



5

Medicines for Veterinary Use



effect, or
ation from
legislation
laws. 2.
lēgis lāti
legislative
ing law
legislat



5 MEDICINES FOR VETERINARY USE

The Veterinary Medicines Regulations SI No. 2297 came into force on October 1st 2009. The regulations are revoked and replaced each year, as necessary.

Full details of the legislation are available on www.opsi.gov.uk and guidance can be found at Veterinary Medicines Directorate (www.vmd.gov.uk)

The Medicines Act 1968 no longer applies to veterinary medicines.

“Veterinary medicinal product” means:

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals or
- (b) any substance or combination of substances that may be used in, or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis.

“animal” means all animals other than man and includes birds, reptiles, fish, molluscs, crustacea and bees.

The following guidance on legal requirements in relation to Medicines for Veterinary Use is presented in the following sections:

- 5.1 Classification and supply of Veterinary Medicinal Products
- 5.2 Prescriptions for Veterinary Medicinal Products
- 5.3 Form of prescription – Schedule 3 Part 1 (6)
- 5.4 Supply of Controlled Drugs 1-3 on Veterinary Prescriptions
- 5.5 Feedingstuffs and Breaking of Bulk
- 5.6 Supply of Veterinary Medicinal Products for use under the Cascade Schedule 3 Part 1(13) and Schedule 4 (1)
- 5.7 Withdrawal Periods – Schedule 4 (2)
- 5.8 Labelling Requirements at the time of retail sale - Schedule 3 (12) and (13)
- 5.9 Record Keeping - Regulation 17 - 24
- 5.10 Annual Audit - Schedule 3 (15)
- 5.11 Supply of a Sheep Dip –Schedule 3 Part 3 (22)
- 5.12 Inspections
- 5.13 Further information

5.1 CLASSIFICATION & SUPPLY OF VETERINARY MEDICINAL PRODUCTS

In accordance with The Veterinary Medicines Regulations 2009 SI No. 2297, the classes of Veterinary Medicinal Products (VMPs) are:

- (a) Prescription Only Medicine - Veterinarian (POM-V)

- (b) Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person* (POM-VPS)
- (c) Non-Food Animal - Veterinarian, Pharmacist, Suitably Qualified Person (NFA-VPS)
- (d) Authorised Veterinary Medicine -General Sale List (AVM -GSL)

A pharmacist who supplies a veterinary medicine classified as POM-V in accordance with a prescription, supplies an NFA-VPS or prescribes a POM-VPS must provide advice on how to administer the medicine safely and when appropriate to advise on any warnings or contraindications on the label or package leaflet. The pharmacist must also be satisfied that the person using the product is competent to use it safely and intends to use it for the purpose for which the product is authorised.

- A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.
- A veterinary medicinal product classified as POM-VPS may only be supplied by a veterinary surgeon, a pharmacist or a suitably qualified person and must be in accordance with a prescription from one of those persons.
- A veterinary medicinal product classified as NFA-VPS may be supplied without a prescription, but may only be supplied by
 - (a) a veterinary surgeon
 - (b) a pharmacist or
 - (c) a suitably qualified person.

“Suitably qualified persons” (SQPs) may prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS. Such persons must undertake a training programme and pass the necessary examinations of the training body and be registered with such a body. The supply of permitted products by a SQP must take place from premises approved by the Secretary of State as being suitable for storage and supply by a SQP. An SQP can also prescribe and supply products classified as POM-VPS and NFA-VPS from a retail pharmacy (in accordance with the paragraph that follows).

A SQP who supplies a product classified as POM-VPS or NFA-VPS must either-

- (a) hand over or dispatch the product himself;
- (b) ensure that, when the product is handed over or dispatched, he is in a position to intervene if necessary; or
- (c) check the product after it has been allocated for supply to a customer, and satisfy himself that the person handing over or dispatching it is competent to do so.

The Secretary of State shall publish a list of persons registered; the premises approved and issue a Code of Practice for suitably qualified persons.

5.2 PRESCRIPTIONS FOR VETERINARY MEDICINAL PRODUCTS

- (a) 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 care, and failure to do so is an offence.
- (b) It is an offence to prescribe (or, in the case of a NFA - VPS product, supply) more than the minimum amount of veterinary medicinal product required for treatment.

