CODE OF PRACTICE

For: Suitably Qualified Persons (SQPs)

Issued by the Secretary of State under the Veterinary Medicines Regulations

Last updated October 2013

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DEFRA CODE OF PRACTICE FOR SUITABLY QUALIFIED PERSONS (SQPs)

SCOPE

1. This Code of Practice sets down the standards that must be complied with by:

   i. bodies that have been recognised to be suitable to provide training and registration for Suitably Qualified Persons (SQPs) by the Secretary of State;

   ii. SQPs who are registered with a recognised body having passed the required examinations and who may therefore supply veterinary medicinal products classified as POM-VPS and NFA-VPS in accordance with the qualification they hold.

2. Any breach of the standards in this Code of Practice by an SQP that is drawn to the attention of a registration body in paragraph 8, including breaches of the Veterinary Medicines Regulations, shall be dealt with by that approved body in accordance with the appeals process referred to in paragraph 14, notwithstanding any action that may be taken by the Secretary of State under the Veterinary Medicines Regulations.

3. 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 that was previously contained within this Code of Practice is now to be found in Veterinary Medicines Guidance Note (VMGN) 3. Annex C contains the Inspection Criteria for SQP Retailer Premises. VMD inspectors will base their inspections on this document.

LEGISLATION

4. 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 regularly. 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.

5. Veterinary Medicines Regulations Schedule 3 Paragraph 14 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.*

Provisions relating to offences in respect of supply by an SQP

6. It is an offence under the Regulations to:

- possess an unauthorised veterinary medicinal product except in accordance with the conditions set in the Regulations or for the purposes of research and development *(Regulation 26);*
- supply an unauthorised veterinary medicinal product except under certain conditions (*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).

7. 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 44(2)).*

REGISTRATION BODIES

8. 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.

9. The courses of study arranged by the recognised 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

10. 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.

11. On request any recognised body must be prepared to arrange further modules to meet the needs of specific sectors.

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 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.

14. 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.

15. A body applying for registration 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

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

    i. a veterinary surgeon who is registered with the Royal College of Veterinary Surgeons (RCVS)
    ii. a pharmacist who is registered with the General Pharmaceutical Council (GPhC) 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

17. 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

18. 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.

19. 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.

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.

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

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

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

SUITABLY QUALIFIED PERSONS

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

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.

22. 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 recognised 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.

23. The bodies that have been recognised 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 recognised and will continue to work in this area.

DUTIES AND RESPONSIBILITIES

24. **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 or may be combined:

- all animals (including food and non food producing)
- food producing animals
- equines
- companion animals including dogs and cats
- avian – poultry and other birds

25. Other types of training and registration categories 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.

26. 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.

27. 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.

28. 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.

29. 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. VMGN 13 provides information regarding the cascade and also includes the labelling requirements. It is available on the VMD website (www.vmd.defra.gov.uk) under Guidance Notes (VMGNs).

PRESCRIPTION

30. 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

31. 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

32. 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;
- supply the product specified in that prescription
- take all reasonable steps to ensure that the product is supplied to the person named in the prescription.
- 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.

33. 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.uk). This describes safe working practice and safe disposal.

34. SQPs supplying veterinary medicines for horses need to advise the customer whether or not the product dispensed is suitable for use in food producing horses. This is to allow horse keepers to fulfill their obligations regarding the Horse Passport Regulations. Please see VMGN 16 - *Guidance on Horse Medicines and Horse Passports* for further guidance on horse medicines and horse passport record keeping. It is available on the VMD website (www.vmd.defra.gov.uk) under Guidance Notes (VMGNs).

Prescribing and supplying by different SQPs in the same premises

35. 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

36. 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

37. 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.

38. 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.

39. An SQP may not break open the immediate packaging of a veterinary medicinal product. 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. E.g. 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

40. It is the responsibility of the SQP who prescribes a POM–VPS product to record the following information relating to all incoming and outgoing transactions. Outgoing transactions includes product sold, product returned to supplier, destroyed or otherwise disposed of. These records must be kept at the approved premises and made available on request.

- 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

41. These records must be kept for at least 5 years. It is good practice to keep these records in respect of all authorised veterinary medicinal products. VMGN 14 provides information regarding record keeping requirements and is available on the VMD website (www.vmd.defra.gov.uk) under Guidance Notes (VMGNs).

