# Inspection Criteria for Veterinary Practice Premises

**Criteria highlighted in bold type are legal requirements;** those in normal type are guidance and/or good practice.

**The requirements set down in this Inspection Criteria apply equally to over the counter and internet suppliers:**

## 1. General Administration

- **The veterinary practice premises (VPPs) and vets supplying veterinary medicines from those premises must be listed on the relevant Royal College of Veterinary Surgeons (RCVS) register (Schedule 3 para 8)**

- **SQPs must be listed on the current register (Schedule 3 para 14(3))**

- **SQPs' qualifications must be appropriate for the product range they prescribe/supply (Schedule 3, Para 14(3))**

## 2. Premises

- Premises should be suitable for the storage and supply of veterinary medicines, and be either:

  - a permanent building with a fixed address
  - a mobile unit, if it is used for animal treatment by a vet and operated from a registered VPP)

- In either case the premises should:

  - be secure from unauthorised access
  - be of such design as to allow all veterinary medicine storage conditions to be met
  - have measures in place to prevent the entrance and harbouring of pests
  - have veterinary medicine storage areas clearly separated from food/drink for human consumption and toilet and washing areas
  - not have veterinary medicines on self-service, except those that have the legal category AVM-GSL, homeopathic remedies and those products marketed under the Exemptions for Small Pet Animals

- A list of other sites, including vehicles, linked to the practice and used to store veterinary medicines should be maintained and available at the premises

## 3. Storage of veterinary medicines

- All veterinary medicines should be stored:

  - in a clean and tidy location in accordance with the manufacturer's recommendations
  - in areas which are not accessible to the public
  - in areas which are not accessible to domestic pets
  - on appropriate and secure shelving

- in such a way as to be protected from adverse effects of light, temperature extremes and moisture

- Wherever temperature sensitive medicines such as vaccines are stored, there should be appropriate monitoring and recording of minimum/maximum temperatures to demonstrate that they have been stored in accordance with the directions specified in their summary of product characteristics (SPCs)

- When transported, measures should be taken to ensure that veterinary medicines remain within the temperature range specified on their SPCs, for example. by use of a cool box or refrigerated unit. The suitability of such measures should be demonstrated

- Ideally, ambient or maximum/minimum temperatures should be recorded in non-refrigerated areas and vehicles where ambient products are stored or transported and where there is potential for the temperature range to exceed or fall below that specified on the products' SPC

- Effective stock control should be carried out to ensure a continuous supply of all products and removal of out-of-date medicines

## 4. Storage and supply of Controlled Drugs (CDs)

- **Schedule 2 and certain Schedule 3 CDs must be kept in a secure, lockable and immovable receptacle that can only be opened by a vet or a person authorised by a vet.**

- It is considered good practice to have a written SOP setting out who is authorised to access the CDs cabinet and for what purposes. The SOP may also cover ordering (requisition), receipt, supply and disposal of CD

- **Where CDs that are subject to special storage conditions are transported in a vehicle, they must be kept securely within a locked container in the vehicle (which could be the locked glove compartment) and the vehicle must be locked when not attended**

- **A CD Register of Schedule 2 drugs obtained, supplied and used must be kept in accordance with the Misuse of Drugs Regulations 2001. Where such drugs are supplied against another vet's prescription, the name of the person collecting the drugs must be noted in the Register**

- **The CD Registers must be kept for two years from the date of the last entry. A separate register must be kept for each location where CDs are stored**

- **The CD Register must**:
  - **be either a bound book (which does not include any form of loose leaf register or card index), or it can be computerised, provided the entries cannot be amended**
  - **be separated into each class of drug**

- **have a separate page for each strength and form of that drug, with this recorded at the top of each page**
- **have the entries in chronological order and made on the day of the transaction or if not reasonably practicable, the next day**
- **have the entries made in ink or in a computerised form in which every entry is capable of being audited**
- **not have cancellations, obliterations or alterations. Corrections must be made by a signed and dated entry in the margin or at the bottom of the page**
- **be kept at the premises to which it relates and be available for inspection at any time. A separate register must be kept for each set of premises**
- **not be used for any other purpose**
- **be kept for a minimum of two years after the date of the last entry**

