

# Suitably Qualified Persons (SQPs) Code of Practice

May 2024

Issued by the Secretary of State for the Department for Environment, Food and Rural Affairs under the Veterinary Medicines Regulations

Together with commentary and guidance from AMTRA February 2025



#### INTRODUCTION FROM AMTRA

The SQP Code of Practice that follows is, in legal terms, issued by the DEFRA Secretary of State, which in practice means the VMD.

It's a document which does a number of things:

- it sets out what VMD expects of AMTRA
- it quotes a few (but not all) relevant bits of the Veterinary Medicines Regulations (VMR) which are legal obligations on RAMAs/SQPs
- it clarifies or amplifies or adds to some of those legal requirements
- it then adds a few other potentially relevant bits and pieces as further background

It's an important document and you as an AMTRA RAMA/SQP are expected to comply with it, but also with the Regulations more generally, and to take account of VMD's guidance, plus where relevant guidance from SCOPS and COWS.

Over the years AMTRA has produced various bits of clarification and interpretation, often in response to queries from students or qualified RAMAs/SQPs, as well as seeking further clarification on some points direct from VMD.

We've decided to bring all this together into a single document which we hope will be more useful as a reference source whether you are studying to gain your AMTRA qualification, or are an experienced RAMA/SQP.

# **Understanding this AMTRA document**

Text written like this forms part of the Code of Practice, but is largely background or not directly relevant to you as a RAMA/SQP. Read it by all means, but we suggest that for most of you, it will not be a section to linger on.

Text written like this is a part of the Code as written and issued by VMD. You should be aware of these sections and should comply with them.

Text written like this is AMTRA guidance and commentary on the Code (some of which is the result of discussions with VMD), and is expected to be helpful in interpreting and following the Code. In some places we have stated what AMTRA expects, and we will take this into account in any cases that come to our Professional Standards Committee.

Unless the context requires otherwise we use the phrase "the Regulations" where the VMD say "VMR".

Feedback on our commentary and guidance, and suggestions identifying any further gaps in interpreting VMD's Code or the Regulations that we should address in the future, would be very welcome.

#### SCOPE

- 1. This Code of Practice ('the Code') sets down the standards for:
  - i) bodies that have been recognised by the Secretary of State as suitable to maintain a register of Suitably Qualified Persons 'registration bodies'.
  - ii) Suitably Qualified Persons (SQPs) who are registered with a registration body and who can prescribe and supply veterinary medicines classified as POM-VPS and NFA-VPS in accordance with the registration the SQP holds. This applies equally to all SQPs whether working in authorised SQP retailer premises, registered veterinary practice premises or registered retail pharmacies.
- 2. Any breach by an SQP of the standards in this Code of Practice that is drawn to the attention of a registration body, including breaches of the Veterinary Medicines Regulations 2013 (VMR), shall be dealt with by that body in line with the disciplinary process referred to in paragraph 16. The Secretary of State may also take action under the VMR.

Note that the 2013 Regulations were heavily amended by the Veterinary Medicines Regulations (Amendment etc.) Regulations 2024: any references to the 2013 Regulations should be taken to be the amended version.

The 2024 amendments apply only to Great Britain (England, Scotland and Wales), so there are two versions of the 2013 Regulations, applying either to Northern Ireland or to Great Britain. This Code of Practice is, however, UK-wide and should be followed by all AMTRA RAMAs/SQPs wherever they are working in the UK.

AMTRA has a Professional Standards Committee that will consider complaints in writing against named RAMAs/SQPs. Anyone (including RAMAs/SQPs, vets, animal owners) can submit a complaint. More information on the AMTRA website <a href="mailto:amtra.org.uk/Complaints">amtra.org.uk/Complaints</a>

We will consider any complaint about a potential breach of the Code, the Regulations, or more generally failing to act professionally: this is deliberately slightly broader than the obligation on AMTRA imposed by the Code.

AMTRA has a Memorandum of Understanding with VMD under which VMD may report information on non-compliances to AMTRA for action under our Professional Standards Committee. They will often take action directly themselves, including through Improvement Notices.

AMTRA may undertake audits or other information-gathering, which may lead to advice to support the RAMAs/SQPs involved, but could lead to action through the Professional Standards Committee.

See also paragraph 16.

3. Guidance for premises that are approved by the Secretary of State to hold and supply veterinary medicines by SQPs is published on GOV.UK under Veterinary Medicines Guidance. The inspection criteria for retail premises the VMD inspects are available from our Inspections Administration Team (inspections@vmd.gov.uk). The criteria are available on the VMD website here and VMD inspectors will base their inspections on this criteria.

The Inspection Criteria for SQP retailer premises are included by AMTRA along with the Code of Practice in our Training Manual and our Compendium, and linked from the guidance on the AMTRA website <a href="mailto:amtra.org.uk/CodeAndGuidance">amtra.org.uk/CodeAndGuidance</a>

Note also the inspection criteria for veterinary practice premises, which are also linked from the AMTRA website link given above.

#### **LEGISLATION**

4. The VMR are periodically reviewed and amended and/or supplemented. This ensures the provisions remain current and fit for purpose. The Code will be updated if future versions of the VMR make changes to the requirements relating to SQPs or SQP registration bodies. Please advise the VMD if you believe there are any errors in the Code.