42. 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

43. SQPs must understand the UK Suspected Adverse Reaction Surveillance Scheme and how to report Suspected Adverse Events. They must also be able to provide their customers with advice on the Scheme if requested. VMGN 11 provides information regarding the suspected adverse reactions surveillance scheme and is available on the VMD website (www.vmd.defra.gov.uk) under Guidance Notes (VMGNs).

44. When prescribing and supplying anthelmintics for sheep and cattle, SQPs should have regard for the recommendation of Sustainable Control of Parasites in Sheep (SCOPS), and the Control of Worms Sustainably (COWS), respectively.

45. It is an offence not to carry out the requirements set down in the Veterinary Medicines Regulations.

Insurance

46. It is recommended that owners of all premises registered for the sale of POM-VPS or NFA-VPS medicines 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

47. An authorised retailer of veterinary medicines may supply such products, which fall within the scope of the qualification they hold, to another authorised retailer, in order to relieve a temporary supply shortage that could be detrimental to animal welfare. This derogation is intended to prevent animal welfare problems associated with lack of availability of medicines and not intended to aid commercial activities.

    Any authorised retailer who routinely supplies another authorised retailer with veterinary medicines must hold a Wholesale Dealer's Authorisation (WDA). VMGN 8 provides information regarding Wholesale Dealers' Authorisations and is available on the VMD website (www.vmd.defra.gov.uk) under Guidance Notes (VMGNs).

Annex

Inspection Criteria for SQP Retailers' Premises

Criteria highlighted in bold type are legal requirements; those in normal type are guidance and/or good practice.

The requirements set down in this Inspection Criteria apply equally to on-premises, internet and mail order suppliers:

1. General Administration

- **The premises must be appropriately approved and registered with VMD for the product range supplied (Schedule 3, Para 14 (4)).**
- **SQPs must be listed on the current AMTRA register. (Schedule 3, Para 14 (3)).**
- **SQPs' qualifications must be appropriate for the product range they prescribe/supply (Schedule 3, Para 14 (3)).**

2. Premises

- **Premises must be suitable for the storage and supply of veterinary medicinal products (VMPs), (Schedule 3 Para 14 (4a))** and be a permanent building with a fixed address.
- Premises should also:
  - be secure from unauthorised access;
  - be of such design as to allow all VMP storage conditions to be met;
  - have measures implemented to prevent the entrance and harbouring of pests;
  - have VMP storage areas clearly separated from food/drink for human consumption and toilet and washing areas;
  - have no VMPs on self-service, except those that have the legal category AVM-GSL, homeopathic remedies and those products marketed under the Exemptions for Small Pet Animals.

3. Storage of VMPs

- All VMPs should be stored:
  - in a clean and tidy location in accordance with the manufacturer's recommendations;
  - in areas which are not accessible to the public;
  - in areas which are not accessible to domestic pets;
  - on appropriate and secure shelving;
  - in such a way as to be protected from adverse effects of light, temperature extremes and moisture.
- Wherever temperature–sensitive medicines, such as vaccines, are stored, there should be proper monitoring and recording of minimum/maximum temperatures

to demonstrate that they have been stored in accordance with the directions specified in their SPCs.

- POM-VPS and NFA-VPS medicines may not be stored on or retail supplied from a vehicle. However, POM-VPS and NFA-VPS medicines that have been retail supplied from approved premises may be delivered by vehicle to a customer provided they are accompanied by a dated, itemised delivery note. A copy of the delivery note should be retained at the issuing premises.

- When transported, measures should be taken to ensure that VMPs remain within the temperature range specified on their SPCs, e.g. by use of a cool box or refrigerated unit. The suitability of such measures should be demonstrated.

- Ideally, ambient or maximum/minimum temperatures should be recorded in non-refrigerated areas and vehicles where ambient products are stored or transported and where there is potential for the temperature range to exceed or fall below that specified on the products' SPCs.

- Effective stock control should be carried out to ensure a continuous supply of all products and removal of out-of-date medicines.

- Returned medicines, packs with illegible labels, damaged packaging or date expired packs should be quarantined and a suitable disposal procedure in place.