- **For each CD purchased the following details must be recorded in the Register:**
  - **the date on which the controlled drug was received**
  - **the name and address of the supplier, e.g. wholesaler, pharmacy**
  - **the quantity received**

- **For each CD supplied the following details must be recorded in the Register:**
  - **the date on which the supply was made**
  - **name and address of the person or firm supplied**
  - **the quantity supplied**
  - **the identity of the person collecting a Schedule 2 controlled drug and if a healthcare professional their name and address**
  - **was proof of identity requested (Yes/No) - Schedule 2 only**
  - **was proof of identity provided (Yes/No) - Schedule 2 only**

- It is considered good practice to keep a running balance of each drug entry in the CD Register and for a weekly stock check to be carried out

- **Where Schedule 2 and 3 drugs are supplied against another vet's prescription, a copy of the prescription, marked with the date of supply (which must be within 28 days of the date of the prescription) must be retained**

- If it is stipulated that a controlled drug medicine be used within a specific time period once broached, it should be labelled with the opening date (alternatively the use by date can be recorded on the label but the practice should be consistent). **The usage date should be observed and once expired the product should be appropriately disposed of (Regulation 8)**

- **CDs should only be ordered from a supplier using a requisition order personally signed by a vet**. It is considered good practice for the vet to keep a copy of the requisition order in case of a query

## 5. Disposal Procedures

- Procedures should be in place to quarantine, and ultimately dispose of, returned or out of date medicines, including medicines whose broach date have been exceeded. Procedures should also be in place to quarantine, and ultimately dispose of leaking, damaged, illegible or unwanted packaging

- Procedures should be in place to deal with spillages and leakages

- **Schedule 2 CDs must be destroyed in the presence of an authorised witness and the resulting destroyed products and containers appropriately disposed of**

- **A separate record should be kept of client returned Schedule 2 CDs and they should not be re-entered in the CD Register.** They do not need to be destroyed in the presence of an authorised witness, but it is considered good practice to do so

- **Any special handling or disposal requirements for medicines classed as hazardous pharmaceuticals, such as for cytotoxic medicines, must be observed**

## 6. Supply Procedures

### (a) General

- **Out of date medicines (all classifications) may not be supplied (Regulation 7(2))**

- **Only the minimum quantity required for treatment may be prescribed and supplied (Schedule 3 para 7(c))**

- If a medicine is supplied in its authorised packaging with labelling specified in the marketing authorisation (MA), for an authorised use, there is no legal requirement for a dispensing label to be applied. **It is an offence to supply such a container 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 (Schedule 3 para 12)**

- **A vet may break open any package containing a veterinary medicine. Where veterinary medicines are supplied in a container other than that specified in the MA, the vet must ensure that the container is suitably labelled and must supply sufficient written information to enable the product to be used safely, for example a copy of the SPC or package leaflet can be provided, or appropriate information such as usage instructions, warnings and contra-indications can be included on the dispensing label (Schedule 3 para 9 and 12)**

- **There should be no supplies of unauthorised medicines or medicines for use outside their MA, unless supplied under the cascade (see section 6(c)) (Regulation 27)**

- If it is stipulated that a veterinary medicine be used within a specific time period once broached, it should be labelled with the opening date (alternatively the use by date can be recorded on the label but the practice should be consistent). **The usage date should be observed and once expired the product should be appropriately disposed of (Regulation 8)**

**(b) Supply of POM-V, POM-VPS and NFA-VPS medicines**

- **For POM-V products, animals must be under the care of the vet, and a clinical assessment must be carried out by that vet before the product is prescribed and supplied (Schedule 3 para 4)** and evidence should be available, for example, from random samples of clinical records

- **For POM-V products, a vet must prescribe and supply the product and authorise each transaction individually (Schedule 3 para 9)** and may do so in a number of ways, for example:

  - hand over a medicine personally following a consultation, or instruct a fellow member of staff to supply the medicine
  - make a note on a client's records that repeat prescriptions could be supplied to the client up until a set period of time
  - a member of staff taking a call from a client may put a medicine aside for the vet to authorise before being supplied
  - in the case of a client unexpectedly coming into the practice, by a phone call to the vet to authorise the supply

