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The new obligation to record the "reason for prescribing that product"

Comments and guidance from AMTRA, 30 October 2024

The requirement

The VMD SQP Code of Practice of 17 May 2024 states the following – we've highlighted the last part as it is key:

> *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.***

Any RAMA/SQP should be able to justify on each transaction that they have satisfied these obligations.

"Written prescription" means one which satisfies the requirements of paragraph 33 (see appendix).

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.

The May 2024 amendments to the Veterinary Medicines Regulations only currently apply to Great Britain (England, Scotland and Wales) and not to Northern Ireland. But the SQP Code of Practice is UK-wide, and AMTRA's expectation is that all SQPs on its Register, including those working in Northern Ireland, must comply with the current Code.

Things to think about

The purpose of the change is to ensure the quality of prescribing. Poor quality prescribing is unacceptable, and the requirement to justify each prescription should put greater emphasis on high quality prescribing.

The requirement is to record the "reason for prescribing that product", which the Code also describes as the "prescribing rationale".

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

- Paragraph 32 (see appendix) of the Code set out 8 bullet points involved in prescribing decisions.
- Paragraph 38 (see appendix) of the Code sets out VMD's expectations of minimum information likely to be needed to prescribe
- Paragraphs 39 to 41 (see appendix) 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?

How and what to record

VMD have been quite limited in their guidance, leaving us to decide for ourselves how best to comply. 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 (see appendix) 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 (see appendix)), 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.

An element of a "light touch" approach may have some merit initially, but in the knowledge than a more robust expectation is likely to follow in the light of experience.

Appendix – extracts from the SQP Code of Practice, 17 May 2024

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- **the disease/condition of the animals requiring treatment**
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- **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.

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.**

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) - www.cattleparasites.org.uk/**

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.

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.

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.**