

Changes in the registration documentation of veterinary medicinal products

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Price
Free



Execution deadline in working days
90
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Recipient
Public law legal person
Private law legal person



Receiving restrictions
-

Description:

The time limit for receiving the service depends on the type of change that you want to make. An expert-examination of the IA type change application shall take 14 days, an expert-examination of the IB type change application - 30 days, an expert-examination of the Type II change application - 60 or 90 days.

Get a service

On-site

E-Service

Others

If it is necessary to make changes to the registration documentation for veterinary medicinal products, the Food and Veterinary Service shall be informed thereof.

Process description

Related documents

Process description

Service requests

The applicant/Marketing Authorisation Holder shall submit a duly formed application, accompanied by:

- documents containing administrative information and scientific documentation necessary to demonstrate the safety, efficacy and quality of the veterinary medicinal products to be registered.

When submitting the application, a supporting document must be attached. The service charge is specified in the price list.

The documents shall be submitted to the PVD or by post. Electronically signed documents must be sent to the nrd@pvd.gov.lv e-mail address.

Documents may also be submitted using the institution's e-address.

Receipt of services

The PVD shall carry out an expert-examination of the dossiers submitted and shall take a decision on the making/non-performance of changes which shall be notified to the applicant

If the owner (holder) of a registration certificate for veterinary medicinal products makes changes to the registration documentation for veterinary medicinal products, for a period of 12 months from the day when a decision regarding approval of changes in the registration documentation for veterinary medicinal products has been taken, the owner (holder) of the registration certificate shall be entitled to distribute the veterinary medicinal products in the stock for which the approved changes to the registration documentation have not been introduced. That condition applies to the wholesale sale of this medicinal product.

After the end of the 12-month period, only veterinary pharmacies, pharmacies, veterinary medical merchants and practising veterinarians may distribute the remaining inventory of medicinal products without approved changes, but not longer than the expiry date of the specified medicinal product.

Get a service

On-site

E-Service

Others

<https://www.pvd.gov.lv/en/services/changes-registration-documentation-veterinary-medicinal-products>