- **POM-VPS medicines must be prescribed and supplied and NFA-VPS supplied by a vet or SQP** (in relation to products for which the SQP is qualified) and each individual transaction authorised by one of those persons, as follows:

  - **A vet must authorise each transaction in the same way as for POM-V medicines) (Schedule 3 para 9)**

  - **An SQP must authorise each transaction by**
  - **personally supplying POM-VPS or NFA-VPS medicines to the end client**
  - **being in a position to intervene when products are handed over**
  - **checking the products before despatch to the customer (Schedule 3 para 14(5))**

- **A vet who prescribes a POM-V or POM-VPS medicine, or supplies an NFA-VPS medicine (or an SQP in the case of prescribing POM-VPS and supplying NFA-VPS medicines):**

  - **before doing so, must be satisfied that the person using the product is competent to do so safely, and intends to use it for a purpose for which it is authorised**
  - **when doing so, must advise on its safe administration and any warnings or contra-indications on the label or package leaflet (Schedule 3 para 7)**

- In the case of supply of POM-VPS and NFA-VPS medicines, the customer does not need to be a registered client of the veterinary practice

- When prescribing for food producing animals, SQPs should take into account the advice given by SCOPS, COWS and RUMA

- For horses and other equidae, the vet should check whether the animal has been declared as non-food producing in their horse passport

- If a horse has not been 'signed out' in its passport, or if the vet cannot confirm that it is signed out, the horse is considered a food producing animal and all the prescribing and record keeping requirements apply

- Vets supplying veterinary medicines for horses should advise whether the medicine is suitable for use in food producing horses. This allows horse keepers to fulfil the requirements of the Horse Passport Regulations. Further information on horse medicines and horse passport record keeping is available on GOV.UK under Veterinary Medicines Guidance

- It is considered good practice to have a written SOP setting out the procedures for authorisation of each veterinary medicine transaction

- There should be evidence of actions taken when no vet/SQP is present to prescribe/supply veterinary medicines

- **In the case of sheep dips, if not previously supplied to the customer, a laminated notice and two pairs of gloves must be supplied with every product prescribed and supplied (Schedule 3 para 22 (4))**

**(c) Supply of medicines under the cascade (for example Non-UK authorised products, authorised products used off-label, human medicines, and extemporaneous medicines)**

- There should be evidence that the cascade is being followed correctly (for example where there is an authorised veterinary medicine available clinical notes could explain why this is not being used for a particular animal)

- Relevant documents, for example, Special Import Certificates (SICs)/Special Treatment Certificates (STCs) must be available for all imported non-UK authorised products

- **Unless the vet who prescribes a veterinary medicine under the cascade both supplies the product and administers it to the animal, the product must be labelled with the following information: (Schedule 3 para 13)**

  - **the name and address of the vet practice**
  - **the name** (or initials) **of the vet who prescribed the product**
  - **the name and address of the animal owner**
  - **the identification (including the species) of the animal or group of animals**
  - **the date of supply**

- **the expiry date of the product, if applicable**
- **the name or description of the product (i.e. name and quantity of active ingredients)**
- **dosage and administration instruction**
- **any special storage precautions**
- **any necessary warnings for the user, target species, administration or disposal**
- **the withdrawal period, if relevant**
- **the words either "keep out of the reach of children" and "for animal treatment only"**

**7. Records**

**(a) Records of receipt and/or supply of all prescription medicines must be available and contain the following information:**

- **the date of receipt/supply (supply includes administration)**
- **the name of the veterinary medicine**
- **the batch number (except that for non-food animals medicines a record of the date of receipt or start of the batch is acceptable)**
- **the quantity of the veterinary medicine**
- **name and address of the supplier or recipient**
- **if there is a written prescription, the name and address of the person who wrote the prescription and a copy of it (Regulation 23(1))**

• **If the product is a sheep dip, a record of the sheep dip certificate of competence number must also be made in addition to the above (Schedule 3 para 22).** Vets may obtain the number by checking the certificate on each occasion, taking a copy of it or, after checking it on the first occasion, recording its number with the customer's details

