



ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

**VETERINARY MEDICINES
GUIDANCE NOTE**

No 3

**GUIDANCE
FOR
RETAILERS**

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QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) details the requirements placed upon veterinary surgeons, pharmacists and Suitably Qualified Persons (SQPs) when prescribing/supplying veterinary medicinal products (VMP) to members of the public. It also provides guidance on veterinary practice premises registration, the import and export of veterinary medicines and the Suspected Adverse Reaction Surveillance Scheme (SARSS).

The quick start guide is a summary of the provisions of the Veterinary Medicines Regulations (VMR); detailed information is found in the body of the VMGNs.

Veterinary medicines used to treat animals fall within the scope of Directive 2001/82/EC, as amended, and the national legislation that transposes the EU legislation into national law. The VMR transpose Directive 2001/82/EC into UK law.

Distribution Categories and Small Animal Exemption Scheme (SAES)

The VMR set out the distribution categories for VMPs which receive marketing authorisations in the UK:

These are:

- Prescription Only Medicine – Veterinarian (POM-V)
- Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS)
- Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)
- Authorised Veterinary Medicine – General Sales List (AVM-GSL)

In addition to the above distribution categories, products may also be made available for supply under the small animal exemption scheme (SAES), which permits certain VMPs to be marketed without a marketing authorisation, subject to certain conditions.

Registered Qualified Persons (RQPs)

Veterinary surgeons, pharmacists and SQPs, collectively known as RQPs, are entitled to prescribe VMPs. An RQP may only prescribe and/or supply the products that fall within the scope of the qualification and the registration they hold. It is the duty of the RQP to ensure that the statutory requirements in respect of the prescription or supply of POM-V, POM-VPS and NFA-VPS are respected.

Requirements at the time of retail supply

When an RQP prescribes a product classified as POM-V or POM-VPS or supplies a product classified as NFA-VPS, he/she must:

- ensure the recipient is competent to use the product for the purpose for which it is prescribed;
- advise on the safe administration of the product and provide information about contraindications/ warnings etc;
- limit the amount of product prescribed to the minimum amount necessary.

Inspection of retail premises

Non-Practice Standard Scheme (PSS) veterinary practice premises (VPPs) and SQP retailer premises are subject to regular inspections by the Veterinary Medicines Directorate

(VMD). Inspection enables the VMD to confirm that these premises are complying with the requirements of the VMR.

Inspections of Non-PSS VPPs will be conducted at least once every four years. Inspection of SQPs retailers' premises are carried out on a risk basis and the frequency varies from once every four to six years.

VPPs which already belong to the Royal College of Veterinary Surgeons (RCVS) Practice Standard Scheme (PSS) are not subject to additional inspection by the VMD. The PSS medicines inspections cover the VMR inspection criteria (see Annex B) and additional criteria specific to the requirements of the PSS.

Pharmacy premises are inspected by the General Pharmaceutical Council (GPhC) and in Northern Ireland by the Pharmaceutical Society of Northern Ireland (PSNI).

Prescriptions

Prescribing is considered to be the action of deciding, instructing and recording which treatment should be administered to an animal and may be oral or put in writing. A written prescription is required when the product is to be supplied by a person working from a different business, or premises, from where the product was initially prescribed. It should be noted that Veterinary Surgery is defined within the Veterinary Surgeons Act (VSA) and care should be taken to ensure compliance with the Act.

Labelling at the time of retail supply

The label information on the product is specifically authorised to provide necessary information for the safe and effective use of the product. This includes warnings for the user and animal owner, so it must not be obscured by any additional labelling or amendments made to the packaging.

Retail supply via the internet

Retailers of veterinary medicines may choose to operate their business via the Internet or mail order. The requirements of UK legislation apply, irrespective of whether a customer personally visits the premises and meets the RQP face-to-face or corresponds with the RQP by other means. Each RQP must be able to demonstrate that they operate in accordance with the VMR including the registration and inspection requirements in respect of premises.

Importation and exportation of veterinary medicinal products

It is an offence to import a VMP not authorised for use in the UK and to supply such a VMP, unless it is supplied under the prescription of a veterinary surgeon and with a suitable import certificate issued by the VMD.

The VMR do not restrict the export of veterinary medicines. If the export is within the European Union (EU) the RQP exporting the medicine must ensure that the product can legally be sold or supplied in the importing Member State. If the product is to be exported outside of the EU the VMD recommends checking the requirements for import in the country concerned.

Supply of sheep dip

If the VMP is a sheep dip, of any type, the supply must be to a person (or a person acting on his behalf) who holds a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate

have been satisfactorily completed, or NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF).

FURTHER INFORMATION

- For more information on the retail of veterinary medicines please contact the VMD's Legislation team on 01932 338321 or alternatively contact VMD reception on 01932 336911 and quote "retail supply".

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Introduction

1. This is one of a series of Veterinary Medicine Guidance Notes (VMGNs) explaining the requirements under the Veterinary Medicines Regulations (VMR). The VMR are revoked and replaced on a regular basis, so the references to the VMR should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument are not shown in the VMGNs. This VMGN will be updated as necessary and the date of the most recent update is shown on the front cover. The VMR set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration.
2. The purpose of this VMGN is to describe the provisions for prescription and supply and the distribution categories of veterinary medicinal products (VMPs) in the UK. Guidance on advertising and internet retailing is also provided.

Distribution Categories

3. The VMR set out the distribution categories for UK veterinary medicines.
These are:
 - Prescription Only Medicine – Veterinarian (POM-V)
 - Prescription Only Medicine – Veterinarian, Pharmacist, SQP* (POM-VPS)
 - Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)
 - Authorised Veterinary Medicine – General Sales List (AVM-GSL)

*SQP refers to a Suitably Qualified Person who is registered with a body recognised under the VMR.
4. In addition to the above distribution categories products may also be made available for supply under the small animal exemption scheme (SAES). For further details please see paragraph 18 of this VMGN.

POM V medicines

5. A VMP that has been classified as a POM-V may only be supplied to the client once it has been prescribed by a veterinary surgeon following a clinical assessment of an animal, or group of animals, under the veterinary surgeon's care. There is no definition of 'clinical assessment' or "under their care" in the VMR and veterinary surgeons are expected to use their professional judgment in deciding how this should be interpreted in their particular circumstances. The Royal College of Veterinary Surgeons (RCVS) has interpreted "clinical assessment" as meaning an assessment of relevant clinical information, which may include an examination of the animal, and "under their care" as meaning:
 - a) the veterinary surgeon must have been given the responsibility for the health of the animal or herd by the owner or the owner's agent
 - b) that responsibility must be real and not nominal
 - c) the animal or herd must have been seen immediately before prescription or,

- d) recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe.
- e) the veterinary surgeon must maintain clinical records of that herd/flock/individual

What amounts to 'recent enough' must be a matter for the professional judgement of the veterinary surgeon in the individual case.

