Guidance

Exemption from authorisation for medicines for small pet animals

How to comply with the exemption from the Veterinary Medicines Regulations that allow certain animal medicines to be sold without a marketing authorisation.

Certain medicines for small pet animals are exempt from the marketing authorisation requirements of the Veterinary Medicines Regulations, as amended, (VMR) under Schedule 6.

By the end of 2024 you need to be registered with the Secretary of State in order to place a product on the UK market under the exemption. Further guidance on how to register will be made available in due course.

Exempt species

Medicines for the following species are exempt provided the animals are kept exclusively as pets and are not intended to produce food for human consumption:

- aquarium animals, including fish only kept in closed water systems
- cage birds; birds kept in cages or aviaries
- homing pigeons; pigeons kept for racing or exhibition
- terrarium animals; reptiles, amphibians and arthropods kept in tanks and cages, including animals free-living in domestic gardens
- small rodents; domestic mammals of the order rodentia
- ferrets
- rabbits

Chickens, ducks and turkeys are classified as food producing animals and so medicines for these species are not, under any circumstances, covered by the exemption.

Active substances

Exempt medicines can only contain active substances which have been approved for the purposes of this exemption by the Secretary of State.

Approval may not be granted if the active substance requires veterinary control, see section ‘Medicines not included in the exemption’.

List of approved active ingredients for small animals (PDF, 464 KB, 19 pages).

If you wish to market a product under the exemption which contains a substance not included on this list or for an exempt species or route of administration not currently included for a substance on the list, you must apply using the application for active approval form (PDF, 89.1 KB, 4 pages).

Your completed application form should be sent to inspections@vmd.gov.uk.

The fee for this is £

You will be sent an invoice upon receipt of a valid application.

Do not submit any studies or reports unless specifically requested. A brief justification for inclusion of the active substance will usually be sufficient.

Under the exemption, combinations of active substances may be marketed within the same product, provided each individual substance is included on the list of approved active substances.

Medicines not included in the exemption

The following medicines are not covered by this exemption:

- antibiotics
- narcotic or psychotropic substances*
- those intended for treatments or pathological processes that require a precise diagnosis by a vet or the use of which may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures

*Certain sedatives may be permitted for use with fish. Please contact us for further information.

Purpose of use and route of administration

Exempt medicines are restricted to topical or oral administration routes only:

- Topical medicines are those that are applied externally to the skin and have a local or systemic action. This excludes products that are administered in the eye or ear canal, intra-nasally or via nebulisation; aerosol delivered to the airways and lungs.
- Oral medicines are defined as those that are administered in feed, in water or directly into the oral cavity.
  This excludes products that are administered by stomach or crop tubing; gavage.

Fish medicines administered via the water and not intended for direct ophthalmic use are acceptable.

Labelling requirements

Exempt products must be clearly labelled to show that they are exempt from having a marketing authorisation, for example by including the following statement on the outer packaging:

This veterinary medicine is marketed in accordance with Schedule 6 of the Veterinary Medicines Regulations - Exemptions for small pet animals.

The labelling must contain the following information either on the label or, if there is insufficient space, on a package leaflet:

- name of the product
- the authorisation number of the manufacturer*
- name and strength of each active substance
- route of administration
- batch number
- expiry date
- the words, For animal treatment only
- contents by weight, volume, or the number of unit doses
- name and address of the manufacturer or distributor
- target species
- the words, Keep out of reach of children
- storage instructions

- the shelf life after the immediate packaging has been opened for the first time
- disposal advice
- full indications, including:
    - therapeutic indications
    - contra-indications
    - interaction with other medicines and other forms of interaction
- dosage instructions

*If no suitable manufacturing authorisation number is issued by the relevant National Competent Authority, we can issue one.

If you apply for an authorisation number you should provide evidence to demonstrate that the manufacture of the product is in accordance with Good Manufacturing Practice (GMP). Further guidance on manufacturing is below.

The label on the product itself must contain at least the following:

- name of the product
- name and strength of each active substance
- route of administration
- batch number
- expiry date
- the words, For animal treatment only
- any additional warnings that are required may be stipulated for the particular active substance. These can be found on the list of approved active substances

Pack sizes

Exempt products must only be sold in pack sizes suitable for a single course of treatment. The VMD considers this condition should be met by ensuring that packs contain only sufficient product to treat the following numbers of animals until symptoms are alleviated or, for preventative treatments, up to six months:

Species	Pack size
Aquarium animals	a single course of treatment should be no more than 7 administrations to an aquarium of up to 25,000 litres. The course of treatment should be clearly defined, for example, Administer to aquarium for 7 consecutive days.
Cage birds	to treat no more than 50 birds
Homing pigeons	to treat no more than 50 birds
Terrarium animals	to treat no more than 5 animals
Small rodents	to treat no more than 5 animals
Ferrets	to treat no more than 5 animals
Rabbits	to treat no more than 5 animals

Manufacturing and supply

Exempt medicines must meet the requirements of the VMR relating to the manufacture (GMP) and wholesale dealing of veterinary medicines.

For further information about how to obtain a manufacturing authorisation, refer to Manufacturing Authorisations for veterinary medicines.

Veterinary medicines marketed under this exemption must be manufactured by the holder of a manufacturing authorisation issued under:

- a certificate issued by the VMD on behalf of the Secretary of State (sites in the UK and all other countries)
- a certificate issued by the competent authority of one of the following countries: the EU, Australia, Canada, New Zealand, Switzerland and the USA

There are no restrictions on the retail supply within the UK of products manufactured under the exemption but they may only be wholesale supplied by the holder of a Wholesale Dealer Authorisation (WDA).

Wholesale dealers supplying products under the exemption are not required to keep wholesale records that duplicate manufacturer's records.

For information on how to obtain a WDA go to Veterinary medicine wholesale dealer's authorisation.

There are no restrictions on the importation of products which fully comply with this exemption.

Pharmacovigilance

Manufacturers and importers must report any serious adverse event to us within 15 days of becoming aware of it; and must keep records of all adverse events for 3 years, which they must make available to us on request.

For further information refer to the Veterinary pharmacovigilance guidance.

Preventing illegal use

When marketing an exempt medicine you must take reasonable measures to prevent its illegal use in animal species not covered by the exemption. For example, you must ensure that any advertising does not falsely describe the product or mislead as to its nature, quality, uses or effect.

Exempt products and the prescribing cascade

As exempt products are not authorised medicines they do not fall under the prescribing cascade. If vets wish to use one of these products not in accordance with its recommended use, this would be classed as use under the cascade and considered an extemporaneous preparation.

For more information refer to The Cascade: Prescribing unauthorised medicines guidance.

Contact

For further information and to be included on our mailing list for updates about the exemption, email pet.exemptions@vmd.gov.uk.