

## **ADVICE NOTE 25**

### **THE VETERINARY MEDICINES REGULATIONS - FREQUENTLY ASKED QUESTIONS**

- 1) The Veterinary Medicines Regulations (VMRs) were introduced in the autumn of 2005 and set out the legal controls associated with veterinary medicinal products. The VMRs superseded the Medicines Act 1968 with regard to the regulation of veterinary medicinal products.
- 2) In addition, the VMRs provide legal controls on medicines authorised for human use, when used for veterinary purposes, but the Medicines Act 1968 continues to be the basis for the legal controls on such medicines.

#### **Frequently Asked Questions (click question to view answer):**

- **What are 'veterinary medicinal products'?**
- **Who may possess a veterinary medicine?**
- **Who may place veterinary medicines on the market?**
- **How may veterinary medicines be advertised?**
- **Which veterinary medicines may a veterinary surgeon import into the UK?**
- **Do the regulations control the export of veterinary medicines?**
- **What are the main classifications of authorised veterinary medicines?**
- **May veterinary surgeons wholesale veterinary medicines?**
- **Who may prescribe which veterinary medicines?**
- **What must be included on a written prescription?**
- **For how long is a prescription valid?**
- **What is retail supply?**
- **What are the rules for the retail supply of authorised veterinary medicines?**
- **What are the duties under the VMRs when a medicine is prescribed or supplied?**
- **What are the labelling requirements for veterinary medicines?**
- **Who may hand over the medicine?**
- **Who may administer a veterinary medicine?**
- **What is the Cascade?**
- **What are the withdrawal periods when administration is in accordance with the Cascade?**
- **Must the administration of homeopathic remedies be in accordance with the Cascade?**
- **May a veterinary surgeon established in another member State use in the UK veterinary medicines authorised in that other member state?**
- **What must be done for the annual audit of medicines?**
- **What records must be kept by veterinary surgeons?**

### **What are ‘veterinary medicinal products’?**

- 3) ‘Veterinary medicinal products’ (veterinary medicines) include any substance presented as having properties for treating or preventing disease; and any substance used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions, including those used to make a medical diagnosis. (Regulation 2)

Regulation 2 of the Veterinary Medicines Regulations 2007 defines “veterinary medicinal product” to mean:

*‘(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.’*

### **Who may possess a veterinary medicine?**

- 4) Anybody may possess a veterinary medicine if the medicine was supplied to them in accordance with the provisions of schedule 3 to the VMRs (Regulation 7(5)), or as provided for elsewhere in the VMRs.
- 5) **For example:** schedule 3 provides that wholesalers may wholesale medicines to those who may supply them by retail, such as veterinary surgeons; and, Regulation 26(5) provides that veterinary surgeons may possess unauthorised veterinary medicines (a) for administration to animals under the Cascade, unless the amount exceeds that expected to be used under the Cascade; and, (b) where they practice in the UK and another member State and the amount does not exceed that expected to be used in the other member State.

### **Who may place veterinary medicines on the market?**

- 6) Only veterinary medicines given a marketing authorisation by the Secretary of State or the Veterinary Medicines Directorate (VMD) European Medicines Agency may be placed on the market in the UK. (Regulation 4)

### **How may veterinary medicines be advertised?**

- 7) POM-V and POM-VPS medicines, and psychotropic drugs or narcotics are subject to advertising restrictions.
- 8) Psychotropic drugs or narcotics may be advertised to veterinary surgeons and pharmacists, but not others.

- 9) POM-V medicines may be advertised to veterinary surgeons, veterinary nurses, pharmacists, or professional keepers of animals, but not others.
- 10) POM-VPS medicines may be advertised to veterinary surgeons, veterinary nurses, and other veterinary health care professionals; pharmacists, professional keepers of animals, suitably qualified persons and owners or keepers of horses, but not others.
- 11) **Price lists** of POM-V medicines and POM-VPS medicines may be advertised [made available] to anybody, for example, a client or potential client. (Regulation 11)
- 12) Authorised human medicines may not be advertised by price lists; except that a wholesaler may send a price list to a veterinary surgeon, provided the veterinary surgeon has requested the list, it states clearly that the medicine does not have a marketing authorisation as a veterinary medicine and may only be prescribed and administered under the cascade, and the list only includes authorised human medicines that may be prescribed and administered legally under the cascade.
- 13) This is subject to an exemption for wholesalers who send a price list following a request from a veterinary surgeon, and if the list clearly states that the medicine does not have a marketing authorisation and may only be prescribed and administered under the Cascade, and the list only includes authorised human medicines that may be prescribed and administered legally under the Cascade. (Regulation 10)
- 14) The *RCVS Guide to Professional Conduct* provides advice on advertising medicines at paragraphs 3-5, Part 2C.

