

CODE OF PRACTICE

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



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

Issued by the Secretary of State under
the Veterinary Medicines Regulations
2005

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DEFRA CODE OF PRACTICE FOR THE REGISTRATION OF SUITABLY
QUALIFIED PERSONS (SQPs) TO SELL POM-VPS AND NFA-VPS MEDICINES
UNDER THE VETERINARY MEDICINES REGULATIONS 2005

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, or
 - iii. retail businesses with premises that are approved to be able to hold and supply veterinary medicinal products.
2. They also set down guidance on the ways in which approval or registration can be obtained.

LEGISLATION

3. The Veterinary Medicines Regulations came into force on 30 October 2005 and are expected to be revoked and re-made each year on 1 October. This will update the provisions and ensure that they do not become unwieldy and out of date. This Code refers to the 2005 Regulations and 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 Codes.
4. Veterinary Medicines Regulations 2005 Schedule 3 Paragraph 9 states:
 1. *The Secretary of State shall recognise bodies that are suitable to provide training for Suitably Qualified Persons to 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 an adequate training programme;*
 - (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 appeals system if it intends to refuse to register anyone with the appropriate qualifications or 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 7.4*);
 - supply an unauthorised veterinary medicinal product (*Regulation 26*);
 - supply a veterinary medicinal product that has passed its expiry date (*Regulation 7.2*);
 - supply a product unless it is in its original packaging and has its original labelling (*Regulation 5*). An SQP may not add or change the authorised label or any of the information provided on the product literature. 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.
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 the body intends to carry out its functions and details of the premises and staff. It should include information on the body's establishment within the UK and how it intends to maintain operations over a period of at least 10 years.
8. The course of study 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 advice 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 system
 - the requirements for registered premises
 - strategies to optimise the use of medicines
 - recognition of the limits of an SQPs knowledge and competence and the implications of actions
 - mandatory 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.
10. The body must provide a monthly update to the VMD on the SQPs registered through their training, including 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 web site 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 2005 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 one of the Registered Qualified Persons and supplied by one of them. (*previously PML, MFSX and some P products*)

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

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

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

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 and AVM - GSL.

SUITABLY QUALIFIED PERSONS ---

18. Veterinary Medicines Regulations 2005 Schedule 3 Paragraph 9(3) states:

To become a suitably qualified person it is necessary to pass examinations set 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 and trainee 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 web site. Initially, the Animal Medicines Training Regulatory Authority (AMTRA) has been approved and will continue to work in this area.

21. An SQP may only supply the products that fall within the scope of the qualification and therefore registration they have obtained. These are separated as follows:-
- all animals (including food and non food producing)
 - all food producing animals
 - equines
 - companion animals
 - specified species.
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 prescriptions and supplies that they are able to make are easily identified.

DUTIES AND RESONSIBILITIES OF SQPs

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 the duty is fully carried out.
24. An SQP is qualified and registered to supply medicines according to their specific registration. Registration may be for:-
- all animals
 - all food-producing animals
 - equines
 - companion animals
 - specified species.
25. An individual SQP may opt to be registered for a single species and this may be acceptable to a registration body according to the training and registration regime they operate.
26. An SQP may not prescribe or supply a product outside the terms of their individual registration.
27. Continuing Professional Development (CPD) must be undertaken by all SQPs and registered at least once each year. This may be accomplished in a number of different ways. For example, an SQP may take a new module to extend their competence, attend a CPD specific event, gain additional practical experience by means of working in a different type of environment under the supervision of another SQP who is qualified in that work, opt to re-take a module that they have already passed to refresh their understanding or fulfil their CPD requirements in other ways acceptable to the Registration Bodies. Bodies that are approved to train and register SQPs must provide registered SQPs an opportunity for CPD at least once each year. An SQP must advise the Registration Body of the CPD they have undertaken each year.

PRESCRIPTION

28. 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
 - the requirement for the person receiving the product to use it for an authorised use according to the marketing authorisation
 - any available animal health plan.
29. The SQP should be prepared to provide a written prescription on request. Each written prescription must contain the following information:
- (a) the name and address 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 species of animal, identification and number of the animals;
 - (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.

SUPPLY AND RECORDS

30. An SQP may prescribe and supply authorised veterinary medicinal products or either prescribe or supply them. The action that is being carried out determines the requirements for the SQP.
31. When prescribing and supplying a product within either the POM - VPS or NFA - VPS category, the SQP must always:-
- be satisfied that the person who will use the product is competent to use it safely;
 - advise as necessary 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 supply is made to a person holding a Certificate of Competence in the Safe Use of Veterinary Medicinal Products issued by the National Proficiency Tests Council (NPTC) or the NPTC in conjunction with the Department of Agriculture and Rural Development Northern Ireland. The supply of sheep dip must be made in accordance with the legislative requirements. It is acceptable for the supply to be made to a person acting on behalf of someone who holds such a Certificate;
- record the following in respect of each transaction of a POM - VPS product :-
 - the date
 - whether the product has been received or supplied
 - the identity of the product including its name, strength and pharmaceutical form
 - the quantity
 - the name and address of the supplier or recipient
 - the name and address of the person who wrote the prescription
 - the batch number
 - the expiry date.

32. When supplying a product against a written prescription from another Registered Qualified Person 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;
- provide advice on the safe administration of the product;
- advise as necessary on any warnings or contra-indications on the label or package insert;
- be satisfied that the person who will use the product is competent to use it safely.
- record the following in respect of each transaction of a POM - VPS product :-
 - the date
 - whether the product has been received or supplied
 - the identity of the product including its name, strength and pharmaceutical form
 - the quantity
 - the name and address of the supplier or recipient
 - the name and address of the person who wrote the prescription
 - the batch number
 - the expiry date.

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. Any exception to this requirement will be included within the terms of the marketing authorisation. For example, it is permissible for an SQP to supply a number of boluses that are individually wrapped and where the marketing authorisation holder supplies sufficient package leaflets for each separate bolus.

34. 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.
35. It is illegal to supply a product, which has passed its expiry date.
36. It is an offence not to carry out these requirements.

REGISTERED PREMISES

37. Veterinary Medicines Regulations 2005 Schedule 3 Paragraph 9(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.

38. 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 merchant in whose name the registration is made.
39. 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.

The Building

40. In order to be approved by the Secretary of State the premises must:-
 - be from 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 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
 - not display POM - VPS and NFA - VPS for customer self-service
 - have the storage area clearly separated from any area used to sell, supply or store food or drink for human consumption

- have suitable fire-fighting equipment available
- have given all staff adequate training in the prevention and control of fire
- have emergency exits clearly marked and clear access maintained
- have smoking prohibited in storage areas.

Storage

41. 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
- not store medicines 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

42. 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.

43. 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

44. It is the responsibility of the business owner to ensure that all suspected adverse reactions that come to their attention are reported to the VMD in accordance with the requirements for pharmacovigilance. A Veterinary Medicines Guidance Note No 13 is available on the VMD web site, which provides information on this.

Enforcement

45. 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 the revocation of the registration or prosecution. Improvement Notices will be published on the VMD web site.
46. The appeals procedure set down in VMG Note 11 applies in respect of Improvement Notices and the suspension or revocation of the approval of premises.



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