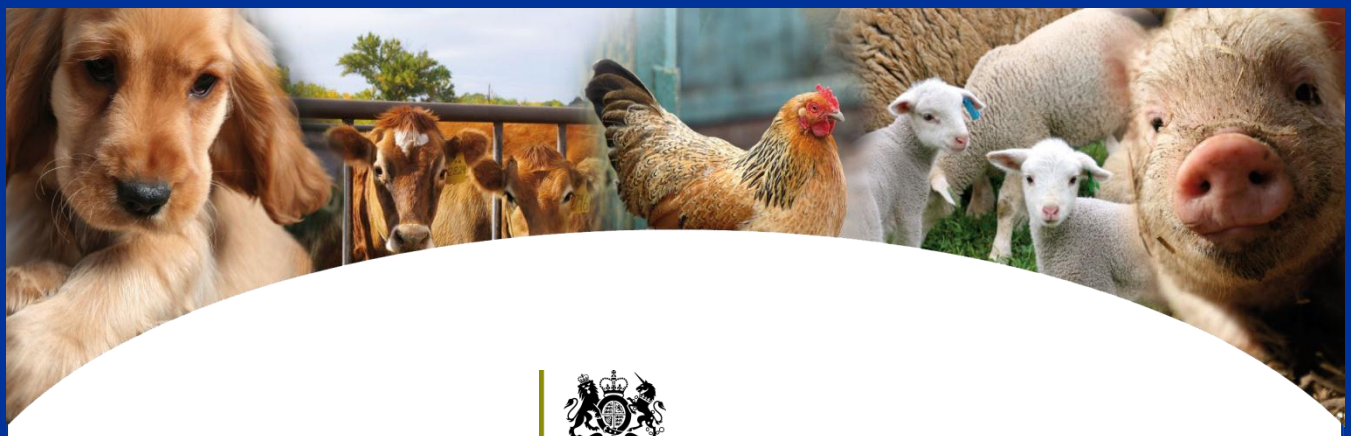

Veterinary Medicines Directorate

VETERINARY MEDICINES GUIDANCE NOTE

No 12

EXEMPTIONS FOR SMALL PET ANIMALS

Last updated December 2014

www.gov.uk

QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed primarily at manufacturers and is intended to provide guidance on the requirements that need to be met for products manufactured under Schedule 6 of the Veterinary Medicines Regulations (VMR) – Exemptions for small pet animals

The quick start guide is a summary of the provisions of the VMR; detailed information is found in the body of the guidance note.

The exemption is a legislative provision in the VMR that allows an exemption from a Marketing Authorisation (MA) for selected minor species, providing certain criteria are met.

- The exemption applies to:
  - Aquarium animals
  - Caged birds
  - Homing Pigeons
  - Terrarium Animals
  - Small Rodents
  - Ferrets
  - Rabbits

- The active ingredient of the product must be approved by the Secretary of State. Actives will not be approved if the substance requires veterinary control or if the product is an antibiotic or contains any narcotic or psychotropic substance.

- Products must be manufactured in accordance with Good Manufacturing Practice (GMP).

- Products under this exemption must be labelled correctly and contain a statement to show they are exempt from the statutory requirement for an MA.

- Administration must be oral or topical, or for fish products by addition to water.

- Products can only be sold in pack sizes that are for a single course of treatment.

FURTHER INFORMATION

For more information on the requirements of Schedule 6 – Exemptions for small pet animals please contact the VMD's Enforcement Team on enforcement@vmd.defra.gsi.gov.uk or alternatively contact VMD reception on 01932 336911 and quote the "Exemptions for small pet animals".

TABLE OF CONTENTS

Introduction

1. This is one of a series of Veterinary Medicines Guidance Notes (VMGNs) explaining the requirements under the Veterinary Medicines Regulations (VMR). The VMR are revoked and replaced on a regular basis so the reference 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 VMGN. This VMGN will be updated as necessary and the date of the most recent update is shown on the front cover.

2. The VMR set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. VMGN 1 Guidance on the Controls of Veterinary Medicines provides basic information about the scope of the VMR and the requirement for Marketing Authorisations (MA). To view this guidance note, search for "VMGN 1" on www.gov.uk.

3. The purpose of this VMGN is to describe the scope of Schedule 6 – Exemptions for small pet animals for medicines intended for minor species, and how it will operate.

4. The VMR permit certain veterinary medicinal products (VMPs) to be marketed without an MA, subject to certain conditions being met. These conditions are set out in the following paragraphs. Exemption products are veterinary medicines marketed in the UK under an exemption from the legislative requirements set in Directive 2001/82 as amended (Article 4(2)). This exemption aims to improve the availability of veterinary medicines to certain minor species.

Exempt Species

5. The exemption applies only to veterinary medicines labelled for use in one or more of the following animals kept exclusively as pets:

   - aquarium animals, (including only 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 to pet animals that are not intended to produce food for human consumption.

Active Substance and Route of Administration

7. Antibiotics, anaesthetics or narcotic or psychotropic substances are not included in the exemption. Certain sedatives may be permitted but confirmation should be sought from the VMD.

8. Active substances requiring veterinary control will not be approved under this exemption.

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. Products can only contain active substances which have been approved for the purposes of this exemption by the Secretary of State. To view the list of approved substances, search for “medicines for small pet animals” on www.gov.uk. The list will be updated periodically when new substances are approved.

11. Companies wishing to market products in accordance with the exemption which do not contain ingredients on the ingredients list should first contact the VMD.

12. Products intended for parenteral or ophthalmic use, or for insertion into the ear canal will not be exempted. Fish medicines administered via the water and not intended for direct ophthalmic use are acceptable.

Labelling

13. All products exempted 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 Schedule 6 of the Veterinary Medicines Regulations - Exemptions for small pet animals”

14. 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).

15. 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:
    - o therapeutic indications
    - o contra-indications
    - o interaction with other medicines and other forms of interaction
- dosage instructions

. If there is insufficient room on the label then this may be on a package leaflet.

16. The label on the product 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”

17. The labels must also include any additional warning that may be stipulated for the particular active. To view the warnings, search for “medicines for small pet animals” on www.gov.uk.

Pack Sizes

18. For a product to be exempt it must only be sold in pack sizes suitable for a single course of treatment. 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 animals	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 sufficient 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

19. Although such products 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 VMR relating to the manufacture (GMP) of veterinary medicines. All the requirements of the VMR relating to wholesale dealing of veterinary medicines must also be met, other than those relating to record keeping requirements. Wholesale dealers supplying products under the exemption are not required to keep wholesale records that duplicate manufacturer's records. For further information please refer to VMGN 15 Guidance for Manufacturers and VMGN 8 Guidance on Wholesale Supply of Veterinary Medicines and related Inspections. To view these guidance notes, search for "VMGN 15" or "VMGN 8" on www.gov.uk.

20. 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), or
- a certificate issued by the Secretary of State (sites in all other countries).

21. There are no restrictions on the retail supply within the UK of products under this exemption.

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

Pharmacovigilance

23. Any serious adverse events should be reported by manufacturers, importers or retailers to the VMD within 15 days of learning of the reaction. Records of all adverse events 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. For further information please refer to VMGN 11 Pharmacovigilance (Suspected Adverse Events). To view this guidance note, search for "VMGN 11" on www.gov.uk.

Preventing Illegal Use

24. 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.

Exemption Products and the Prescribing Cascade

25. Exemption products do not fall under the cascade. If a veterinary surgeon chooses to use an exemption product not in accordance with its product literature then he/she may do so – but it will no longer be deemed to be an exemption product. It is the veterinary surgeon's decision which product to use, based on his/her clinical judgment. For further information on the Cascade please refer to VMGN 13 Guidance on the Use of the Cascade. To view this guidance note, search for "VMGN 13" on www.gov.uk.

Further Information

26. 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 www.gov.uk.

List of Abbreviations

AE	Adverse Event
Defra	Department for Environment, Food & Rural Affairs
EU	European Union
GMP	Good Manufacturing Practice
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations

VETERINARY MEDICINES GUIDANCE NOTE

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone (+44) (01932) 336911 Fax: (+44) (01932) 336618
Search for VMD on www.gov.uk