



# Veterinary Medicines Guidance Note

## Marketing Authorisation Exemption Scheme for Pet Animal Medicines

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ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES



**THESE NOTES ARE ONLY A GENERAL GUIDE AND MUST NOT BE TREATED AS A COMPLETE OR AUTHORITATIVE STATEMENT OF THE LAW ON ANY PARTICULAR CASE**

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**INVESTOR IN PEOPLE**

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## INTRODUCTION

1. This is one of a series of Veterinary Medicines Guidance (VMG) Notes explaining requirements under the Veterinary Medicines Regulations ('the Regulations'). The Regulations are revoked and replaced every year, so the references to them should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument are not shown in this VMG Note. The VMG notes will be updated as necessary and the date of the most recent update is shown on the front cover. The Regulations set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration.
2. VMG Note 1: *An introduction to marketing controls on veterinary medicines* provides basic information about the scope of the Regulations and the requirements for Marketing Authorisations (MAs). Additional information is set out in VMG Note 2: *Marketing authorisations for veterinary medicinal products – applications and renewals*.
3. The purpose of this VMG Note is to describe the scope of the Small Animal Exemption Scheme for medicines intended for minor species, and how it will operate.
4. The Regulations permit certain veterinary medicinal products (VMPs) to be marketed without a marketing authorisation, subject to certain conditions being met. These conditions are set out in the following paragraphs.
5. The VMPs must be manufactured by the holder of an appropriate authorisation.

## EXEMPT SPECIES

6. This exemption scheme applies only to veterinary medicines labelled exclusively for use in one or more of the following animals:
  - aquarium fish, (meaning fish kept in closed water systems)
  - cage birds (meaning birds kept in cages or aviaries)
  - homing pigeons (meaning pigeons kept for racing or exhibition)
  - terrarium animals (meaning reptiles, amphibians and arthropods kept in tanks and cages – including animals free-living in domestic gardens)
  - small rodents (meaning domestic mammals of the order *rodentia*)
  - ferrets
  - rabbits

7. The exemption applies to pet animals that are not intended to produce food for human consumption. The Scheme includes animals that are:
  - kept at rescue centres (including those to be released into the wild);
  - bred as food for other species;
  - kept for laboratory purposes; and
  - kept for financial gain (e.g. sport, exhibition, sale).

### ACTIVE SUBSTANCES AND ROUTES OF ADMINISTRATION

8. Products containing antibiotics, anaesthetics or any narcotic or psychotropic substances are not included in the exemption scheme. Certain sedatives may be permitted but confirmation should be sought from VMD.
9. Products containing active substances requiring veterinary control may not be granted approval under this scheme.
10. Products must not be intended for treatments or pathological processes that require a precise diagnosis by a veterinary surgeon, or the use of which may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures.
11. Since 1 November 2007 products can only contain active substances which have been approved for the purposes of this Scheme by the Secretary of State. The list of approved substances is available on the VMD's website [www.vmd.gov.uk](http://www.vmd.gov.uk). The list will be updated periodically when new substances are approved.
12. Companies wishing to market products in accordance with the Scheme which do not contain ingredients on this list should first contact VMD.
13. Products intended for parenteral or ophthalmic use, or for insertion into the ear canal are not exempted under this scheme. Fish medicines administered via the water and not intended for direct ophthalmic use are acceptable.

### LABELLING

14. All products exempted under this scheme must be labelled clearly to show that they are exempt from the statutory requirement for an MA. This requirement may be met by including the following statement on labelling:

“This veterinary medicine is marketed in accordance with the Small Animal Exemption Scheme.”
15. The labelling must show a manufacturing authorisation number. If no suitable authorisation number is issued by the relevant National Authorities, a

manufacturing authorisation number can be issued by the VMD. Application for this authorisation number should be accompanied by evidence to demonstrate manufacture in accordance with Good Manufacturing Practice (GMP).

16. The labelling must contain the following information –

- ♦ 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:
  - (i) therapeutic indications
  - (ii) contra-indications
  - (iii) interaction with other medicines and other forms of interaction
- ♦ dosage instructions.

### PACK SIZES

17. For a product to be exempt under this scheme it must only be sold in pack sizes suitable for a single course of treatment for one animal, bird or reptile, or for one aquarium. The VMD considers that this condition may be met by ensuring that packs contain only sufficient product to treat the following numbers of animals until symptoms are alleviated, or, for prophylactic treatments, for a period of no longer than six months:

**aquarium fish:** for a single course of treatment, of no more than 7 administrations to an aquarium of up to 25,000 litres; The course of treatment should be a clearly defined regimen that has no ambiguity (e.g. administer to aquarium for 7 consecutive days). The pack should only contain enough product to complete the stated course of treatment.

**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

18. Although products covered by this scheme are exempted from the requirement to hold an MA, they are still legally classed as veterinary medicines. Therefore, they must meet all the requirements of the Regulations relating to the manufacture and wholesale dealing of veterinary medicines (see VMG Note 10: *Wholesale Dealers Authorisations for Veterinary Medicines and VMG Note 17 Authorisations for Manufacturer's*).
19. Veterinary medicines marketed under this Scheme must be manufactured by the holder of a manufacturing authorisation issued under:
- Directive EC No 2001/82 (sites in UK and EU);
  - a certificate issued by the competent authority (sites in Australia, Canada, New Zealand and Switzerland); or
  - a certificate issued by the Secretary of State (sites in all other states).

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

### PHARMACOVIGILANCE

20. Any serious adverse reactions should be reported to the VMD within 15 days of learning of the reaction. Records of all adverse reactions are required to be kept by manufacturers, importers or retailers and should be made available to the VMD on request. These records should be kept for 3 years. Further information is provided in VMG Note 13: *Marketing Authorisation for Veterinary Medicinal Products Supplementary Guidance on Pharmacovigilance*.

### PREVENTING ILLEGAL USE

21. The company/individual placing an exempt product on the market is also responsible for taking all reasonable measures to prevent its illegal use in animal species not covered by the exemption. These include, for example, ensuring that any advertising does not falsely describe the product, or mislead as to its nature, quality, uses or effect.
22. To assist companies and individuals to meet this requirement the VMD will hold a list of products marketed under this Scheme that have been notified to us. This list will be published on the VMD website [www.vmd.gov.uk](http://www.vmd.gov.uk). Companies and

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individuals who wish their products to appear on this list should contact the VMD in writing with details of the following:

- ◆ name of the product;
- ◆ name and address of the manufacturer and distributor of the product;
- ◆ manufacturer's authorisation number;
- ◆ animal groups for which the product is intended;
- ◆ active substances and their level of inclusion;
- ◆ dosage form;
- ◆ route of administration

### USE IN OTHER SPECIES

23. It is illegal to administer exempt products to a species for which they are not intended, unless prescribed by a veterinary surgeon under the terms of the prescribing cascade (see VMG Note 15: *Guidance on the use of the Cascade*).
24. A veterinary surgeon may choose to use a Schedule 6 product at any time under the cascade if in his professional judgement such products provide a safer or better option for treatment.

### FURTHER INFORMATION

25. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: +44 (0)1932 336911; Fax: +44 (0)1932 336618 or E-mail: [VMGNotes@vmd.defra.gsi.gov.uk](mailto:VMGNotes@vmd.defra.gsi.gov.uk). Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website ([www.vmd.gov.uk](http://www.vmd.gov.uk)).



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