



Veterinary Medicines Guidance Note

Marketing Authorisation Exemption Scheme for Pet Animal Medicines

No 14



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES



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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 guidance notes explaining requirements under the Veterinary Medicines Regulations 2005. These regulations came into effect on 30 October 2005 and set out controls on veterinary medicinal products in the UK. Basic information about the scope of the Regulations and the requirements for marketing authorisations is given in VMG Note 1: *An introduction to marketing controls on veterinary medicines*. Additional information is set out in VMG Note 2: *Marketing authorisations for veterinary medicinal products – applications and renewals*.
2. The purpose of this Guidance Note is to describe the scope of the Small Animal Exemption Scheme for medicines intended for minor species, and how it will operate.
3. The Regulations permit certain veterinary medicinal products to be marketed without a marketing authorisation, subject to certain conditions being met. These conditions are set out in the following paragraphs.
4. The veterinary medicinal products must be manufactured in the United Kingdom, another member state or in Australia, Canada, New Zealand or Switzerland. In the case of Australia, Canada, New Zealand or Switzerland the product must have been manufactured by the holder of an authorisation from the competent authority permitting him to manufacture medicinal products.

EXEMPT SPECIES

5. 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.
6. The exemption applies only to pet animals that are not intended to produce food for human consumption. The Scheme includes animals kept at rescue centres (including those to be released into the wild), animals bred as food for other species, animals kept for laboratory purposes and animals kept for financial gain (e.g. sport, exhibition, sale).

ACTIVE SUBSTANCES AND ROUTES OF ADMINISTRATION

7. Products containing antibiotics or any narcotic or psychotropic substances are not included in the exemption scheme. Certain anaesthetics may be permitted but confirmation should be sought from VMD.
8. If the active substance is one which is contained in an authorised veterinary medicine, then the authorisation must have been held for at least five years for the substance to be eligible under this scheme.
9. 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.
10. From 1 November 2007 products may only contain substances listed in the Regulations. The list of permitted substances will be reviewed before coming into force and will be updated on a yearly basis with the revision of the Regulations. Until this time products currently on the market containing substances not on the provisional list may continue to be marketed. This list is available on the VMD's website www.vmd.gov.uk.
11. Companies wishing to market products in accordance with the Scheme which do not contain ingredients on this list should, in the first instance, contact VMD.
12. 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

13. All products exempted under this scheme need to be labelled clearly to show that they are exempt from the statutory requirement for a marketing authorisation. 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."
14. The labelling must show the manufacturing authorisation number, or for a product manufactured outside the EU, the wholesale dealing Authorisation number of the importer.
15. The labelling must contain the following information –

- ◆ name of the product;
- ◆ 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 importer;
- ◆ 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;

16. The labelling requirements come into force on 1 November 2007.

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 consider 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 – to treat fish living in a volume of water no greater than 25,000 L.

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

18. Although products covered by this scheme are exempted from the requirement to hold a marketing authorisation, they are still legally classed as veterinary medicines. They must therefore meet all the requirements of the Regulations relating to the manufacture and wholesale dealing of veterinary medicines (See VMG Note 10 – *Manufacturing and Wholesale Dealers Authorisations for Veterinary Medicines*). This requirement will not come into force until 1 November 2007, to allow companies time to apply for such licenses.

PHARMACOVIGILANCE

19. Any adverse reactions should be reported to the VMD within 15 days of learning of the reaction. Records are required to be kept by manufacturers and wholesale dealers and should be made available to the VMD on request. Further information is provided in VMG Note 13 – *Marketing Authorisation for Veterinary Medicinal Products Supplementary Guidance on Pharmacovigilance*.

PREVENTING ILLEGAL USE

20. 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.
21. To assist companies and individuals to meet this requirement the VMD will hold a list of all products marketed under this Scheme that have been notified to us. This list will be published on the VMD website www.vmd.gov.uk. Companies and individuals who wish their products to appear on this list should contact the VMD on tel: 01932 338306 and notify the following details:
 - ◆ name of the product;
 - ◆ name and address of the manufacturer and distributor of the product;
 - ◆ manufacturer's licence 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

22. 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 (VMG Note 15 – *Controls on the Administration of Veterinary Medicines*).

FURTHER INFORMATION

23. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS – Tel: (+44) (01932) 336911, or Fax: (+44) (01932) 336618. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website (www.vmd.gov.uk)

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