#### **Which veterinary medicines may a veterinary surgeon import into the UK?**

- 15) A veterinary surgeon may import any **authorised** veterinary medicine.
- 16) A veterinary surgeon may import (personally or through a wholesale dealer or pharmacist) an **unauthorised** veterinary medicine if it is authorised in another member State (of the EU); and, the import is in accordance with an appropriate certificate from the Secretary of State (e.g. a Special Treatment Certificate or Special Import Certificate); and the unauthorised veterinary medicine is for administration to an animal under the care (or responsibility) of the veterinary surgeon and it is for administration in accordance with the provisions of the Cascade (or the exceptional circumstances referred to in Schedule 4 of the VMRs).

#### **Do the regulations control the export of veterinary medicines?**

- 17) Yes, the relevant controls are set out in Regulation 30.

#### **What are the main classifications of authorised veterinary medicines?**

- 18) The main classifications of authorised veterinary medicines are:

- a) Prescription Only Medicine – Veterinarian, abbreviated to POM-V;
- b) Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified person , abbreviated to POM-VPS;
- c) Non-Food Animal – Veterinarian, Pharmacist, Suitably Qualified Person, abbreviated to NFA-VPS; and,
- d) Authorised Veterinary Medicine – General Sales List, abbreviated to AVM-GSL.  
(Schedule 3, paragraph 1)

**May veterinary surgeons wholesale veterinary medicines?**

- 19) Yes, veterinary surgeons who supply veterinary medicines retail may wholesale medicines to another retailer of veterinary medicines provided that in any one year the amount wholesaled does not exceed 5% (of the turnover of the medicines in terms of their value).  
(Schedule 3, paragraph 2)

**Who may prescribe which veterinary medicines?**

- 20) **POM-V** medicines may be prescribed by a veterinary surgeon, who must first carry out a clinical assessment\* of the animal, and the animal must be under the prescribing veterinary surgeon's care\*.
- 21) **POM-VPS** medicines may be prescribed by a veterinary surgeon, pharmacist or SQP, as a responsible supply function. A pharmacist or SQP may only prescribe POM-VPS medicines for administration in accordance with the medicine authorisation.
- 22) A prescription may be oral or written, and must be written if the retail supply of the veterinary medicine will be made by somebody other than the prescriber.  
(Schedule 3, paragraph 3, 4, 5 and 13)
- 23) As a matter of fact, a veterinary surgeon may prescribe POM-VPS medicines, or other veterinary medicines, to animals that are under his or her care and following a clinical assessment (for example, animals owned by a client of the practice), even though this is not a requirement of the VMRs.

\*The RCVS provide an interpretation of the terms 'under his or her care' and 'clinical assessment' as follows:

***'Under his care***

*The Veterinary Medicines Regulations do not define the phrase 'under his care' and the RCVS has interpreted it as meaning that:*

- a) the veterinary surgeon must have been given the responsibility for the health of the animal or herd by the owner or the owner's agent*

- b) that responsibility must be real and not nominal*
- c) the animal or herd must have been seen immediately before prescription or,*
- d) recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe.*
- e) the veterinary surgeon must maintain clinical records of that herd/flock/individual*

*What amounts to 'recent enough' must be a matter for the professional judgement of the veterinary surgeon in the individual case.*

### ***Clinical assessment***

*The Veterinary Medicines Regulations do not define "clinical assessment", and the RCVS has interpreted this as meaning an assessment of relevant clinical information, which may include an examination of the animal under the veterinary surgeon's care.'*

*(Part 2H of the RCVS Guide to Professional Conduct)*

### **What must be included on a written prescription?**

24) Written prescriptions must include:

- a) the name, address and telephone number of the person prescribing the product;
- b) the qualifications enabling the person to prescribe the medicine;
- c) the name and address of the owner or keeper;
- d) the identification (including the species) of the animal or group of animals to be treated;
- e) the premises at which the animals are kept if this is different from the 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 the product prescribed;
- i) the dosage and administration instructions;
- j) any necessary warnings;
- k) the withdrawal period if relevant; and
- l) if it is prescribed under the Cascade, a statement to that effect.

