- The date of the prescription.
- The signature or other authentication of the prescriber.
- The name and amount of product prescribed.
- The dosage and administration instructions ('as directed' is not acceptable).
- Any necessary warnings.
- The withdrawal period (if necessary).
- If it is prescribed under the cascade (vets only), a statement to that effect.

Prescriptions for Schedule 2 or 3 Controlled Drugs have additional requirements as specified in the Misuse of Drugs Regulations. 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.

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 when these medicines are handed over.

In particular, a pharmacist prescribing a product classified as POM-VPS or supplying a product classified as NFA-VPS must:

- Be satisfied that the medicine is appropriate for the animal and condition to be treated

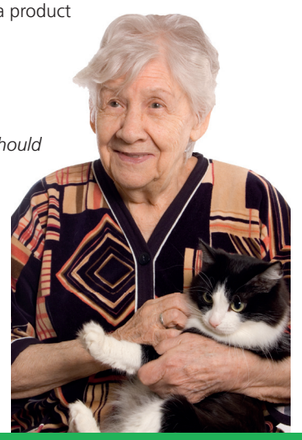
  As an example, the pharmacist should consider asking the following questions as appropriate:

  – *When was the last treatment?*

  – *Age and weight of animal?*

  – *Any concurrent medication?*

  – *Any other disease?*



- Be satisfied that the person who will use the product is competent to do so safely, and must advise on safe administration and any warnings or contra-indications:

  For example, the pharmacist should emphasise any safety precautions:

  – *Directions to wear gloves or wash hands after use*

  – *Restrictions on children petting animals after administration with spot-on products*

  – *Restrictions on bathing of animals or allowing animals to swim in water courses after administration with spot-on products*

- Not supply more than the minimum amount required for the treatment

  – *The Regulations allow pharmacists to break open packages for the purposes of supply, except the immediate packaging of an injectable product.*

- Ensure that the medicine is labelled correctly

  – *In particular, if the product is supplied in a container other than the marketed pack, this container must be suitably labelled and sufficient information supplied to enable the product to be used safely (this could be the SPC or the package leaflet).*

- Record and report any adverse events involving the medicine promptly

  – *Adverse events should be reported to the VMD using the online form on our website.*

Record Keeping

Pharmacists must keep all documents relating to the receipt or supply of POM-V and POM-VPS products for at least 5 years, showing:

- The date
- The name of the veterinary medicine
- The batch number
- The quantity
- The name and address of supplier or recipient
- The name and address of prescriber and a copy of the prescription (if a written prescription)

If a pharmacist supplies veterinary medicines on **prescription**, there is a legal requirement for a detailed audit of these medicines to be conducted at least once a year. This requirement may be satisfied by a system linking incoming and outgoing transactions with stock held, in combination with an annual or more frequent stock take.

Internet Retail of Veterinary Medicines

Veterinary medicines (prescription and non-prescription) may be supplied via the internet. However, the premises from which the internet retailer operates must be registered and inspected in accordance with the legislation and the transactions are subject to the same legislative controls as for a community pharmacy, unless they are only supplying AVM-GSL medicines.

Under the VMD's 'Accredited Internet Retailer Scheme', online retailers who meet the VMD's accreditation criteria are able to display a special logo on their website: the VMD's Internet Retailer logo. This scheme is a means of facilitating self-regulation by UK-based internet retailers supplying veterinary medicines. Further information about the scheme is available on the VMD's website.

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

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VMD/Leaflet

VETERINARY MEDICINES VMD DIRECTORATE

ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

Pharmacy

Veterinary Medicines Advice for Pharmacists

defra
Department for Environment Food and Rural Affairs

The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food & Rural Affairs

www.vmd.defra.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, fleas 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 undergoes 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

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-VPS 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.

Medicines in the AVM-GSL category may be supplied by any retailer without any restrictions, or provision of advice.

There is an additional category of veterinary medicines in relation to products intended solely for use in small, non-food producing animals (e.g. cage birds, small rodents, aquarium animals, etc). These are known as Small Animal Exemption Scheme (SAES) products. They are not authorised (so they have not been assessed for quality, safety or efficacy) but may be legally marketed and administered according to the instructions on their labelling. Further information can be obtained from the VMD website.

Prescribing, Dispensing, Supply

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.
- Dispense those medicines in accordance with a prescription written by another veterinary surgeon.

Pharmacists can:

- 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.

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-VPS 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).