- 6. The client may request a written prescription if they wish to obtain the product from a supplier other than the prescribing veterinarian. In all cases, the prescribing veterinary surgeon shall accept clinical responsibility for the treatment and the animal or group of animals should be under his/her care. Any registered veterinary surgeon or registered pharmacist may supply POM-V products or products to be used under the Cascade in accordance with a written prescription from a veterinary surgeon. The supplying veterinary surgeon or pharmacist should use their specialist knowledge to check that the prescription accords with their own understanding of the product. If they have concerns about the prescription they should raise them with the prescribing veterinary surgeon before dispensing the medicine. It is open to any supplier to refuse to supply against a prescription.
- 7. A product will generally be included in the POM-V category when it:
 - requires a strict limitation on its use for specific safety reasons;
 - requires the specialised knowledge of a veterinary surgeon for its use/application;
 - has a narrow safety margin requiring above average care in its use;
 - is Government policy to demand professional control at a high level.
- 8. For example, products containing controlled drugs (CDs) in Schedule 2 or 3 of the Misuse of Drugs Regulation 2001 are classified as POM-V and will be clearly identified on their labels with "CD" and the relevant schedule.
- 9. Products containing new active substances will usually be categorised as POM-V, although in very rare cases the nature of the substance, indications, supporting data and other data may enable a product to be categorised as POM-VPS.
- 10. A product for a food-producing species will be classified as either POM-V or POM-VPS unless all of the POM exemption criteria are met. These criteria are set out in VMGN 1 Controls of Veterinary Medicines, which is published on the Veterinary Medicines Directorate's (VMD's) website
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

POM-VPS medicines

- 11. A veterinary medicine classified as POM-VPS may be prescribed by any Registered Qualified Person (RQP - a veterinarian, a pharmacist or an appropriately qualified SQP). A clinical assessment of the animal(s) is not required when prescribing this category of veterinary medicine and the animal does not have to be seen by the prescriber. However sufficient information about the animal and the way it is kept must be known to the prescriber in order to prescribe and supply appropriately.

12. The customer may request a written prescription if they wish to obtain the product from a supplier other than the prescribing RQP. An RQP may supply POM-VPS medicines in accordance with a written prescription from another RQP.
13. Pharmacists and SQPs may supply a POM-VPS medicine for use under the cascade if prescribed by a veterinary surgeon and in the case of SQPs if they hold the relevant qualification to supply that medicine.
14. A medicine will generally be included in the POM-VPS category when:
 - it is used to reduce or prevent the effects of endemic disease in herds, flocks or in individual animals (such as treatment for worms and other parasites);
 - its use implies risks for the user, the animal, consumer safety or the environment but users can be made aware of suitable countermeasures through simple, oral or written, advice;
 - a professional user can be given adequate training in its regular use.
15. As discussed above, medicines containing new active substances will usually be categorised as POM-V, although in very rare cases the nature of the substance, indications, supporting data etc. may enable a product to be categorised as POM-VPS.

NFA-VPS medicines

16. A veterinary medicine classified as NFA-VPS may be supplied by any RQP provided the requirements for supply are met. These medicines do not require a prescription.
17. A medicine will generally be included in the NFA-VPS category when:
 - it is indicated for use only in non-food animals;
 - it is used routinely to prevent or limit the effects of endemic disease in non-food animals;
 - its use implies risks for the user, the animal, for consumer safety or for the environment but users can be made aware of suitable countermeasures through simple, oral or written advice;
 - the animal keeper can be given sufficient practical advice to permit effective/safe usage.

AVM-GSL medicines

18. There are no legal restrictions in the VMR for the retail supply of veterinary medicines classified as AVM-GSL (“over the counter“ medicine) but a responsible approach to the supply of these medicines is still expected.
19. A medicine will generally be included in the AVM-GSL category when:
 - its use has a wide margin of safety;
 - it is used to alleviate or prevent the signs of disease or support the treatment of common ailments;
 - special advice is not required to permit safe/effective use.
 -

Small Animal Exemption Scheme (SAES)

20. The SAES permits certain medicines to be placed on the market without a marketing authorisation (MA), subject to certain conditions. This exemption scheme applies only to veterinary medicines labelled exclusively for use in one or more of the following animals that are not intended for human consumption:
- aquarium animals (including fish kept in closed water systems)
 - cage birds (meaning birds kept in cages or aviaries)
 - homing pigeons (meaning pigeons kept for racing or exhibition)
 - terrarium animals (meaning reptiles, amphibians and arthropods kept in tanks and cages – including animals free-living in domestic gardens)
 - small rodents (meaning domestic mammals of the order *rodentia*)
 - ferrets
 - rabbits
21. Products marketed under the SAES may be sold by any retailer. For further information please refer to VMGN 12 Exemption Scheme for Small Pet Animals, which is published on the VMD's website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Veterinary Surgeons

22. A veterinary surgeon may only prescribe and supply veterinary medicines (other than those classified as AVM-GSL) if he or she is a registered member of the RCVS and supply must take place from premises which have been registered with the RCVS as a Veterinary Practice Premises (VPP).
23. The requirement for registration of a VPP places the onus on a veterinary surgeon to supply from practice premises that are registered with the RCVS as a VPP. This does not mean that every veterinary surgeon must have registered premises of his/her own.
24. The type of premises that must be registered are likely to fall into one or more of the categories below:
- a) premises from which the veterinary surgeons of a practice provide veterinary services;
 - b) premises advertised or promoted as premises of a veterinary practice;
 - c) premises open to members of the public to bring animals for veterinary treatment and care;
 - d) premises not open to the public, but which are the base from which a veterinary surgeon practises or provides veterinary services to more than one client;
 - e) premises to which medicines are delivered wholesale, on the authority of one or more veterinary surgeons in practice.

This is not an exhaustive list of premises that may be considered as a veterinary practice premise.

25. The provisions are intended to ensure veterinary surgeons' compliance with the VMR and to bring veterinary surgeons in line with other authorised retail suppliers of VMP who are permitted to supply only from registered premises and who are regularly inspected. The provisions are designed to enable checks to be made on compliance with the controls on the storage and supply of veterinary medicines, including controlled drugs.
26. The provisions will also enable a risk-based inspection regime to be developed for all UK veterinary practice premises.