(Schedule 3, paragraph 6 and 13)

## **Controlled Drugs**

25) There are five schedules of controlled drugs under the Misuse of Drugs Regulations 2001; a Home Office licence is required for possession of schedule 1 drugs; schedule 4 and 5 are subject to fewer controls)

26) Prescriptions for controlled drugs of schedule 2 and 3 (but not prescriptions for phenobarbitone) must, in addition to the above, have:

- a) a declaration that the drugs are for an animal or herd under his care;
- b) if to be supplied in instalments, the amount of the instalments and the interval between instalments;  
and in the prescriber's own handwriting:-
- c) the name and address of the person to whom the drug will be delivered (unless this is the same (as) or (e) above and is in the prescriber's own handwriting)
- d) the total quantity of the drug in words and figures (or where the prescription is for a preparation, the form and, where appropriate, the strength of the preparation, and either the total quantity (in both words and figures) of the preparation, or the number (in both words and figures) of dosage units, as appropriate, to be supplied)
- e) the date and the usual signature of the prescriber, both written in ink or otherwise so as to be indelible

(Regulation 15 and 16 of the Misuse of Drugs Regulations 2001, as amended)

## **For how long is a prescription valid?**

27) A prescription for a medicine is valid for six months from the date of the prescription or for any shorter period specified in the prescription; except for prescriptions for controlled drugs of schedules 2 and 3, which are valid for 28 days.

28) A repeat prescription may be repeated once, or the number of repeats specified.  
(Schedule 3, paragraph 6)

## **What is retail supply?**

29) Retail supply means any supply other than to or from the holder of a wholesaler's authorisation and whether or not for payment; and a person may supply a product irrespective of who owns it. (Schedule 3, paragraph 3)

**What are the rules for the retail supply of authorised veterinary medicines?****POM-Vs****Prescribing veterinary surgeon**

30) POM-V medicines may be supplied by the prescribing veterinary surgeon; who has first carried out a clinical assessment and who has the animal(s) under his or her care; from 1 April 2009, if the supply is from veterinary practice premises they must be registered in accordance with the regulations (the Royal College of Veterinary Surgeons).

**Supply only by the veterinary surgeon**

31) POM-V medicines may be supplied by one veterinary surgeon in accordance with the written prescription of another veterinary surgeon; from 1 April 2009, the supply from veterinary practice premises registered in accordance with the regulations (the Royal College of Veterinary Surgeons).

**Supplying pharmacist**

32) POM-V medicines may be supplied by a pharmacist in accordance with the written prescription of a veterinary surgeon; premises from which supplies are made must be registered with the Royal Pharmaceutical Society of Great Britain (RPSGB). (Schedule 3, paragraph 3, 8 and 10)

**POM-VPS**

33) POM-VPS medicines may be supplied by the prescribing veterinary surgeon, pharmacist or SQP. Alternatively the prescriber may write a prescription and the POM-VPS medicine may be supplied in accordance with a prescription from a veterinary surgeon, pharmacist or SQP.

34) From 1 April 2009, SQPs may supply POM-VPS medicines from veterinary practice premises registered in accordance with the regulations (the Royal College of Veterinary Surgeons). (Schedule 3, paragraph 3 and 14)

**What are the duties under the VMRs when a medicine is prescribed or supplied?**

35) The responsibilities are set out in the *RCVS Guide to Professional Conduct*, which states:

*'13. A veterinary surgeon who prescribes a POM-V or POM-VPS veterinary medicinal product, or supplies a NFA-VPS veterinary medicinal product, must:*

- a. before he does so, be satisfied that the person who will use the product is competent to use it safely and intends to use it for a use for which it is authorised;*
- b. when he does so, advise on the safe administration of the veterinary medicinal product;*

- c. when he does so, advise as necessary\* on any warnings or contra-indications on the label or package leaflet; and
- d. not prescribe (or in the case of a NFA-VPS product, supply) more than the minimum quantity required for the treatment.

14. *The Veterinary Medicines Regulations do not define 'minimum amount' and the RCVS considers this must be a matter for the professional judgement of the veterinary surgeon in the individual case.'*

(Part 2H of the *RCVS Guide to Professional Conduct*)

\*The word 'necessary' is not included in the VMRs, but is in the guidance notes issued by the Veterinary Medicines Directorate.  
(Schedule 3, paragraphs 5 and 7)

### **Supplies**

36) In addition, for supplies of medicines, the person supplying a medicine in accordance with a prescription must take all reasonable steps to be satisfied that the prescription is from (and has been signed by) a person entitled to prescribe the medicine; may only supply the medicine specified; and must take all reasonable steps to ensure the medicine is supplied to the person named in the prescription. (Schedule 3, paragraph 5)

### **What are the labelling requirements for veterinary medicines?**

37) If a veterinary medicine is supplied within the authorisation of the medicine and in the original container, it may be supplied without any additional (dispensing) label. If a veterinary medicine is supplied under the Cascade, the labelling requirements below are mandatory.

