.** | **Assessment of periodic safety update report (PSUR) for veterinary medicinal product which requires detailed scientific expertise** | report | **275.00** |
| **5.3.** | **Assessment of periodic safety update report (PSUR) for veterinary medicinal product which does not requires detailed scientific expertise (national procedure)** | report | **75.00** |
| **6. APPROVAL OF VARIATIONS ON DOCUMENTATION FOR VETERINARY MEDICINAL PRODUCTS** (per each product) |
| 6.1. | Minor Type I A notification | one variation | 132.50 |
| 6.2. | Minor Type I B notification | one variation | 199.50 |
| 6.3. | Major type II variation requiring detailed scientific evaluation of documentation or line extension | one variation | 391.50 |
| 6.4. | Major type II variation not requiring detailed scientific evaluation of documentation | one variation | 229.00 |
| 6.5. | Major type II variation related to the change of the marketing authorisation holder (new marketing authorisation holder and current marketing authorisation holder are not the same person/entity) | one variation | 132.50 |
| 6.6. | Approval of common Baltic labelling for veterinary medicinal products | expertise | 132.50 |
| 6.7.  | Approval of mock-ups | expertise | 135.50 |
| 6.8. | Approval of changes in mock-ups | expertise | 41.50 |
| **II Issuing of certificates related to the circulation of veterinary medicinal products**  |
| **7. Parallel imported veterinary medicinal products** |
| 7.1. | Application and attached documentation expertise for the distribution of parallel imported veterinary medicinal product in Latvia | expertise | 225.00 |
| 7.2. | Approval of variations on the package leaflet of parallel imported veterinary medicinal product | expertise | 65.50 |
| 7.3. | Approval of variations on the product labelling of parallel imported veterinary medicinal product | expertise | 65.50 |
| 7.4. | Approval of variations on the documentation of parallel imported veterinary medicinal product (the change of legal address of the firm of a merchant) | expertise | 26.50 |
| 7.5. | Issuing of permission for the distribution of parallel imported veterinary medicinal product in Latvia | permission | 6.65 |
| **8. Distribution of veterinary medicinal products imported under special permit** |
| 8.1. | Evaluation (requires detailed scientific expertise) of application and documentation to issue an import and distribution permission for the purpose of carrying on activities of veterinary medical practice institution (per each product) | one product expertise | 70.00 |
| 8.2. | Evaluation (not requires detailed scientific expertise) of application and documentation to issue an import and distribution permission for the purpose of carrying on activities of veterinary medical practice institution (per each product) | one product expertise | 35.00 |
| 8.3. | Approval of variations to the import and distribution permission for the purpose of carrying on activities of veterinary medical practice institution (per each product) | one product expertise | 15.00 |
| 8.4. | Issuing of permission for the import and use in exceptional cases (including immunological veterinary medicinal products) at the request of the wholesaler or importer (per each product) | permission for one product  | 28.15 |
| 8.5. | Issuing of permission for the import and use in exceptional cases (including immunological veterinary medicinal products) at the request of the veterinary medical practice institution or practicing veterinarian (per each product) | permission for one product  | 5.85 |
| 8.6. | Issuing of permission for the import and use of immunological veterinary medicinal products in exceptional cases where immunological veterinary medicinal products are required for routine vaccination | permission | 28.15 |
| 8.7. | Approval of variations on the permission of the import and use in exceptional cases (including immunological veterinary medicinal products) (per each product) | permission for one product  | 15.00 |
| 8.8. | Issuing of permission of import and distribution of veterinary medicinal products imported under special permit (additionally to sections 8.1., 8.2. and 8.3.) | permission | 6.65 |
| **9. PRODUCT COMPLIANCE ASSESSMENT** |
| 9.1. | Assessment of the product to determine its compliance to the definition of veterinary medicinal product (without laboratory tests)  | expertise | 275.00 |
| **10. The clinical trial**  |
