

CODE OF PRACTICE

**For Suitably Qualified
Persons (SQPs) and
Guidance for the
Registration
of Retail Premises**

**Issued by the Secretary of State under
the Veterinary Medicines Regulations**

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DEFRA CODE OF PRACTICE FOR SUITABLY QUALIFIED PERSONS (SQPs) AND GUIDANCE FOR THE REGISTRATION OF RETAIL PREMISES

SCOPE

1. This Code of Practice sets down the standards that must be complied with by:-
 - i. bodies that have been approved to be suitable to provide training and registration for Suitably Qualified Persons (SQPs) by the Secretary of State;
 - ii. SQPs who are registered with an approved body having passed the required examinations and who may therefore supply veterinary medicinal products classified as POM-VPS and NFA-VPS.
2. It also provides guidance for retail businesses with premises that are approved by the Secretary of State to be able to hold and supply certain veterinary medicinal products through SQPs and sets down guidance on the ways in which approval can be obtained.

LEGISLATION

3. The Veterinary Medicines Regulations 2005 replaced the Medicines Act 1968 in relation to veterinary medicines and govern such products in the United Kingdom. The Regulations are revoked and re-made annually with the new Regulations coming into force on 1 October each year. This ensures the provisions remain current and fit for purpose. This Code will only be updated if future versions of the Regulations make changes to the rules governing this area. Please advise VMD (Tel: 01932 336911) if you believe there are any errors or omissions in the Code.
4. Veterinary Medicines Regulations Schedule 3 Paragraph 14 states:
 1. *The Secretary of State shall 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.*

Provisions relating to offences in respect of supply by an SQP

5. It is an offence under the Regulations to:
 - possess an unauthorised veterinary medicinal product except in accordance with the Regulations or for the purposes of research and development (*Regulation 26.1*)
 - supply an unauthorised veterinary medicinal product (*Regulation 27*);
 - supply a veterinary medicinal product 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 veterinary surgeon. It should be noted that a veterinary surgeon is able to use the prescribing cascade and may therefore prescribe a product for use outside the terms of the marketing authorisation. However, the ability to do this rests solely with a veterinary surgeon and may not be exercised by any other person;
 - substitute a different product for a medicine that has been prescribed by another Registered Qualified Person (RQP).
6. Penalties under the Regulations apply to a qualified person appointed for the purposes of the Regulations, as well as a corporate body, if the offence is proved to have been attributable to any consent, connivance or neglect on their part (*Regulation 42.2*).

REGISTRATION BODIES

7. The VMD requires a body that wishes to become recognised by the Secretary of State to submit an application including full details of the way in which it intends to carry out its functions and details of the premises and staff. It should include information on its establishment within the UK and how it intends to maintain operations over a period of at least 10 years.
8. The courses of study arranged by the approved body must be accredited, or shown to be working to become accredited, as a coherent training programme at the higher education level, consistent with the Quality Assurance Agency for Higher Education (covering England, Wales and Northern Ireland) and the corresponding Scottish Credit and Qualifications Framework (SCQF) frameworks. The syllabus must include:-
 - basic knowledge of anatomy, physiology and nutrition
 - knowledge of the legislation, in particular the distribution category and the SQP section of this Code of Practice
 - information on products sufficient to sell appropriate medicine and advise on use, storage, handling waste disposal, despatch/distribution (postal regulations)
 - how to obtain knowledge of a farm to enable appropriate advice to be given
 - how to interpret Animal Health Plans

- disease control / parasite control strategies (including husbandry methods which minimise disease and medicines interactions)
 - what each RQP type can sell and when to refer a customer to a veterinary surgeon
 - how to submit information to the VMD Suspected Adverse Reaction Surveillance Scheme
 - the requirements for registered premises
 - strategies to optimise the use of medicines
 - recognition of the limits of an SQP's knowledge and competence and the implications of actions
 - mandatory Continuing Professional Development (CPD) (this should be at least one additional option to be available to SQPs at least once each year).
9. A modular approach to the separate areas of expertise should be followed with at least the following modules:-
- Food producing animals
 - Equines
 - Companion animals, including dogs and cats.

