Veterinary Medicines Directorate

Suitably Qualified Persons (SQPs) Code of Practice

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Issued by the Secretary of State for the Department for Environment, Food and Rural Affairs under the Veterinary Medicines Regulations

This publication is available at: www.gov.uk/official-documents or https://www.gov.uk/guidance/appy-for-a-suitably-qualified-persons-sqp-retailer-premises.

Any enquiries regarding this publication should be sent to us at postmaster@vmd.gov.uk.

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SCOPE

1. This Code of Practice ('the Code') sets down the standards for:

   i. bodies that have been recognised by the Secretary of State as suitable to maintain a register of Suitably Qualified Persons – 'registration bodies'.

   ii. Suitably Qualified Persons (SQPs) who are registered with a registration body and who can prescribe and supply veterinary medicines classified as POM-VPS and NFA-VPS in accordance with the registration the SQP holds. This applies equally to all SQPs whether working in authorised SQP retailer premises, registered veterinary practice premises or registered retail pharmacies.

2. Any breach by an SQP of the standards in this Code of Practice that is drawn to the attention of a registration body, including breaches of the Veterinary Medicines Regulations 2013 (VMR), shall be dealt with by that body in line with the disciplinary process referred to in paragraph 16. The Secretary of State may also take action under the VMR.

3. Guidance for premises that are authorised by the Secretary of State to hold and supply veterinary medicines by SQPs is published on GOV.UK under Veterinary Medicines Guidance. The inspection criteria for retail premises which the VMD inspects are available from our Inspections Administration Team (inspections@vmd.gov.uk). The criteria are available on the VMD website here and VMD inspectors will base their inspections on this criteria.

LEGISLATION

4. The VMR are periodically reviewed and amended and/or supplemented. This ensures the provisions remain current and fit for purpose. The Code will be updated if future versions of the VMR make changes to the requirements relating to SQPs or SQP registration bodies. Please advise the VMD if you believe there are any errors in the Code.

5. Schedule 3 Paragraph 14 of the VMR states:

   (1) The Secretary of State may recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

   (2) In order to recognise such a body, the Secretary of State must be satisfied that the body:

   (a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations
   (b) has adequate standards in deciding whether or not to register someone as a suitably qualified person
   (c) maintains a programme of continuing professional development for persons registered with it

(d) operates an adequate appeal system if it intends to refuse to register anyone with the appropriate qualifications or to remove anyone from the register

(7) The Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph must take appropriate action in accordance with any disciplinary code that applies to that body if a suitably qualified person registered with it does not comply with the Code of Practice.

Offences relating to supply by an SQP

6. It is an offence under the VMR and a breach of this Code (see paragraph 2) for an SQP to:

- supply a POM-VPS or NFA-VPS medicine (as described below) unless the SQP supplies the product in accordance with the VMR
- supply a veterinary medicine that has passed its expiry date
- supply a medicine that has not been stored (including during transport) 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
- import an authorised veterinary medicine that the SQP is not permitted to supply in the UK
- fail to keep records on the receipt or supply of POM-VPS medicines
- possess an unauthorised veterinary medicine supply an unauthorised veterinary medicine
- supply a veterinary medicine unless it is in its original packaging or immediate packaging; if the product is not supplied in its original packaging, sufficient written information – which may include a copy of the summary of product characteristics or the package leaflet – must be provided to enable the product to be used safely
- add or change the authorised label or any of the information provided on the product literature (including covering any safety information) unless the amendment is in line with the prescription from a vet against which the supply is being made (see also paragraph 31)
- supply a POM-VPS or an NFA-VPS product for administration under the cascade unless it is supplied against a written prescription by a vet for that purpose
- substitute a different product for a medicine that has been prescribed by another SQP, a vet or a pharmacist.

SQPs should read this Code in conjunction with the VMR (see: The Veterinary Medicines Regulations 2013 (legislation.gov.uk)) where a full list of offences can be found.