- The storage requirements above apply whether in the premises or being transported in a vehicle.

4. Disposal Procedures

- Procedures should be in place to quarantine, and ultimately dispose of, out of date medicines and leaking, broken or unwanted containers.

- Procedures should be in place to deal with spillages and leakages.

5. Supply Procedures

(a) General

- **Out of date medicines (all classifications) may not be supplied** (**Regulation 7(2)).**

- **Only the minimum quantity required for treatment may be prescribed and supplied (Schedule 3 Para 7 (c)).**

- **All medicines must be supplied in the authorised packaging with labelling specified in the Marketing Authorisation (MA).**

- **However, an SQP may break open any package (other than the immediate packaging) provided that the necessary product literature is provided to the client (Schedule 3 Para 14 (9)).**

(b) SQPs should carry out their duties as described in the Code of Practice for SQPs

- **POM-VPS medicines must be prescribed and supplied and NFA-VPS supplied by an SQP and each individual transaction authorised as follows:-**

  personally supplying POM-VPS or NFA-VPS medicines to the end client or being in a position to intervene when products are handed over or checking the products before despatch to the customer (Schedule 3 Para 14 (5)).

- **An SQP who prescribes a POM-VPS medicine or supplies an NFA-VPS medicine:**
  - **before doing so, must be satisfied that the person using the product is competent to do so safely and intends to use it for a purpose for which it is authorised;**
  - **when doing so, must advise on its safe administration and any warnings or contra-indications on the label or package leaflet. (Schedule 3 Para 7 (1)).**

- When prescribing for food producing animals, SQPs should take into account the advice given by SCOPS, COWS and RUMA.

- There should be evidence of actions taken when no SQP is present to prescribe/supply VMPs.

- It is considered good practice to have a written SOP setting out the procedures for authorisation of each VMP transaction.

- **In the case of supply of POM-VPS sheep dips, the customer/user's 'Certificate of Competence in the safe use in Sheep Dips' number must be checked and recorded (Schedule 3 Para 22 (3)).**

- **In the case of sheep dips, if not previously supplied to the customer, a laminated notice and two pairs of gloves must be supplied with every product prescribed and supplied (Schedule 3 Para 22 (4)).**

6. Records

- **Records of receipt and/or supply of all prescription medicines must be available and contain the following information:**

  - **the date of receipt/supply;**
  - **the name of the veterinary medicinal product;**
  - **the batch number *(except that for non-food animal medicines a record of the date of receipt or start of the batch is acceptable);***
  - **the quantity of the veterinary medicinal product;**
  - **name and address of the supplier or recipient; and**
  - **if there is a written prescription, the name and address of the person who wrote the prescription and a copy of it (Regulation 23 (1)).**

- **If the product is a sheep dip, a record of the sheep dip certificate of competence number must also be made in addition to the above (Schedule 3 Para 22 (3)).**

- **All records must be retained for 5 years (Regulation 23 (4)) except sheep dip certificate of competence numbers which must be kept for 3 years (Schedule 3 Para 22 (3)).**

- A means of recording the disposal of VMPs and the transfer of VMPs to another premises, store or vehicle should be implemented, to ensure traceability and enable stock reconciliation.

7. Written prescriptions

- **If issued, written prescriptions must include all the information required under the Veterinary Medicines Regulations:**
  - **the name, address and telephone number of the person prescribing the product;**
  - **the qualifications 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;**
  - **the withdrawal period if relevant; and**
  - **if it is prescribed under the cascade, a statement to that effect. (Schedule 3 Para 6 (1))**

- **A written prescription is valid for six months or such shorter period as may be specified in the prescription (Schedule 3 Para 6 (3)).**

  If the prescription is repeatable it must specify the number of times the veterinary medicinal product may be supplied. (Schedule 3 Para 6 (4)) If the prescription is not repeatable, it is considered good practice for this to be stated.

- **When a POM-VPS medicine is dispensed under a written prescription from a veterinary surgeon, a pharmacist or an SQP, a copy of the prescription must be retained by the supplying SQP for five years (Regulation 23). It is considered good practice for copies of prescriptions issued by a veterinary surgeon, pharmacist or an SQP to be retained in case of query.**

8. Audit

- **An audit of POM-VPS medicines must be carried out at least annually and a record of the most recent audit must be available (Schedule 3 Para 15 (1)).**

- A system linking incoming and outgoing transactions with stock held, for example, may provide an ongoing running total which, with the addition of a periodic physical stock count to verify the stock held, may meet the audit requirement.

