Guidance

Retail of veterinary medicines

Prescribing or supplying veterinary medicines including requirements for registration and inspection of premises.

Guidance for vets, pharmacists and suitably qualified persons (SQPs) on prescribing or supplying veterinary medicines including the requirements for the registration and inspection of premises.

Registered Qualified Persons (RQP)

Under the Veterinary Medicines Regulations (VMR) vets, pharmacists and SQPs, collectively known as RQPs, can prescribe or supply certain categories of authorised veterinary medicines that they are qualified and registered to supply.

The distribution categories for authorised medicines 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)

The details and distribution categories for all medicines authorisaed for use in the UK can be found on the Veterinary Medicines Directorate's Product Information Database.

In addition to the above there is also an <u>exemption under Schedule 6</u> <u>of the VMR</u> that allows products for small pet animals to be supplied legally without a marketing authorisation.

For information on how to prescribe a product under the <u>cascade</u>, the provision in the VMR that allows a vet to prescribe medicines that would not otherwise be permitted, refer to the <u>cascade</u> guidance.

POM-V medicines

A POM-V medicine may only be supplied if it has been prescribed by a vet following a clinical assessment of the animal, which must be under their care.

The VMR does not define 'clinical assessment' or 'under their care' and vets should use their professional judgment to interpret what this means in individual cases. However the <u>Royal College of Veterinary Surgeons (RCVS)</u> has interpreted both phrases.

A vet may supply a POM-V product they have prescribed or, if a client requests one, issue a written prescription for the client to buy the product from another supplier. In either case, the prescribing vet must retain clinical responsibility for the treatment and the animal under their care.

The vet or pharmacist should use their specialist knowledge to check that the prescription matches their own understanding of the product. If they have any concerns about the prescription, they should contact the prescribing vet before supplying the medicine. Suppliers can refuse to supply against a prescription.

POM-VPS medicines

A POM-VPS medicine may be prescribed by any RQP. A clinical assessment of the animal does not have to be carried out when prescribing POM-VPS medicines and the animal does not have to be under the RQP's care. However, the RQP must have sufficient information about the animal and the condition to be treated to enable them to prescribe and supply the most appropriate product.

A customer may request a written prescription if they want to buy the product from a supplier other than the prescribing RQP. RQPs may supply POM-VPS medicines against a written prescription from another RQP.

Pharmacists and SQPs may supply a POM-VPS, NFA-VPS or AVM-GSL medicine for use under the cascade if prescribed by a vet against a written prescription.

NFA-VPS medicines

A NFA-VPS medicine does not have to be prescribed but it may only be supplied by an RQP, provided the requirements for supply are followed.

AVM-GSL medicines

There are no legal restrictions on the retail supply of veterinary medicines classified as AVM-GSL.

Specific requirements: vets, pharmacists, SQPs

Vets

Registration

A vet may only prescribe and supply veterinary medicines, other than those classified as AVM-GSL, if they are registered with the RCVS.

Vets may only supply medicines from premises registered with the RCVS as a Veterinary Practice Premises (VPP).

A premises will be inspected following its initial registration and then at a frequency based on the risks associated with the premises' history and the nature of the products handled.

For details of registration requirements under the VMR see the guidance on Registration and Inspection of VPPs.

Supplying

Vets must ensure that they meet the legal requirements for prescribing and supplying POM-V, POM-VPS and NFA-VPS however the product is supplied, for example, a postal supply.

A vet supplying a veterinary medicine, other than one classified as AVM-GSL, must be present when it is handed over unless they:

- authorise each transaction individually before the product is supplied
- are satisfied that the person who hands it over is competent to do so

Delegating supply

If the vet intends to delegate supply to other competent personnel, the supply must still be made from a registered VPP.

However, in exceptional circumstances, for example animal welfare reasons, a vet may instruct a <u>wholesale dealer authorisation</u> (WDA) holder to deliver medicines directly to the client's premises.

Mobile units

A mobile treatment unit operated by a vet does not require individual registration if it is linked to a registered VPP. However, it will be inspected with the practice. Refer to the section on registering trade stands.

