

Practice guidance for community pharmacists on the Veterinary Medicines Regulations 2005

This practice guidance for community pharmacists on the new Veterinary Medicines Regulations 2005 has been prepared by the Royal Pharmaceutical Society's Practice and Quality Improvement Directorate

Introduction

The Veterinary Medicines Regulations 2005 came into force on 30 October 2005. This means that from 30 October 2005 the Medicines Act 1968 no longer applies to veterinary medicines.

The Veterinary medicine regulations relate to medicines supplied for animals, which includes birds, reptiles, fish, molluscs, crustacea and bees.

The Veterinary Medicines Directorate (VMD) is planning to issue new Veterinary Medicines Regulations each year.

Classification of veterinary medicines

There will be a new classification for veterinary medicines (see Panel).

A pharmacist who supplies a veterinary medicine classified as POM-V, POM-VPS or NFA-VPS must always provide advice on how to administer the medicine safely and also, when necessary, advise on any warnings or contraindications on the label or package leaflet. Pharmacists must also be satisfied that the person who will use the product is competent to use it safely, and intends to use it for a purpose for which it is authorised.

Prescriptions

A veterinary surgeon who prescribes a POM-V medicine must first carry out a clinical assessment of the animal, and the animal must be under his or her care. It is an offence if this does not happen. It is also an offence to prescribe more than the minimum amount of a veterinary medicine required for a treatment. Pharmacists should check with the veterinary surgeon if they are concerned about the quantities prescribed on a prescription.

A prescription for a Controlled Drug as specified in the Misuse of Drugs Regulations is valid for three weeks from the date on the prescription. A prescription for any other drug is valid for six months unless a shorter period is specified.

If the prescription is a repeatable prescription that does not specify the number of times the product may be supplied then the prescription may only be repeated once.

For a pharmacist to dispense a prescription it must be a written prescription in ink or other indelible format, eg, computer-generated, and must include the following information:

- Name and address of the person prescribing the product
- Qualifications enabling the person to prescribe the product

- Name and address of the owner or keeper of the animal
- Species of animal, identification and number of animals
- Premises at which the animals are kept if this is different from the address of the owner or keeper
- Date of prescription
- Signature or other authentication of the person prescribing the product
- Name and amount of the product prescribed
- Dosage and administration instructions
- Necessary warnings
- Withdrawal period if relevant (particularly important for food-producing animals)

Supply

Pharmacists must supply a licensed veterinary product if one is available, ie, they must not fill a prescription with a human medicine if an equivalent veterinary product is available. It is an offence to supply a medicine licensed for humans for administration to an animal unless it is in accordance with a prescription from a veterinary surgeon for administration under "the cascade" (see below).

It is also an offence to supply a veterinary medicine that has passed its expiry date.

Administration under the cascade

A veterinary medicine for use under the cascade must be prescribed by a veterinary surgeon and may only be supplied by a

veterinary surgeon or a pharmacist. If there is no authorised veterinary medicine in the UK for a condition the veterinary surgeon responsible for the animal may, to avoid unacceptable suffering, treat the animals concerned with the following cascade:

- A veterinary medicine licensed in the UK for use in another animal species, or for another condition in the same species
- If and only if there is no such product that is suitable, either (i) a medicinal product licensed in the UK for human use or (ii) a veterinary product not licensed in the UK but licensed in another member state of the EU for use with any animal species for a non food-producing species (for a food-producing animal it must be a product licensed for a food-producing animal)
- If, and only if, there is no such product that is suitable, a veterinary medicine could be prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation allowing the manufacture of that type of product

Horses are considered to be food-producing animals. However, they may be exempt from the restrictions applying to food-producing animals if they have a passport and it is clear that they are not intended to be slaughtered for human consumption.

Classification of veterinary medicines

Old category	New category	Retail supply
POM	POM-V (POM- veterinarian)	Veterinary surgeon or pharmacist in accordance with a prescription from a veterinary surgeon
*P	POM-V or POM-VPS (veterinarian, pharmacist and specially qualified person)	
PML	POM-VPS for food-producing animals	Veterinary surgeon, pharmacist or [†] suitably qualified person in accordance with a prescription from one of those persons
PML	NFA-VPS for non food-producing animals	Veterinary surgeon, pharmacist or suitably qualified person
GSL	AVM-GSL (authorised veterinary medicine GSL)	No restrictions on the supply

*The P category will disappear

[†]Suitably qualified person includes merchants

SHEEP DIPPING

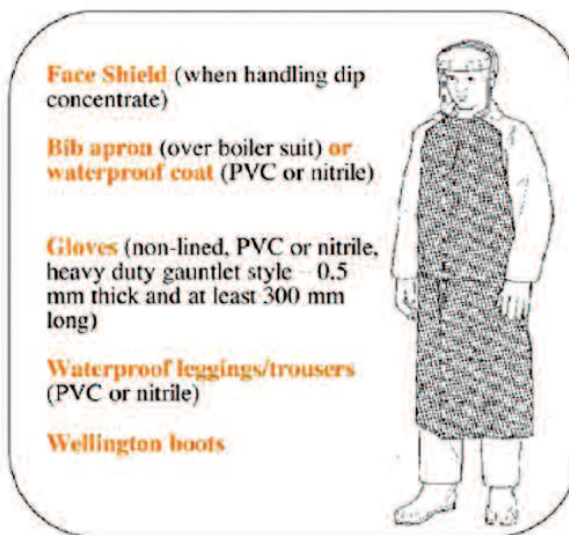
PLEASE READ THIS NOTICE FOR YOUR OWN SAFETY

1. The product label carries important advice. Please read it and do what it says.
2. Always wear the recommended protective clothing, including gloves. Sheep dip is absorbed through the skin.
3. Always wash protective clothing before taking it off.
4. If you get sheep dip on your skin wash it off immediately.
5. If you have questions, ask your sheep dip supplier. At your merchants you should speak to the Suitably Qualified Person.
6. Read the label for instructions on measuring and diluting concentrate.
7. Check that you have spare protective clothing, especially gloves, in case of damage.

A well designed sheep dip, with splash screens to limit contamination, reduces the risks, makes the job easier and makes wearing protective clothing more practical.

Everyone doing the job must be adequately trained. If they are not absolutely sure how to dip safely consider a training course.

The recommended protective clothing is:



For more information you are recommended to read the Government's leaflet 'Sheep dipping' (AS29rev2).

Figure 1: Front and back of advice card to be provided with organophosphorous sheep dips (Crown Copyright © 2005)

Withdrawal periods

A veterinary surgeon must specify the withdrawal period of medicine for a food-producing animal.

There are specified minimum withdrawal periods. These are not shorter than:

- Seven days for eggs
- Seven days for milk
- 28 days for meat from poultry and mammals including fat and offal
- 500 degree days for fish (the number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius)

Labelling requirements

The label must include at least the following information:

- Name and address of the dispensing pharmacy
- Name of the prescriber
- Name and address of the animal owner
- Identification of the animal or group of animals
- Date of dispensing
- Expiry date of the product, if applicable
- Name or description of the product, which should include at least the name and quantity of active ingredients

- Dosage and administration instructions
- Special storage precautions
- Necessary warnings for the user, target species, administration or disposal of the product

Supply of sheep dip

Supplies of sheep dip must be to a person who holds a Certificate of Competence in the Safe Use of Sheep Dips issued by the National Proficiency Tests Council, showing parts 1 and 2 of the assessment referred to in the certificate have been satisfactorily completed; or to a person acting on behalf of such a person.

A record of the certificate number must be made at the time of supply or as soon as is reasonably practicable and kept for at least three years.

If the active ingredient is an organophosphorus compound then the buyer must give the following:

- A double-side laminated notice providing safety advice (see above)
- Two pairs of gloves (see above)

Record keeping

For all POM-V and POM-VPS medicines the following information must be kept relating to transactions:

- Date
- Identity of veterinary medicine
- Quantity
- Name and address of supplier or recipient
- If there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription
- If the documents do not include this information a record of the missing information must be made as soon as it is reasonably practicable
- A record of the batch number and the date must be made when supplying a veterinary medicine

The documentation must be kept for at least five years

Annual audit

At least once a year pharmacists who supply veterinary medicines on prescription must carry out a detailed audit of incoming and outgoing veterinary medicines and this is to be reconciled with products currently held in stock. Any discrepancies are to be recorded.

Inspection of pharmacies

The Royal Pharmaceutical Society's inspectors will undertake inspection of pharmacies supplying veterinary medicines.