- Where an annual or more frequent stock take, which includes the main features set out above, is carried out for any reason such as, for example, tax purposes, the VMD would consider that the "detailed audit" requirement is being met.

9. In-feed Veterinary Medicinal Products (premixes) and feedingstuffs:

- **Premixes authorised for incorporation into feedingstuffs may only be supplied to approved manufacturers (a register of approved manufacturers is published on the VMD website – www.vmd.defra.gov.uk) (Schedule 3 Para 11).**

- **If the manufacturer is the end-user of the feedingstuff, the supply of premix must be in accordance with a Medicated Feedingstuff (MFS) prescription (Schedule 5 Para 18 (4)).**

- **Premixes may not be supplied for top-dressing, unless that method of administration is permitted by the product's MA or the product is supplied under the cascade (Schedule 5 Para 9).**

- **An MFS prescription for feedingstuffs containing a VMP must contain the following:**

  - **the name and address of the person prescribing the product;**
  - **the qualifications enabling the person to prescribe the product;**
  - **the name and address of the keeper of the animals to be treated;**
  - **the species of animal, identification and number of the animals;**
  - **the premises at which the animals are kept if this is different from the address of the keeper;**
  - **the 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;**
  - **the withdrawal period;**
  - **the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose);**
  - **if the validity exceeds one month, a statement that not more than 31 days supply may be provided at any time;**
  - **the name, type and quantity of feedingstuffs to be used;**
  - **the inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance;**
  - **any special instructions;**
  - **the percentage of the prescribed feedingstuffs to be added to the daily ration; and**
  - **if it is prescribed under the cascade, a statement to that effect. (Schedule 5 Para 19 (1))**

- **An SQP may prescribe a feedingstuff containing a POM-VPS medicine but additional approval as a Distributor is required to supply medicated feedingstuffs (see VMGN 17 Medicated Feedingstuff and Specified Feed Additives, which is published on the VMD's website (Schedule 5 Para 18 (1)).**

10. Wholesale supply

- **A wholesale dealer's authorisation (WDA) is required if veterinary medicines are bought on a wholesale basis for the purposes of supply to other retailers or wholesalers (Schedule 3 Para 2(1)).**
- **There is an exemption from this requirement, where a retailer supplies another retailer with a small number of wholesale transactions in order to relieve a temporary, emergency supply problem that could be detrimental to animal welfare.**
- **The above exemption is intended to enable retailers (veterinary surgeons, pharmacists and SQPs) to supply each other in an emergency or if there are shortages of supply.**

11. Advertising

- **The advertising of POM-VPS products may only be aimed at appropriate persons, which do not include the general public.** This includes adverts on websites, brochures and those displayed in retail areas to which the general public have access. Price lists are not considered to be advertising, provided that they meet the conditions set in VMGN 4 Controls on Advertising, which is published on the VMD's website. **(Regulation 11(5)).**
- **All products must only be advertised for their authorised use. (Regulation 10 (1)).**
- **Human medicines cannot be advertised for administration to animals (Regulation 10 (2)).**

12. Other

SQPs should be aware of SARSS and the system for reporting adverse events/lack of efficacy to the MA holder or directly to the VMD. Reports to the VMD can be made using the SARSS yellow form or the VMD's online service:

http://www.vmd.defra.gov.uk/adversereactionreporting/

13. Abbreviations and definitions:

AMI	Animal Medicines Inspectorate
AMTRA	Animal Medicines Training and Regulatory Authority
COWS	Control of Worms Sustainably
MA	Marketing Authorisation
MFS	Medicated Feedingstuff
Premix	VMP authorised for incorporation into animal feedingstuffs
RUMA	Responsible Use of Medicines in Agriculture

SARSS	Suspected Adverse Reaction Surveillance Scheme
SCOPS	Sustainable Control of Parasites in Sheep
SQP	Suitably Qualified Person
SPC	Summary of Product Characteristics
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
WDA	Wholesale Dealer's Authorisation

ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES