Veterinary Medicines Directorate

Guidance

Inspection Criteria for SQP Retailers' Premises

Legal requirements and good practice guidance for SQP retailers' premises inspections.

Last updated 17 May 2024

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ANIMAL MEDICINES TRAINING REGULATORY AUTHORITY

QUALITY | CARE | EXCELLENCE

Contents

The requirements and guidance set down in this inspection criteria apply equally to over the counter and internet suppliers.

For full details of the requirements refer to The Veterinary Medicines Regulations 2013 (legislation.gov.uk)[1] (VMR).

1. General Administration

- The premises must be appropriately authorised 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)).
- Premises should also:
    - be secure from unauthorised access
    - 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 from toilet and washing areas

[1] www.legislation.gov.uk/uksi/2013/2033/contents

- 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

- Veterinary medicines must be stored in accordance with the terms of any specific instructions on the label of the product and in accordance with the relevant summary of product characteristics, including during transport (Schedule 3, para 3E)
- Records must be kept demonstrating that veterinary medicines have been stored, including during transport, at the appropriate temperature ranges and these made available on request by VMD inspectors (Schedule 3, para 3E)
- All veterinary medicines should be stored:
  - in a clean and tidy location
  - in areas that are not accessible to the public
  - in areas that are not accessible to domestic pets
  - on appropriate and secure shelving
- POM-VPS and NFA-VPS medicines may not be stored in or retail supplied from a vehicle.
- POM-VPS and NFA-VPS medicines that have been retail supplied from authorised premises may be delivered by vehicle to a customer but they must be accompanied by a dated, itemised delivery note. A copy of the delivery note should be retained at the issuing premises.
- 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, such as having a spill kit.

5. Supply Procedures

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))

SQP Code of Practice

SQP should carry out their duties as described in the Code of Practice for SQPs[2]. Failure to comply with the Code of Practice will result in an SQP's registration body being informed and potential disciplinary action being taken.

[2] www.gov.uk/government/uploads/system/uploads/attachment_data/file/620494/_1060282-v11-SQP_Code_of_Practice.pdf

- POM-VPS medicines must be prescribed and supplied, and NFA-VPS supplied by an SQP
- An SQP who supplies a POM-VPS or NFA-VPS medicine must be present when it is handed over unless the SQP:
    - authorises each transaction individually before it is supplied, and
    - is satisfied that the person handing it over is competent to do so
- 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[3], COWS[4] and RUMA[5]
- Before an SQP can prescribe, administer or dispense any medicine for use in a horse, they must:
    - ask to be shown the passport for the horse if they do not have prior knowledge of its status. If they have seen the passport recently and are aware of the horse's current status, they do not have to see it before each treatment
    - satisfy themselves that the passport supplied relates to the horse in question
    - note whether the horse is declared as 'intended' for human consumption in the passport or there is no declaration or the horse is declared as 'not intended' for human consumption. If the declaration is not signed, they must consider the horse as being 'intended' for human consumption
    - satisfy themselves it is a valid passport. If the document does not contain the relevant Section covering this, it is not a valid horse passport
- 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 (as per Regulation 23 and Schedule 3 paragraph 5):
    - the date of receipt/supply
    - the name of the veterinary medicine
    - the pharmaceutical form and strength of the 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 product received or supplied
    - the company name and the permanent address or registered place of business of the supplier or recipient
    - the expiry date

[3] www.scops.org.uk
[4] www.cattleparasites.org.uk
[5] www.ruma.org.uk

- if there is a written prescription, the name and address of the person who wrote the prescription and a copy of it
- if the prescription is not a written prescription, the person who prescribes the product must make a record of the reason for prescribing the product

- 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 . If supplying to a contract dipper please refer to the SCOPS Code of Practice[6].
- 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 full name, address and contact details of the person prescribing the product, including that person's professional registration number, if available
  - the full name, address and contact details of the animal 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 issue date
  - the signature or electronic signature of the prescriber
  - the name and amount of the product prescribed
  - the pharmaceutical form and strength of the product
  - as regards veterinary medicinal products that are antibiotics which are prescribed for prophylactic purposes or metaphylactic purposes (as the case may be), a statement to that effect
  - the dosage regimen
  - any warnings necessary to ensure the proper use, including, where relevant, to ensure prudent use of antimicrobials
  - the words "It is an offence under the Veterinary Medicines Regulations 2013 for a person to alter a written prescription unless authorised to do so by the person who signed it"
  - for food-producing animal species, the withdrawal period or a statement that the withdrawal period is equal to zero days
  - if the prescription relates to a product 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))