7. Penalties under the VMR apply to an SQP, as well as a corporate body or partnership, if the offence is proved to have been due to any consent, connivance, or neglect on their part (Regulation 44(2) of the VMR).

REGISTRATION BODIES

8. Registration bodies that have been recognised by the Secretary of State to provide training and registration for SQPs are published on GOV.UK.

9. The VMD requires a body that wishes to become recognised by the Secretary of State to submit an application that includes:

- full details of how it intends to carry out its functions
- details of the premises and staff
- information on its establishment within the UK
- how it intends to maintain operations over a period of at least 5 years.

10. Qualifications arranged by the body must be accredited as a training programme at higher education level (level 4 or above). However, qualifications may be accepted at level 3 if the SQP qualification is integrated within a broader veterinary nursing qualification. This should be consistent with the framework set out by England's statutory regulator for qualifications (Ofqual), the UK's Quality Assurance Agency for Higher Education (QAA) or the Scottish Credit and Qualifications Framework (SCQF) framework.

11. Each registration body is expected to provide their own syllabus. The syllabus must include:

- basic knowledge of anatomy, physiology and nutrition
- knowledge of the legislation relevant to SQPs
- information on products sufficient to enable an SQP to prescribe and retail supply the most appropriate veterinary medicine for the target species, the disease or condition and advise on its safe use, storage, handling, waste disposal, and despatch/distribution in accordance with Schedule 3 Paragraph 14(5) of the VMR
- how to obtain knowledge of the type of environment that the animal is kept in, for example farm, stables, kennels, small holding or private residence, in order to give appropriate advice
- how to interpret Animal Health Plans
- disease control/parasite control strategies (including husbandry methods which minimise disease and medicines interactions)
- information on who can prescribe and retail supply each class of veterinary medicine and how to report adverse events to the VMD and marketing authorisation holders (MAHs)
- strategies to optimise the use of medicines and to minimise the development of resistance, for example anthelmintic resistance
- recognition of the limits of an SQP's knowledge and competence and when to refer a customer to a vet
- the requirements for authorised premises
- the requirements for supplying against a written prescription.

12. A modular approach to the separate areas of expertise should be followed with at least the following modules:

    - Farm animals
    - Avian – poultry and other birds
    - Equines
    - Companion animals, including dogs, cats and rabbits.

13. The body must be prepared to arrange further modules to meet the needs of specific sectors if requested by the VMD.

14. The body must implement and maintain a system of mandatory Continuing Professional Development (CPD) for all SQPs registered with it.

15. The body must provide a monthly update to the VMD on the SQPs registered through their training. This update must include:

    - the name of the person
    - the modules that they have completed successfully
    - a geographical reference such as the town in which they live.

    The VMD publishes a list of SQPs on GOV.UK and updates it monthly.

16. The body must have a published disciplinary process. This must be used by the body if it intends to refuse entry to the register to anyone who is qualified. This process should include disciplinary action for the removal of anyone from the register if they have breached the Code. The process must include an independent appeal process.

17. A body applying for registration should submit a forecast of income and expenditure for a period of at least 5 years. Registration bodies must provide details to the VMD of their charges and expected income and spending at the beginning of each financial year.

18. Registration bodies will allocate numbers to SQPs so the categories they are able to prescribe and retail supply for can be identified.

REGISTERED QUALIFIED PERSONS

19. There are 3 different types of Registered Qualified Person (RQP):

    - a veterinary surgeon who is registered with the Royal College of Veterinary Surgeons (RCVS)
    - a pharmacist who is registered with the General Pharmaceutical Council (GPhC) or the Pharmaceutical Society of Northern Ireland
    - an SQP who is registered with one of the bodies recognised by the Secretary of State.

20. Schedule 3 Paragraph 14 of the VMR states:

(3) For the purposes of these Regulations, a suitably qualified person is a person who has passed examinations specified by such a body and is registered with such a body as a suitably qualified person.

