Q&A – Advertising

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 <u>vmr@vmd.gov.uk</u>.

Please submit comments on the proposed changes as part of your official consultation response using <u>citizen space</u>. 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 <u>vmr@vmd.gov.uk</u>.

You can also find more information about the consultation and supporting documents on gov.uk and $\underline{VMD \ Connect}$

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

Contents

Introduction	1
Prescription Only Medicines	2
Online and Electronic Advertising	3
Educational Material	4
Gifts and Hospitality	5
Enforcement	5
General	6

Prescription Only Medicines

Q) Can price lists of POM-V and POM-VPS medicines be provided to professional keepers of animals and over the internet?

Price lists that follow the guidance on price lists, available under <u>Advertise veterinary</u> <u>medicines legally</u> on GOV.UK, are not considered as promotional material. This includes both physical and electronic price lists, such as those available on company websites.

Q) Can POM-V and POM-VPS products still be displayed in store?

Products will still be allowed to be stored on display in premises that are authorised to prescribe and supply those products. Displaying POM-V and POM-VPS products behind the sales counter in a retailer's premises is not considered advertising provided no product is promoted over another.

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

The categorisation of current medicines will not be changing. 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, the proposed change will only apply to new applications for Marketing Authorisations.

Q) What is the rationale for restricting advertising to professional keepers of animals to immunological veterinary medicines?

The rationale for amending the advertising regulations is to ensure that veterinary medicines are used appropriately and responsibly.

By restricting the promotion of veterinary medicines to those with the knowledge and training to prescribe them, this should prevent pressure being placed on prescribers from animal owners who have been influenced by promotional material. We agree that immunological products should be promoted to professional keepers of animals as this encourages prevention of veterinary disease which can help reduce the risk of AMR. We have received anecdotal information that some animal owners apply pressure to prescribers to supply a specific product, particularly in regard to food producing animals, and the prescriber is reluctant to refuse that request.

Q) Can a manufacturer of veterinary medicines for use under the cascade, such as a manufacturer of extemporaneous veterinary medicines, advertise their products?

A manufacturer of products for use under the cascade can advertise the services they provide but cannot advertise their products.

Further guidance can be found under <u>Advertise veterinary medicines legally</u> on GOV.UK.

Q) Can a manufacturer of extemporaneous veterinary medicines have sales representatives out in the field talking to vet practices?

Manufacturers of extemporaneous veterinary medicines are permitted to have sales representatives, they can advertise the services they provide, but cannot advertise their products.

Further guidance can be found under <u>Advertise veterinary medicines legally</u> on GOV.UK.

- Q) Will the advertising requirements apply to sales representatives who speak directly to retailers of prescription only veterinary medicines?
- Q) Will the advertising regulations apply to industry groups, such as SCOPS, and online marketplaces?

The VMR requirements for advertising apply to anyone who promotes a veterinary medicine.

Further guidance can be found under <u>Advertise veterinary medicines legally</u> on GOV.UK.

Online and Electronic Advertising

- Q) Can online retailers display discounts for prescription drugs on their website?
- Q) Can a manufacturer of extemporaneous veterinary medicines provide commercial deals on their products?

Veterinary medicine use must be based on their medical suitability rather than for any financial gain. Suppliers of veterinary medicines to prescribers should not undertake promotions such as discounts or 'buy one get one free' to try to influence prescribers of medicines.

This applies to all suppliers of veterinary medicines to prescribers.

Q) Can a retailer send email reminders on preventative/routine medicine?

Reminders on products which have already been prescribed but require routine administration, such as wormers, are not considered advertising.

Q) Is there a definition for professional keeper? Would it include a breeder or animal shelter?

We have not included a definition of professional keepers in the VMR. If you think this is required, please add this into your response to the consultation.

Q) Will online retailers and marketplaces be regulated if they sell prescription only veterinary medicines?

All suppliers of veterinary medicines categorised as POM-V, POM-VPS, NFA-VPS will need to be authorised under the VMR and must meet the same requirements, regardless of whether they retail online or over the counter.

Q) How does this relate to the Accredited Internet Retailers Scheme (AIRS)?

AIRS is a voluntary scheme to demonstrate an online retailer complies with the VMR and the additional AIRS requirements by linking to the AIRS online register.

The online retailer register is a different scheme and will require all online retailers of veterinary medicines in GB to register with the VMD. The applicant must submit their name and address to the VMD at least 2 months before they begin selling on the internet.

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

They will need to ensure their website has:

- A retailer logo approved by the SoS
- The contact details of the SoS (VMD)
- A link to the register of online retailers.

