



Veterinary Medicines Guidance Note

Marketing Authorisation Exemption Scheme for Pet Animal Medicines

DRAFT

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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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INTRODUCTION

1. This is one of a series of guidance notes explaining requirements under the Veterinary Medicines Regulations. The Regulations are revoked and replaced every year, so the references to the Regulations should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument has not been detailed in this guidance note. These guidance 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. 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 by the holder of an appropriate authorisation.

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, 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.
8. 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.
9. From 1 November 2007 products may 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. The list will be updated periodically when new substances are approved
10. 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.
11. 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

12. 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."
13. The labelling must show a manufacturing authorisation number, or for a product manufactured outside the EU, the wholesale dealing authorisation number of the importer.

14. 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;
 - ◆ 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;
15. The labelling requirements come into force on 1 November 2007.

PACK SIZES

16. 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 – For a single course of treatment, of no more than 5 administrations to an aquarium of 25,000 litres

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

17. 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.
18. 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

19. Any serious 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 in writing with details of the following:
 - ◆ 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 (if included in Annex A) 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*).
23. Products exempt from the requirements for a Marketing Authorisation under the Small Animal Exemption Scheme may be used in the cascade according to the professional clinical judgement of the prescribing Veterinary surgeon.

FURTHER INFORMATION

24. 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. 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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