

# [Detailed guide: Exemption from authorisation for medicines for small pet animals](#)

*Updated:* Approved active ingredients table updated

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

## **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 only fish kept in closed water systems)
- cage birds (e.g 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

## **Active substances and ingredients**

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

[approved active ingredients for small animals](#)

(PDF, 896KB, 38 pages)

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If you wish to market a product under the exemption which does not contain ingredients on this list you should complete the

[application for active approval form](#)

(MS Word Document, 59.9KB)

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Do not submit any studies or reports unless specifically requested. A short paragraph will usually be sufficient.

Certain sedatives may be permitted. You should confirm this with the VMD

## **Medicines not included in the exemption**

The following medicines are not covered by this exemption:

- antibiotics
- narcotic or psychotropic substances
- medicines intended to be injected or infused into the body (eg. intravenously) or ophthalmic use, or for insertion into the ear canal

## **Purpose of use and route of administration**

Exempted medicines must not be 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.

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

## **Labelling requirements**

Exempted products must be clearly labelled to show that they are exempt from having a Marketing Authorisation, using the following statement meets this requirement:

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 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 authorisation number is issued by the relevant National Authority, the VMD can issue a manufacturing authorisation number.

When applying for this authorisation number you should provide evidence to demonstrate manufacture in accordance with Good Manufacturing Practice (GMP).

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 warning that may be stipulated for the particular active substance.

## Pack sizes

Exempted 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, eg. 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

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

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

For further information refer to [Manufacturing Authorisations for veterinary medicines](#) and [Apply for manufacturer or wholesaler of medicines licences](#) pages.

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

- Directive EC No 2001/82 as amended (sites in UK and EU)
- a certificate issued by the competent authority (sites in Australia, Canada, New Zealand and Switzerland)
- a certificate issued by the Secretary of State (sites in all other countries)

There are no restrictions on the retail supply within the UK of exempted products.

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

## **Pharmacovigilance**

Any serious adverse events should be reported to the VMD within 15 days. Manufacturers, importers and retailers must keep records of all adverse events for 3 years to be shown to the VMD on request. For further information see the [Veterinary pharmacovigilance](#) page.

## **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.

## **Exempted products and the prescribing cascade**

As exempted products are not authorised medicines they do not fall under the prescribing cascade. However, if a vet chooses to use an exempted product not in accordance with its product literature then they may do so in line with the principles of the prescribing cascade. By doing so, however, the medicine will no longer be deemed to be an exempted product.

For more information on exempt product please see the [The Cascade: Prescribing unauthorised medicines](#) page.