Manufacturing of Veterinary Medicinal Products

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Requirements for the Manufacturer/Importer of Veterinary Medicinal Products

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In order to operate in the area of the manufacture or import of veterinary medicinal products or investigational veterinary medicinal products from third countries (non-member states of the European Union or European Free Trade Association countries, which are signatories to the Agreement on the European Economic Area), a special permit (licence) for the manufacturing/importing of veterinary medicinal products must be received. A special permit (licence) is also required in the cases, where:

- the veterinary medicinal products are not intended for distribution in the territory of the Republic of Latvia or are intended only for export to third countries;
- for carrying out the whole or part of the production process (packing, packaging, presentation of the finished product).

Obligations of the Manufacturer/Importer of Veterinary Medicinal Products

The manufacturer/importer must adhere to the principles and guidelines of Good Manufacturing Practice (GMP) for Veterinary Medicinal Products set out in Cabinet Regulation No. 319 of 15 May 2007Regulations Regarding the Manufacture and Control of Veterinary Medicinal Products, the Procedure for the Issuance of a Good Manufacturing Practice Certificate to a Manufacturer of Veterinary Medicinal Products and Regarding the Requirements for the Qualification and Professional Experience of the Official Responsible for the Manufacture of Veterinary Medicinal Products and the guidelines of the European Commission, which are published in Volume 4 of the Rules Governing Medicinal Products in the European Union.

Documents to be Submitted

The procedure to be followed for obtaining a special permit (licence) is specified in Cabinet Regulation No. 35 of 11 January 2011, Procedures for the Issuing, Suspension, Re-Registration and Revoking of Special Permits (Licences) for Veterinary Pharmaceutical Activity. A person in whose name the issue of a special permit (licence) is planned, shall first submit the following to the Food and Veterinary Service (hereinafter - FVS) at the head office or a territorial unit:

- an application for the issue or re-registration of a special permit (licence) for the manufacturing and import of a veterinary medicinal product (Annex No.1),
- description of the manufacturing site (Annex No. 2),
- if the veterinary medicinal products are manufactured exclusively for exporting, the list of manufactured veterinary medicinal products that are intended for export (Annex No. 3).

Review time of the Application:

FVS shall review the application for the issue or re-registration of a special permit (licence) for the manufacturing or import of veterinary medicinal products and the documents enclosed with the application within 5 business days. If additional information is required during the examination of the documents, it shall be requested from the applicant.

Inspection Process and Timelines

Within 20 business days after the examination of the application, the FVS shall assess the compliance of the manufacturer (including foreign manufacturers)/importer of veterinary medicinal products by performing an inspection. During the inspection, the conformity of the premises, equipment, devices, personnel and documentation intended for the manufacture or import of veterinary medicinal products with the requirements set out in the legislation on the manufacture and control of veterinary medicinal products, the procedures for the issuing of the good manufacturing practice compliance certificates to the manufacturer of medicinal products, and with the requirements for the qualification and professional experience of the official responsible for the manufacture of the veterinary medicinal product shall be verified.

The inspection shall be carried out, within the scope of their competences, by authorised officials of the FVS, who have been trained to control compliance with the requirements of good manufacturing practice and have the right:

- to inspect manufacturers and laboratories that perform the control of veterinary medicinal products on commission by the licence holder (owner),
- to take samples, including for the purpose of independent analysis of veterinary medicinal products by a laboratory authorised to carry out the control of medicinal products. The costs associated with the inspection and testing of the veterinary medicinal products shall be borne by the person being examined,
- to examine the documents relating to the inspected object as regards the description of the production methods, within the limits of their authority.

Initially, the FVS agrees with the veterinary medicinal product manufacturer/importer on the time of inspection by sending an electronic mail. Not later than within 10 business days prior to the inspection, the FVS shall send an official letter to the manufacturer/importer of the veterinary medicinal product, informing him of the time, procedure, documents to be inspected and inspectors participating in the inspection, as well as indicating that the inspection plan may be changed, depending on the deficiencies found.