• **All records must be retained for 5 years, except sheep dip certificate of competence numbers which must be kept for 3 years (Regulation 23(4) and Schedule 3 para 22(3))**

• A means of recording the disposal of veterinary medicines and the transfer of veterinary medicines to another premises, store or vehicle should be implemented, to ensure traceability and enable stock reconciliation

**(b) Records of products administered to food-producing animals by a vet (Regulation 18)**

• **A vet who administers prescription medicines to food producing animals must personally enter the following information into the livestock keeper's record book or give written information to the livestock keeper (to enter):**

- **the name of the vet**
- **the name of the product and the batch number**
- **the date of administration of the product**
- **the amount of product administered**
- **the identification of the animals treated**

- **the withdrawal period**

**(c) Records of products administered to food-producing animals under the cascade (Regulation 24)**

- **A vet administering a veterinary medicine, which includes a human medicine or product imported under an SIC/STC, to food-producing animals under the cascade (or another person under the vet's permission) must record:**

  - **the date of examination of the animals**
  - **the name and address of the owner of the animals**
  - **the identification and number of animals treated***
  - **the result of the vet's clinical assessment**
  - **the trade name of the product, if there is one**
  - **the manufacturer's batch number shown on the product, if there is one**
  - **the name and quantity of the active substances**
  - **the doses administered or supplied**
  - **the duration of treatment**
  - **the withdrawal period**

    * when a whole herd/flock is treated with a medicine, it is acceptable to record "whole herd" or "whole flock" not every individual animal's number.

**8.Written prescriptions**

- **If issued, written prescriptions must include all the information required under the VMR (Schedule 3 para 6(1)):**

  - **the name, address and telephone number of the person prescribing the product**
  - **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 or group of animals to be treated**
  - **the premises at which the animals are kept if this is different from the address of the owner or keeper**
  - **the date of the prescription**
  - **the signature or other authentication of the person prescribing the product**
  - **the name and amount of the product prescribed**
  - **the dosage and administration instructions**
  - **any necessary warnings**
  - **the withdrawal period if relevant**
  - **if it is prescribed under the cascade, a statement to that effect**

- **A written prescription for a CD as specified in the Misuse of Drugs Regulations 2001(a) is valid for 28 days. A written prescription for a CD may be hand-written, typed in a computerised form or computer generated, but must be signed by the person issuing it. It is an offence to supply against a faxed or emailed prescription (Schedule 3 para 6(2))**

- **A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription (Schedule 3 para 6(3))**

- **If the prescription is repeatable it must specify the number of times the veterinary medicine may be supplied. (Schedule 3 para 6(4))** If the prescription is not repeatable, it is considered good practice for this to be stated

- **When a POM-V or POM-VPS medicine is dispensed under a written prescription from another vet (or in the case of POM-VPS, a pharmacist or SQP) a copy of the prescription must be retained by the supplying vet for five years (Regulation 23).** It is considered good practice for copies of prescriptions issued by a vet, pharmacist or SQP to be retained in case of query

## 9. Audit

- **An audit of prescription medicines must be carried out at least annually and a record of the most recent audit must be available (Schedule 3 Para 15 (1)),** in particular for CDs recorded in the CD Register

- 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 reason such as, for example, tax purposes, the VMD would consider that the “detailed audit” requirement is being met

## 10. In-feed veterinary medicines (premixes) and feedingstuffs

- **Premixes authorised for incorporation into feedingstuffs may only be supplied to approved manufacturers (a register of approved manufacturers is published on GOV.UK (Schedule 3 Para 11). The above does not apply in the case of premixes supplied only for domestic use (i.e. for non-food producing animals or food-producing animals whose produce is not commercially sold or supplied.** A Medicated Feedingstuff (MFS) prescription is not required but the product must be prescribed/supplied as if it was a (non-premix) POM-VPS

- **If the manufacturer is the end-user of the feedingstuff, the supply of premix must be in accordance with a MFS prescription (Schedule 5 Para 16 (4))**

- **Premixes may not be supplied for top-dressing, unless that method of administration is permitted by the product’s MA or the product is supplied under the cascade. (Schedule 5 Para 9)**