At the time of writing the current Veterinary Medicines Regulations are from 2013, but heavily amended by the Veterinary Medicines (Amendment etc.) Regulations 2024

The 2024 amendments to the 2013 Veterinary Medicines Regulations apply only in Great Britain (England, Scotland and Wales), so a different version of the 2013 Regulations applies in Northern Ireland. (See also paragraph 2.).

This Code of Practice dates from May 2024, though it may be updated at any time. This version with linked AMTRA notes and guidance may be updated more often, and the latest version will always be at <a href="mailto:amtra.org.uk/CodeAndGuidance">amtra.org.uk/CodeAndGuidance</a>

- 5. Schedule 3 Paragraph 14 of the VMR states:
- 1. The Secretary of State may recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS
- 2. In order to recognise such a body, the Secretary of State must be satisfied that the body:
- (a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations
- (b) has adequate standards in deciding whether or not to register someone as a suitably qualified person
- (c) maintains a programme of continuing professional development for persons registered with it
- (d) operates an adequate appeal system if it intends to refuse to register anyone with the appropriate qualifications or to remove anyone from the register

[...]

7. The Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph must take appropriate action in accordance with any disciplinary code that applies to that body if a suitably qualified person registered with it does not comply with the Code of Practice

# Offences relating to supply by an SQP

6. It is an offence under the VMR and a breach of this code (see paragraph 2) for an SQP to:

- supply a POM-VPS or NFA-VPS medicine (as described below) unless the SQP supplies the product in accordance with the VMR
- supply a veterinary medicine that has passed its expiry date
- supply a medicine that has not been stored (including during transport) in accordance with the terms of any specific instructions on the label of the product and in accordance with the relevant summary of product characteristics
- import an authorised veterinary medicine that the SQP is not permitted to supply in the UK
- fail to keep records on the receipt or supply of POM-VPS medicines
- possess an unauthorised veterinary medicine supply an unauthorised veterinary medicine
- supply a veterinary medicine unless it is in its original packaging or immediate packaging; if the product is not supplied in its original packaging, sufficient written information which may

include a copy of the summary of product characteristics or the package leaflet – must be provided to enable the product to be used safely

- add or change the authorised label or any of the information provided on the product literature (including covering any safety information) unless the amendment is in line with the prescription from a vet against which the supply is being made (see also paragraph 31)
- supply a POM-VPS or an NFA-VPS product for administration under the cascade unless it is supplied against a written prescription by a vet for that purpose
- substitute a different product for a medicine that has been prescribed by another SQP, a vet or a pharmacist.

"Supply" (sometimes described as "retail supply") includes supply free of charge.

Note the newly highlighted requirement for RAMAs/SQPs to ensure that medicines are stored (including during transport) in accordance with their SPC/label.

For avoidance of doubt, the  $6^{th}$  bullet point should really be written as two:

- possess an unauthorised veterinary medicine
- supply an unauthorised veterinary medicine

See paragraph 46 for more on "immediate packaging".

Reference to the "cascade" here is to the prescribing cascade under which a vet, under certain circumstances, may prescribe a product for use off-label: the key point is that a RAMA/SQP must not supply a POM-VPS or NFA-VPS product for administration outside the terms of the SPC ("off label"), unless acting under a written prescription from a vet.

7. Penalties under the VMR apply to an SQP, as well as a corporate body or partnership, if the offence is proved to have been due to any consent, connivance or neglect on their part (Regulation 44(2)).

In other words, it's not just your direct actions that must meet the rules: additionally, indirect ones such as consent, connivance or neglect can be failures to comply, too.

#### **REGISTRATION BODIES**

- 8. Registration bodies that have been recognised by the Secretary of State to provide training and registration for SQPs are published on GOV.UK.
- 9. The VMD requires a body that wishes to become recognised by the Secretary of State to submit an application that includes:
  - full details of how it intends to carry out its functions
  - details of the premises and staff
  - information on its establishment within the UK
  - how it intends to maintain operations over a period of at least 5 years.
- 10. Qualifications arranged by the body must be accredited as a training programme at higher education level (level 4 or above). However, qualifications may be accepted at level 3 if the SQP qualification is integrated within a broader veterinary nursing qualification. This should be consistent with the framework set out by England's statutory regulator for qualifications (Ofqual), the UK's Quality Assurance Agency for Higher Education (QAA) or the Scottish Credit and Qualifications Framework (SCQF) framework.
- 11. Each registration body is expected to provide their own syllabus. The syllabus must include:

- basic knowledge of anatomy, physiology and nutrition
- knowledge of the legislation relevant to SQPs
- information on products sufficient to enable an SQP to prescribe and retail supply the most appropriate veterinary medicine for the target species, the disease or condition and advise on its safe use, storage, handling, waste disposal, and despatch/distribution in accordance with Schedule 3 Paragraph 14(5) of the VMR
- how to obtain knowledge of the type of environment that the animal is kept in, for example farm, stables, kennels, small holding or private residence, in order to give appropriate advice
- how to interpret Animal Health Plans
- disease control/parasite control strategies (including husbandry methods which minimise disease and medicines interactions)
- information on who can prescribe and retail supply each class of veterinary medicine and how to report adverse events to the VMD and marketing authorisation holders (MAHs)
- strategies to optimise the use of medicines and to minimise the development of resistance, for example anthelmintic resistance
- recognition of the limits of an SQP's knowledge and competence and when to refer a customer to a vet
- the requirements for authorised premises
- the requirements for supplying against a written prescription.
- 12. A modular approach to the separate areas of expertise should be followed with at least the following modules:
  - Farm animals
  - Avian poultry and other birds
  - Equines
  - Companion animals, including dogs, cats and rabbits.
- 13. The body must be prepared to arrange further modules to meet the needs of specific sectors if requested by the VMD.
- 14. The body must implement and maintain a system of mandatory Continuing Professional Development (CPD) for all SQPs registered with it.
- 15. The body must provide a monthly update to the VMD on the SQPs registered through their training. This update must include:
  - the name of the person
  - the modules that they have completed successfully
  - a geographical reference such as the town in which they live.

The VMD publishes a list of SQPs on GOV.UK and updates it monthly.

16. The body must have a published disciplinary process. This must be used by the body if it intends to refuse entry to the register to anyone who is qualified. This process should include disciplinary action for the removal of anyone from the register if they have breached the Code. The process must include an independent appeal process.

#### See also paragraph 2

- 17. A body applying for registration should submit a forecast of income and expenditure for a period of at least 5 years. Approved bodies must provide details to the VMD of their charges and expected income and spending at the beginning of each financial year.
- 18. Registration bodies will allocate numbers to SQPs so the categories they are able to prescribe and retail supply for can be identified.

# **REGISTERED QUALIFIED PERSONS**

- 19. There are 3 different types of Registered Qualified Person (RQP):
- a veterinary surgeon who is registered with the Royal College of Veterinary Surgeons (RCVS)
- a pharmacist who is registered with the General Pharmaceutical Council (GPhC) or the Pharmaceutical Society of Northern Ireland
- an SQP who is registered with one of the bodies approved by the Secretary of State

You may occasionally see the term R-SQP, meaning an SQP with the prefix 'R' in their AMTRA Number (such as QR98765), where the 'R' in this context means 'all species': it's important to avoid confusing R-SQP and RQP. You are expected to understand "RQP".

20. Schedule 3 Paragraph 14(3) states:

(3) For the purposes of these Regulations, a suitably qualified person is a person who has passed examinations specified by such a body, and is registered with such a body as a suitably qualified person.

## **Distribution Categories**

21. Schedule 3 of the VMR deals with classification and supply of veterinary medicines. Each authorised veterinary medicine is granted a distribution category when it is authorised. Changes to these categories may be made, for example, for reasons of safety or availability. All currently authorised veterinary medicines are listed on the VMD's Product Information Database which SQPs should be familiar with and know how to use. Any medicines that have been recently changed will be highlighted in yellow.

For the most part, changes to the authorised details of medicines, including the distribution category, will in practice take effect when you encounter updated packaging. However, where there are particular safety concerns, changes may be implemented immediately so read carefully any notices you receive regarding such changes.

#### 22. The distribution categories under the VMR are:

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

Prescribed by a vet and supplied by either a vet or a pharmacist.

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

Prescribed by any one of the RQPs and supplied by any one of them.

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

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

Supplied by any retailer.

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

In addition, while not formally a distribution category, there are products marketed under the Exemption Scheme for Small Pet Animals (also known as the Small Animal Exemption Scheme or SAES), which may be supplied by any retailer.

There are also Specified Feed Additives (SFA) which again are not a distribution category as such, but are subject to Schedule 5 of the Veterinary Medicines Regulations — see VMD's guidance "Manufacture and supply of medicated feedingstuffs".

While businesses may choose to supply AVM-GSL or SAES medicines without the involvement of a RAMA/SQP, nevertheless AMTRA expects that any RAMA/SQP involved in the supply of such medicines will do so professionally.

# **SQPs' DUTIES AND RESPONSIBILITIES**

23. All SQPs must follow this Code of Practice.

As discussed under paragraphs 2 and 4, this version of the Code of Practice is UK-wide and must be followed by all AMTRA RAMAs/SQPs, including those working in Northern Ireland, even though the 2024 amendments to the Regulations apply only to Great Britain.

- 24. Prospective SQP students should ask a registration body for information on the syllabus and courses available before registering to ensure it meets their training and qualification needs.
- 25. An SQP may only retail supply products that have been authorised with a distribution category of POM-VPS, NFA-VPS or AVM-GSL.

See comments under paragraph 22.

26. An SQP may only prescribe and/or retail supply the products that fall within the scope of the registration they hold.

Registrations are separated as follows or may be combined:

- all animals (including food and non-food producing)
- farm animals (livestock)
- avian poultry and other birds
- · companion animals including dogs, cats and rabbits
- equines.

For avoidance of doubt, the AMTRA division of species modules has significant overlap between the Farm and Avian modules. Those who have the Farm registration status are permitted to prescribe and supply poultry POM-VPS medicines and do not need the separate Avian module which is aimed at those who want to prescribe/supply for avians but not other farm animal species.

- 27. Other types of registration categories may be provided as described under paragraph 13. An SQP may opt to be registered for a single category if that is allowed by their registration body.
- 28. It is the duty of an SQP to comply with their professional responsibilities and ensure that the legal requirements for prescribing and retail supply of veterinary medicines classified POM-VPS and NFA-VPS are complied with, however the product is supplied, for example in-store, postal or online supply.

