How to Register a Veterinary Homeopathic Remedy (VHR)

Apply to register, renew, or vary a Veterinary Homeopathic Remedy.

A VHR is a veterinary medicinal product prepared from homeopathic stocks using a homeopathic manufacturing procedure.

A VHR must be registered before it can be placed on the market for sale and supply unless the VHR:

- was already on the market before 1st January 1994 (MS Excel Spreadsheet, 4.74MB), and
- has Grandfather Rights, and
- is named on the list held by the VMD

The proposed registration holder of a VHR must be established within the UK or the European Economic Area (EEA).

For companies this means they must be formed in accordance with the law of the UK or the EU and have their registered office, central administration, or principle place of business within the EEA.

Eligibility

A single registration may cover multiple dosage forms and routes of administration and different degrees of dilution providing they are all derived from the same homeopathic stock or stocks.

To be eligible for registration a VHR must be:

- prepared from substances called homeopathic stocks using a homeopathic manufacturing procedure described in the European Pharmacopoeia
- administered either orally or topically as described in a pharmacopoeia,
- sufficiently dilute to guarantee safety, that is it may not contain more than 1 part on 10,000 of the mother tincture

The following remedies are considered veterinary medicines and require a Marketing Authorisation (MA):

- remedies making specific therapeutic claims including immunological ones
- remedies not considered sufficiently dilute to guarantee safety
- remedies where the route of administration is not as described in the European Pharmacopeia, or an official pharmacopeia of a member state

Authorisation routes

The routes for getting a registration are the same as those for getting an MA with the exception of the centralised procedure, which does not apply. For further information refer to the Marketing authorisations for veterinary medicines page.

Most registrations are obtained through the national route. If you wish to submit an application under the Mutual Recognition or Decentralised procedures, please contact the us.

Post registration steps

Once a VHR is registered, it will be appear on the Product Information Database.

Pharmacovigilance

Pharmacovigilance requirements for homeopathic remedies, including products eligible for grandfather rights, are the same as for products with MAs. For further information refer to Veterinary Pharmacovigilance: your responsibilities.

Variation to a VHR

If you wish to make any changes to your registration, you will need to submit a variation application. The procedure for varying a VHR is the same as the one for varying a Marketing Authorisation. For further information refer to the Apply to change a marketing authorisation for an animal medicine guidance.

Implementation period

Following approval of a variation, you will have 6 months to introduce any agreed changes for sale and supply. By the deadline all products released by the Qualified Person (QP) must reflect the agreed changes. This deadline may be shorter if the change made is for safety reasons. Longer deadlines may also be agreed if you request them.

The deadline for implementation will be stated on the certificate issued to you at the end of the application procedure.

The VH symbol

A registered VHR will have a registration number preceded by the symbol Vh on its product literature, for example, the label.

Distribution category

An authorised product will have a distribution category, which relates to the retail supply of the product, for example, a product classified as Prescription Only Medicine - Veterinarian (POM-V) may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.

It is normally expected that a VHR will be distributed through the AVM-GSL category, which allows it to be sold off the shelf. For further information refer to the Retail of veterinary medicines guidance.

The distribution category can also be referred to as the legal category.

Contact us

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