Pharmacists

A registered pharmacist may only supply veterinary medicines, other than those classified as AVM-GSL, from premises:

- registered as a pharmacy with either the General Pharmaceutical Council (GPhC) or the Pharmaceutical Society of Northern Ireland (PSNI)
- registered as a VPP

 authorised for the storage and supply of veterinary medicines by an SQP (see Suitably Qualified Persons)

A pharmacist supplying veterinary medicines, 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

A pharmacist must ensure that they meet the legal requirements for the prescribing and supplying POM-VPS, and NFA-VPS however the product is supplied, for example, supply in a shop or postal supply.

A pharmacist may prepare and supply an extemporaneous preparation for use under the cascade, against a written prescription from a vet. The product should be made using pharmacopoeia compliant raw materials. The product should meet the requirements of the relevant general monographs of the pharmacopoeia. It may be supplied directly to the user.

Suitably Qualified Persons

SQPs may only supply veterinary medicines that they are qualified and registered to supply. For example, an SQP registered in companion animals may only supply companion animal products.

SQPs must ensure that they meet the legal requirements for prescribing and supplying POM-VPS and NFA-VPS however the product is supplied, for example, supply in a shop or postal supply.

An SQP must comply with the Code of Practice for <u>Suitably Qualified</u> <u>Persons</u>. Information on how to become an SQP is available from the <u>Animal Medicines Training Regulatory Authority (AMTRA)</u>, <u>VetSkill</u> Ltd and Vetpol Ltd.

An SQP supplying a veterinary medicine, other than one classified as AVM-GSL, must be present when it is handed over, unless the SQP:

- authorises each transaction individually before the product is supplied
- is satisfied that the person who hands it over is competent to do so

SQPs may only supply from the following premises:

- premises authorised as an SQP retailer
- a pharmacy registered with the GPhC
- a VPP registered with the RCVS

Authorised SQP Premises

Each premises an SQP supplies medicines from must be authorised separately. The premises is considered to be under the control of the business in whose name the authorisation is granted.

To be authorised and retain that authorisation, each premises must have a registered SQP. Authorised SQP retailers must notify the VMD of any proposed change to their registered SQP.

Domestic premises may be authorised as SQP retailer premises if they meet the required criteria, that is a permanent building with a fixed address. For the purpose of authorisation and inspection, the part of the premises used for the retail supply of POM-VPS and NFA-VPS medicines must be made accessible to inspectors who have given reasonable notice.

If an SQP considers that the premises in which they're operating no longer comply with the requirements of authorisation, they must immediately notify the VMD. This is necessary to ensure that the products are prescribed and supplied in accordance with the VMR and are stored correctly to maintain their quality.

You can apply for authorisation of an SQP retailer premises using the application form and guidance on <u>applying for authorisation of an SQP retailer premises</u>.

We will only authorise your premises following a satisfactory inspection. We will then inspect authorised premises at a frequency based on the risks associated with the premises' history and the nature of the products handled.

SQP retailer distribution centres

A company's distribution centre, to which POM-VPS or NFA-VPS veterinary medicines are delivered from a wholesale dealer for onward transfer to the company's own authorised SQP retailer premises, should itself be authorised as an SQP retailer premises.

The distribution centre should have a named SQP with overall responsibility for the intake, storage and transfer of POM-VPS and NFA-VPS products. The SQP does not need to authorise each and every transfer to the company's other authorised retail premises.

If the distribution centre is used to store veterinary medicines for supply to third party companies, it will need a <u>Wholesale Dealer's Authorisation</u>.

You can find all approved SQP Retailers on the Register of Approved SQP Retailers Premises.

Requirements for all RQPs

Retail supply

"Retail supply" means the supply of a veterinary medicine to the owner or keeper of an animal for administration to that animal, whether for payment or not.

Supply of a medicine can happen irrespective of who owns the medicine.

A retailer of veterinary medicines must store them, including during transport, in accordance with the terms of any instructions on the label and in accordance with the relevant summary of product characteristics.