This is a fundamental point – the rules must be complied with, regardless of the route of supply, but also regardless of other circumstances: for instance, a long-standing relationship with a customer may reduce the need for detailed conversations but does not remove the need to be able to demonstrate that you have complied with the obligations in the Regulations and this Code.

The rules also apply to you personally as a RAMA/SQP: instructions or pressure from a colleague or management does not absolve you of a personal responsibility (both professional and legal) to ensure you comply with the rules. If you suspect another RQP elsewhere may not comply with the rules, that is not justification for you not to comply: consider making an anonymous report to the VMD, or making a written complaint to AMTRA (or other professional body where relevant).

29. SQPs should assure themselves that the medicines they are supplying have been appropriately obtained and stored; and where applicable, unsaleable products are appropriately disposed of. SQPs have a duty to report any issues of non-compliance with the VMR at authorised premises to the VMD. For example if the SQP is aware that sales of VPS medicines are being made without appropriate RQP oversight. Report any information you have about suspected illegal medicines and breaches of the VMR to <a href="mailto:enforcement@vmd.gov.uk">enforcement@vmd.gov.uk</a> or by using the reporting tool which can be found <a href="mailto:here">here</a>.

In practice you may reasonably raise concerns with management first, but if there is not a quick and satisfactory resolution, you should notify the VMD: this can be done anonymously via their reporting tool at <a href="https://www.gov.uk/quidance/report-illegal-animal-medicines">https://www.gov.uk/quidance/report-illegal-animal-medicines</a>

While there does not appear to be a similar legal requirement on RAMAs/SQPs working in Veterinary Practice Premises or Pharmacies, AMTRA would strongly encourage similar discussion and then reporting in case of non-compliance.

30. All SQPs must undertake CPD to meet the requirements and standards set by their registration bodies to ensure they keep up to date. For example, SQPs can:

- undertake additional learning
- read relevant publications, such as books or trade journals
- gain practical experience by taking on a relevant new role
- work shadow a colleague who works in a different area of the business.

To continue to be registered an SQP must satisfy their registration body that they have fulfilled their CPD requirements.

Every AMTRA RAMA/SQP has a personal minimum CPD obligation, which may include an overall points minimum and potentially also minimum points of a particular type. See the Frequently Asked Questions and other guidance on the AMTRA website <a href="mailto:amtra.org.uk/CPD">amtra.org.uk/CPD</a> and on the regular emailed and posted CPD points updates.

31. An SQP may retail supply an authorised veterinary medicine that falls within the scope of the registration they hold, against a prescription from a vet for use under the prescribing cascade (Schedule 3 Paragraph 14 of the VMR). Where a product is supplied under the cascade, it must be labelled in accordance with the requirements specified in the VMR. Further information on the cascade and the labelling requirements is available on GOV.UK under Veterinary Medicines Guidance.

This should be read in conjunction with paragraph 44.

AMTRA considers that the supplying RAMA/SQP should have a registration status including the species categories relevant to the label of the authorised medicine and the species it has been prescribed for.

If the prescription is one which is "off-label" by a veterinary surgeon, then AMTRA considers the supplying RAMA/SQP should have a registration which covers both the medicine itself and the animals it is being supplied for. So for example, a farm-animal medicine being prescribed for an equine should only be supplied by someone with farm and equine registration (R or G prefix in the AMTRA Number).

If you supply a POM-VPS medicine against a written prescription from another prescriber, you must retain a copy of the prescription for five years.

# REQUIREMENTS FOR PRESCRIBING AND SUPPLY Prescribing

- 32. To retail supply a POM-VPS medicine, an SQP first has to prescribe it, unless they are supplying against a written prescription from another RQP. Prescribing covers both the decision-making process on which veterinary medicine to supply and the decision itself. When prescribing, SQPs must take into account:
- the disease/condition of the animals requiring treatment
- the type of holding and the animals being treated
- the authorised veterinary medicines on the market, and their warnings and contra-indications
- the responsible use of medicines (further information on this can be found in paragraphs 39-41)
- the requirement to prescribe the minimum amount of medicine needed for the treatment and condition presented (subject to the minimum pack size manufactured and whether the packs can be split without contravening the VMR; further information on this can be found in paragraph 46)
- the requirement for the person receiving the product to use it for an authorised use
- the abilities and competence of the person administering the product
- any available farm or animal health plan

Where a medicine is supplied in accordance with a prescription which is not a written prescription, the person who prescribes the product must make a record of the reason for prescribing that product; their prescribing rationale.

All these elements are important, and any RAMA/SQP should be able to justify on each transaction that they have satisfied these obligations.

"Written prescription" in this context means one which satisfies the requirements of paragraph 33. Any other prescription may be regarded as "verbal" and requires the record of the reason for prescribing that product, including information known or not known.

In practice, SQPs will rarely issue written prescriptions consistent with paragraph 33 of the Code, but if they do, AMTRA would strongly recommend that the "reason for prescribing that product" be recorded in all cases.

Any other prescription should be regarded as "verbal" (including, for instance, those resulting from email exchanges, or information otherwise recorded in a computer system) and requires the record of the "reason for prescribing that product".

