Inspection Criteria for SQP Retailers' 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 premises must be appropriately approved and registered with the Veterinary Medicines Directorate (VMD) for the product range supplied (Schedule 3, Para 14 (4))**
- **SQPs must be listed on the current SQP 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 must be suitable for the storage and supply of veterinary medicines, (Schedule 3 Para 14 (4a))** and be a permanent building with a fixed address.
- Premises should also:
  - be secure from unauthorised access
  - have areas and facilities that enable veterinary medicine storage conditions to be met
  - have in place measures to prevent the entrance and harbouring of pests
  - have veterinary medicine storage areas clearly separated from food/drink for human consumption and from 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

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 that are not accessible to the public
  - in areas that 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)

- POM-VPS and NFA-VPS medicines may not be stored in or retail supplied from a vehicle. However, POM-VPS and NFA-VPS medicines that have been retail supplied from approved premises may be delivered by vehicle to a customer provided they are accompanied by a dated, itemised delivery note. A copy of the delivery note should be retained at the issuing premises

- When transported, measures should be taken to ensure that veterinary medicines remain within the temperature range specified on their SPCs, e.g. 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' SPCs

- Effective stock control should be carried out to ensure a continuous supply of all products and removal of out-of-date medicines

4. Disposal Procedures

- Procedures should be in place to quarantine, and ultimately dispose of, returned or out of date medicines, and leaking, damaged, illegible or unwanted packaging

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

5. 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))**

- **An SQP may break open any package (other than the immediate packaging) provided that the necessary product literature is provided to the client (Schedule 3 Para 14 (9))**

(b) SQPs should carry out their duties as described in the Code of Practice for SQPs

- **POM-VPS medicines must be prescribed and supplied and NFA-VPS supplied by an SQP**

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

- **An SQP who prescribes a POM-VPS medicine or supplies an NFA-VPS medicine:**
  - **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 (1))**

- 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 SQP should check whether the animal has been declared as non-food producing in their horse passport

- SQPs supplying veterinary medicines for horses should advise whether the medicine is suitable for use in food producing horses. This allows horse keepers to fulfill 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

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

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

- **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))**

6. Records

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

  - **the date of receipt/supply**
  - **the name of the veterinary medicinal product**

- **the batch number *(except that for non-food animal medicines a record of the date of receipt or start of the batch is acceptable)***
- **the quantity of the veterinary medicinal product**
- **name and address of the supplier or recipient; and**
- **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 (3)).** SQPs supplying POM-VPS sheep dips should record the certificate number against each transaction; they should therefore check the certificate on each occasion or take a copy of it or record its number with the customer's details

- **All records must be retained for 5 years (Regulation 23 (4)) except sheep dip certificate of competence numbers which must be kept for 3 years (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

7. 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 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 medicinal product 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-VPS medicine is dispensed under a written prescription from a veterinary surgeon, a pharmacist or an SQP, a copy of the prescription must be retained by the supplying SQP for five years (Regulation 23).** It is considered good practice for copies of prescriptions issued by a veterinary surgeon, pharmacist or an SQP to be retained in case of query

8. Audit

- **An audit of POM-VPS medicines must be carried out at least annually and a record of the most recent audit must be available (Schedule 3 Para 15 (1))**

- 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

9. 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);** paragraph 30 of Schedule 5 of the VMR provides an exemption for domestic keepers mixing medicated feed and for their SQP suppliers of premixture. A Medicated Feedingstuff (MFS) prescriptions 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 18 (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 medicinal product 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**

- **An SQP may prescribe a feedingstuff containing a POM-VPS medicine but additional approval as a Distributor is required to supply medicated feedingstuffs. Further information can be found on GOV.UK (Schedule 5 Para 18 (1))**

10. 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 (veterinary surgeons, pharmacists and SQPs) to supply each other in an emergency or if there are shortages of supply and should not be a regular occurrence

11. Advertising

- **The advertising of 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-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**

12. Other

- 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

- **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