| **10.1.** | **Application and attached documentation assessment for the clinical trial** |
| 10.1.1. | food-producing animals | application | 376.25 |
| 10.1.2. | other animals | application | 270.00 |
| **10.2.** | **Approval of variations on the application and attached documentation for the clinical trial** |
| 10.2.1. | food-producing animals | application | 160.00 |
| 10.2.2. | other animals | application | 130.00 |
| **10.03** | **Issuing of permission for the clinical trial** | **permission** | **6.65** |
| **11. ISSUING OF OTHER CERTIFICATES** |
| **11.1.** | **Import of veterinary medicinal product sample:** |
| 11.1.1. | application and attached documentation expertise for import of veterinary medicinal product samples | expertise | 135.50  |
| 11.1.2. | issuing of authorisation for import of veterinary medicinal product samples | authorisation | 6.65 |
| **11.2.** | **Distribution of remaining stock:** |
| 11.2.1. | application and attached documentation expertise for distribution of remaining stock of veterinary medicinal roduct | expertise | 26.50 |
| 11.2.2. | issuing of authorisation for distribution of remaining stock of veterinary medicinal product | authorisation | 6.65 |
| **III The conformity assessment, registration of activities and licensing** |
| **12. The conformity assessment** |
| 12.1. | The document conformity assessment | document expertise | 40.00 |
| 12.2. | The conformity assessment in a veterinary pharmacy (including evaluation of documents and preparation of protocol) | 1 pharmacy | 52.95 |
| 12.3. | The conformity assessment in wholesaler (including evaluation of documents and preparation of protocol) | 1 wholesaler | 210.60 |
| 12.4. | Conformity assessment of a person who is not working under veterinary medical practice institution but is eligible to purchase a veterinary medicinal product in a wholesaler for the purpose of carrying on his activity without the right to distribute veterinary medicinal products (according to the actual inspection time per working hour per one inspector) | 1 hour | 17.60 |
| **13.** |
| **13.1.** | **The verification of the conformity assessment in import/manufacturing company of veterinary medicinal products, the verification of the good manufacturing practice (EEA country) in the veterinary medicinal product manufacturing company or in the laboratory, which according to contract is responsible for quality control in the manufacturing company (without including costs of missions and external experts):** |
| 13.1.1. | one day (one inspector) | import/ manufacturing company | 350.00 |
| 13.1.2. | two days (one inspector) | import/ manufacturing company | 444.00 |
| 13.1.3. | three days (one inspector) | import/ manufacturing company | 538.00 |
| 13.1.4. | four days (one inspector) | import/ manufacturing company | 632.00 |
| 13.1.5. | five days (one inspector) | import/ manufacturing company | 726.00 |
| **13.2.** | **The verification of the conformity assessment in import/manufacturing company of veterinary medicinal products, the verification of the good manufacturing practice (a third country (non-EEA country)) in the veterinary medicinal product manufacturing company or in the laboratory, which according to contract is responsible for quality control in the manufacturing company (without including costs of missions and external experts):** |
| 13.2.1. | one day (one inspector) | import/ manufacturing company | 525.00 |
| 13.2.2. | two days (one inspector) | import/ manufacturing company | 666.00 |
| 13.2.3. | three days (one inspector) | import/ manufacturing company | 807.00 |
| 13.2.4. | four days (one inspector) | import/ manufacturing company | 948.00 |
| 13.2.5. | five days (one inspector) | import/ manufacturing company | 1088.50 |
| **13.3.** | **Issuing of certificate for the good manufacturing practice of veterinary medicinal product** | **certificate** | **40.00** |
| **13.4.** | **Evaluation of documents for the good manufacturing practice of veterinary medicinal product** | **document expertise** | **142.30** |
| **IV CONTROL OF VETERINARY MEDICINAL PRODUCTS SAMPLES** |
| **14. Veterinary medicinal products samples** |
| 14.1. | Sampling | sample | 17.60 |
| **V** **data processing of veterinary medicinal products** |
| **15. Statistics, information** |
| 15.1. | Information on request (with agreement) per each working hour | 1 hour | 15.00 |