When prescribing a medicine classified as POM-V or POM-VPS or supplying a medicine classified as NFA-VPS, 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 an authorised purpose
- must advise on its safe administration and on any necessary warnings or contra-indications on the label or package leaflet
- must not prescribe or, in the case of a NFA-VPS product, supply, more than the minimum amount required for the immediate treatment. However, it is a defence to show that:
 - the veterinary medicine prescribed or supplied was in a container specified in the marketing authorisation (MA)
 - the marketing authorisation does not permit smaller containers
 - the RQP is not a person authorised to break open the package before supply

In order to meet the above requirements RQPs must satisfy themselves by all reasonable means that the customer is competent to use the product safely; and satisfy themselves that the product is suitable for the animal concerned. The following sets out VMD's expectation of what information is likely to be necessary to be assessed by the RQP prior to supply taking place. It should be noted that this information does not necessarily need to be recorded – the information that must be kept when a veterinary medicinal product is supplied is detailed in Record keeping requirements for veterinary medicines.

For pets/companion animals the following in respect of each animal:

- 1. Species
- 2. Number of animals
- 3. Weight, of each animal if more than one
- 4. Age
- 5. Whether the animal is in general good health
- 6. Whether the animal is pregnant or lactating
- 7. Whether the animal is on any other medication
- 8. Whether the customer knows how to use the product safely/effectively
- 9. Whether the customer knows what the product is supposed to do

Whether the customer has been provided with the warnings on the SPC

For food producing animals:

As above and:

- What is the animals intended food use, for example, milk/meat/eggs
- 2. Does the customer know the applicable withdrawal period
- 3. In the case of sheep dip products, is the RQP satisfied that the person, or a person acting on that person's behalf, holds a Certificate of Competence or Level 2 Award in the Safe Use of Sheep Dips. 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
- 4. In the case of anthelmintic products for sheep and cattle, RQPs should follow the recommendations of Sustainable Control of Parasites in Sheep (SCOPS), and the Control of Worms Sustainably (COWS), respectively
- 5. In the case of horses and other equidae, whether the animal has been declared as non-food producing in their horse passport

Disclaimers

The requirements on the RQP are non-delegable and cannot be transferred to the customer. 'Disclaimers' that simply inform a customer that they must answer yes or no to a list of questions will not be considered by the VMD to meet this requirement.

Labelling at the time of retail supply

The label information on the product is specifically authorised to provide essential information for its safe and effective use. 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.

A vet or pharmacist supplying a product against a written prescription may amend the authorised label to reflect the prescription, for example, to change the dose. However, none of the other information on the outer packaging or the immediate container must be obscured. SQPs may only supply a product in accordance with the authorised label, except when supplying a product under the cascade against a written prescription from a vet.

If a product is placed into a container which hasn't been authorised as part of the MA, for example, tablets being supplied in a standard bottle with a child resistant closure) sufficient written information must still be provided to make sure the product is used safely.

There are additional labelling requirements for products supplied under the cascade.

When prescribing

"Prescribing" refers to the action of assessing the customer's requirements, which should be a clinical assessment in the case of a POM-V medicine or a medicine for use under the cascade, and deciding on the most appropriate medicine to supply for that particular animal and indication. It is the process of an RQP deciding, instructing and recording the treatment required for an animal.

RQPs can prescribe in accordance with the distribution categories for veterinary medicines for which they are qualified. A prescription from a vet may be for an authorised veterinary medicine or for a product for use under the cascade.

We refer to "prescription" as the means by which the action of prescribing is relayed to the customer. Prescriptions may be verbal or in writing.

A prescription product can only be supplied by an RQP working from a different business or premises from where the product was initially prescribed against a written prescription. However, a written prescription is not necessary when the prescribing RQP and supplying RQP are different but working on the same site, provided they interact in the transaction.

If the prescription is not repeatable, it is sensible for this to be stated on the prescription.

If the prescription has a section that states number of repeats, it is recommended that this is crossed out by the prescriber if the prescription is not to be repeated.