- **An MFS prescription for feedingstuffs containing a veterinary medicine must contain the following:**

  - **the name and address of the person prescribing the product**

- **the qualifications enabling the person to prescribe the product**
- **the name and address of the keeper of the animals to be treated**
- **the species of animal, identification and number of the animals**
- **the premises at which the animals are kept if this is different from the address of the keeper**
- **the date of the prescription**
- **the signature or other authentication of the person prescribing the product**
- **the name and amount of the product prescribed**
- **the dosage and administration instructions**
- **any necessary warnings**
- **the withdrawal period**
- **the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose)**
- **if the validity exceeds one month, a statement that not more than 31 days supply may be provided at any time**
- **the name, type and quantity of feedingstuffs to be used**
- **the inclusion rate of the veterinary medicine and the resulting inclusion rate of the active substance**
- **any special instructions**
- **the percentage of the prescribed feedingstuffs to be added to the daily ration**
- **if it is prescribed under the cascade, a statement to that effect. (Schedule 5 Para 19(1))**

- **A MFS prescription is valid for a maximum of 3 months and must only be for one course of treatment**

- **Medicated feedingstuffs containing POM-V medicines may only be prescribed by a vet. A vet or SQP may prescribe a feedingstuff containing a POM-VPS medicine. Additional approval as a Distributor is required to supply medicated feedingstuffs. Further information can be found on GOV.UK (Schedule 5 Para 18 (1))**

## 11. Wholesale supply

- **A wholesale dealer's authorisation (WDA) is required if veterinary medicines are bought on a wholesale basis for the purposes of supply to other retailers or wholesalers (Schedule 3 Para 2(1))**

- **There is an exemption from this requirement, where a retailer supplies another retailer with a small number of wholesale transactions in order to relieve a temporary, emergency supply problem that could be detrimental to animal welfare**

- The above exemption is intended to enable retailers (vets, pharmacists and SQPs) to supply each other in an emergency or if there are shortages of supply and should not be a regular occurrence

## 12. Advertising

- **The advertising of POM-V and POM-VPS products may only be aimed at**

**appropriate persons, which do not include the general public.** This includes adverts on websites, brochures and those displayed in retail areas to which the general public have access. POM-V and POM-VPS products may be on display behind the retail counter or similar, secure areas provided none are promoted inappropriately. Price lists are not considered to be advertising, provided that they meet the conditions in the advertising guidance published on GOV.UK **(Regulation 11(5))**

- **All products must only be advertised for their authorised use (Regulation 10(1))**

- **Human medicines cannot be advertised for administration to animals (Regulation 10(2)). This includes human general sales list medicines.**

## 13. Other

- Vets and SQPs should be aware of the UK's pharmacovigilance system, whereby reports of suspected adverse reactions or lack of efficacy can be made to the MA holder directly or to the VMD via the following link: www.gov.uk/report-veterinary-medicine-problem

- **Extemporaneous preparations/Specials**
  A vet is allowed to possess and use unauthorised extemporaneous veterinary medicines for use in individual animals under the cascade. These products can be made by the vet or can be made by another vet, pharmacist or the holder of an appropriate manufacturing authorisation in accordance with the prescribing vet's instruction (Schedule 4 para 1). Further information is available on GOV.UK under Veterinary Medicines Guidance

- **Animals (Scientific Procedures) Act (ASPA)**
  The controls set out in the VMR do not apply to veterinary medicines which are being used in accordance with a Project Licence issued under the ASPA (Regulation 3)

- **Antimicrobial resistance**
  The VMD recommends that practices have a protocol to help prevent the development of antimicrobial resistance. Information on combating antimicrobial resistance can be found on the BVA and BSAVA websites:

  - http://www.bva.co.uk/News-campaigns-and-policy/Newsroom/News-releases/Measures-to-tackle-antimicrobial-resistance-must-be-science-based-says-BVA/
  - https://www.bsava.com/Resources/Veterinary-resources/PROTECT

- **Product information database**
  All currently authorised veterinary medicines are listed on the VMD's Product Information Database. Any medicines that have been recently changed will be highlighted in yellow