Registration of Practice Premises

27. The register of practice premises will be held by the RCVS on behalf of the Secretary of State.
28. Veterinary practices that are registered with the RCVS Practice Standards Scheme (PSS) already fulfil the registration requirements of the VMR and owners of these businesses do not need to apply for additional registration as long as the veterinary practice concerned remains accredited with the PSS.
29. The application form for registering a practice premises is available on the RCVS website www.rcvs.org.uk. All applications must be submitted directly to the RCVS at the following address:

Registration Department
Royal College of Veterinary Surgeons
Belgravia House
62-64 Horseferry Road
London
SW1P 2AF62

30. A veterinary surgeon supplying a veterinary medicine (other than one classified as AVM-GSL) must be present when it is handed over unless the veterinary surgeon:
 - authorises each transaction individually before the product is supplied;
 - is satisfied that the person who hands it over is competent to do so.
31. It is considered good practice for veterinary surgeons to have in place a practice Standard Operating Procedure (SOP) if they intend to delegate supply of veterinary medicines under their responsibility. This would enable support staff to achieve and maintain an appropriate level of competence.

Mobile units

32. In certain cases veterinary surgeons set up mobile treatment centres as an extension to their veterinary practice premise. These mobile units do not require individual registration if they are linked to a main practice as an "ambulatory service". However, they are still subject to inspection along with the main practice.

However, if a veterinary surgeon wishes to retail medicines at a show, for example, from a mobile unit which is independent from a registered veterinary practice premise then the mobile unit must be registered and inspected as a separate entity.

Supply of medicines from vehicles and cold calling

33. The supply of medicines for animal treatment is part of a veterinary surgeon's business. However, unsolicited visits to farms by veterinary surgeons exclusively to sell veterinary medicines ("cold calling") is considered unprofessional and strongly discouraged by the VMD.

Pharmacists

34. A registered pharmacist may only supply VMPs (other than those classified as AVM-GSL) or products prescribed by a veterinarian for use under the cascade either from premises which have been registered as a pharmacy with either The General Pharmaceutical Council (GPhC) or the Pharmaceutical Society of Northern Ireland, or registered VPP or premises approved and registered for the storage and supply of VMPs by an SQP.
35. A pharmacist supplying a VMP (other than one classified as AVM-GSL) must be present when it is handed over unless the pharmacist:
- authorises each transaction individually before the product is supplied;
 - is satisfied that the person who hands it over is competent to do so.
36. A pharmacist may prepare and supply an extemporaneous preparation prescribed by a veterinarian for use under the Cascade. This preparation should be made using pharmacopoeia-compliant raw materials and the product should meet the requirements of the relevant general monographs of the pharmacopoeia and may be supplied directly to the end-user.

Suitably Qualified Persons

37. SQPs may only supply veterinary medicines for which they are qualified from the following premises:
- Premises approved by the VMD acting on behalf of the Secretary of State (see next paragraph);
 - a pharmacy registered with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland; or
 - a veterinary practice premise registered with the RCVS

Approval as an SQP retailer permits the premises to be entered into the register of premises for a calendar year and must be re-confirmed annually. Each premise from where medicines are to be supplied by an SQP must be approved separately. The premises are considered to be under the control of the business in whose name the approval is granted. Domestic premises may be approved as SQPs retailers' premises and will be subject to the same criteria, i.e. permanent building with a fixed address, and inspection requirements. For the purpose of approval and inspection, the section of premises allocated to retail supply of POM-VPS and NFA-VPS medicines must be made accessible to inspectors following reasonable notice.

38. The Register of Approved SQPs Retailers' Premises is published on the VMD's website and updated monthly. In order to be approved and retain that approval, each premise must have a registered SQP. Any proposed change to the registered SQP must be immediately notified to the VMD. It may be helpful for retail businesses to register an alternative SQP to maintain availability of VMPs.
39. If an SQP considers that the premises in which they are operating no longer comply with the requirements of the approval granted by the Secretary of State, they must notify the VMD without unreasonable delay. This is necessary to ensure that the products are prescribed and supplied in accordance with the VMR and are stored correctly to maintain their safety and efficacy.
40. The application form for registering an SQP retailers premises is available on the VMD website www.vmd.defra.gov.uk. Applications for approval of SQP retailers' premises must be made to:

VMD
Woodham Lane
New Haw
Addlestone
KT15 3LS
tel: 01932 338475
email:inspections@vmd.defra.gsi.gov.uk

Approval will only be granted following a satisfactory inspection. Guidance on the requirements for approval is given on the VMD's website:
www.vmd.defra.gov.uk/vet/sqp_guidance.aspx

41. 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. It is the duty of the 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.
42. An SQP must comply with the Code of Practice for Suitably Qualified Persons (SQPs) which is available on the VMD website www.vmd.defra.gov.uk. Information on how to become an SQP may be obtained from the Animal Medicines Training regulatory Authority - AMTRA (<http://www.amtra.org.uk/>).
43. An SQP supplying a VMP (other than one classified as AVM-GSL) must:
- hand over or despatch the product personally or;
 - ensure that, when the product is handed over or despatched, the SQP is in a position to intervene if necessary or;
 - check the product after it has been allocated for supply to a customer and be satisfied that the person handing over or dispatching it is competent to do so.

Inspection of Retail Premises

44. Non-PSS veterinary practice premises and SQPs retailers' premises are subject to regular inspections by the VMD. Inspection enables the VMD to confirm that these premises are complying with the requirements of the VMR.
45. Inspections of retailers' premises are carried on a risk basis and the determined level of risk sets the frequency of inspection. Further explanation is given in the table at paragraph 54.
46. Veterinary practices which are already accredited under the RCVS PSS are not subject to additional inspection by the VMD. The PSS medicines inspections cover the VMR inspection criteria (see Annex B) and additional criteria specific to the requirements of the PSS.
47. Pharmacy premises are inspected by the General Pharmaceutical Council (GPhC) and in Northern Ireland by the Pharmaceutical Society of Northern Ireland (PSNI).
48. The Inspection Criteria applicable to veterinary practice premises is at Annex B.
49. The Inspection Criteria applicable to SQP retailer premises is at Annex C.
50. Amongst other things, VMD inspectors are empowered to:
 - inspect the premises, organisational arrangements and procedures used in the storage and distribution of medicinal products;
 - interview key personnel named on the authorisation;
 - take samples, and
 - examine any documentation or records relating to the manufacture, assembly, storage and distribution of VMs.
51. It is a requirement of UK legislation that retailer's premises shall be available for inspection by the Licensing Authority following reasonable notice.
52. Following an inspection, the VMD inspector will issue a report to the retailer detailing any deficiencies noted. For deficiencies other than minor deficiencies, the inspector will request details of the measures that have been, or will be, taken to correct them.
53. For the purposes of inspections VMD categorises deficiencies as critical, major and other (minor):

Minor (Other) Deficiencies

- A deficiency, which is minor and poses no potential risk to human or animal health, or the environment; or
- A deficiency which does not indicate a significant deviation from the requirements of the Veterinary Medicines Regulations (VMR), Codes' of Practice or Guidance; or
- A deficiency which cannot be classified as either critical or major, because there is insufficient information to classify it as such.

Major Deficiencies

- A non-critical deficiency which has produced, or has the potential to produce, a possible risk to human or animal health, or the environment; or
- A deficiency which indicates a major deviation from the requirements of the VMR; or
- A deficiency which indicates a failure to carry out satisfactory procedures to ensure that products are manufactured, stored or distributed in accordance with their specific requirements; or
- A combination of more than six other (minor) deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such; or
- Other (minor) deficiencies that have been brought to the attention of the business on previous occasions but have not been resolved.

Critical Deficiencies

- Deficiencies that have produced, or have the potential to produce, a significant risk to human or animal health, or the environment; or
- A deficiency which indicates a significant deviation from the requirements of the VMR through serious negligence or intent.

54. Inspection of veterinary retailers premises are scheduled at intervals based on the number and type of deficiencies noted during an inspection, as follows:

Inspection findings	Compliance rating	Max inspection interval (months) by category		
		VPP, AM*	AM	AS, AJ, AC
≤ 6 minor (other)	Good	48	60	72
> 6 minor ≤ 3 major	Acceptable	36	45	54
>3 ≤ 5 major	Poor	24	30	36
≥ 6 major; any critical	Unacceptable	Follow up inspection as specified on Improvement Notice, then next scheduled inspection within 9-12 months		

Key to table:

Category	Category Name	Activity Description
VPP	Veterinary Practice Premises	Premises registered with the Royal College of Veterinary Surgeons as practice premises

AM*	Agricultural Merchant*	Approved retail supplier of veterinary medicinal products by Suitably Qualified Persons (SQPs), including the supply of vaccines and sheep dips.
AM	Agricultural Merchant	Approved retail supplier of veterinary medicinal products by Suitably Qualified Persons (SQPs), with the exception of vaccines and sheep dips.
AS	Horses & Companion Animals	Approved retail supplier of veterinary medicinal products for the treatment of horses and companion animals only by Suitably Qualified Persons (SQPs)
AJ	Horses Only	Approved retail supplier of veterinary medicinal products for the treatment of horses only by Suitably Qualified Persons (SQPs)
AC	Companion Animals Only	Approved retail supplier of veterinary medicinal products for the treatment of companion animals only by Suitably Qualified Persons (SQPs)

55. In the case of the most serious deficiencies or failure to comply with the VMR, the VMD may consider formal action which can include the refusal to grant an approval, suspension or revocation of the approval, issuing of an Improvement or Seizure Notice or prosecution. The VMD may also take action against the RQP for any failings or omissions by that person. For further information please refer to VMGN 10 Guidance on Enforcement, which is published on the VMD's website. http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
56. Where the VMD takes a decision to suspend or revoke an approval, retailers have the right to appeal against such decisions. For further information please refer to VMGN 9 Guidance on Appeals Against Regulatory Decisions, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Prescriptions

57. A prescription may be oral or in writing. Prescribing is considered to be the action of deciding, instructing and recording which treatment should be administered to an animal. It can be carried out by a veterinary surgeon, or a pharmacist or an SQP, according to the distribution category of the VMP concerned. A written prescription is required when the product is to be supplied by a person working from a different business, or premises, from where the product was initially prescribed. A written prescription is not necessary when the prescribing and supplying persons are different people working on the same site who personally interact in the transaction.
58. As well as specifying an authorised VMP, a prescription from a veterinary surgeon may be for a product that has been prescribed under the Cascade. In these cases the prescription may be written for a human medicine or a preparation that is to be made up to meet the particular circumstances. For further information please refer to VMGN 13 Guidance on the Use of the Cascade, which is published on the VMD's website. http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Written prescriptions

59. No particular format is required for a written veterinary prescription but prescribers must include the following information:

- the name, address and telephone number of the person prescribing the product;
- the qualifications enabling the person to prescribe the product. It is good practice to cite MRCVS or the SQP's registration number;
- the name and address of the owner or keeper;
- identity (including the species) of the animal or group of animals;
- 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;
- if it is prescribed under the cascade, a statement to that effect.

60. A specimen veterinary surgeon's prescription is obtainable from the British Veterinary Association (BVA) at: www.bva.co.uk. Prescription pads for SQPs are available from the Animal Health Distributors Association (AHDA) at www.ahda.co.uk.

61. Prescriptions are valid for a maximum of 6 months from the date of signing, or 28 days for CD listed in Schedules 2-4 of the Misuse of Drugs Regulations 2001. A prescription must only be dispensed once, unless it says that it may be repeated, in which case the number of repeats must be specified. If the prescription is not repeatable it is considered prudent for this to be stated on the prescription. It is also recommended that if the prescription has a section that states 'number of repeats' this should be crossed out by the prescriber if the prescription is not to be repeated.

'Repeat dispense' prescriptions (multiple prescriptions issued at the same time, setting out doses to be supplied over a period of time, usually up to a year) are not allowed for CD in Schedules 2 and 3. This is due to the fact that a prescription for these drugs is only valid for 28 days. However, 'repeat prescriptions' (single prescription, with multiple repeats (within 28 days of issue) are allowed for drugs in all Schedules as a prescription can legally be issued without a consultation. It is considered good practice, however, that a patient should be reviewed before prescribing a Schedule 2 or 3 controlled drug but this is a clinical decision not a legal requirement.

Prescription tampering

62. A supplier who supplies a veterinary medicine against a written prescription must take reasonable steps to ensure that the prescription is genuine and prescribers may choose to use various methods, such as stickers or serial numbers, to help with this. If the supplier is in any doubt about the validity of a prescription, then a telephone conversation with the prescriber should be regarded as a minimum step to confirm its validity. Please note:

- If an amendment (such as a typographic error) to a written prescription is necessary before a product can be supplied then the prescriber may give the supplier permission to make an amendment on his/her behalf, and this action should be recorded;
- If orders against faxed or electronic prescriptions are accepted then the supplier may need to check that each prescription is genuine;
- Unless the use of electronic transmission for prescriptions is an agreed and familiar practice between the prescriber and supplier, or needed for particular urgency to avoid an animal suffering, it is recommended good practice that an original hard copy is always received by the supplier before the supply is made.

63. Any person who alters a written prescription without authorisation to do so by the prescriber commits an offence.

Requirements at the Time of Retail Supply

64. When an RQP prescribes a medicine classified as POM-V or POM-VPS, or supplies a medicine classified as NFA-VPS:

- before doing so, the RQP must be satisfied that the person who will use the medicine is competent to do so safely, and intends to use it for a purpose for which it is authorised;
- when doing so, the RQP must advise on its safe administration and on any necessary warnings or contra-indications on the label or package leaflet (which are derived from the Summary of Product Characteristics (SPC)). The SPC for products authorised in the UK can be found on the VMD's website www.vmd.defra.gov.uk; and
- the RQP must not prescribe (or, in the case of a NFA-VPS product, supply) more than the minimum amount required for the immediate treatment; but it is a defence to show that:
 - i) the veterinary medicine prescribed or supplied was in a container specified in the marketing authorisation;
 - ii) the marketing authorisation does not permit smaller containers; and
 - iii) the RQP is not a person authorised to break open the package before supply.

Controlled drugs

65. Controlled Drugs used in veterinary medicine are subject to additional legislative requirements. For further information please refer to VMGN 20 Controlled Drugs, which is published on the VMD's website:

http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Buying groups

66. RQPs may supply POM-VPS medicines to farmers who are members of a buying group, provided that they fulfil the prescribing requirements of the VMR and the record keeping requirements as detailed in VMGN 14 Record-Keeping Requirements

for Veterinary Medicinal Products, which is published on the VMD's website. http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

To fulfil these requirements the RQP must have made contact with each member of the buying group and have knowledge of the animals intended for administration. The RQP may invoice the buying group provided the terms and conditions of the group make it clear that it is acting only as an agent of the individual member supplied with the VPS medicines and is not the principal in the transaction with the RQP, i.e. the group does not take ownership of the goods supplied.

Auctions

67. Because of the requirements set out above, veterinary medicines should not be offered or supplied via auctions – with the exception of AVM-GSL and SAES products. This also applies to internet auctions.

Out of date products

68. It is illegal to supply a product after the expiry date, as detailed on the pack, has passed. Any such product should be disposed of in accordance with the wording on the product literature. Some products (for example injectables) must be discarded within 28 days after opening and this will be stated on the packaging. This is due to requirements in the EU and national legislation to ensure the stability and safety of the product. In these cases the expiry date becomes the 28th day after opening, unless the original expiry date is shorter.

Emergency wholesale supply between authorised retailers

69. An authorised retailer of veterinary medicines may supply 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 exempt wholesale dealing from the need for a wholesale dealer's authorisation.

70. Only the Manufacturer of a VMP or a holder of a Wholesale Dealer's Authorisation (WDA) may routinely supply authorised retailers with veterinary medicines. For further information please refer to VMGN 8 Wholesale Dealer's Authorisations for Veterinary Medicines, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Supplying medicines for horses

71. RQPs 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 fulfil their obligations regarding the Horse Passport Regulations. For further information please refer to VMGN 16 Guidance on Horse Medicines and Horse Passports, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Importation of veterinary medicines

72. It is an offence to import a VMP not authorised for use and to supply such a VMP in the UK, unless it is supplied under the prescription of a veterinary surgeon and with a suitable import certificate. For further information please refer to VMGN 5 Import Certificates Scheme, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Export of veterinary medicines

73. The VMD do not restrict the export of veterinary medicines. If the export is within the European Union (EU) the RQP exporting the medicine must ensure that the product can legally be sold or supplied in the importing Member State.
74. If the product is to be exported outside of the EU the VMD recommends checking the requirements for import in the country concerned. For products manufactured or marketed in the UK the VMD can issue an Export Certificate at the request of the manufacturer or exporter of the VMP. They serve to certify that the product which is to be exported out of the EU was manufactured in accordance with a UK Marketing Authorisation, if there is one, or if not, that the manufacturer holds a manufacturing authorisation in the UK for that type of product. For further information please refer to VMGN 19 Export Certificates Scheme, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
75. The export of CD raw materials and finished preparations within *Schedules 2, 3 and 4 Part 1 of the Misuse of Drugs Regulations 2001* are subject to a licensing regime which is operated by Home Office Drugs Licensing and Compliance Unit. Further guidance and information on these licensing requirements can be found on this link <http://www.homeoffice.gov.uk/drugs/licensing>

Export under a prescription from an EEA veterinary surgeon

76. Veterinary surgeons and pharmacists may export medicines within the EU against prescriptions from the European Economic Area (EEA) and Swiss veterinarians provided that they are satisfied the prescription for the product to be exported is valid and the medicines will be used in the country where the prescription was written. The supplying veterinary surgeon or pharmacist should endeavour to ensure that:
- the prescriber is appropriately registered in the relevant EEA country or Switzerland;
 - the medicines will be used in the country where the prescription was written;
 - the product can legally be sold or supplied in that Member State,
77. The Heads of Medicine Agency (HMA) publishes a list of all competent authorities in Europe and the VMD recommends contacting the relevant authority for the importing Member state before any trade commences. Details of competent authorities is available <http://www.vmd.defra.gov.uk/business/links.aspx>
78. The responsibility for supply remains with the exporting veterinary surgeon or pharmacist and care should be taken to ensure all of the above criteria are met. The veterinary surgeon or pharmacist may decide not to supply the medicine if they feel they do not have sufficient assurances to do so legally.
79. EEA and Swiss veterinarians are allowed to prescribe for animals in the UK provided that: they are registered with the RCVS in accordance with the Veterinary Surgery Qualifications (European Recognition) Regulations 2008, the animals are under their care and a clinical assessment has been carried out.

Labelling at the Time of Supply

80. The label information on the product is specifically authorised to provide necessary information for the safe and effective use of the product. This includes warnings for the user and animal owner, so it must not be obscured by any additional labelling or amendments made to the packaging.
81. A veterinary surgeon or pharmacist supplying a product against a written prescription may amend the authorised label in accordance with the prescription, for example, to change the dose. However, none of the other information on the outer packaging or the immediate container may be obscured (SQPs may only supply in accordance with the authorised label, except when supplying a product under a written prescription from a veterinary surgeon under the cascade).
82. Where a product is placed into a container which has not been authorised as part of the marketing authorisation (MA), such as tablets being supplied in a standard bottle with a child resistant closure, sufficient written product information must still be provided in writing. It may be convenient to use a copy of the package leaflet or a copy of the SPC. Copies of all authorised SPCs are published on the VMD website www.vmd.defra.gov.uk/ProductInformationDatabase.
To access the SPC, you will have to find the product, then click on the +sign to the left of the product name.
83. Where a product is supplied under the Cascade there are additional labelling requirements to be met, and these can be found in VMGN 13 Guidance on the Use of the Cascade, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Retail Supply via the Internet

84. Retailers of veterinary medicines may choose to operate their business via the Internet or mail order. The requirements of UK legislation apply, irrespective of whether a customer personally visits the premises and meets the RQP face-to-face or corresponds with the RQP by other means. Each RQP must be able to demonstrate that they operate in accordance with the VMR including the registration and inspection requirements in respect of premises.
85. There are some websites selling veterinary medicines which appear to be based in the UK but they are not. This is because anyone can purchase a 'co.uk' domain name without the business having to be in the UK. Anyone buying medicines from these websites is at risk of committing the offence of importing unauthorised veterinary medicines into the UK. There are also risks to the animal from potentially ineffective or unsafe medicines because there is no guarantee that the products supplied are genuine or have been stored correctly.
86. The General Pharmaceutical Council operates an Internet Pharmacy Logo scheme to identify legitimate on line pharmacies so that the public can be sure they are purchasing safe and genuine medicines online;
www.pharmacyregulation.org/regulatingpharmacy/registration/internetpharmacy/index.aspx

Specific Requirements for Supply of Sheep Dips

87. If the VMP is a sheep dip, of any type, the supply must be to a person (or a person acting on his behalf) who holds a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed and issued, or NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF):
- in England, Wales, and Northern Ireland by the National Proficiency Tests Council (NPTC); or by
 - NPTC Part of the City & Guilds Group; or City & Guilds NPTC;
 - in Scotland, by one of those organisations or the Scottish Skills Testing Service.
88. A record of the Certificate number must be made as soon as is reasonably practicable and kept for at least three years.
89. If the active substance of the VMP is an organophosphorus compound, the supplier must give to the buyer:
- a double sided laminated notice, as shown at Annex A, unless the notice has been provided to the buyer within the previous twelve months and the supplier knows or has reasonable cause to believe that the buyer still has it available for use. The notice must be at least A4 size with a laminated transparent cover, coloured and printed to scale on front and back substantially in accordance with two diagrams shown at Annex A, except that in Wales it may be in Welsh as well as in English;
 - two pairs of gloves, which must be non-lined, PVC or nitrile, heavy duty gauntlet style – 0.5mm thick and at least 300mm long, or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves described.

Adverse Events (AE) - Pharmacovigilance

90. Reports of any AE to a veterinary or human medicine may be made to the VMD by the animal owner, the prescribing veterinary surgeon, pharmacist or SQP, or the person who dispensed the prescription. If an animal owner wishes to seek veterinary advice about an AE in their animal they should consult the prescribing person or a veterinary surgeon. Reports of AEs may also be reported to the MA Holder as well as the VMD in order that such events may be fully and properly investigated while the event is ongoing. For further information please refer to VMGN 11 Pharmacovigilance Guidance on Adverse Events, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
91. A new electronic AE report form, which is an alternative to the existing paper version, is now available online and can be found on the home page of the VMD website www.vmd.defra.gov.uk under "Report an Adverse Event (yellow form)".
92. The VMD would like to encourage reporters to make use of this interactive form to facilitate notification of any AE in animals or humans involving VMPs, or in animals

following treatment with a human medicine. AEs can be reported for all authorised veterinary medicines, including those classified as AVM-GSL.

Further Information

93. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS. Tel: +44 (0)1932 336911; Fax: +44 (0)1932 336618 or E-mail: VMGNotes@vmd.defra.gsi.gov.uk. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website www.vmd.defra.gov.uk

ANNEX A

SHEEP DIPPING NOTICE

SHEEP DIPPING

PLEASE READ THIS NOTICE FOR YOUR OWN SAFETY

1. The product label carries important advice. Please read it and do what it says.
2. Always wear the recommended protective clothing, including gloves. Sheep dip is absorbed through the skin.
3. Always wash protective clothing before taking it off.
4. If you get sheep dip on your skin wash it off immediately.
5. If you have questions, ask your sheep dip supplier. At your merchants you should speak to the Suitably Qualified Person.
6. Read the label for instructions on measuring and diluting concentrate.
7. Check that you have spare protective clothing, especially gloves, in case of damage.

A well designed sheep dip, with splash screens to limit contamination, reduces the risks, makes the job easier and makes wearing protective clothing more practical.

Everyone doing the job must be adequately trained. If they are not absolutely sure how to dip safely consider a training course.

The recommended protective clothing is:

Face Shield (when handling dip concentrate)

Bib apron (over boiler suit) **or**
waterproof coat (PVC or nitrile)

Gloves (non-lined, PVC or nitrile, heavy duty gauntlet style – 0.5 mm thick and at least 300 mm long)

Waterproof leggings/trousers
(PVC or nitrile)

Wellington boots



For more information you are recommended to read the Government's leaflet 'Sheep dipping' (AS29rev2).

ANNEX B

VETERINARY PRACTICE PREMISES INSPECTION CRITERIA

Inspection Criteria for Veterinary Practice 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 veterinary practice premises (VPPs) and veterinary surgeons supplying veterinary medicines from those premises must be listed on the relevant RCVS register (Schedule 3 para 8)**
- **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 should be suitable for the storage and supply of veterinary medicinal products (VMPs), and:
 - be a permanent building with a fixed address; or
 - a mobile unit, if it is used for animal treatment by a veterinary surgeon and the supply and storage of VMPs. based at a fixed address (which fixed address is registered)
- In either case the premises should:
 - 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 VMPs 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 SAE S.
- A list of other sites, including vehicles, linked to the Practice and used to store VMPs should be maintained and available at the premises.

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 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 SPC.

- Ideally temperature sensitive medicines should only be taken out on vehicles on a “by use” basis, but whether being stored or transported, measures should be taken to ensure that products remain within the temperature range specified on their SPC, 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 and where there is potential for the temperature range to exceed or fall below that specified on the products’ SPC.
- 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 practice premises or in a vehicle.

4. Storage and supply of Controlled Drugs (CDs)

- **Schedule 2 and certain Schedule 3 CDs must be kept in a secure, lockable and immovable receptacle that can only be opened by a veterinary surgeon or a person authorised by a veterinary surgeon. This does not apply to any substances listed in Schedule 1 of the Misuse of Drugs (Safe Custody) Regulations.**
- It is considered good practice to have a written SOP setting out who is authorised to access the CDs cabinet and for what purposes. The SOP may also cover ordering (requisition), receipt, supply and disposal of CD.
- **Where CDs which are subject to special storage conditions are transported in a vehicle, they must be kept securely within a locked receptacle in the vehicle (which could be the locked glove compartment) and the vehicle must be locked when not attended;**
- **A CD Register of Schedule 2 drugs obtained, supplied and used must be kept in accordance with the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001. Where such drugs are supplied against another veterinary surgeon’s prescription, the name of the person collecting the drugs must be noted in the Register.**
- Ketamine should ideally be stored in a secured, locked cabinet and its use recorded in an informal register (this is a requirement of the RCVS Guide to Professional Conduct).

- The CD Register/informal register may be computerised but the system must be secure from unauthorised access and the Register/entries incapable of being amended.
- It is considered good practice to keep a running balance of each drug entry in the CD Register and for a weekly stock check to be carried out.
- **Where Schedule 2 and 3 drugs are supplied against another veterinary surgeon's prescription, a copy of the prescription, marked with the date of supply (which must be within 28 days of the date of the prescription) must be retained.** It is considered good practice to follow the same procedure when supplying Ketamine against another veterinary surgeon's prescription.
- As for other medicinal products, if it is stipulated that a CD must be used within a specific time period once broached, it should be labelled with the opening or use by date. The usage date should be observed and once expired the product should not be used and, ultimately, appropriately disposed of.
- **CDs should only be ordered from a supplier using a requisition order personally signed by a veterinary surgeon.** It is considered good practice for the veterinary surgeon to keep a copy of the requisition order in case of a query.

5. 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.
- **Schedule 2 CDs must be destroyed in the presence of an authorised witness and the resulting destroyed products and containers appropriately disposed of.**
- **A separate record should be kept of client returned Schedule 2 CDs and they should not be re-entered in the CD Register. They do not need to be destroyed in the presence of an authorised witness, but it is considered good practice to do so.**
- **Any special handling or disposal requirements, such as for cytotoxic medicines, must be observed.**

6. 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 7.1)**
- **If a medicine is supplied in its authorised packaging with labelling specified in the Marketing Authorisation (MA), for an authorised use,**

there is no legal requirement for a dispensing label to be applied and it is an offence to supply such a container if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way (Schedule 3 para 12)

- **A veterinary surgeon may break open any package containing a VMP. Where VMPs are supplied in a container other than that specified in the MA, the veterinary surgeon must ensure that the container is suitably labelled and must supply sufficient written information to enable the product to be used safely, e.g. a copy of the SPC or package leaflet can be provided, or appropriate information such as usage instructions, warnings and contra-indications can be included on the dispensing label (Schedule 3 para 9 and 12)**
- **There should be no supplies of unauthorised medicines or medicines for use outside their MA, unless supplied under the cascade (see section 6(c) (Regulation 27)**
- **If it is stipulated that a VMP be used within a specific time period once broached, it should be labelled with the opening date (alternatively the use by date can be recorded on the label but the practice should be consistent). The usage date should be observed and once expired the product should be appropriately disposed of (Regulation 8)**

(b) Supply of POM-V, POM-VPS and NFA-VPS medicines

- **For POM-V products, animals must be under the care of the veterinary surgeon, and a clinical assessment must be carried out by that veterinary surgeon before the product is prescribed and supplied (Schedule 3 para 4) and evidence should be available e.g. from random samples of clinical records.**
- **For POM-V products, a veterinary surgeon must prescribe and supply the product and authorise each transaction individually (Schedule 3 para 9) and may do so in a number of ways, e.g:**
 - hand over a medicine personally following a consultation, or instruct a fellow member of staff to supply the medicine;
 - make a note on a client's records that repeat prescriptions could be supplied to the client up until a set period of time;
 - a member of staff taking a call from a client may put a medicine aside for the veterinary surgeon to authorise before being supplied;
 - in the case of a client unexpectedly coming into the practice, by a phone call to the veterinary surgeon to authorise the supply.
- **POM-VPS medicines must be prescribed and supplied and NFA-VPS supplied by a veterinary surgeon or SQP (in relation to products for which the SQP is qualified) and each individual transaction authorised by one of those persons, as follows:**

- A veterinary surgeon must authorise each transaction in the same way as for POM-V medicines) (Schedule 3 para 9);
- an SQP must authorise each transaction by:
 - 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))
- A veterinary surgeon who prescribes a POM-V or POM-VPS medicine, or supplies an NFA-VPS medicine (or an SQP in the case of prescribing POM-VPS and supplying NFA-VPS medicines):
 - 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)

NB. In the case of supply of POM-VPS and NFA-VPS medicines, the customer does not need to be a registered client of the veterinary practice.

- When prescribing for food producing animals, SQPs should take into account the advice given by SCOPS, COWS and RUMA.
 - It is considered good practice to have a written SOP setting out the procedures for authorisation of each VMP transaction.
 - There should be a procedure to be taken when no veterinary surgeon/SQP is present to prescribe/supply VMPs, for example, in the case of a client unexpectedly coming into the practice to purchase a medicine; and evidence that the procedure has been followed.
 - **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 & 23)**
 - **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 & 23)**
- (c) **Supply of medicines under the cascade (e.g. Non-UK authorised products, authorised products used off-label, human medicines, and extemporaneous medicines)**
- There should be evidence that the cascade is being correctly followed (for example where there is an authorised veterinary medicine available clinical notes could explain why this is not being used for a particular animal).

- Relevant documents e.g. Special Import Certificates (SICs) / Special Treatment Certificates (STCs) must be available for all imported non-UK authorised products.
- **Unless the veterinary surgeon who prescribes a VMP under the cascade both supplies the product and administers it to the animal, the product must be labelled with the following information: (Schedule 3 para 13)**
 - the name and address of the veterinary surgery;
 - the name (or initials) of the veterinary surgeon who prescribed the product;
 - the name and address of the animal owner;
 - the identification (including the species) of the animal or group of animals;
 - the date of supply;
 - the expiry date of the product, if applicable;
 - the name or description of the product (i.e. name and quantity of active ingredients);
 - dosage and administration instruction;
 - any special storage precautions;
 - any necessary warnings for the user, target species, administration or disposal;
 - the withdrawal period, if relevant; and
 - the words either “keep out of the reach of children” and “for animal treatment only”.

7. Records

- **Records of receipt and/or supply of all prescription medicines must be available and contain the following information: (Regulation 23)**
 - the date of receipt/supply (supply includes administration);
 - the name of the veterinary medicinal product;
 - the batch number (except that for non-food animals 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.
- **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)**
- **All records must be retained for 5 years, except sheep dip certificate of competence numbers which must be kept for 3 years (Regulation 23(4) and Schedule 3 para 22)**
- **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**

(b) Records of products administered to food-producing animals by a veterinary surgeon (Regulation 18)

- A veterinary surgeon who administers POM medicines to food producing animals must personally enter the following information into the livestock keeper's record book or give written information to the livestock keeper (to enter):
 - the name of the veterinary surgeon;
 - the name of the product and the batch number;
 - the date of administration of the product;
 - the amount of product administered;
 - the identification of the animals treated; and
 - the withdrawal period.

