

Suitably Qualified Persons (SQPs) Code of Practice

April 2017

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

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

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SCOPE

- 1. This Code of Practice sets down the standards for:
 - i. bodies that have been recognised to be suitable for registration of Suitably Qualified Persons (SQPs);
 - ii. SQPs who are registered with a recognised body and who can supply veterinary medicines classified as POM-VPS and NFA-VPS in accordance with the registration they hold. This applies equally to all SQPs whether working in SQP retailers, vet practices or pharmacies.
- 2. Any breach of the standards in this Code of Practice by an SQP that is drawn to the attention of a registration body, including breaches of the Veterinary Medicines Regulations (VMR), shall be dealt with by that body in line with the disciplinary process referred to in paragraph 14. The Secretary of State may also take action under the VMR.
- 3. Guidance for premises that are approved 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 the VMD inspects are available from our Inspections Administration Team inspections@vmd.gov.uk. The criteria will be sent to a retailer's premises if notified of an inspection and VMD inspectors will base their inspections on this document.

LEGISLATION

- 4. The VMR are periodically withdrawn and re-written. This ensures the provisions remain current and fit for purpose. This Code will be updated if future versions of the VMR make changes to the requirements relating to SQPs. Please advise the VMD if you believe there are any errors in the Code.
- 5. Schedule 3 Paragraph 14 of the VMR states:
 - 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 (paragraph 2) to:
 - possess an unauthorised veterinary medicine except under certain conditions or for the purposes of research and development (Regulation 26)
 - supply an unauthorised veterinary medicine except under certain conditions (*Regulation 27*)
 - supply a veterinary medicine that has passed its expiry date (Regulation 7(2))
 - supply a product unless it is in its original packaging or immediate packaging; if the product is not supplied in its original packaging, sufficient written information must be provided to enable the product to be used safely:
 - an SQP may not add or change the authorised label or any of the information provided on the product literature, unless the supply is being made under a prescription from a vet
 - a vet is able to use the prescribing cascade and may therefore prescribe a product for use outside the terms of the marketing authorisation
 - substitute a different product for a medicine that has been prescribed by another SQP, a vet or a pharmacist
- 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)*).

REGISTRATION BODIES

- 8. 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 10 years
- 9. Qualifications arranged by the body must be accredited, or shown to be working to become accredited, as a training programme at higher education level (level 4 or above). 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 <u>national regulator of awarding organisations</u>, the <u>Quality Assurance Agency for Higher Education</u> (covering England, Wales and Northern Ireland) or the <u>Scottish Credit and Qualifications Framework</u> (SCQF) frameworks.

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 retail supply the most appropriate veterinary medicine for a disease or condition <u>and</u> advise on its safe use, storage, handling waste disposal, and despatch/distribution (postal regulations)
- how to obtain knowledge of a farm 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 retail supply each class of veterinary medicine and how to report adverse events to the VMD and Marketing Authorisation Holders
- strategies to optimise the use of medicines and to minimise the development of resistance, e.g. 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 approved premises
- the requirements for supplying against a written prescription
- 10. 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 and cats
- 11. The body must be prepared to arrange further modules to meet the needs of specific sectors if requested by the VMD.
- 12. The body must implement a system of mandatory Continuing Professional Development (CPD) for all SQPs.
- 13. 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.

14. 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.

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

REGISTERED QUALIFIED PERSONS

- 16. There are 3 different types of Registered Qualified Person (RQP):
 - a vet 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 approved by the Secretary of State
- 17. It is an offence for anyone to retail supply a POM-VPS or NFA-VPS medicine (as described below) unless that person is an RQP and supplies the product in accordance with the VMR.

SUITABLY QUALIFIED PERSONS

Schedule 3 Paragraph 14(3) states:

- 18. 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.
- 19. Each recognised body is expected to provide their own syllabus. Students should ask an approved body for information before registering for training. All SQPs must follow this Code of Practice.
- 20. The bodies that have been recognised by the Secretary of State to provide training and registration for SQPs are published on GOV.UK.

