Q&A – Prescription and Supply

Introduction

We have provided responses to questions received to further aid consideration of the proposals for the review of the Veterinary Medicines Regulations 2013 (VMR).

We may have paraphrased or consolidated similar questions from the focus sessions held in early March to make the document easier to navigate. If your question has not been answered, email vmr@vmd.gov.uk.

Please submit comments on the proposed changes as part of your official consultation response using citizen space. It is helpful to include details about any impacts these changes may incur in your response, for example costs and savings, environmental impacts, social impacts or any other impacts.

You can also include comments on the implementation of these changes in your response, for example your views on what guidance would be needed or how long it would take you to put any changes into practice.

If you have any specific questions on the proposed changes, email vmr@vmd.gov.uk.

You can also find more information about the consultation and supporting documents on gov.uk and VMD Connect

The Q&As from the other sessions are available on VMD Connect and GOV.UK.

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Temporary restrictions

Q) How will temporary restrictions be applied under Schedule 1, paragraph 41A?

The temporary restrictions proposals will allow the Secretary of State to:

- restrict the supply of a veterinary medicine
- restrict the use of a veterinary medicine
- suspend the MA of a veterinary medicine
- require an MAH to submit a variation for their MA

These restrictions will only be applied where urgent action is necessary for protecting human or animal health or the environment.

Immunological Products

Q) What is the rationale for all future immunological products being categorised as POM-V?

We will not change the legal category of currently authorised medicines. The change is intended to align the VMR with what happens in practice, which is that new immunological products are classified as POM-V medicines.

Online Retailers

Q) Does the registration of online retailers relate to UK or GB retailers?

This consultation does not include proposals that impact the VMR as they apply in NI.

Q) When does an online retailer need to register under the online registration requirements? How long it takes from the application to approval?

We are proposing a requirement to register a website for sale of veterinary medicines in GB. The applicant must submit their name and address to the SoS at least 2 months before they begin selling on the internet.

For existing websites, they will have 2 months following the date it comes into force to register.

A retailer that registers to sell online will already need to be an authorised supplier of veterinary medicines and will be subject to regular inspections.

The VMD have not committed to a timeframe for registering an online retailer and providing the registration logo.

Q) How will we ensure that products, such as antibiotics and anthelmintics, are being prescribed and supplied properly by online retailers?

Q) Can the duties at the time of supply be fulfilled without dialogue, for example using tick boxes?

The VMR apply to the sale of veterinary medicines on the internet in the same way as they do to 'over the counter' sales. We will be reviewing the procedure for online retailing and discussing with stakeholders to ensure this supply route is appropriately regulated. However, the following sets out our current thoughts.

As antibiotic medicines are all classified as POM-V, an online retailer should only be supplying such a product on receipt of a written prescription from a vet. The same applies for anthelmintic medicines classified as POM-V.

For anthelmintic medicines classified as POM-VPS or NFA-VPS, the Registered Qualified Person (RQP - either a vet, pharmacist or SQP) at the online retailer should have sufficient information to make an informed decision about which product to prescribe/supply. and then record their rationale for that decision. The RQPs could acquire that information from direct discussion with the animal owner or keeper, for example by phone or email or by reviewing responses on a detailed questionnaire. However, they should not simply be fulfilling an order submitted via a questionnaire without due consideration and if necessary, further direct discussion with the animal owner/keeper. The RQP should be prepared to refuse the order if they are not satisfied that the treatment ordered is the correct one.

Further information can be found under Retail of veterinary medicines on GOV.UK, and this will be updated when any proposed changes come into effect.

Q) Does Schedule 3, paragraph 5(1A) account for electronic prescriptions of meds sold via online pharmacy with no oral exchange?

The intention is that RQPs should record their prescribing decisions unless supplying a veterinary medicine against a written prescription.

Record Keeping

Q) Is a written veterinary health plan sufficient to fulfil the record keeping requirements?

The regulations specify what information must be recorded rather than how and where. If all the required information is recorded on a health plan, then that would be acceptable.

Q) Would the VMD consider establishing a register of approved Practice Management Software?

Practice Management Software is not regulated under the VMR and we are not proposing to establish a register of this software in this review.

Prescriptions

Q) Can POM-V veterinary medicines (such as antibiotic, immunological and hormonal products) be prescribed by a pharmacist?

The current requirements allow pharmacists to supply products categorised as POM-V, however only in accordance with a prescription from a veterinary surgeon.

We have not proposed any changes to this requirement.

Q) Will the proposed changes provide criteria for the recognition of electronic prescriptions?

There is no current system for the recognition of electronic prescriptions in GB and we have not considered this for this review of the VMR.