[6] www.scops.org.uk/external-parasites/code-of-practice-for-mobile-dippers

- 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

- At least once a year, a retailer of prescription only veterinary medicines must carry out a detailed audit of stock and compare the incoming and outgoing medicines recorded with products currently held and make a record of this audit. (Schedule 3 Para 15 (1))
- Where, as a result of the audit mentioned in sub-paragraph (1), the retailer identifies a discrepancy the retailer must make a record of the fact. (Schedule 3 Para 15 (2))
- The retailer must keep the records mentioned in sub-paragraphs (1) and (2) for a period of five years from the date of the audit and the Secretary of State may require the retailer to provide a copy of it at any time within that period. (Schedule 3 Para 15 (3))
- 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 (medicinal premixes) and feedingstuffs:

- Medicinal premixes authorised for incorporation into feedingstuffs may only be supplied to authorised manufacturers. Refer to the register of authorised manufacturers[7] (Schedule 3 Para 11). The above does not apply in the case of medicinal premixes supplied only for domestic use, this is, 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 intermediate feedingstuffs. 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 medicinal premix must be in accordance with a MFS prescription (Schedule 5 Para 18 (4))
- Medicinal 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 diagnosed disease to be treated or prevented. In the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects

[7] www.vmd.defra.gov.uk/registers/approved-premises.aspx

- the date of the prescription
- the signature or other authentication of the person prescribing the product
- the name, the active substance, the amount of the product prescribed and the inclusion rate of the medicinal premix and resulting inclusion rate of the active substance
- the dosage and administration instructions
- any necessary warnings
- a statement that the prescription may not be re-used
- the withdrawal period
- the manufacturer or the distributor of the feedingstuffs (who must be authorised for the purpose), whichever is the supplier to the end user
- 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 overall amount of feedingstuff to be supplied under the prescription
- any special instructions
- the percentage of the prescribed feedingstuffs to be added to the daily ration; and
- if it is prescribed under the cascade, a statement to that effect

- A MFS prescription is valid for a maximum of 3 months (the prescriber may set a shorter validity on the prescription) and must only be for one course of treatment
- In the case of a prescription which relates to an antibiotic, the time between a prescription being issued and the course of treatment starting must be no more than five working days
- a prescription for a medicated feedingstuff containing a medicinal premix which includes an antibiotic may not be issued for prophylactic purposes
- An SQP may prescribe a feedingstuff containing a POM-VPS medicine but additional authorisation as a Distributor is required to supply medicated feedingstuffs. Further information can be found on manufacturing and supplying guidance[8] (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 medicines 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

[8] www.gov.uk/guidance/manufacturing-and-supplying-veterinary-medicines-for-animal-feed

considered to be advertising, provided that they meet the conditions in the advertising guidance[9] (Regulation 11(5)).

- No person may issue an advertisement relating to a relevant substance unless the advert:
    - is set out in such a way that it is clear that the message is an advertisement for the purpose of promoting the supply, sale, prescription, distribution or use of the substance
    - encourages responsible use of the substance while presenting its characteristics in an objective manner
    - contains no information which is misleading, is incompatible with the summary of product characteristics in relation to the substance, or might encourage improper use of the substance
    - where the relevant substance is a veterinary medicinal product, it must not suggest that the substance is a feedingstuff or a biocide
- Human medicines cannot be advertised for administration to animals (Regulation 10 (2)). This includes human general sales list medicines.

12. Other

Pharmacovigilance

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 online reporting form[10]

Product Information Database

All currently authorised veterinary medicines are listed on the VMD's Product Information Database[11].

Any medicines that have been recently changed will be highlighted in yellow.

[9] www.gov.uk/guidance/advertise-veterinary-medicines-legally
[10] www.gov.uk/report-veterinary-medicine-problem
[11] www.vmd.defra.gov.uk/productinformationdatabase