Responsibilities when Supplying Veterinary Medicines

A pharmacist has specific responsibilities when supplying a veterinary medicine (other than AVM-GSL) in order to ensure that it is used appropriately. The pharmacist must be present when it is handed over, unless the pharmacist authorises each transaction individually beforehand and is satisfied that the person handing it over is competent to do so. Note that this differs from the legal situation regarding supply of pharmacy and prescription-only medicines to a human patient which requires a pharmacist to be physically present at the premises where these medicines are handed over.

In particular, a pharmacist prescribing a product classified as POM-VPS or supplying a product classified as POM-VPS or supplying a product In particular, a pharmacist prescribing a product at the premises when these medicines are handed over. A pharmacist has specific responsibilities when supplying a veterinary medicine to which is available from the VMD website. Further information can be found in Veterinary Medicines Guidance Note 20 on the use of controlled drugs in the veterinary sector, a link to which is available from the VMD website.

Medicines Responsibilities when Supplying Veterinary Medicines

Use of Human Medicines in Animals

Human medicines can be used in animals if a suitable authorised veterinary medicine is not available, but only under the authority of a veterinary surgeon in accordance with the prescribing cascade. The prescribing cascade is an EU initiative which increases the range of medicines available to veterinary surgeons. Further information on the cascade, including requirements for prescriptions and labelling can be found in the Veterinary Medicines Regulations and Veterinary Medicines Guidance Note 13; links to which are available from the VMD website. Pharmacists must not otherwise supply human medicines over the counter if they are intended for animal administration, even where oral authorisation from a veterinary surgeon has been given – a written prescription is required.

Further Information

Further information including a link to the Veterinary Medicines Regulations, Veterinary Medicines Guidance Notes and other VMD information leaflets may be obtained via the VMD website (www.vmd.defra.gov.uk). The Royal Pharmaceutical Society’s professional guide for pharmacists – Medicines, Ethics and Practice is also a useful reference (www.rpharms.com/support/mep.asp). You can also phone the VMD on 01932 336911 for any additional assistance about veterinary medicines, or visit our website at www.vmd.defra.gov.uk You can also reach us by e-mail at: postmaster@vmd.defra.gsi.gov.uk
Introduction

This leaflet explains the specific requirements for prescribing and supplying veterinary medicines by pharmacists. In addition to supplying medicines against a prescription from a veterinary surgeon, pharmacists may also supply certain medicines against a ‘pharmacist’s prescription’. The range of veterinary medicines that pharmacists may prescribe includes products for the treatment or prevention of worms, flies and other parasites in a range of species including dogs, cats, poultry and horses. Some vaccines are also available on a pharmacist’s prescription.

This leaflet does not discuss wholesale supply of veterinary medicines. If necessary, please refer to Veterinary Medicines Guidance Notes No. 3 (Guidance for Retailers) and No. 8 (Wholesale Dealers’ Authorisation for Veterinary Medicines) on the VMD website (www.vmd.defra.gov.uk).

Regulation of Veterinary Medicines in the UK

The Veterinary Medicines Directorate (VMD), an Executive Agency of the Department for Environment, Food & Rural Affairs (Defra), is responsible for the authorisation of veterinary medicines in the UK and for monitoring these medicines following authorisation.

The authorisation of veterinary medicines is not very different to the authorisation of human medicines and is subject to similar controls. Before a veterinary medicine can be placed on the UK market, a large quantity of scientific data needs to be produced in a rigorous assessment to ensure that the medicine meets EU standards for quality, safety and efficacy and the benefits of using the product outweigh the risks.

The data on quality have to provide evidence that the veterinary medicine has been formulated appropriately and will be consistently manufactured to required standards. The veterinary medicine must be shown to retain appropriate strength, efficacy and safety over the entire shelf life.

The veterinary medicine must be shown to be safe when used in accordance with the label instructions by not causing unacceptable side-effects or harm to:

• the animal being treated
• the person administering the medicine
• the consumer of milk, meat, eggs or honey (if administered to a food producing animal)
• the environment

Where necessary, specific warnings are added to the labels or package leaflet to minimise any risks.