5.3 FORM OF PRESCRIPTION – SCHEDULE 3 PART 1(6)

A prescription may be ORAL or WRITTEN, but must be written, if the veterinary medicinal product is not supplied by the person who has prescribed it.

No person may alter a written prescription unless authorised to do so by the person who signed it.

A prescription, where written, must include:

- (a) the name, address and telephone number of the person prescribing the product;
- (b) the qualifications enabling the person to prescribe the product;
- (c) the name and address of the owner or keeper;
- (d) the species of animal, identification and number of the animals;
- (e) the premises at which animals are kept (if different from address of the owner or keeper);
- (f) the date of the prescription;
- (g) the signature, or other authentication, of the person prescribing the product;
- (h) the name and amount of product prescribed;
- (i) the dosage and administration instructions;
- (j) any necessary warnings;
- (k) the withdrawal period if relevant;
- (l) if it is prescribed under cascade, a statement to that effect;

A written prescription for a controlled drug under the Misuse of Drugs Regulations is valid for 28 days. A written prescription for any other drug is valid for 6 months or such shorter period as may be specified in the prescription. If the prescription is repeatable, but does not specify the number of times the product may be supplied, the prescription may only be repeated once.

5.4 SUPPLY OF CONTROLLED DRUGS 1-3 ON VETERINARY PRESCRIPTIONS

Veterinary prescriptions are excluded from the requirements that all non-NHS Schedule 1, 2 and 3 controlled drugs prescriptions must be issued on a standard form (PCD1) which includes the prescriber's unique identification number.

The Veterinary Medicines Regulations 2009 require all documents and records pertaining to prescription-only medicines for veterinary use (including a copy of the prescription) to be retained for at least five years.

5.5 FEEDINGSTUFFS AND BREAKING OF BULK

A pharmacist may only supply a Veterinary Medicinal Product which is intended to be incorporated into a premixture or feedingstuff, to an approved premixture manufacturer or an approved feedingstuffs manufacturer. Note: An approved feedingstuffs manufacturer may be a farmer. It is advisable to seek expert advice from a source such as the Veterinary Medicines Directorate (www.vmd.gov.uk) before making a supply.

In relation to any specialised activity, such as breaking bulk, which, for example, might include the mixing of a VMP with feeding stuff, or mixing VMPs with liquid feed supplements or trace elements, depending on the nature of the business, advice should be obtained from the Veterinary Medicines Directorate.

The VMD advises that VMPs should not be mixed with other supplements unless in accordance with a prescription from a veterinary surgeon.

Contact details for the Veterinary Medicines Directorate are below:

Veterinary Medicines Directorate,
Woodham Lane, New Haw,
Addlestone, Surrey KT15 3LS.
Tel: 01932 336911
E-mail: enquiries@vmd.defra.gsi.gov.uk

5.6 SUPPLY OF VETERINARY MEDICINAL PRODUCTS UNDER THE CASCADE SCHEDULE 3 PART 1(6) AND SCHEDULE 4(1)

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 pharmacist. The written prescription must state that the medicinal product is for administration under the cascade.

If there is no authorised veterinary medicinal product in the UK for a condition, the veterinary surgeon responsible for the animal may treat the animal with the following "cascade". This is to avoid unacceptable suffering to the animal concerned.

The vet may:

- (a) use a veterinary medicinal product authorised in the UK for use in another animal species, or for another condition in the same species; or

- (b) if no such product is suitable, either:
- i a medicinal product authorised (licensed) in the UK for human use;
 - ii a veterinary medicinal product not authorised in the UK but authorised in another member State(of EU) for use with any animal species (in the case of a food producing animal, it must be a product licensed for use in a food-producing species);
 - iii if there is no product suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation allowing the manufacture of that type of product.

Pharmacists may not supply licensed human GSL or P medicines OTC for animal administration, unless prescribed by a veterinary surgeon for use under the cascade.

5.7 WITHDRAWAL PERIODS - SCHEDULE 4(2)

A veterinary surgeon administering a veterinary medicinal product to a food-producing animal under the cascade must specify an appropriate withdrawal period.