On request any approved body must be prepared to arrange further modules to meet specific requirements for additional modules.

10. 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 and a geographical reference such as the town in which they live. The VMD will publish a consolidated list of SQPs on their website and update it once a month.
11. The body must have an independent appeals process, which can be invoked by any person who has been refused entry onto the register having successfully passed the relevant examinations or any person who has been removed from the register. Details of the appeals process must be published.
12. A body applying for approval should submit forecast income and expenditure for at least 5 years. An approved body must provide details to the VMD of their charges and anticipated income and expenditure at the beginning of each financial year.

REGISTERED QUALIFIED PERSONS ---

13. There are 3 different types of Registered Qualified Person (RQP):-
- i. a veterinary surgeon who is registered with the Royal College of Veterinary Surgeons
 - ii. a pharmacist who is registered with the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland
 - iii. an SQP who is registered with one of the bodies approved by the Secretary of State as detailed above.
14. It is an offence for any person to supply a veterinary medicinal product by retail within the distribution categories POM-VPS or NFA-VPS (as described below)

unless that person is an RQP and supplies the product in accordance with the Regulations.

Distribution Categories

15. Schedule 3 of the Regulations deals with classification and supply and wholesale dealers. Each authorised veterinary medicinal product is granted a specific distribution category when it is first authorised. Changes to these categories may be made from time to time either for reasons of safety or following a case being made to the VMD.

16. The distribution categories under the Veterinary Medicines Regulations are:-

Prescription Only Medicine - Veterinarian (abbreviated to POM-V)

Prescribed by a veterinary surgeon and supplied by either a veterinary surgeon or a pharmacist. (*previously POM, MFS and some P products*)

Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS)

Prescribed by any one of the Registered Qualified Persons and supplied by any one of them. (*previously PML, MFSX and some P products*)

Non-Food Animal - Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS)

Supplied by any one of the Registered Qualified Persons. (*previously PML and some P products*)

Authorised Veterinary Medicine - General Sales List (abbreviated to AVM-GSL).

Supplied by any retailer. (*previously GSL products*)

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

SUITABLY QUALIFIED PERSONS

18. Veterinary Medicines Regulations Schedule 3 Paragraph 14(3) states:

To become a suitably qualified person it is necessary to pass examinations specified by such a body [a body approved by the Secretary of State as set down above], and to be registered with such a body.

19. The principles that must be met in respect of training and qualifications in order to be registered as an SQP are set down above. Each approved body is expected to provide their own syllabus and training regime so students should consult an approved body to obtain additional information before registering for training. All SQPs must follow this Code of Practice.

20. The bodies that have been approved by the Secretary of State as suitable to provide training and registration for SQPs are published on the VMD website. Initially, the Animal Medicines Training Regulatory Authority (AMTRA) has been approved and will continue to work in this area.

DUTIES AND RESPONSIBILITIES

21. **An SQP may only prescribe and/or supply the products that fall within the scope of the qualification they have obtained and the registration they hold.** Registrations are separated as follows:-

- all animals (including food and non food producing)
- food producing animals
- equines
- companion animals including dogs and cats

Other types of training may be provided as described under paragraph 9. An SQP may opt to be registered for a single species if that is acceptable to their registration body.

22. A body may provide training and register SQPs for one or more of the above. Registration bodies will allocate numbers to SQPs registered with them so that the types of animals they are able to prescribe and supply for can easily be identified.
23. It is the duty of an SQP to ensure that the statutory requirements in respect of the prescription and supply of POM - VPS and NFA - VPS are respected. The SQP is responsible for ensuring this irrespective of how the product is supplied, e.g. supply in a merchant's store, postal supply etc. However, in every case the sole responsibility rests with the SQP concerned who must ensure that their duties are fully carried out.
24. Continuing Professional Development (CPD) must be undertaken by all SQPs to ensure they keep up to date. This may be accomplished in a number of different ways e.g. by undertaking additional learning, reading relevant publications which may include books or trade journals, gaining practical experience by taking on a relevant new role or working in a different environment such as with a colleague who works in a different area etc and details of what is acceptable will be provided by the registration body. In order to continue to be registered an SQP must satisfy their registration body annually that they have fulfilled their CPD requirements.
25. An SQP may supply an authorised veterinary medicinal product, which falls within the scope of the qualification they hold, for use "off-label" against a prescription from a veterinary surgeon for use under the cascade. Where a product is supplied under the cascade it must be labelled in accordance with Schedule 3 Para 13. Veterinary Medicines Guidance (VMG) Note 15 provides information regarding the cascade and also includes the labelling requirements. It is available on the VMD website (www.vmd.gov.uk).