The veterinary medicine must be shown to be effective and perform as intended when the instructions on the label are followed. Detailed instructions for the correct use of authorised veterinary medicines can be found in the Summary of Product Characteristics (SPC) for the product. SPCs for UK authorised veterinary medicines are available through the VMD’s Product Information Database on the VMD website.

Distribution Categories of Veterinary Medicines

Distribution categories provide controls on the supply of veterinary medicines to help ensure that appropriate advice is given at the point of sale so that products can be used safely and effectively.

The distribution category of a veterinary medicine is decided by the VMD following evaluation of scientific data provided by the Marketing Authorisation Holder. The distribution category uses the concept of a ‘registered qualified person’. A registered qualified person may be:

• a UK registered veterinarian
• a UK registered pharmacist (operating from registered pharmacy premises)
• a UK registered suitably qualified person (SQP).

An SQP is an individual who must be suitably trained and qualified and is included on the SQP register of the Animal Medicines Training Regulatory Authority (AMTRA). This category may include veterinary nurses, agricultural merchants, pet shop personnel and internet retailers.

The existing distribution categories for veterinary medicines in the UK are:

- Prescription medicines
  - POM-V Prescription Only Medicine – Veterinarian
  - POM-VPS Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person
- Non-prescription medicines
  - NFA-VPS Non-Food Animal – Veterinarian, Pharmacist, Suitably Qualified Person
  - AVM-GSL Authorised Veterinary Medicine – General Sales List

Prescriptions

As described above, POM-V and POM-VPS medicinal products may only be supplied in accordance with a prescription. A prescription does not need to be written, but may be oral. This would be appropriate in the situation where a pharmacist prescribes a POM-V/PS medicine and also supplies it. However, if a veterinary medicine is to be supplied by a person other than the prescriber, then the prescription must be in writing. A pharmacist supplying under a written prescription must take all reasonable steps to ensure that the prescription has been written and signed by a person entitled to prescribe the product. A written prescription is valid for 6 months (or such shorter period as stated on the prescription). Prescriptions must include the following information:

• The name, address and telephone number of the prescriber.
• The qualifications enabling the person to prescribe the product.
• The name and address of the owner or keeper.
• The identification (including the species) of the animal(s) to be treated.
• The premises at which the animals are kept (if different from the owner’s/keeper’s).

The highest level of control is the POM-V category. This would include veterinary medicines containing controlled drugs and those intended for administration only following a diagnosis and clinical assessment by a veterinary surgeon.

Medicines in the POM-V category must also be prescribed, but this can be by a pharmacist, SQP or a veterinary surgeon, whereas NFA-VPS products do not require a prescription. Products in these categories must be provided with appropriate advice at point of sale in order to ensure that the products will be properly administered.

Medicines intended for use in food-producing animals would normally be classified as POM-VPS. The NFA-VPS category contains many of the dog and cat worm and flea control products.

Pharmacists can:

• Dispense those medicines in accordance with a prescription written by another veterinary surgeon.
• Dispense POM-V and POM-VPS medicines in accordance with prescriptions written by a UK registered veterinary surgeon.
• Dispense veterinary medicines prepared extemporaneously, but only against a prescription from a veterinary surgeon.
• Dispense human medicines for use under the cascade in accordance with prescriptions written by a veterinary surgeon (see further information below).
• Prescribe and supply POM-VPS veterinary medicines.
• Supply NFA-VPS, AVM-GSL veterinary medicines and SAES products.

SQPs can:

• Prescribe and supply POM-VPS veterinary medicines.
• Supply NFA-VPS, AVM-GSL veterinary medicines and SAES products.

Any retailer can:

• Supply AVM-GSL veterinary medicines and SAES products.

Only veterinary surgeons can diagnose clinical conditions in animals. However, the prescribing, dispensing and supply of veterinary medicines is permitted as follows:

Veterinary Surgeons can:

• Prescribe and supply all categories of authorised veterinary medicines and also human medicines for veterinary use (under the prescribing cascade – see further information below), extemporaneously prepared medicines and SAES products.