Such records may be inspected by VMD at routine inspections or requested at other times; AMTRA may look at such records if we are considering a complaint against an SQP.

#### Prescribing rationale - things to think about

All POM-VPS medicines must be prescribed – including a decision by the prescriber as to which product to prescribe (and usually supply).

- Paragraph 32 of the Code sets out 8 bullet points involved in prescribing decisions.
- Paragraph 38 of the Code sets out VMD's expectations of minimum information likely to be needed to prescribe
- Paragraphs 39 to 41 of the Code set out further obligations around prescribing choices, particularly in the context of responsible use and requirements to follow SCOPS and COWS guidance.

How did you reach that prescribing decision taking into account all of the above? What information was available? What information was not? Why did you prescribe product A with active ingredient X, rather than product B with active X or product C with active Y? Why that pack size?

"The customer said they wanted to worm their sheep" is not a satisfactory answer. "To treat against fluke" is not a satisfactory answer — indeed when a flukicide has been prescribed, it adds no information at all!

How many sheep, what weights, what's their housing situation, what information is there on the parasites involved on that farm at this time of year, and their resistance status? Why that active? Why a combination product (or not)? Why that method of application? Are there constraints in terms of handling or competency, or when they are going to market, or particular environmental considerations? Is there relevant previous treatment history and/or outcomes?

More generally, how, if challenged by someone else (VMD, AMTRA, a local vet, a competitor, a journalist) would you justify that the product prescribed was a reasonable one bearing in mind all the circumstances?

#### Prescribing rationale - how and what to record

It is very difficult to be prescriptive as what needs to be recorded, as it may indeed vary greatly from case to case.

How to record is very open – many of you will already have systems that capture key information including that required to be recorded by paragraph 47 of the Code as well as in keeping customer records, and may only need minor changes to capture the additional information, be that a computer system or a medicines book.

Systems need to be pragmatic to implement in a busy business — but we do caution against inadequate record of the "reason for prescribing that product": this is one area we believe VMD will be looking at in future inspections.

A list of pieces of information (at least some of the information in paragraph 38 of the Code), such as species, number of animals and weight, is useful background, but it unlikely to be sufficient on its own.

A system entirely based on tick-boxes or drop-down lists on a computer is unlikely entirely to capture the "reason for prescribing that product", and some free text should be expected in a large majority of cases.

It should reasonably be expected that it will take a little bit of time to record the reason for prescribing that product – this is an important legal and professional obligation, and must be treated as such. That free text should not normally be trivially short.

#### Sufficient information

Sufficient information should be gained from the customer or already known to the RAMA/SQP to make an appropriate decision. RAMAs/SQPs who are not speaking with the customer at the time of the prescription (such as via Internet supply) should consider whether they have sufficient information in writing or need to obtain further information.

#### **Minimum amounts**

See also paragraphs 34 and 46 as regards the requirement on prescribing the minimum required for the treatment.

#### Responsible use

Responsible use is also referenced in paragraphs 39 to 41. In grazing animals, AMTRA recommends that where possible the resistance status of the parasites in question should be determined, and appropriate use made of worm egg counts.

Responsible use crucially includes appropriate product choice, notably with a view to minimisation of resistance. But responsible use also includes using a product on the right animals, at the right time, in the right way, at the right dose, with the right equipment.

#### Requirements of prescription

Note that the requirements of prescription should be followed in every case. Unless you're dealing with the rare circumstance that you are acting on the basis of a written prescription (that complies with the rules on written prescriptions in the Regulations) from a vet, another RAMA/SQP or a pharmacist, then you must always prescribe in order to be able to supply. The Regulations don't allow for supply in the absence of prescription, and unless the prescriber and supplier are the same person, then a formal written prescription is required by the Regulations.

A "recommendation" from a vet, whether verbal or written, even if involving diagnosis or test result interpretation by the vet, does not amount to a prescription and if faced with such, you must prescribe yourself based on the full set of information available (which could include information from the vet).

- 33. An SQP should provide a written prescription on request. Each written prescription must contain 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
- 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 you do issue a written prescription for supply by someone else, it is good practice to retain a copy in case of query.

AMTRA considers that the "person's professional registration number" should always be available, and so should always be included.

The reference to "antimicrobials" needs to be read in the context of the World Health Organisation's definition of "antimicrobial" as embracing antiparasitics as well as antibiotics, antivirals and antifungals. Note that paragraph 32 already requires every prescription (not just written ones) to take account of the need for responsible use of all POM-VPS medicines, not just "antimicrobials".

# Supply

34. When prescribing and supplying a POM-VPS medicine or supplying an NFA-VPS medicine, the SQP must always (unless they are supplying against a written prescription from another RQP):

- be satisfied that the person who will administer the product is competent to use it safely, and intends to use it for the purpose for which it is authorised
- advise on any warnings or contra-indications on the label or package leaflet
- provide advice on the safe administration of the product

Note the use of the word "always" in this paragraph 34, which applies to all of the bullet points.

#### Minimum amount

The Regulations require that a RAMA/SQP must not prescribe (or, in the case of a NFA-VPS product, supply) more than the minimum amount required for the treatment – this is referenced in paragraph 32 against prescription.