If required, the letter shall be accompanied by the list containing information on the documents that the manufacturer of the veterinary medicinal products must submit prior to the planned inspection and time limits for the submission thereof, to enable the FVS to properly prepare for the inspection.

Depending on the size and complexity of the company, the inspection can last from 1 to 5 days.

Post-Inspection Activities

After the inspection, the FVS shall draw up inspection report within 10 business days, where the deficiencies found during the inspection that are classified as critical, major or other shall be indicated. The inspection report shall be sent to the manufacturer/importer together with the cover letter, which indicates the date when the manufacturer must submit the Corrective and Preventive Action Plan.

If the inspection report points to critical or significant deficiencies, the manufacturer /importer shall, within 5 business days after the receipt of the inspection report, submit to the FVS the Corrective and Preventive Action Plan for elimination of deficiencies, where the timeframe of the elimination of deficiencies shall be indicated.

After the elimination of the deficiencies, the FVS, in accordance with the procedure provided for by the Administrative Procedure Law, shall decide on the issue or refusal to issue a special permit (licence).

If, after the issue of the licence, additional inspections of the company are required to assess whether the deficiencies found during the previous inspection have been eliminated, the FVS shall agree with the manufacturer/importer on the time of the inspection.

Price List of Services

Information on the costs involved in the processing of the application, the issue of a licence or certificate and inspection is available HERE.

Further Monitoring

Within 3-6 months after the receipt of the special permit (licence) for the manufacturing /importing of veterinary medicinal products by the manufacturer/importer, the FVS shall conduct a repeated inspection to ascertain that the company complies with the principles and guidelines of good manufacturing practice of veterinary medicinal products in its operations.

The FVS shall, within one month after the completion of the inspection, make the decision on the issue of a certificate of good manufacturing practice.

After the receipt of a certificate of good manufacturing practice, no less than once in every three years, the FVS shall perform a repeated inspection at the company to ascertain that the company observes the principles and guidelines of good manufacturing practice in their work. After each of the repeated inspections, the FVS shall issue a new certificate of good manufacturing practice.

FVS is also entitled to carry out unannounced inspections.

Useful Information

Important! In accordance with Paragraph 12, Section 10 of the Pharmaceutical Law, the State Agency of Medicines (hereinafter - SAM) issues special licences (licences) for pharmaceutical activities as well as special licences (licences) for pharmaceutical activities, which specify the production and import of veterinary medicinal products as a special area of activity. For more information, see the website of SAM.

Information on all companies that have received a special permit (licence) for veterinary pharmaceutical activity from SAM or FVS is available in the Register of Enterprises subject to FVS surveillance.

For more details on the companies licensed for manufacture/import of both medicinal products for human use and veterinary medicinal products, visit the website of SAM.

Information on the holders of the special permit (licence) is available on thewebsite of FVS.

The information on special permits (licences) that have been issued, suspended or annulled and good manufacturing practice conformity certificates is also published in the data base of the European Medicines Agency.

Action in the Case of Non-Compliance

In cases where the manufacturer/importer fails to comply with the principles and guidelines of good manufacturing practice, the FVS is entitled to make the following decisions regarding:

certificate of good manufacturing practice:

- a temporary suspension of the issue, stating the reasons and the time period within which the required remedial measures must be implemented,
- a refusal to issue a certificate of good manufacturing practice, by issuing a statement of non-compliance with good manufacturing practice.

The action after the issuing of a statement of non-compliance with good manufacturing practice has been prescribed in the Compilation of Community Procedures on Inspections and Exchange of Information

In the event of significant violations in the manufacture/importing and distribution of veterinary medicinal products, the FVS shall be entitled to make a decision on:

the refusal to issue a special permit (licence),

the suspension of the validity of the special permit (licence) until the deficiencies have been eliminated,

the withdrawal of the special permit (licence).

Contacts

If you have any questions or queries, please email Division of the Marketing Authorisation for the Veterinary Medicinal Products at vzr@pvd.gov.lv or call +371 67084618

https://www.pvd.gov.lv/en/manufacturing-veterinary-medicinal-products