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. 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.

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

SOPS' DUTIES AND RESPONSIBILITIES

24. 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
- equines
- companion animals
- avian poultry and other birds
- 25. Other types of registration categories may be provided as described under paragraph 11. An SQP may opt to be registered for a single category if that is allowed by their registration body.
- 26. Registration bodies will allocate numbers to SQPs so the categories they are able to prescribe and retail supply for can be identified.
- 27. It is the duty of an SQP to ensure that the legal requirements for prescription and retail supply of POM-VPS and NFA-VPS are complied with, however the product is supplied, for example, supply in a store or postal supply.
- 28. CPD must be undertaken by all SQPs 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.

29. An SQP may retail supply an authorised veterinary medicine that falls within the scope of the registration they hold, against a prescription from a vet for use under the prescribing cascade. 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.

PRESCRIPTION

- 30. 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 is the decision made by the SQP on which veterinary medicine to supply. 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 35 and 36)
 - 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)
 - 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
- 31. An SQP should provide a written prescription on request. Each written prescription must contain the following information:
 - the name, address and telephone number of the person prescribing the product
 - the qualifications/registration 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
 - for food producing species, the withdrawal period, even if nil

REQUIREMENTS FOR PRESCRIPTION AND SUPPLY

Prescribing and supply

- 32. 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 administer the product is competent to use it safely
 - advise on any warnings or contra-indications on the label or package leaflet
 - provide advice on the safe administration of the product
- 33. 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 paragraph 30 and 32. 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 42.

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
- 34. 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 the legal requirements. For organophosphorus (OP) dips this includes the supply of protective gloves and the laminated notice specified in 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.

- 35. For horses and other equidae, the SQP must 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.
- 36. 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/
- 37. 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

- 38. An SQP may delegate the handing over or despatch of the product to a colleague provided they:
 - have prescribed or supplied the medicine
 - have checked that the medicine has been correctly picked from stock
 - have set aside the medicine for the specific customer
 - are satisfied that the person handing over or despatching the product is competent to do so correctly

Prescribing and supplying by different RQPs in separate premises

- 39. 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 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
- 40. An SQP should 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.

41. An SQP may not break open the immediate packaging of a veterinary medicine. For example an SQP may not supply a small number of tablets from a single tub or bottle and keep the rest of the tablets to supply later. An SQP is allowed to supply a lesser number of boluses from a carton which are individually wrapped and where there are enough package leaflets for each separate bolus. It is also 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

- 42. An SQP supplying POM–VPS products must ensure the following information is recorded in relation to all incoming and outgoing POM-VPS transactions.
 - the date
 - the name of the product
 - the batch number
 - the quantity
 - the name and address of the supplier or recipient
 - in the case of a written prescription, the name and address of the person who wrote the prescription
- 43. Outgoing transactions include medicines sold, returned to a supplier, destroyed or otherwise disposed of. These records must be kept for five years at the approved premises. The records may be kept electronically and must be available on request. Further information on record keeping is available on GOV.UK under Veterinary Medicines Guidance.
- 44. It is not necessary to keep individual batch records providing that it is possible, using all the records together, to carry out a full batch recall.

OTHER REQUIREMENTS

45. SQPs must understand how to report adverse events. They must also be able to provide their customers with advice on pharmacovigilance reporting if requested. More information on adverse events is available on GOV.UK under Veterinary Medicines Guidance.

SQP nomination

46. An individual SQP should be nominated to be responsible for professional standards within a registered premises. The nominated SQP should take overall responsibility for how veterinary medicines are obtained, stored, supplied and disposed of. They should also ensure that colleagues recognise the professional responsibilities of SQPs. A business with multiple registered premises may nominate a single SQP to be the responsible person for multiple premises within the business.

Wholesale supply

47. 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.