Q&A - Wholesale

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.

Contents

Northern Ireland

Q) What is being proposed for Northern Ireland, will this mirror the framework for human medicines?

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

On 27 February 2023, the government announced the agreement in principle reached by the UK and EU regarding the Windsor Framework.

As per the agreement in December 2022, the cliff edge on vet meds has been removed, protecting the supply of veterinary medicines in Northern Ireland through to 2025 whilst we work through a sustainable, long-term solution. During this time, veterinary medicines authorised or approved in the UK, or which are moved via Great Britain, can continue to be placed on the market in Northern Ireland. This safeguards those supplies while providing time to establish a long-term solution which maintains the uninterrupted flow of veterinary medicines into Northern Ireland from Great Britain as is the case now.

The Government is clear that a solution must guarantee the existing and long-established flows of trade between Great Britain and Northern Ireland on which so many people and businesses rely. Information on changes to NI can be found in the VMD Information Hub available on GOV.UK.

Inspection Reports

Q) Is it possible for inspection reports to be published?

The VMD do not publish inspection reports.

A list of authorised manufacturers and distributors is available under Veterinary Medicines Registers: manufacturing and distribution on GOV.UK.

RCVS Governance

Q) Does the VMD regularly review the RCVS inspection programme to ensure it is fit for purpose?

We have a governance structure with all delivery partners. This is not covered by the VMR.

If you have concerns about a particular premises you can report this to the VMD Inspections Team under Report a problem on GOV.UK.

Supply issues

Q) How will the VMD ensure that they only act on reliable information in regard to supply issues from MAHs? Poor information could lead to wholesalers importing alternative medicines and the authorised veterinary medicine coming back into supply.

Reports of shortages will be reviewed on a case-by-case basis. The VMD will work with MAHs and wholesalers to ensure information is reliable and available as soon as an issue is known. In instances of temporary supply issues, we will only permit import of alternatives until the supply issue is resolved or another suitable product becomes authorised. Wholesalers importing these medicines will need to consider the likely quantities needed and purchase stock appropriately.

Q) What is considered as ‘a threat to continued supply’ and supply shortage?

The VMD will publish guidance on what could be considered as ‘a threat to continued supply’.

A ‘supply shortage’ of a veterinary medicinal product occurs when supply does not meet demand at a national level within Great Britain.

Any comments or opinions on how this should be interpreted should be included in your consultation response, as this will help us understand the requirements needed for the various supply chains and demands.

MAH/WDA requirement

Q) Do the proposed changes mean that a MAH will need to have a wholesale dealers authorisation even if they do not manufacture?

The current VMR do not require an MAH to hold a wholesale dealers authorisation to wholesale veterinary medicines. We have proposed an amendment to ensure that anyone who wholesales veterinary medicines must demonstrate they comply with Good Distribution Practice.

This will not mean that all MAHs have to hold a wholesale dealers authorisation if they do not manufacture or supply veterinary medicines. An MAH that also holds a manufacturing authorisation will not need to apply for a wholesaler dealers authorisation to wholesale supply the products they manufacture.

Samples

Q) Do samples need to be labelled under good manufacturing practice conditions?

Samples that are clearly marked as such would not need to comply with the labelling requirements under Good Manufacturing Practice.

Storage

Q) Will retailers of veterinary medicines have to comply with the same storage requirements as wholesalers on 24/7 monitoring of storage areas?

Retailers will need to ensure that medicines are kept under the right conditions throughout their storage.

Further guidance will be provided on how to comply with these requirements.

Thefts and Losses

Q) Will there be a process for reporting thefts and losses to the VMD?

This is not part of this proposed review of the VMR, however cases of theft and loss may be reported to the VMD for information purposes. A more formal system of reporting can be considered for future reviews, please provide feedback on this as part of your consultation response.

Good Distribution Practice guidelines

Q) Which Good Distribution Practice guidelines will be applied under the changes to the VMR?

We will provide more information on the requirements for Good Distribution Practice in guidance on GOV.UK. We haven't proposed to make major changes to what is currently considered as Good Distribution Practice.

Please add any areas you think need further clarification than is in the current Good Distribution Practice guidelines in your consultation response.

Q) Is the VMD considering the implementation of the RPi framework similar to human medicines for the importation of VMP that were not released by an UK QP?

We are not proposing to implement the RPi framework as it was considered to be unnecessary for batch release in GB.

You can include comments on this in your consultation feedback. We will also be holding a separate consultation on proposed changes to the batch testing and release process.

Recalled products

Q) Why do wholesalers need to check that recalled products have been stored and transported correctly?

Q) What situations would allow for a recalled product to be resold?

This requirement is to ensure wholesalers only return recalled products to stock where appropriate. Most recalled products will not be suitable to be placed back into stock, however this proposal will ensure that it would not be prevented by the VMR if it was still suitable for sale.

WDA Audit

Q) What is considered an acceptable discrepancy?

We would deal with these on a case-by-case basis. But the focus would be on whether a discrepancy meant that medicines had been supplied not in accordance with the VMR.

Self inspection

Q) Will the VMD consider aligning with EU Regulation 2021/1248 regarding timeframes?

No, EU Regulation 2021/1248 doesn't specify timeframes regarding how frequently self-inspections should be conducted. We believe that covering all wholesale activities on an annual basis is appropriate. However, please provide any comments on this approach as part of your consultation response.

Special Imports

Q) Will the special imports scheme be updated as part of the proposed changes?

We are not proposing to make changes to the requirements for applying for import certificates under the special import scheme. However, we are currently developing a new online special import service. We're doing this to make the service easier to use, more secure and reliable, and to meet accessibility legislation. We're soon launching a fully working pilot of the new service and need veterinary surgeons' help to test it. For more information, visit VMD Connect, here.

Q) Could the VMD improve monitoring by asking vets to submit an annual list of veterinary medicines prescribed under the special imports scheme to monitor the species prescribed for, check compliance and update the approved products list accordingly?

We do not plan to collect retrospective records of medicines used under the Special Import Scheme. We will deal with instances of non-compliance, such as import of an unauthorised medicine without the correct certificate under our enforcement policy.

Q) Can special import certificates be issued for vet practices rather than for specific vets, and for product configurations rather than for a product for a specific species?

Special Import Certificates are issued on an individual vet and product basis. This is because the named vet is personally responsible for the decision to use the cascade and their choice of medicine is based on their clinical judgement. We therefore do not plan to change our current requirements that you must be an RCVS registered vet, working for a registered veterinary premise to be eligible to apply for a Special Import Certificate. Upon application, the vet must provide information on the species and number of animals they intend to treat with the imported product. This information informs our import:benefit risk assessment and varies for each new product that enters the UK, or species indicated for treatment. Again, we do not intend to change these requirements as part of our proposed changes to the VMR.

Q) Can wholesale dealer import certificates be issued per product configuration rather than having one certificate for multiple products configurations?

Wholesaler Dealer Import Certificates are issued on a product-specific basis. Should you wish to receive a certificate on an individual presentation basis, please contact the VMD's Supply Team.

Q) Where a pharmacist does not need to be authorised as a wholesaler to supply an unauthorised veterinary medicine under a special import certificate, can a special imports wholesaler supply the product to a pharmacist with no additional checks?

A wholesale dealer should check the individual they are supplying is in possession of a valid Special Import Certificate. A vet is expected to supply their certificate to a pharmacist where using them as an agent to facilitate a product's importation.