Educational Material

Q) Will the changes restrict information available for veterinary surgeon students, vet nurses and vet nurse students, such as CPD at events?

We include students in the category of veterinary surgeons and vet nurses/other healthcare professionals. This will allow vets, nurses and students of those professions to have access to promotional material for POM-V and POM-VPS medicines.

Educational material for vets can also be made available to vet students.

Q) Does this prevent the sponsorship of educational events for farmers (and other professional keepers)?

Professional keepers would still be able to access educational material that follows the guidance on educational material for the general public, available under <u>Advertise veterinary</u> <u>medicines legally</u> on GOV.UK. The material should aim to give a balanced overview of a disease and all available treatment options, as long as product and brand names (so using active ingredient names instead) are not mentioned and other advertising restrictions are met.

Educational material can contain a small strap line at the top or bottom of the article stating 'this information was provided by [company] makers of [product]'

Q) Can you enforce clear declarations of conflicts of interest with Key Opinion Leaders discussing products/active ingredients, where they or their study was subsidised/sponsored by a MAH or manufacturer?

We do not intend to include this in the VMR. It is considered best practice, however any educational material should follow the guidance to avoid being considered as promotional.

Q) Can MAHs or manufacturers sponsor articles that discuss veterinary medicines or active ingredients?

This should follow our guidance on educational material available under <u>Advertise veterinary</u> <u>medicines legally</u> on GOV.UK.

Educational material can contain a small strap line at the top or bottom of the article stating 'this information was provided by [company] makers of [product]'

Gifts and Hospitality

Q) How will terms like 'reasonable in level' or 'inexpensive' be defined, and how regularly will these be reviewed?

We do not intend to specify price limits in the VMR, as this may limit our ability to update the limits quickly. We intend to explain these terms in guidance to set a consistent framework but it will ultimately be based on a case-by-case basis. Please provide comments in your response on how you would like this to be implemented.

- Q) Is the VMD intentionally seeking to prevent customary low value gifts (for example Christmas/Diwali) being provided?
- Q) How will this impact event sponsorship and the providing of refreshments etc.?

We do not intend the proposed changes to impact on any requirements or allowances applied to usual business practice, this relates only to the sale and promotion of veterinary medicines and what can be justified (such as with hospitality for scientific events).

Further guidance can be found under <u>Advertise veterinary medicines legally</u> on GOV.UK.

Enforcement

Q) Will there be an open Enforcement channel for reporting offence?

The VMD is updating the reporting system for non-compliance with the VMR. This will include a hotline and the ability to report anonymously.

Further information can be found on the VMD enforcement of animal medicines by searching <u>Report illegal animal medicines</u> on GOV.UK.

Q) Can online marketplaces be effectively monitored for non-complaint sales of veterinary medicines? Is the current system well regulated?

We do monitor online marketplaces and also work with several major platforms to regulate the marketing, sale and supply of veterinary medicines in accordance with the VMR.

The system is well regulated and we aim to tackle issues of non-compliance in a timely fashion.

General

- Q) Can the draft wording, specifically for Regulation 10A, be reworded to clearly align with the explanation provided in the consultation document?
- Q) Is the guidance used to apply additional requirements or disapply requirements under certain conditions?

We can only create a legal requirement in the VMR; however these requirements can only be updated through a statutory instrument.

The guidance is the VMD's advice on how to comply with the VMR, such as how to advertise veterinary medicines or comply with manufacturing requirements. Guidance can be updated by the VMD to reflect developments in industry and to provide additional clarity where needed.

Please provide feedback on the draft VMR text as part of your consultation response.

Q) Would encouraging prescribing generically help availability and access to medicines whilst also reducing price to the end user by encouraging competition?

The proposed changes are intended to help increase the availability of veterinary medicines where possible, whilst ensuring the safe and secure supply of veterinary medicines. The changes are also intended to remove unnecessary regulatory burden which will allow prescribers of veterinary medicines to treat animals effectively.

Q) Is it appropriate for manufacturers of extemporaneous veterinary medicines to price their products lower than the authorised product made with the same active but in a different pharmaceutical form?

We intend to introduce an offence for a manufacturer of extemporaneous veterinary medicines to market a product which is pharmaceutically equivalent to one which is available under an MA, unless there is a reported supply issue. This will prevent unfair competition from unauthorised products and ensure medicines are prescribed based on their suitability.

Q) Is there a way for an online retailer to validate a prescription? There are so many different templates that it is hard to know if it is legitimate or been used before.

If you have any concerns, then you should check with the prescriber named on the prescription to ensure that the prescription is valid and genuine. We have no plans to produce a standard template, but if you think this would be beneficial, please include this in your consultation response.