PRESCRIPTION

26. In order to supply a product authorised as POM - VPS, an SQP first has to prescribe the product. The act of prescribing is taken to be the decision made by the SQP as to which product should be supplied taking account of:-
- the circumstances of the holding and the animals being treated

- the available authorised veterinary medicinal products
- the need for responsible use of medicines and the requirement to prescribe the minimum amount of product necessary for the treatment (subject to the minimum pack size manufactured and any authority to break bulk in the Regulations)
- the requirement for the person receiving the product to use it for an authorised use according to the marketing authorisation
- the abilities and competence of the person who will administer the product
- any available animal health plan.

27. An SQP should be prepared to provide a written prescription on request. Each written prescription must contain the following information:

- (a) the name and address and telephone number of the person prescribing the product;
- (b) the qualifications enabling the person to prescribe the product;
- (c) the name and address of the owner or keeper;
- (d) the identification (including the species) of the animal, or group of animals to be treated;
- (e) the premises at which the animals are kept if this is different from the address of the owner or keeper;
- (f) the date of the prescription;
- (g) the signature or other authentication of the person prescribing the product;
- (h) the name and amount of the product prescribed;
- (i) the dosage and administration instructions;
- (j) any necessary warnings;
- (k) the withdrawal period if relevant.

REQUIREMENTS FOR PRESCRIPTION AND SUPPLY ---

PRESCRIBING AND SUPPLYING BY A SINGLE SQP ---

28. When prescribing and supplying a product within the POM-VPS category or supplying a product within the NFA-VPS category, the SQP must always:-

- be satisfied that the person who will use 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;
- be satisfied that the person using the product intends to use it for an authorised use;
- in the case of a sheep dip product, 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 issued in England, Wales and Northern Ireland by the National Proficiency Tests Council or the NPTC part of the City and Guilds Group or in Scotland by one of these organisations or the Scottish Skills Testing Service. The supply of sheep dip must be made in accordance with the legislative requirements, including, for OP dips, the supply of protective gloves and the laminated notice contained in the Regulations.

29. When supplying Sheep Dip products it is considered to be good practice for the SQP to recommend that the purchaser refer to the leaflet Sheep Dipping

(AS29.rev3) which is available on the Health and Safety Executive website (www.hse.gov). This describes safe working practice and safe disposal.

PRESCRIBING AND SUPPLYING BY DIFFERENT SQPs IN THE SAME PREMISES —

30. When supplying a product that another SQP, within the same registered premises, has prescribed for POM-VPS products or carried out the SQP duties of supply for NFA-VPS products, the SQP who hands over the product must check that the product which has been taken from store is the one that has been prescribed or supplied and that the person to whom the product is handed over or despatched has been given the necessary advice by their other SQP colleague.

DELEGATING SUPPLY TO A NON-SQP IN THE SAME PREMISES —

31. Should an SQP have prescribed a POM-VPS product or carried out the duties in respect of the supply of an NFA-VPS product, and then checked that the product has been correctly picked from stock and set aside for the specific customer, he may delegate the actual handing over or despatch of the product to a colleague who is not an SQP. However, in such a case the SQP must be 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—

32. When supplying a product against a written prescription from another RQP an SQP must:-
 - check from their own knowledge that the prescription is suitable. If there appears to be a problem the SQP should contact the prescriber before supplying the product;
 - take all reasonable steps to ensure that the prescription has been written by a person who is entitled to prescribe the product;
 - ensure that it is supplied to the person named in the prescription.