We are aware of a system for the recognition of electronic prescriptions in the Republic of Ireland. If you would like to submit data to support this for a future review of the VMR then please add this to your consultation response.

Q) How will it be determined if the reason for use is sufficient?

In the first instance inspectors will check that RQPs are recording the rationale for their prescribing decisions. However, we believe inappropriate prescribing decisions should be considered by the prescriber's peers – so we will discuss how these could be dealt with by prescribers' professional bodies.

Q) When a product is prescribed orally under Schedule 3, paragraph 5(1A), does the prescriber have to include the quantity prescribed and the active in the reason for prescribing the product?

The proposed change will only require the prescriber to record the reason under paragraph 5(1A). The quantity and active prescribed should still be recorded under Regulation 23, records of the receipt or supply of prescription products.

We will work with industry and professional bodies to agree what information we expect to see recorded and update the guidance on GOV.UK to advise stakeholders on how to comply with the requirements under the VMR.

Q) Will the offence of submitting a non-repeatable prescription to more than one retailer also apply to repeat prescriptions?

The offence is intended to cover where a repeat prescription has been submitted to a retailer where the full number of repeats has already been fulfilled.

If this is not clear, please put this feedback into your consultation response.

Q) Will a requirement to obtain informed consent from the animal keeper/owner be included in the section on cascade use?

The requirement for consent to use a veterinary medicine under the cascade is already an RCVS requirement and not something we propose to include in the VMR.

Q) Will the RCVS amend their guidance on 'clinical assessment' with 'clinical examination or other proper assessment' following the changes coming into force?

This would be for the RCVS to consider.

The Cascade

Q) What constitutes ‘encouragement’ and ‘inappropriate use’ of the cascade?

This offence covers promotion of products for use under the cascade, encouraging vets to prescribe products under the cascade over authorised veterinary medicines and any other activity designed to influence a vet to prescribe under the cascade inappropriately.

Q) Will the offence under Schedule 4, paragraph 9A prevent specials manufacturers from discussing treatment options available with a vet?

Manufacturers of extemporaneous preparations (also known as veterinary specials) may not advertise the specific substances that they can manufacture but they may promote the services they provide to vets.

They may provide information on the different types of dosage forms that can be produced. They may not make medicinal claims or refer to specific diseases or conditions.

On a vet’s request, the manufacturers of extemporaneous preparations may provide a list of active substances, formulations with prices and placebo samples.

Guidance can be found by searching Advertise veterinary medicines legally on GOV.UK.

Q) Q) Will the offence under Schedule 4, paragraph 9A apply to Key Opinion Leaders presenting to vets at a vet conference?

The offence will apply to anyone who encourages or facilitates the illegal use of the cascade.

Guidance on how to comply with the VMR, such as when presenting educational material to vets at events can be found on our online guidance Advertise veterinary medicines legally on GOV.UK.

Q) What is the rationale for increasing the fees for a vet to apply for a Special Import Certificate to £13?

Government policy is that those who carry out an activity (for example marketing or supplying veterinary medicines) should bear its full cost. As a cost-recovery agency, the VMD is required to recover the majority of its costs from fees and charges according to principles laid down by HM Treasury in their document 'Managing Public Money'.

This fee has been introduced to ensure full cost-recovery of the services we provide, capturing the costs associated with reviewing and issuing SICs, and maintaining the online service.

Supply

Q) Who is considered a competent person when a vet delegates the handing over of a veterinary medicine?

The competence of a person to hand over a veterinary medicine must be determined by the vet. We expect this person would have the necessary knowledge and training to carry out the handover and fulfil the duties for supplying a product under Schedule 3, paragraph 7.

Q) Will SQPs still be able to supply POM-VPS and NFA-VPS products prescribed off-label by a vet under the cascade?

An SQP will still be able to supply a veterinary medicine they are authorised to supply for use under the cascade in accordance with a veterinary prescription.

Q) Will there be any provisions intended on protecting the supply chain from falsified medicines?

There will be a new requirement under Schedule 3, paragraph 21 for wholesale dealers to notify the VMD of any product they have been offered which they suspect to be counterfeit.

Wholesale Supply & Storage

Q) The section in the consultation on the supply of veterinary medicines from wholesalers to retail premises does not include suitably qualified persons, is this intentional?

We already require supply to SQPs by wholesalers to be to authorised premises in the current VMR. This proposed change is to ensure that supply to vets and pharmacists is also to authorised/registered premises.

Q) Would the VMD consider moving retail in line with manufacturing and wholesale encouraging the use of real-time temperature monitoring systems to store veterinary medicines?

We have proposed a new requirement under Schedule 3, paragraph 3B for retailers to store veterinary medicines in line with the product's summary of product characteristics.