Written prescriptions

No particular format is required for a written prescription. But they must include the following information:

- the full name, address and contact details of the person prescribing the product, including that person's professional registration number if available
- the full name, address and contact details of the animal 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 issue date
- · the signature or electronic signature of the prescriber
- the name and amount of the product prescribed
- the pharmaceutical form and strength of the product
- for antibiotic veterinary medicines which are prescribed for prophylactic or metaphylactic purposes, a statement to that effect
- · the dosage regimen
- any warnings necessary to ensure the proper use, including, where relevant, to ensure prudent use of antimicrobials
- the words "It is an offence under the Veterinary Medicines Regulations 2013 for a person to alter a written prescription unless authorised to do so by the person who signed it"
- for food-producing animal species, the withdrawal period or a statement that the withdrawal period is equal to zero days
- if the prescription relates to a product prescribed under the cascade, a statement to that effect

 if the prescription is repeatable, the number of times the veterinary medicine may be supplied

It is a legal requirement for the prescriber to include all of the above information on the prescription. If any information is missing the prescription is not valid and no supply should be made against it. An example of a vet's prescription is available from the <u>British Veterinary Association (BVA)</u>.

Prescription pads for SQPs are available from the <u>Animal Health</u> Distributors Association (AHDA).

Prescriptions are valid from the date of signing for up to 6 months as standard or up to 28 days if a controlled drug, unless the prescriber specifies a shorter period.

It is an offence to submit a written prescription to a retailer more than once, unless it is a repeat prescription.

Prescriptions other than written prescriptions

If a veterinary medicine is supplied against a prescription that is not in writing, then the person who prescribes the product must make a record of the reason for prescribing it. This record must be kept by the prescriber for a period of five years from the date of prescribing.

Ongoing and repeat 'verbal' prescriptions

A vet can prescribe an ongoing prescription and capture the details of this in clinical notes for repeat supply by the same practice, referred to as an 'ongoing verbal prescription'.

For POM-V products, we expect the records or clinical notes to show that the vet has conducted a clinical assessment after which they prescribed a product with a dosage, any warnings, etc. In the particular case of a vet practice giving the pet owner a repeat of the medication, a 'repeat verbal prescription', then we would expect the clinical notes to detail the following:

- the product name
- the pack size/volume/quantity of the product

- the dosage instructions
- any necessary warnings or instructions
- either a frequency and time period, for example "1 bottle a month for the next 3 months", or a number of repeats, for example "can be repeated twice".
- an end time for the repeats, for example the decision on when the vet next wants to see the animal

When the vet prescribes a product for treatment across several months, they should consider the age or life stage of the animal and whether the weight is likely to change during the period covered by the prescription. This is to ensure that the person dispensing is clear on which products should be dispensed in the situation of weight loss or gain.

The vet should record in the clinical notes what action should be taken if the animal's weight changes. They should make it clear that the animal's weight needs to be checked prior to the medicine being supplied, and a record of that weight check should be made on the clinical notes. If a change to the animal's weight would mean that a different presentation of the same product would be required, for example 2-10kg to 10-20kg, the vet should note either:

- the presentation and pack size to be supplied in the case of weight change, or
- the need to have another full check-up before a different product can be supplied.

In all cases of supply under a verbal repeat prescription, the 'competent person' to whom the vet has delegated handing over the product must check the animal's details before completing the supply, for example to confirm that it is the same animal, whether its weight has changed or whether it is pregnant/nursing.

Prescriptions for Controlled Drugs (CDs)

There are specific requirements for prescriptions for CDs.

Prescriptions for antimicrobials

A vet who prescribes antimicrobials must ensure that the product is prescribed for the most limited period that is consistent with the risk to be addressed.

Prescriptions for antibiotics

Subject to the professional obligations of a vet to ensure the health and welfare of animals under their care, a vet must not prescribe an antibiotic to be used:

- routinely
- to compensate for poor hygiene, inadequate animal husbandry, or poor farm management practices, or
- to promote growth or increase yield

A vet must not prescribe an antibiotic veterinary medicine for prophylactic purposes, unless it is an exceptional circumstance where the risk of an infection or of an infectious disease is very high and where the consequences of not prescribing the antibiotic are likely to be severe.