It is not open to an SQP to substitute a different product instead of the one that has been prescribed or to amend a prescription written by someone else. If the SQP is either unable to supply the prescribed product or disagrees with the prescription, he should refuse to supply the product and suggest that the purchaser may wish to discuss the problem further with the person who prescribed it.

33. An SQP may not break up a bulk package of product in order to supply a lesser amount. This prohibition relates to breaking the immediate packaging; 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. However, it is permissible for an SQP to supply a lesser number of boluses from a carton which are individually wrapped and where the marketing authorisation holder supplies sufficient package leaflets for each separate bolus. It is equally acceptable for an SQP to copy the package leaflet or SPC and give that to the customer provided that the copy contains all the required information.

RECORD KEEPING

34. It is the responsibility of the SQP who prescribes a POM–VPS product to keep the documents relating to the prescription or make a record of it, irrespective of who supplies it. The following must be recorded in each case:-
- the date
 - the identity of the product
 - the batch number
 - the quantity
 - the name and address of the recipient
 - in the case of a written prescription their name and address

These records must be kept for at least 5 years.

35. It is good practice for an SQP who supplies a NFA-VPS product and carries out the related SQP duties in respect of the supply, to keep the related documents or make a record of the information as set out above.
36. It is not necessary to keep individual records which tie receipt of a batch of product to its individual supply providing it is possible, using all the records together, to identify which batch has been supplied to which person and carry out a full batch recall.

OTHER REQUIREMENTS

37. SQPs must understand the UK Suspected Adverse Reaction Scheme and how to report Suspected Adverse Reactions. They must also be able to provide their customers with advice on the Scheme if requested.
38. It is an offence not to carry out the requirements set down in the Veterinary Medicines Regulations.

GUIDANCE FOR REGISTERED PREMISES

39. Veterinary Medicines Regulations Schedule 3 Paragraph 14(4) states:

The supply of products permitted to be supplied by a suitably qualified person must take place from premises approved by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products, and it is an offence to supply other than from those premises.

40. The approval permits the establishment to be entered into the register of premises for a calendar year. Every site from where medicines are to be supplied by an SQP must be registered separately. Approval will only be granted following a satisfactory inspection. Approvals must be re-confirmed annually by means of the payment of the annual registration fee. The premises are considered to be under the control of the business in whose name the registration is made. Applications for approval must be made to the Animal Medicines Inspectorate (AMI), National Agricultural Centre, Stoneleigh Park, Warwickshire, CV8 2LZ (Tel. 024 7684 9260) or in Northern Ireland,

Department of Health, Social Services and Public Safety (DHSSPS NI) Castle Buildings, Stormont Estate, Belfast, BT43SQ (Tel. 028 90520500)

41. A register of approved premises will be published by VMD and updated monthly. Each registered premises must have a registered SQP in order to maintain the registration. It may be helpful for retail businesses to register an alternative SQP to maintain availability. A business must ensure that supplies for veterinary medicines are not made from their premises by anyone who is not an RQP.
42. The procedure for the suspension or revocation of the authorisation of the premises is the same as for the holder of a manufacturing authorisation. Veterinary Guidance Note 11 provides information regarding the appeals procedures and is available on the VMD website (www.vmd.gov.uk)

The Building

43. In order to be approved by the Secretary of State the premises must:-
 - be within a permanent building
 - not have areas used for sale, supply or storage within any residential part of a dwelling house. If premises have been first registered after 1 January 1989, the areas detailed above must be separate and distinct from any part of a dwelling house and have a separate entrance
 - be capable of being made secure
 - be of such design and construction as to ensure that product storage conditions, as set out in the marketing authorisation of products to be supplied, can be met
 - be regularly maintained and cleaned and steps taken to prevent the entry of pests and vermin
 - have emergency exits clearly marked and clear access maintained
 - have the storage area clearly separated from any area used to sell, supply or store food or drink for human consumption
 - have smoking prohibited in any enclosed area