The withdrawal period must not be less than:

- (a) 7 days for eggs
- (b) 7 days for milk
- (c) 28 days for meat from poultry and mammals including fat and offal
- (d) 500 degree days for fish meat (this is calculated by dividing 500 by the mean temperature of the water in degrees Celsius).

A pharmacist may only supply a VMP which is intended to be incorporated into a premixture or feeding stuff, to an approved premixture manufacturer or an approved feeding stuffs manufacturer.

In the case of the approved manufacturer being the livestock keeper (i.e. an on-farm manufacturer) the supply of the VMP must also be in accordance with a medicated feedingstuffs prescription.

5.8 LABELLING REQUIREMENTS

If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it is an offence to supply it if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.

However, the above does not apply to a veterinary surgeon who amends a label, or a pharmacist who amends it in accordance with a prescription from a veterinary surgeon, provided that the unamended information remains clearly visible.

If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must ensure that the container is suitably labelled and must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely, and failure to do so is an offence.

In relation to supply of veterinary medicinal products for use under the cascade, unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information:

- (a) the name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;
- (b) the name of the veterinary surgeon who has prescribed the product;
- (c) the name and address of the animal owner;
- (d) the identification (including the species) of the animal or group of animals;
- (e) the date of supply;
- (f) the expiry date of the product, if applicable;
- (g) the name or description of the product, which should include at least the name and quantity of active ingredients;
- (h) dosage and administration instructions;
- (i) any special storage precautions;
- (j) any necessary warnings for the user, target species, administration or disposal of the product;
- (k) the withdrawal period, if relevant; and
- (l) the words "Keep out of reach of children" and "For animal treatment only".

The keeper of a food-producing animal must keep proof of purchase of all veterinary medicinal products (or, if he did not buy them, documentary evidence of how he acquired them) acquired for the animal. This can be in the form of a till receipt from the pharmacy.

5.9 RECORD KEEPING - PART 3(23)

When any person permitted to supply a veterinary medicinal product classified as POM-V or POM-VPS receives or supplies any such veterinary medicinal product he must keep all documents relating to the transaction including:

- (a) the date;
- (b) the name of the veterinary medicinal product;
- (c) the quantity;
- (d) the name and address of the supplier or the recipient;
- (e) if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription;
- (f) the batch number.

However, where the VMP is for a non-food-producing animal, the batch number need only be recorded either on the date he receives the batch or the date he starts to use it.

If all the information is not included in the documents, the missing information must be recorded as soon as reasonably possible. The batch number and the date must be recorded at the time of supply.

The documentation and records must be kept for at least 5 years.

5.10 ANNUAL AUDIT – SCHEDULE 3 PART 1 (10)

At least once a year, every person entitled to supply a veterinary medicinal product on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicinal products must be reconciled with the products held in stock. Discrepancies must be recorded. It is an offence to fail to comply with this requirement. It would be good practice to audit stocks of NFA-VPS medicines although this is not mandatory. There is no requirement to audit stocks of AVM-GSL medicines.

5.11 SUPPLY OF A SHEEP DIP – SCHEDULE 3 PART 1 (11)

The supply of a sheep dip must either be to a person who holds a Certificate of Competence in the Safe Use of Sheep Dips (The certificate shows that Parts 1 and 2 of the assessment have been completed satisfactorily), or NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF) issued by the National Proficiency Tests Council and the Department of Agriculture Northern Ireland or to a person acting on behalf of such a person. The certificate shows that Parts 1 and 2 of the assessment have been completed satisfactorily. The supplier must make a record of the Certificate number as soon as reasonably practical and keep it for at least 3 years.

If the active ingredient of the veterinary medicinal product is an organophosphorus compound the supplier must give the buyer:

- (a) a double sided laminated notice providing the relevant safety advice;
- (b) two pairs of gloves to provide protection.

For full details see the Regulations.

5.12 INSPECTIONS

Pharmacies supplying veterinary medicines will be subject to inspection by the DHSSPS.

5.13 FURTHER INFORMATION

The Veterinary Medicines Inspectorate publish a series of useful Veterinary Medicines Guidance Notes (VMGNs) at the following URL:
<http://www.vmd.gov.uk/General/VMR/vmgn.htm>