DISTRIBUTION CATEGORIES

21. Schedule 3 of the VMR deals with classification and supply of veterinary medicines. Each authorised veterinary medicine is granted a distribution category when it is authorised. Changes to these categories may be made, for example, for reasons of safety or availability. All currently authorised veterinary medicines are listed on the VMD's Product Information Database which SQPs should be familiar with and know how to use. Any medicines that have been recently changed will be highlighted in yellow.

22. The distribution categories under the VMR are:

Prescription Only Medicine - Veterinarian (abbreviated to POM-V)
Prescribed by a vet and supplied by either a vet or a pharmacist.

Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS)
Prescribed by any one of the RQPs and supplied by any one of them.

Non-Food Animal - Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS)
Supplied by any one of the RQPs.

Authorised Veterinary Medicine - General Sales List (abbreviated to AVM-GSL)
Supplied by any retailer.

There are no legal restrictions on the retail supply of veterinary medicines classified as AVM-GSL.

SQPs' DUTIES AND RESPONSIBILITIES

23. All SQPs must follow this Code of Practice.

24. Prospective SQP students should ask a registration body for information on the syllabus and courses available before registering to ensure it meets their training and qualification needs.

25. An SQP may only retail supply products that have been authorised with a distribution category of POM-VPS, NFA-VPS or AVM-GSL.

26. An SQP may only prescribe and/or retail supply the products that fall within the scope of the registration they hold.

Registrations are separated as follows or may be combined:

- all animals (including food and non-food producing)
- farm animals (livestock)
- avian – poultry and other birds
- companion animals including dogs, cats and rabbits
- equines.

27. Other types of registration categories may be provided as described under paragraph 13. An SQP may opt to be registered for a single category if that is allowed by their registration body.

28. It is the duty of an SQP to comply with their professional responsibilities and ensure that the legal requirements for prescribing and retail supply of veterinary medicines classified POM-VPS and NFA-VPS are complied with, however the product is supplied, for example in-store, postal or online supply.

29. SQPs should assure themselves that the medicines they are supplying have been appropriately obtained and stored; and where applicable, unsaleable products are appropriately disposed of. SQPs have a duty to report any issues of non-compliance with the VMR at authorised premises to the VMD. For example if the SQP is aware that sales of VPS medicines are being made without appropriate RQP oversight. Report any information you have about suspected illegal medicines and breaches of the VMR to enforcement@vmd.gov.uk or by using the reporting tool which can be found here.

30. All SQPs must undertake CPD to meet the requirements and standards set by their registration bodies to ensure they keep up to date. For example, SQPs can:

    - undertake additional learning
    - read relevant publications, such as books or trade journals
    - gain practical experience by taking on a relevant new role
    - work shadow a colleague who works in a different area of the business.

    To continue to be registered an SQP must satisfy their registration body that they have fulfilled their CPD requirements.

31. An SQP may retail supply an authorised veterinary medicine that falls within the scope of the registration they hold, against a written prescription from a vet for use under the prescribing cascade (Schedule 3 Paragraph 14 of the VMR). Where a product is supplied under the cascade, it must be labelled in accordance with the requirements specified in the VMR. Further information on the cascade and the labelling requirements is available on GOV.UK under Veterinary Medicines Guidance.

REQUIREMENTS FOR PRESCRIBING AND SUPPLY

Prescribing

32. To retail supply a POM-VPS medicine, an SQP first has to prescribe it, unless they are supplying against a written prescription from another RQP. Prescribing covers both the decision-making process on which veterinary medicine to supply and the decision itself. When prescribing, SQPs must take into account:

- the disease/condition of the animals requiring treatment
- the type of holding and the animals being treated
- the authorised veterinary medicines on the market, and their warnings and contra-indications
- the responsible use of medicines (further information on this can be found in paragraphs 39-41)
- the requirement to prescribe the minimum amount of medicine needed for the treatment and condition presented (subject to the minimum pack size manufactured and whether the packs can be split without contravening the VMR; further information on this can be found in paragraph 46)
- the requirement for the person receiving the product to use it for an authorised use
- the abilities and competence of the person administering the product
- any available farm or animal health plan.

Where a medicine is supplied in accordance with a prescription which is not a written prescription, the person who prescribes the product must make a record of the reason for prescribing that product; their prescribing rationale.

33. An SQP should provide a written prescription on request. Each written prescription must contain the following information:

- 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
- 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.

Supply

34. When prescribing and supplying a POM-VPS medicine or supplying an NFA-VPS medicine, the SQP must always (unless they are supplying against a written prescription from another RQP):

    - be satisfied that the person who will use the product is competent to do so safely, and intends to use it for the purpose for which it is authorised
    - advise on any warnings or contra-indications on the label or package leaflet
    - provide advice on the safe administration of the product.

35. A veterinary medicine that has been correctly prescribed and supplied by an SQP from an authorised retail premises (or registered veterinary practice premises/ pharmacy) may be delivered to the customer or handed over to the customer from a vehicle, provided it is accompanied by a dated, itemised delivery note and a duplicate copy of that note is readily available at the premises from which it was supplied. The itemised delivery note/invoice should clearly show the following information:

    - The date the product was prescribed
    - Date of delivery
    - Name and address of supplier
    - Name and address of recipient
    - Quantity
    - Name of product
    - Batch number
    - Expiry Date
    - Identity of prescribing SQP and
    - Identity of SQP/designated person responsible for selecting and packing the product (if not done by the prescribing SQP).

36. Where medicines requiring specific storage conditions (such as having to be stored at specified temperatures) are packed for delivery, there must be evidence to demonstrate that the correct storage conditions have been maintained during transport.

37. Training records for the designated person responsible for selecting and packing the product should be available at the premises. Evidence that the SQP has checked the delivery before despatch should also be retained.

38. The following sets out the VMD's expectation of what information is likely to be necessary to be assessed by the SQP prior to supplying a POM-VPS or NFA-VPS

medicine, in addition to that listed in paragraphs 32-34. This information does not necessarily need to be recorded. The information that must be kept when a veterinary medicine is supplied is detailed in paragraph 47.

For pets/companion animals the following should be assessed in respect of each animal:

- species
- total number of animal(s)
- weight (of each animal if more than one)
- age of animal(s)
- whether the animal is in general good health
- whether the animal is pregnant or lactating
- whether the animal is on any other medication
- whether the customer knows how to use the product safely/effectively
- whether the customer knows what the product is supposed to do
- whether the customer has been provided with the warnings on the SPC.

For food producing animals, as above and also:

- what is the animal's intended food use (milk/meat/eggs etc)
- does the customer know the applicable withdrawal period.

39. For anthelmintic products for sheep and cattle, SQPs should follow the recommendations of:

- the Sustainable Control of Parasites in Sheep (SCOPS) - www.scops.org.uk
- the Control of Worms Sustainably (COWS) - www.cattleparasites.org.uk/

40. For sheep dips, the SQP must be satisfied that the product is supplied only to a person (or a person acting on his behalf) who holds a Certificate of Competence in the Safe Use of Sheep Dips. Sheep dip supply must be in accordance with Schedule 3 paragraph 22 of the VMR. For organophosphorus (OP) dips this includes the supply of protective gloves and the laminated notice specified in Schedule 3 paragraph 23 of the VMR.

It is good practice for the SQP to recommend that the purchaser reads the leaflet Sheep Dipping (AIS41) which is available on the Health and Safety Executive website (www.hse.gov.uk/pubns/ais41.htm). This describes safe working practice and safe disposal. SQPs should also be aware of SCOPS' Code of Practice for Mobile Sheep Dipping, which can be found here.

41. For horses and other equidae, the SQP must check whether the animal has been declared as non-food producing in their horse passport. If the owner or keeper of a horse does not have the passport for the horse to hand at the time of treatment, or the SQP has not seen the passport, the SQP must presume the horse is intended for

human consumption. SQPs should also be aware of the latest guidance from the Controlling Antiparasitic Resistance in Equines Responsibly (CANTER) group.

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.

42. The requirements on the SQP cannot be delegated and cannot be transferred to the customer. 'Disclaimers' that, for example, simply inform a customer that they must answer yes or no to a list of questions will not be considered to meet this requirement.

Delegating supply to a non-SQP in the same premises

43. An SQP may delegate to a colleague the handing over or despatch of the product, provided the SQP:

- authorises each transaction individually before the product is supplied, and
- is satisfied that the person handing over or despatching the product is competent to do so correctly (see also paragraph 37).

Prescribing and supplying by different RQPs in separate premises

44. When supplying a product against a written prescription from another RQP an SQP must:

- only supply the product specified in that prescription
- ensure that the prescription has been written by an RQP allowed to prescribe the product
- check the prescription is valid and suitable for the condition; if in any doubt, the SQP should contact the prescriber before supplying the product
- ensure that it is supplied to the person named in the prescription.

45. An SQP may not substitute a different medicine to the one on the prescription or amend a prescription written by another RQP. If the SQP cannot supply the prescribed product or disagrees with the prescription, they should refuse supply and return the prescription to the purchaser. The SQP could prescribe a different product that falls within the scope of the registration they hold, ensuring they follow the requirements for prescription and supply.

46. SQPs are allowed to break open any package (other than immediate) of a medicine they are authorised to supply. The immediate packaging of a veterinary medicine is the packaging directly in contact with the medicinal substance itself. For example, an SQP may not supply a small number of unwrapped tablets from a single tub or bottle and keep the rest of the tablets to supply later.

However, they may supply one or more individual boluses/pipettes/blister strips from a carton provided the boluses/pipettes/blister strips are individually wrapped, within

an outer carton. In this situation, SQPs must be satisfied that the person will use the medicine in accordance with its authorisation and/or prescription. They must also provide sufficient written information to enable the product to be used safely and, as per paragraph 34, advise on any warnings or contra-indications on the label or package leaflet and provide advice on the safe administration of the product.

It is acceptable for an SQP to give a copy of the package leaflet or SPC to the customer, provided that it has all the required information.

RECORD KEEPING

47. An SQP supplying POM-VPS products must ensure the following information is recorded in relation to all incoming and outgoing (which include medicines sold, returned to a supplier, destroyed or otherwise disposed of) POM-VPS transactions:

- the date of the transaction under which the product was received or supplied
- the name of the product
- the pharmaceutical form and strength of the product
- the batch number (if the product is for a non-food producing animal then the batch number can be recorded on the date it is first received or on the date product from that batch is first supplied)
- the quantity of product received or supplied
- the company name and the permanent address or registered place of business of:
  - in respect of a purchase, the supplier
  - in respect of a sale, the recipient
- if there is a written prescription, the name and contact details of the prescriber
- the expiry date
- In the case of a medicine which has been prescribed but not against a written prescription, the reason for prescribing that medicine.

48. These records must be kept for five years at the authorised premises. The records may be kept electronically and must be made available for inspection by a duly authorised person on request. Further information on record keeping is available on GOV.UK under Veterinary Medicines Guidance.

50. The VMR apply to the retail supply of veterinary medicines on the internet in the same way as they do to ‘over the counter’ sales. Further information on retail supply and internet sales is available on GOV.UK under Veterinary Medicines Guidance.

OTHER REQUIREMENTS

Adverse event reporting

51. SQPs must understand how to report adverse events to the VMD or MAH. They must also be able to provide their customers with advice on such reporting if

requested. More information on adverse events is available on GOV.UK under Veterinary Medicines Guidance.

Wholesale supply

52. Any business that routinely supplies veterinary medicines to another business must hold a Wholesale Dealer's Authorisation (WDA). Further information on WDAs is available on GOV.UK under Veterinary Medicines Guidance. However, in an emergency, an authorised retailer may supply veterinary medicines they hold to another authorised retailer in order to relieve a temporary supply shortage that could be detrimental to animal welfare. This is intended to prevent animal welfare problems associated with availability of medicines and must not be a regular commercial activity.