Though it is not currently mentioned in this Code of Practice, this limitation is also nevertheless a legal requirement when supplying NFA-VPS medicines.

The Regulations only allow you to prescribe/supply more than the minimum required for "the treatment" if that's the smallest pack size available and you are not permitted to break open the package (see paragraph 46).

#### "The treatment"

The Regulations do not define "the treatment". In the case of POM-VPS, AMTRA would normally expect such a prescription to be for the immediate need and not to account for potential future needs. For NFA-VPS medicines, a moderate future supply may be justified, but consideration should be given to whether there is any likelihood as to whether the circumstances of the animal or household may change (for example pregnancy, new animals in the house, any other health conditions), and thus the suitability for future use of the medicine being supplied, and discuss this with the customer.

#### **Advice**

"Advice" is a key word in the RAMA/SQP role. At its core that includes the key regulatory demands such as advice on product choice, on safe administration, on warnings and contraindications.

Note that while this paragraph 32 says to be satisfied that the person who will administer the product is competent to use it safely, and to provide advice on the safe administration of the product, good practice should also encompass discussion of effective use as well as safety – this is reflected in paragraph 33 which says you should assess "whether the customer knows how to use the product safely/effectively".

AMTRA recommends that RAMAs/SQPs should consider whether the customer understands how to administer the product for maximum effectiveness and minimisation of resistance as well as pure safety. Other relevant aspects of animal health should also be considered including biosecurity, the benefits of quarantine treatments and the risks associated with any movement of animals. Owners should be encouraged to weigh animals and thus ensure the right dose is given. Administration equipment should be calibrated.

#### Use for a purpose authorised

The Regulations and Code require you before prescribing a POM-VPS or supplying an NFA-VPS product to be satisfied that the person who will use the product intends to use it for a purpose for which it is authorised. In particular therefore, if you have reasonable grounds to believe that the product will be used "off-label" (for example for a different indication, a different species, or a different route of administration) then you must not prescribe/supply it.

You may find in the SPC of some products that there is further information (for instance in the pharmacodynamics section) which may support wider use (for instance against additional parasite species). RAMAs/SQPs must only prescribe/supply consistent with the label of the product and the official indications section (section 4.2 of a product's SPC).

35. A veterinary medicine that has been correctly prescribed and supplied by an SQP from an authorised retail premises (or registered veterinary practice premises/ pharmacy) may be delivered to the customer or handed over to the customer from a vehicle, provided it is accompanied by a dated, itemised delivery note and a duplicate copy of that note is readily available at the premises from which it was supplied. The itemised delivery note/invoice should clearly show the following information:

- The date the product was prescribed
- Date of delivery
- Name and address of supplier
- Name and address of recipient
- Quantity
- Name of product
- Batch number
- Expiry Date
- Identity of prescribing SQP and
- Identity of SQP/designated person responsible for selecting and packing the product (if not done by the prescribing SQP).
- 36. Where medicines requiring specific storage conditions (such as having to be stored at specified temperatures) are packed for delivery, there must be evidence to demonstrate that the correct storage conditions have been maintained during transport.
- 37. Training records for the designated person responsible for selecting and packing the product should be available at the premises. Evidence that the SQP has checked the delivery before despatch should also be retained.
- 38. The following sets out the VMD's expectation of what information is likely to be necessary to be assessed by the SQP prior to supplying a POM-VPS or NFA-VPS medicine, in addition to that listed in paragraphs 32-34. This information does not necessarily need to be recorded. The information that must be kept when a veterinary medicine is supplied is detailed in paragraph 47.

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

- species
- total number of animal(s)
- weight (of each animal if more than one)
- age of animal(s)
- whether the animal is in general good health
- whether the animal is pregnant or lactating
- whether the animal is on any other medication
- whether the customer knows how to use the product safely/effectively
- 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 also:

- what is the animal's intended food use (milk/meat/eggs etc)
- does the customer know the applicable withdrawal period
- 39. For anthelmintic products for sheep and cattle, SQPs should follow the recommendations of:
- the Sustainable Control of Parasites in Sheep (SCOPS) www.scops.org.uk
- the Control of Worms Sustainably (COWS) <u>www.cattleparasites.org.uk/</u>

AMTRA would strongly encourage RAMAs/SQPs to take account of all the recommendations of SCOPS and COWS, not just those that relate to anthelmintics. Note again the requirement in paragraph 32 that every prescription should take into account the responsible use of medicines.

When published, RAMAs/SQPs should take account of guidance from CANTER on good practice in prescribing equine anti-parasitic medicines.

40. For sheep dips, the SQP must be satisfied that the product is supplied only to a person (or a person acting on his behalf) who holds a Certificate of Competence in the Safe Use of Sheep Dips. Sheep dip supply must be in accordance with Schedule 3 paragraph 22 of the VMR. For organophosphorus (OP) dips this includes the supply of protective gloves and the laminated notice specified in Schedule 3 paragraph 23 of the VMR.

It is good practice for the SQP to recommend that the purchaser reads the leaflet Sheep Dipping (AIS41) which is available on the Health and Safety Executive website (www.hse.gov.uk/pubns/ais41.htm). This describes safe working practice and safe disposal. SQPs should also be aware of SCOPS' Code of Practice for Mobile Sheep Dipping, which can be found here.

You should record the Certificate of Competence number against each transaction; you should therefore check the Certificate on each occasion or take a copy of it or record its number with the customer's details. This information should be retained for 3 years (though as other records of POM-VPS medicines must be kept for 5 years, it may be more practical to keep all records for 5 years).

#### Mobile sheep dipping code of practice

RAMAs/SQPs dealing with sheep dip should be familiar with the Mobile Sheep Dipping Code of Practice amtra.org.uk/documents/mobile-sheep-dip-code-of-practice.pdf

AMTRA RAMAs/SQPs who are prescribing and supplying up to 7 days to a sheep dipping contractor should follow the Mobile Sheep Dipping Code of Practice and supply only to contractors who have signed to confirm they are following that Code. Otherwise, prescription and supply should follow all the normal rules of this SQP Code of Practice, and should therefore be to individual farmers in respect of the sheep on that single farm, and bulk supplies in advance are not permitted.

41. For horses and other equidae, the SQP must check whether the animal has been declared as non-food producing in their horse passport. If the owner or keeper of a horse does not have the passport for the horse to hand at the time of treatment, or the SQP has not seen the passport, the SQP must presume the horse is intended for human consumption. SQPs should also be aware of the latest guidance from the Controlling Antiparasitic Resistance in Equines Responsibly (CANTER) group.

SQPs supplying veterinary medicines for horses should advise whether the medicine is suitable for use in food producing horses. This allows horse keepers to fulfill the requirements of the Horse Passport Regulations. Further information on horse medicines and horse passport record keeping is available on GOV.UK under Veterinary Medicines Guidance.

The Code says you "must check whether the animal has been declared as non-food producing in their horse passport" but the VMD's guidance says you "must ask to be shown", which isn't the same as seeing/checking it.

AMTRA's expectation is clear: you should ask to see the passport. That's not saying you should expect to see it since few if any owners will have the passport with them in the store, and so the apparent requirement that you "must check" is impractical.

You must assume the horse will go into the human food-chain at the end of its life (and prescribe accordingly) unless you've seen a valid passport with the horse signed out of the human food-chain. In the absence of the physical passport in front of you, you should assume the horse will go into the human food-chain.

If the passport is available, and if all of the following are true:

- you are satisfied that the passport supplied relates to the horse in question, and
- the horse is declared as 'not intended' for human consumption in the passport (this is not the case if there is no declaration or the horse is declared as 'intended' for human consumption, or the declaration is not signed), and
- you are satisfied that it is a valid passport and in particular that it contains Section IX then you may consider the horse to be signed out of the human food-chain, and you may prescribe/supply any appropriate POM-VPS horse medicine.

In such circumstances, if you choose to prescribe/supply a medicine that does not have a horse withdrawal period (so is only suitable for non-food horses) you should advise the owner and draw their attention to the contraindications on the product labelling.

Otherwise, which will be most of the time, you must assume that the horse may enter the human food-chain at the end of its life, and you must prescribe/supply only POM-VPS medicines that have a withdrawal period for horses – DO NOT prescribe/supply any horse medicine contraindicated for use in horses intended for human consumption.

In practice, most POM-VPS horse medicines do have a withdrawal period and so can be prescribed/supplied to any horse (but the requirement to ask to see the horse passport remains). Familiarise yourself with the medicines that don't: these must only be prescribed/supplied where you've seen an appropriate horse passport with the required declaration.

These rules apply to all prescription and supply by RAMAs/SQPs, whatever the retail environment - including traditional stores, internet retailers, and RAMAs/SQPs working under their own authority in veterinary practices or pharmacies.

42. The requirements on the SQP cannot be delegated and cannot be transferred to the customer. 'Disclaimers' that, for example, simply inform a customer that they must answer yes or no to a list of questions will not be considered to meet this requirement.

# Delegating supply to a non-SQP in the same premises

43. An SQP may delegate to a colleague the handing over or despatch of the product, provided the SQP:

- authorises each transaction individually before the product is supplied, and
- is satisfied that the person handing over or despatching the product is competent to do so correctly (see also paragraph 37).

For avoidance of doubt, both of these bullet points must be complied with for this option in the Code of Practice.

In this Code and the Regulations, the word "supply" has specific legal connotations and carries specific duties described elsewhere in this Code: it is distinct from the action of "handing over". VMD has unhelpfully used the word "Supply" in the heading of this paragraph 43: the Code uses the words "handing over" in the body of paragraph 43, which is correct. There is no provision to delegate the supply duties detailed elsewhere in the Code, only the act of handing over.

## Prescribing and supplying by different RQPs in separate premises

44. When supplying a product against a written prescription from another RQP an SQP must:

- only supply the product specified in that prescription
- ensure that the prescription has been written by an RQP allowed to prescribe the product
- check the prescription is suitable for the condition, if in any doubt, the SQP should contact the prescriber before supplying the product
- ensure that it is supplied to the person named in the prescription

See paragraph 31 – these two should be read in conjunction with each other.

45. An SQP may not substitute a different medicine to the one on the prescription or amend a prescription written by another RQP. If the SQP cannot supply the prescribed product or disagrees with the prescription, they should refuse supply and return the prescription to the purchaser. The SQP could prescribe a different product that falls within the scope of the registration they hold, ensuring they follow the requirements for prescription and supply.

The last sentence is important: choosing to prescribe/supply a different product to that on the written prescription is an option available to the RAMA/SQP, provided the rules for prescription/supply are followed. It is good practice to contact the original prescriber to discuss their thinking and the circumstances of the case if you consider their prescription may be inappropriate.

46. SQPs are allowed to break open any package (other than immediate) of a medicine they are authorised to supply. The immediate packaging of a veterinary medicine is the packaging directly in contact with the medicinal substance itself. For example, an SQP may not supply a small number of unwrapped tablets from a single tub or bottle and keep the rest of the tablets to supply later.

However, they may supply one or more individual boluses/pipettes/blister strips from a carton provided the boluses/pipettes/blister strips are individually wrapped, within an outer carton. In this situation, SQPs must be satisfied that the person will use the medicine in accordance with its authorisation and/or prescription. They must also provide sufficient written information to enable the product to be used safely and, as per paragraph 34, advise on any warnings or contraindications on the label or package leaflet and provide advice on the safe administration of the product.

It is acceptable for an SQP to give a copy of the package leaflet or SPC to the customer, provided that it has all the required information.

"Immediate packaging" may be regarded as the packaging directly in contact with the medicine itself. So any splitting or opening of other packaging must be done in such a way that the medicine is not exposed to the air.

Note that the requirement to provide sufficient written information could also be met by providing a copy of the product data sheet as an alternative to the SPC or package leaflet. (A photocopy or printout is fine.)

#### RECORD KEEPING

- 47. An SQP supplying POM-VPS products must ensure the following information is recorded in relation to all incoming and outgoing (which include medicines sold, returned to a supplier, destroyed or otherwise disposed of) POM-VPS transactions.
- the date of the transaction under which the product was received or supplied
- the name of the product
- the pharmaceutical form and strength of the product
- the batch number (if the product is for a non-food producing animal then the batch number can be recorded on the date it is first received or on the date product from that batch is first supplied)
- the quantity of product received or supplied
- the company name and the permanent address or registered place of business of:
  - in respect of a purchase, the supplier
  - in respect of a sale, the recipient
- if there is a written prescription, the name and contact details of the prescriber
- the expiry date
- In the case of a medicine which has been prescribed but not against a written prescription, the reason for prescribing that medicine.

For avoidance of doubt, the words "received or supplied" in the first bullet point apply to all transactions, incoming and outgoing, including all the examples in the first sentence.

"Incoming" will normally be from a Wholesale Dealer (which might include the manufacturer with a Wholesale Dealer Authorisation), but any other sources should also be included such as any exceptional emergency supplies from another retailer.

Such record-keeping is not legally required for NFA-VPS or AVM-GSL medicines (nor those marketed through the Exemption Scheme for Small Pet Animals / SAES), but a number of businesses choose to do so, and this may be regarded as good practice, as it could support an effective batch recall should that be required.

See paragraph 32 for more on the "reason for prescribing that medicine".

48. These records must be kept for five years at the authorised premises. The records may be kept electronically and must be made available for inspection by a duly authorised person on request. Further information on record keeping is available on GOV.UK under Veterinary Medicines Guidance.

50. The VMR apply to the retail supply of veterinary medicines on the internet in the same way as they do to 'over the counter' sales. Further information on retail supply and internet sales is available on GOV.UK under Veterinary Medicines Guidance.

The requirements do indeed apply to Internet supply, but there are additional requirements in respect of Internet retailers – see the VMD guidance for more.

# OTHER REQUIREMENTS Adverse event reporting

51. SQPs must understand how to report adverse events to the VMD or MAH. They must also be able to provide their customers with advice on such reporting if requested. More information on adverse events is available on GOV.UK under Veterinary Medicines Guidance.

"MAH" means "Marketing Authorisation Holder".

See AMTRA guidance on pharmacovigilance reporting, and a link to the VMD reporting website via <a href="mailto:amtra.org.uk/CodeAndGuidance">amtra.org.uk/CodeAndGuidance</a>

# Wholesale supply

52. Any business that routinely supplies veterinary medicines to another business must hold a Wholesale Dealer's Authorisation (WDA). Further information on WDAs is available on GOV.UK under Veterinary Medicines Guidance. However, in an emergency, an authorised retailer may supply veterinary medicines they hold, to another authorised retailer in order to relieve a temporary supply shortage that could be detrimental to animal welfare. This is intended to prevent animal welfare problems associated with availability of medicines and must not be a regular commercial activity.

# Other points

#### **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. POM-VPS products may be on display behind the retail counter or similar, secure areas provided none are promoted inappropriately. Price lists are not considered to be advertising, provided that they meet the conditions in the advertising guidance published on GOV.UK

All products must only be advertised for their authorised use.

Human medicines cannot be advertised for administration to animals. This includes human general sales list medicines.

#### RAMA/SQP nominated person within a business

Although not a formal requirement, AMTRA recommends that an individual SQP should be nominated to be responsible for professional standards within a registered premises. The nominated

RAMA/SQP should take overall responsibility for how veterinary medicines are obtained, stored, supplied and disposed of. They should also ensure that colleagues recognise the professional responsibilities of SQPs. A business with multiple registered premises may nominate a single RAMA/SQP to be the responsible person for multiple premises within the business.

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