The person responsible for the premises must ensure that they:-

- have POM-VPS and NFA-VPS veterinary medicinal products stored in an area to which members of the public do not have access, either by being partitioned off or otherwise separated from the rest of the premises
- do not display POM-VPS and NFA-VPS for customer self-service
- have suitable fire-fighting equipment available
- have given all staff adequate training in the prevention and control of fire

Record keeping

44. The approved business must keep documents relating to each receipt of a POM-VPS product or make a record of at least the following information:-
 - the date of receipt
 - the identity of the product including its name, strength and pharmaceutical form
 - the quantity
 - the name and address of the supplier

- the batch number

The documents or record must be kept for at least 5 years. It is good practice to keep these records in respect of all authorised veterinary medicinal products. Veterinary Medicines Guidance (VMG) Note 16 provides information regarding record keeping requirements and is available on the VMD website (www.vmd.gov.uk).

Storage

45. An SQP must ensure compliance with the following storage requirements: -

- veterinary medicinal products must be stored in accordance with instructions detailed in the Summary of Product Characteristics
- they must be stored safely and attention paid to the prevention of damage through inappropriate or insecure shelving and fittings
- storage areas should be kept clean
- they may not be stored within toilet and washing areas
- products must be protected from potential adverse effects of light, temperature extremes or moisture with particular attention paid to volatile materials.
- store gangways must be kept clear, particularly of packaging and similar materials which may constitute a fire or accident risk
- effective stock control should be practised, in particular by :-
 - keeping accurate records
 - ensuring that older stock is issued before new
 - removing packs with illegible labels, damaged packs or opened containers or those that are date expired which should be stored separately before being disposed of
- adequate measures must be provided for the safe disposal of spillages and of leaking, broken or unwanted containers
- products that have been sold and are awaiting delivery must be accompanied by a dated, itemised delivery note, and must be clearly separated from unsold stocks.

Temperature control

46. It is essential that temperature sensitive products are stored in a controlled environment in accordance with the authorised instructions from the product literature. Records, at least at daily intervals, must be kept of storage temperatures within the stores in which temperature sensitive medicines are kept. These records must be made available for inspection.

47. Products which are required to be stored below 25 degrees, and are not required to be refrigerated, may be stored at normal room temperature. Stores for products stored at room temperature should be monitored during periods when the outside temperature is unusually high or remains high for longer periods than normal. Products to be stored at less than 25 degrees may also be sensitive to low temperatures and may be adversely affected if temperatures approach freezing point.

Suspected Adverse Reactions

48. It is the responsibility of the business owner to ensure that all suspected adverse reactions associated with their business are reported to the VMD in accordance with the requirements for pharmacovigilance. Veterinary Medicines Guidance (VMG) Note No 13, provides information regarding the suspected adverse reactions surveillance scheme and is available on the VMD website (www.vmd.gov.uk)

Enforcement

49. The business owner must permit an inspector access to their premises at any reasonable time. Inspectors may take samples or documents away but this will be done to minimise the impact on the normal work of the business. Inspectors are able to issue an Improvement Notice to anyone who does not follow the required procedures. This is an interim step before any further action such as the revocation of the registration or prosecution. Improvement Notices will be published on the VMD website. A seizure notice can be issued where an inspector feels it necessary to remove stock from sale. Veterinary Medicines Guidance (VMG) Note 12 provides information regarding improvement and seizure notices and is available on the VMD website (www.vmd.gov.uk).

Insurance

50. It is good practice for owners of all premises registered for the sale of POM-VPS or NFA-VPS medicines to have liability insurance that will not only protect the business against risks associated with the supply of medicines, but may also protect any SQPs in the business from risks associated with prescribing medicines and/or offering advice on their use

Wholesale supply

51. The approved business may supply veterinary medicinal products, which fall within the scope of the qualification they hold, to another approved business, providing the amount does not exceed 5% in terms of annual turnover. Any amount supplied over 5% requires a Wholesale Dealer's Authorisation (WDA). Veterinary Medicines Guidance (VMG) Note 10 provides information regarding Wholesale Dealer's Authorisations and is available on the VMD website (www.vmd.gov.uk)



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

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