A vet must only prescribe an antibiotic veterinary medicine for administration to a group of animals for prophylactic purposes if:

- the rationale for prescribing the product to the group of animals is clearly recorded by the vet prescribing it, and
- a management review is carried out by a vet when the antibiotic is administered, or as soon as reasonably practicable afterwards, to identify factors and implement measures to eliminate the need for future administration due to the same circumstances

A vet who prescribes an antibiotic veterinary medicine must make a record of the details of fulfilling the above conditions and keep the record for at least five years.

Further information can be found under the antimicrobial resistance guidance.

Prescription tampering

Anyone supplying a veterinary medicine against a written prescription must take reasonable steps to ensure the prescription is genuine. Anyone who alters a written prescription without authorisation to do so by the prescriber is committing an offence under Schedule 3, paragraph 5(3) of the VMR. 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 their 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.

Prescribers may choose to use methods such as stickers or serial numbers to help with this. If the supplier doubts the validity of a prescription then they should telephone the prescriber to check its validity.

Unless the use of electronic transmission for prescriptions is an agreed and familiar practice between the prescriber and supplier or it is needed urgently to avoid an animal suffering, the supplier should make sure they have the original hard copy prescription before supplying the medicine.

How to reduce or discourage unauthorised alterations

For prescribers:

- placing a poster in the practice waiting room educating clients that it is an offence under the Veterinary Medicines Regulations (VMR) to alter a written prescription (Schedule 3 para 5(3))
- vets use only the prescription template offered by the BVA or other reputable organisations
- SQP use only the prescription template offered by AHDA

- RQP use typed text rather than handwritten prescriptions
- RQP write quantities as numbers and text
- RQP initial and date any alterations to hard copy prescriptions
- RQP include a sequential numbering system on prescriptions, where a unique identifier is added enabling suppliers to check with prescribers
- RQP recommend clients obtain medicines from internet retailers who are accredited by the VMD's Accredited Internet Retailer Scheme (AIRS)
- RQP can email prescriptions directly to the dispensing business (if known)

See here for a list of accredited internet retailers.

For suppliers:

- if the client is new, telephone the vet named on the prescription
- check the name and address of the vet or practice on the RCVS website. Not all veterinary premises are published on the RCVS website, if in any doubt contact the RCVS.
- check the name and address of the pharmacist on the GPhC or PSNI website
- check the <u>List of SQPs</u> and <u>Register of Approved SQP Retailers</u>
 <u>Premises</u>
- if the prescription is unclear or there are amendments check with the prescriber
- if you do dispense against faxed or emailed prescriptions ask for the original prescription

For online retailers:

do not offer template electronic prescriptions on websites
 when a client adds a Prescription Only Medicine to their 'basket'
 or when proceeding to the checkout, include a warning that
 tampering with a prescription is an offence

Anyone who becomes aware of potential prescription misuse should report it using this form

Retail supply via the internet

The VMR apply to the sale of veterinary medicines on the internet in the same way as they do to 'over the counter' sales. Anyone wishing to sell veterinary medicines online must have the appropriate authorisation or registration in place to supply those medicines.

Internet retailers and online suppliers of POM-V, POM-VPS and NFA-VPS medicines must register with the VMD. An application for registration must be submitted at least two months before the sale of the veterinary medicines begins.

Internet retailers of AVM-GSL medicines only do not have to register and will not be included on the register.

The VMD has published a Register of Online Suppliers of veterinary medicines.

The internet retailer or online supplier must include on each part of the website where the product is offered—

- the statement "registered internet retailer of veterinary medicines"
- the contact details of the Secretary of State, and
- a link to the register published by the VMD

Information on how to register to supply POM-V, POM-VPS and NFA-VPS veterinary medicines on the internet can be found on the <u>Sell</u> <u>veterinary medicines on the internet GOV.UK</u> page.

Import and export of veterinary medicines

It is an offence to import a veterinary medicine that is not authorised for use in the UK unless it is under an import certificate issued by the VMD. For more information refer to the Special Import scheme guidance.

The VMR allow the export of veterinary medicines, for more information see <u>guidance on export certificates</u>.