(c) Records of products administered to food-producing animals under the cascade. (Regulation 24)

- A veterinary surgeon administering a VMP, which includes a human medicine or product imported under an SIC/STC, to food-producing animals under the cascade (or another person under the vet's permission) must record:
 - the date of examination of the animals;
 - the name and address of the owner of the animals;
 - the identification and number of animals treated*;
 - the result of the veterinary surgeon's clinical assessment;
 - the trade name of the product, if there is one;
 - the manufacturer's batch number shown on the product, if there is one;
 - the name and quantity of the active substances;
 - the doses administered or supplied;
 - the duration of treatment; and
 - the withdrawal period.

* when a whole herd/flock is treated with a medicine, it is acceptable to record "whole herd" or "whole flock" not every individual animal's number.

- Such records must be retained for 5 years.

8. Written prescriptions

- If issued, written prescriptions must include all the information required under the VMR (Schedule 3 para 6);
 - 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.
- A written prescription for a CD as specified in the Misuse of Drugs Regulations 2001(a) is valid for 28 days. A written prescription for a CD may be hand-written, typed in a computerised form or computer generated, but must be signed by the person issuing it. It is an offence to supply against a faxed or emailed prescription.
 - A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.
 - If the prescription is repeatable it must specify the number of times the VMP may be supplied. If the prescription is not repeatable, it is considered good practice for this to be stated.
 - When a POM-V or POM-VPS medicine is dispensed under a written prescription from another veterinary surgeon (or in the case of POM-VPS, a pharmacist or SQP) a copy of the prescription must be retained by the supplying veterinary surgeon for five years (Regulation 23). It is considered good practice for copies of prescriptions issued by a veterinary surgeon, pharmacist or SQP to be retained in case of query.

9. Audit

- A record of the most recent annual audit (Schedule 3 para 15) must be available, in particular for CDs recorded in the CD Register.
- 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.

10. 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 http://www.vmd.defra.gov.uk/pdf/register_approvedpremises.pdf under Industry Info/Feedingstuffs’ Manufacturers and Distributors); (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 16 (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 8)
- 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 VMP 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 17 (1)).
- Medicated feedingstuffs containing POM-V medicines may only be prescribed by a veterinary surgeon. A veterinary surgeon or SQP may prescribe a feedingstuff containing a POM-VPS medicine. Additional approval as a Distributor is required to supply medicated feedingstuffs. (For further information please refer to VMGN 17 Medicated Feedingstuff and Specified Feed Additives, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx (Schedule 5 Para 16 (1)).

11. 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.

12. Advertising

- **The advertising of POM-V and 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 the VMGN 4 Controls on Advertising, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx - **(Regulation 11(4))**.
- **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)).**

13. Other

- Veterinary surgeons and SQPs should be aware of SARSS and the system for reporting AEs/lack of efficacy to the MA holder or directly to VMD. Reports to the VMD can be made using the SARSS yellow form or the VMD's online service www.vmd.defra.gov.uk/adversereactionreporting/
- **Extemporaneous preparations/Specials**
A veterinary surgeon is allowed to possess and use unauthorised extemporaneous veterinary medicines for use in individual animals under the cascade. These products can be made by the veterinary surgeon or can be made by another veterinary surgeon, pharmacist or the holder of an appropriate manufacturing authorisation in accordance with the prescribing veterinary surgeon's instruction (Schedule 4 para 1). For further information please refer to VMGN 13 Guidance on the Use of the Cascade and VMGN 15 Guidance for Manufacturers, which are published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
- **Horse medicines and passports**
Vets should be aware of the Horse Passports legislation and their responsibilities regarding checking whether each horse they treat is destined for the food-chain before beginning any treatment. For further information please refer to VMGN 16 Guidance on Horse Medicines and Horse Passports, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
- **Animals (Scientific Procedures) Act (ASPA)**
The controls set out in the VMR do not apply to veterinary medicines which are being used in accordance with a Project Licence issued under the ASPA

(Regulation 3). For further information please refer to VMGN 7 Guidance on the Homeopathic Registration Scheme, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

14. Abbreviations and definitions

AMTRA	Animal Medicines Training and Regulatory Authority
ASPA	Animals (Scientific Procedures) Act
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
SIC	Special Import Certificate
STC	Special Treatment Certificate
SQP	Suitably Qualified Person
SPC	Summary of Product Characteristics
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
WDA	Wholesale Dealer's Authorisation

ANNEX C

SUITABLY QUALIFIED PERSON PREMISES INSPECTION CRITERIA

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 Small Animal Exemption Scheme.

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 (1c))**
- **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 VMP;**
 - **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 VMP;**
 - **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 VMR:**
 - 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 VMP 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 VMP (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 – http://www.vmd.defra.gov.uk/pdf/register_approvedpremises.pdf) (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 VMP 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 (For further information please refer to VMGN 17 Medicated Feedingstuff and Specified Feed Additives, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx (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 the VMGN 4 Controls on Advertising, which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx (Regulation 11(4)).
- 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

SQP should be aware of SARSS and the system for reporting AE/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

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
VMP	Veterinary Medicinal Product
WDA	Wholesale Dealer's Authorisation

List of Abbreviations

AE	Adverse Event
AHDA	Animal Health Distributors Association
AMTRA	Animal Medicines Training Regulatory Authority
AVM-GSL	Authorised Veterinary Medicine – General Sales Lists
CD	Controlled Drug
Defra	Department for Environment, Food & Rural Affairs
EC	European Commission
EEA	European Economic Area
EU	European Union
GPhC	General Pharmaceutical Council
HMA	Heads of Medicine Agency
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MFS	Medicated Feedingstuff
MS	Member State
NFA-VPS	Non-Food Animal – Veterinarian, Pharmacist, SQP
POM-V	Prescription Only Medicine - Veterinarian
POM-VPS	Prescription Only Medicine - Veterinarian, Pharmacist, SQP
PSNI	Pharmaceutical Society of Northern Ireland
PSS	Practice Standards Scheme
RCVS	Royal College of Veterinary Surgeons
RQP	Registered Qualified Person
SAES	Small Animal Exemption Scheme
SARSS	Suspected Adverse Reaction Surveillance Scheme
SIC	Special Import Certificate
SOP	Standard Operating Procedure
SQP	Suitably Qualified Person
STC	Special Treatment Certificate
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
VPP	Veterinary Practice Premises
VSA	Veterinary Surgeons Act
WDA	Wholesale Dealers Authorisation