



Veterinary Medicines Guidance Note

Marketing Authorisations for Veterinary Medicinal Products - Distribution Categories

No 3



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES



VETERINARY MEDICINES GUIDANCE NOTE 3

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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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INTRODUCTION

1. This is one of a series of guidance notes (VMG 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 on the application process is set out in VMG Note 2: Marketing Authorisation for Veterinary Medicinal Products - Applications and Renewals.
2. The purpose of this guidance note is to describe the distribution categories for veterinary medicinal products in the UK.

DISTRIBUTION CATEGORIES

3. The Veterinary Medicines Regulations 2005 sets out the distribution categories for UK veterinary medicinal products. These are as follows:
 - Prescription Only Medicine – Veterinarian (POM-V)
 - Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS)
 - Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)
 - Authorised Veterinary Medicine - General Sales List (AVM-GSL)

POM - V

4. A veterinary medicinal product that has been classified as a POM-V may only be dispensed once it has been prescribed by a veterinary surgeon following a clinical assessment of the animal or group of animals. The client may request a written prescription when they decide that they do not want the prescribing veterinary surgeon to supply the product. In all cases, the prescribing veterinary surgeon shall accept clinical responsibility for the treatment and the animal or group of animals should be under his/her care.
5. Any registered veterinary surgeon or registered pharmacist may dispense the written prescription. The dispensing veterinary surgeon or pharmacist should use their specialist knowledge to check that the prescription accords with their own understanding of the product. If they have concerns about the prescription they should raise them with the prescribing veterinary surgeon before dispensing the medicine.
6. Reports of any suspected adverse reaction (SAR) may be made to the VMD by the animal owner, the prescribing veterinary surgeon, or the person who dispensed the prescription. If an animal owner wishes to seek veterinary advice about a SAR in their animal they should consult the prescribing veterinary surgeon.

MAS FOR VMPs - DISTRIBUTION CATEGORIES

7. A product will generally be included in the POM-V category when it:
- contains a new active ingredient not previously used in a veterinary medicine in the EU;
 - requires a strict limitation on its use for specific safety reasons;
 - requires the specialised knowledge of a veterinary surgeon for its use/application;
 - has a narrow safety margin requiring above average care in its use;
 - is Government policy to demand professional control at a high level;
 - requires specific use, linked to a prior clinical assessment of the animals as detailed above.

MFS

8. A veterinary medicinal product, previously classified as a MFS, is for incorporation into animal feedingstuffs that may only be supplied to keepers of animals on presentation of a medicated feedingstuff prescription written by a veterinary surgeon. Such a product is therefore included in the POM-V category.

POM - VPS

9. A veterinary medicinal product classified as POM-VPS may only be prescribed by a Registered Qualified Person (RQP) defined as follows:
- i) a registered veterinary surgeon;
 - ii) a registered pharmacist; or
 - iii) a registered suitably qualified person (SQP).
10. The customer may request a written prescription if they decide that they do not want the prescribing RQP to supply the product. Any RQP may supply POM-VPS medicines in accordance with a written prescription from another RQP.
11. A clinical assessment of animal(s) is not a pre-requisite when prescribing this category of veterinary medicines. The prescribing RQP, however, must be satisfied that the person administering the medicine has the competence to do so safely and that the medicine is intended for its authorised use. The RQP should provide advice on how to use the product, taking special account of any warnings or contra-indications relevant to the medicine. The RQP should also take into account directions in Flock/Herd Health Plans, where available, when prescribing.
12. A product will generally be included in the POM-VPS category when:
- it is used to reduce or prevent the effects of endemic disease in herds or flocks or in individual animals;
 - its use implies risks for the user, the animal, consumer safety or the environment but users can be made aware of suitable countermeasures through simple, oral or written, advice;
 - a professional user can be given adequate training in its regular use.

MFSX

13. A veterinary medicinal product, previously classified as a MFSX, was for incorporation into animal feedingstuffs that was able to be supplied to keepers of animals without a prescription. However under the amended legislation, if the product is for the treatment of food producing animals it will be included within the POM – VPS category. Special arrangements will be used for dispensing the products.

NFA - VPS

14. A veterinary medicinal product classified as NFA-VPS may be supplied by a RQP as follows:
- i) a registered veterinary surgeon;
 - ii) a registered pharmacist; or
 - iii) a registered suitably qualified person (SQP).
15. A clinical assessment is not a pre-requisite for supply of this category of veterinary medicine. The RQP, however, must be satisfied that the person administering the medicine has the competence to do so safely and the medicine is intended for its authorised use. The RQP should provide advice related to any warnings or contra-indications relevant to it.
16. A product will generally be included in the NFA-VPS category when:
- it is indicated for use in non-food animals;
 - it is used routinely to prevent or limit the effects of endemic disease in non-food animals;
 - its use implies risks for the user, the animal, for consumer safety or for the environment but users can be made aware of suitable countermeasures through simple, oral or written, advice;
 - the animal keeper can be given sufficient practical advice to permit effective/safe usage.

AVM - GSL

17. A veterinary medicinal product classified as an AVM-GSL may be supplied by any retailer as there are no restrictions on its supply.
18. A product will generally be included in the AVM-GSL category when:
- its use has a wide margin of safety;
 - it is used to alleviate, prevent the symptoms or support the treatment of common ailments;
 - special advice is not required to permit safe/effective use.

PRESCRIPTIONS

19. A definition of a prescription from a veterinary surgeon should relate to the instruction by means of defining the product, dose and other relevant instructions. If it is not to be supplied by the person issuing the prescription, it must be in writing and include the following information:
- the name and address of the prescriber;
 - the particulars which substantiate that the prescriber is a veterinary surgeon e.g. MRCVS;
 - the name and address of the person to whom the product is supplied;
 - a description of the animal (s) it is prescribed for;
 - the date;
 - should be written in ink or another indelible format;
 - it should be signed or otherwise authenticated by the prescriber.

FURTHER INFORMATION

20. 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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