Vets and pharmacists may export medicines directly to other countries provided that:

- they are satisfied the product to be exported can be lawfully supplied or administered in that country
- the product is exported directly and not supplied to another person to transport to that country (unless they are a recognised courier)

Supply of sheep dip

A sheep dip must be prescribed for a specified group of sheep on a particular farm and can only be supplied to a person, or a person acting on their 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.

A contract sheep dipper who holds this Certificate or Award can collect sheep dip on behalf of a farmer – if this dip has been prescribed for that farm. They cannot buy sheep dip to sell on to the farmer, or bulk purchase dip to use on an ad hoc basis.

The supplier must make a record of the Award or Certificate number as soon as is reasonably practicable and keep it for at least three years.

When supplying a product containing an active substance that is an organophosphorus compound, the supplier must give the buyer a double-sided laminated notice. This is 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.

The notice must be at least A4 size with a laminated transparent cover and must tell the user of the sheep dip:

- to read and act in accordance with the label, including instructions on measuring and diluting concentrate
- that sheep dip is absorbed through the skin
- always to wear the recommended protective clothing, including gloves, and have spare protective clothing available
- · always to wash protective clothing before taking it off

to direct any questions to the supplier or manufacturer

The notice must contain a diagram showing recommended protective clothing. In Wales the notice may be in Welsh as well as in English.

The supplier must also provide two pairs of gloves which must be non-lined, PVC or nitrile, heavy duty gauntlet style. They must be 0.5mm thick and at least 300mm long or provide demonstrably superior protection to the user than gloves of these specified measurements.

Mobile sheep dippers are expected to comply with the Mobile Sheep Dipping Code of Practice For Farmers, Mobile Dipping Contractors and Prescribers published by the Sustainable Control of Parasites in Sheep (SCOPS) group, including the requirements for a contractor to purchase and store sheep dip containing organophosphates for up to 7 days in advance.

Buying groups

RQPs may supply POM-VPS medicines to farmers who are members of a buying group provided they fulfil the prescribing requirements of the VMR and the record keeping requirements detailed in Record-keeping Requirements for Veterinary Medicines.

To comply with these requirements the RQP must have made contact with each member of the buying group and have knowledge of the animals to be treated.

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 POM-VPS medicine and does not take ownership of the goods supplied at any time.

Auctions

Veterinary medicines, apart from AVM-GSL and products marketed under the Exemption for Small Pet Animals should not be offered or supplied via auctions, including on the internet.

Out of date products

It is illegal to supply a product, even if free of charge, after the expiry date shown on the pack. Any out of date products should be disposed of in accordance with the wording on the product literature.

Some products, for example injectables, once opened must be discarded after a period of time stated on their packaging. This is due to EU and national legislative requirements to ensure the stability and safety of the product. The expiry date is usually 28 days after opening but it can be shorter or longer.

Emergency wholesale supply between authorised retailers

An authorised retailer of veterinary medicines may supply products they are qualified to supply to another authorised retailer to relieve a temporary supply shortage, without a wholesale dealer's authorisation (WDA). This exemption from the VMR is intended to prevent shortages of available medicines causing animal welfare problems and should not be a regular occurrence. It is not intended to exempt wholesale supply from the need for a WDA.

Only the <u>manufacturer</u> of a veterinary medicine or a holder of a WDA may routinely supply authorised retailers with veterinary medicines.

Supply of samples

Vets, pharmacists, holders of a manufacturing authorisation and holders of a wholesale dealer's authorisation may only supply a veterinary medicine for promotional purposes, if samples of the product are labelled in a way that clearly identifies them as samples to:

- sales representatives who are responsible for promoting the product, or
- those entitled to supply the product during sponsored events.

Antimicrobial veterinary medicines must not be supplied for promotional purposes.

Trade stands

Trade stands can be registered as a VPP, SQP retailer premises or pharmacy at a trade show or exhibition for the retail supply of veterinary medicines provided that the stand is within a permanent building, such as an exhibition hall, with a specific address, and the relevant storage requirements of the medicines are met.