38) However, the *RCVS Practice Standards Manual* advises that all medicines supplied by a veterinary surgeon should include the name and address of the veterinary practice supplying the medicine.

39) In addition, the *RCVS Practice Standards Manual* provides for the labelling for POM-V medicines supplied by a veterinary surgeon as follows:

#### **'POM-V**

*All POM-V medicines supplied by the practice must be labelled with the following information:*

- a) *The name and address of the animal owner;*
- b) *The name and address of the veterinary practice supplying the medicine;*
- c) *The date of supply;*

- d) *The words “keep out of the reach of children”;*
- e) *The words “for animal treatment only” unless the package or container is too*
- f) *small for it to be practicable to do so;*
- g) *The words “for external use only” for topical preparations;*
- h) *The name and quantity of the product, its strength and directions for use.*

**MEDICINE SUPPLIED FOR USE UNDER THE CASCADE**

*Medicines for supply under the Cascade, must include the following **additional Information***

- a) *Identification of the animal or group of animals;*
- b) *name of the veterinary surgeon who has prescribed the product;*

*And unless already specified on the manufacturer’s packaging*

- c) *any special precautions;*
- d) *the expiry date*
- e) *any necessary warnings for the user, target species, administration or disposal of the product’*

40) The labelling of medicines supplied under the Cascade applies to all categories of medicines.

41) If the veterinary medicine is dispensed in the manufacturer’s container, any information on the container that is un-amended by the prescription (the prescriber’s instructions to the animal owner) should not be obscured by the additional (dispensing) label.

**Who may hand over the medicine?**

42) In the case of a **POM-V** medicine, a **veterinary surgeon** may hand over the medicine, or if another person does so, the veterinary surgeon must authorise each transaction individually before the product is supplied and be satisfied that the person handing it over is competent to do so.

43) Generally, **pharmacists** are present at the retail pharmacy premises registered with the RPSGB and supervise the supply of prescription only medicines from the premises.

44) **SQPs** may hand over or despatch **POM-VPS and NFA-VPS** medicines personally, or if handed over or dispatched by somebody else, the SQP must (a) be satisfied he or she is competent to do so; (b) be in a position to intervene; and, (c) check the medicine allocated for supply to the customer.

**Who may administer a veterinary medicine?**

45) A veterinary medicine may be administered in accordance with its authorisation. If there is no authorisation for the veterinary medicine or the way in which the medicine is used or administered, it must be administered in accordance with the directions of a veterinary surgeon under the provisions of the Cascade (Schedule 4 of the VMRs). (Regulation 8)

**What is the Cascade?**

46) The 'Cascade' is the term applied to the (cascading) options of veterinary medicines available to a veterinary surgeon to treat an animal. If there is no authorised veterinary medicine in the UK for a condition, the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following (the cascade), cascaded in the following order-

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

47) In the case of a veterinary medicinal product imported from another member State, if the veterinary surgeon has not obtained a certificate from the Secretary of State permitting importation, the veterinary surgeon must obtain a certificate from the Secretary of State before administration.

48) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the Cascade must be listed in Annex I, II or III to Council Regulation (EEC) No. 2377/90. (Schedule 4, paragraph 2)

More information can be found in Veterinary Medicine Guidance Notes 15: *Guidance on the use of the Cascade* and 19: *Veterinary Medicinal Products Authorised for the Treatment of Horses*)

**What are the withdrawal periods when administration is in accordance with the Cascade?**

49) A veterinary surgeon prescribing or administering a veterinary medicinal product to a food-producing animal under the Cascade must specify an appropriate withdrawal period.

Unless the Secretary of State has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period must not be less than;

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

**Must the administration of homeopathic remedies be in accordance with the Cascade?**

50) The administration of homeopathic remedies (those not authorised as veterinary medicines) need not be in accordance with the Cascade, but must be in accordance with the requirements of Schedule 4 of the VMRs – the administration of veterinary medicines outside the terms of a marketing authorisation, which are:

- a) Anyone may administer:
  - i) a homeopathic remedy that was on the market before 1 January 1994;
  - ii) a registered homeopathic remedy (proof of efficacy is not required for registered homeopathic remedies) prepared extemporaneously by a pharmacist, on premises registered with the RPSGB, prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia (or if not there in a pharmacopoeia published by the British Pharmacopoeial Commission or by the competent authority of any member State) and intended to be supplied directly to the end user.
- b) A veterinary surgeon may administer, or under his or her responsibility another person may administer:
  - i) a homeopathic remedy authorised for human use;
  - ii) a homeopathic remedy prepared extemporaneously by a veterinary surgeon, pharmacist or person holding a manufacturing authorisation authorising the manufacture of that type of product.