Supplying medicines for horses

Refer to specific guidance on <u>Horse Medicines and Horse Passports</u> record keeping.

Inspection of retail premises

We inspect authorised SQP retailer premises and registered VPPs, except those VPPs accredited by the RCVS as <u>Practice Standards</u> <u>Scheme (PSS) premises</u>, to ensure they comply with the VMR.

Inspections are carried out on a risk basis; the higher the risk the more frequent the inspections. VPPs are inspected at least every four years. SQP retailers' premises are inspected at least every four to six years depending on the medicines being supplied. The VMD will generally give retailers reasonable notice that they intend carrying out a routine inspection.

The VMD have published inspection criteria for <u>SQP Retailer</u> Premises and non-PSS VPPs.

There is further information on the inspection process on our Registration and inspection of veterinary practice premises page.

Inspectors are authorised under the VMR 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
- examine any documentation or records relating to the manufacture, assembly, storage and distribution of veterinary medicines

Following an inspection, the inspector will give the retailer a report detailing any deficiencies, also referred to as non-compliances. For major and critical deficiencies, the inspector will request details of the measures that have been, or will be, taken to correct them.

The VMD categorises deficiencies as critical, major and other (minor). The report will also include recommendations; observations made by the inspector which, whilst not a legal requirement, would be considered good practice.

Minor (Other) Deficiencies:

- minor and poses no potential risk to human or animal health, or the environment
- does not indicate a significant deviation from the requirements of the VMR, Codes of Practice or Guidance
- cannot be classified as either critical or major because there is insufficient information to classify it as such

Major Deficiencies:

- non-critical but has produced, or has the potential to produce, a
 possible risk to human or animal health or the environment
- · a major deviation from the requirements of the VMR
- a failure to carry out satisfactory procedures to ensure that products are manufactured, stored or distributed in accordance with their specific requirements
- 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
- 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
- a significant deviation from the requirements of the VMR through serious negligence or intent

Inspections are scheduled at intervals based on the number and type of deficiencies noted during an inspection, as follows:

Inspection findings	Compliance category	Inspection Points*	Max inspection interval in months by category		
			VRP, L*, A* AM*	L, A AM	C, E, AS, AJ, AC
0 deficiencies; recommendations only	5	0	48	60	72
1-6 minor (other)	4	1-6	48	60	72
More than 6 minors and/or 1-3 Majors	3	7-21	36	45	54
3 Majors plus 1 or more minors up to and including 5 Majors	2	22-35	24	30	36
More than 5 Majors and/or any Critical	1	36 and over	12	15	18

^{*}A minor deficiency = 1 point, a Major deficiency = 7 points and a Critical deficiency = 36 points

Key to table:

Category	Category name	Activity description
VPP	Veterinary Practice Premises	Premises registered with the RCVS as practice premises
L	Livestock	SQP premises authorised to supply livestock medicines, with the exception of vaccines and sheep dips

Category	Category name	Activity description			
L*	Livestock	SQP premises authorised to supply livestock medicines, including the supply of vaccines and sheep dips			
A	Avian	SQP premises authorised to supply avian medicines, with the exception of vaccines			
A *	Avian	SQP premises authorised to supply avian medicines, including the supply of vaccines			
С	Companion	SQP premises authorised to supply companion animal medicines			
E	Equine	SQP premises authorised to supply equine medicines			
AM*	Agricultural Merchant*	Approved retail supplier of veterinary medicinal products by SQPs, including the supply of vaccines and sheep dips			
AM	Agricultural Merchant	Approved retail supplier of veterinary medicinal products by 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 SQPs			
AJ	Horses Only	Approved retail supplier of veterinary medicinal products for the treatment of horses only by SQPs			
AC	Companion Animals Only	Approved retail supplier of veterinary medicinal products for the treatment of companion animals only by SQPs			

Enforcement

For the most serious deficiencies or failure to comply with the VMR, we may take formal action in accordance with our <u>Enforcement Policy for animal medicines</u>.

If we decide to suspend or revoke an authorisation, retailers have the right to <u>appeal against that decision</u>.