(Schedule 4, paragraph 8)

51) The administration of medicines is also subject to the Veterinary Surgeons Act 1966, in particular Schedule 3 of that Act.

**May a veterinary surgeon established in another member State use in the UK veterinary medicines authorised in that other member state?**

- 52) Yes, a veterinary surgeon established in another member State may use in the UK, veterinary medicines authorised in that other member state (except immunological veterinary medicines such as vaccines), provided that:
- a) the quantity of medicines does not exceed the requirements for the treatment of specific animals;
  - b) the medicine is transported by the veterinary surgeon in the original manufacturer's packaging;
  - c) the veterinary surgeon is acquainted with the *RCVS Guide to Professional Conduct*;
  - d) in the case of administration to food producing animals, there is an equivalent veterinary medicine authorised in the UK that has the same qualitative and quantitative composition in terms of active substances, and the veterinary surgeon ensures the withdrawal period specified on the label (or the UK withdrawal period if this is longer) is complied with;
  - e) the veterinary surgeon only supplies to the owner or keeper enough veterinary medicine to complete the treatment of the animals concerned;
  - f) the veterinary surgeon keeps detailed records of the animals treated, the diagnosis or clinical assessment, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied and keeps these records in the UK for at least three years; and,
  - g) the overall range and quantity of veterinary medicines carried by the veterinary surgeon does not exceed that generally required for the daily needs of good veterinary practice.

**What must be done for the annual audit of medicines?**

- 53) At least once a year every person entitled to supply a veterinary medicine on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicines must be reconciled with medicines currently held in stock, any discrepancies being recorded. The VMD advice on the annual audit states:

*'AUDIT REQUIREMENTS*

*The VMD considers that audit requirements may be met in the following way. For each product:*

- a) noting the amount held in stock at the beginning of the audit period;*
- b) totalling the amount received during the period;*
- c) adding a) and b);*

- d) *subtracting from c) the amount supplied during the audit period;*
- e) *comparing the results with the amount held in stock at the end of the audit period and noting discrepancies.'*

54) The method outlined above is intended only to illustrate the components that the VMD consider necessary to meet the audit requirements. The Regulations do not specify a system of procedure for conducting the audit, nor does it prescribe the frequency with which it should be carried out except that it should be at least annually.

55) Practices and pharmacies will wish to consider systems that fit best with their current procedures. A system linking incoming and outgoing transactions with stock held, for example, may provide an ongoing running total which, with the addition of a periodic physical stock count to verify the stock held, may meet the audit requirement. Where an annual or more frequent stock-take which includes the main features set out above is carried out for any other reason such as, for example, for tax purposes, the VMD would consider that the "detailed audit" requirement is being met.'

### **What records must be kept by veterinary surgeons?**

#### **Generally**

56) Veterinary surgeons (as well as all those permitted under the VMRs to supply POM-V and POM-VPS medicines) must make a record of all receipts and supplies of these medicines, or keep documents relating to those receipts and supplies, to show for each receipt or supply: the date; the name of the veterinary medicine; the batch number (except that for a non-food producing animal it is sufficient to have the date on which that batch of medicines was received or first used); the quantity; the name and address of the supplier or recipient; and if there is a written prescription, and, the name and address of the person who wrote the prescription and a copy of the prescription.

#### **Food Producing Animals**

57) A veterinary surgeon who administers a veterinary medicine to a food producing animal must enter the following information in the keeper's records or give it to the keeper in writing (and the keeper must enter the information into his or her records): the name of the veterinary surgeon; the name of the product and batch number; the date of administration of the product; the date of administration; the amount administered; the identification of the animals treated; and, the withdrawal period. (Regulation 18)

58) If the veterinary medicine administered by the veterinary surgeon is administered under the provisions of the Cascade (where the medicine or its use on that occasion has no authorisation), or where a veterinary surgeon has made a retail supply of the medicine for administration under the Cascade, the veterinary surgeon must (as soon as is reasonably practicable) record in addition to the requirements of Regulation 18, the following: the name and address of the animal owner; the number of animals treated; the date the

animals were examined; the results of his or her clinical assessment; the trade name of the product if there is one; the name and quantity of the active substances; the doses administered or supplied; and, the duration of treatment.

(A keeper of a food producing animal must also keep a record of veterinary medicines bought or otherwise acquired for a food-producing animal as well as a record of the administration of that veterinary medicine or a record of its disposal as provided in the VMRs. (Regulation 19))

**JUNE 2008**