Q&A – Marketing Authorisations

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

Definitions

Q) Could the definition of immunological veterinary medicinal product be added?

Q) Is there any intention of adding more definitions as part of the proposed changes?

The definition for “immunological veterinary medicinal product” is provided in Regulation 2(2).

Definitions within the VMR apply across all requirements and are not exclusive to the section of the VMR they are set out in.

If you believe a definition is required in the VMR, please add this to your consultation response.

Q) Why is there no definition for a biological veterinary medicinal product?

If you believe a definition is required in the VMR, please add this to your consultation response.

Advertising

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

Any sponsorship should follow our guidance available under Advertise veterinary medicines legally on GOV.UK.

Supply shortages

Q) What is the rationale for shortages to be declared two months in advance?

The rationale for requiring shortages to be reported two months in advance is to provide greater transparency on the supply chain and give the VMD an improved ability to respond to supply shortages and help protect animal welfare.

The VMD will publish guidance on what could be considered as not meeting demand at a national level.

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.

Q) What does ‘demand at a national level within the UK’ mean?

For ‘demand’ to be satisfactorily met, the veterinary medicine will need to be acquired in time and sufficient quantity to allow continuity of best care of the animals receiving treatment.

‘National level’ refers to the situation in a specific territory, i.e., if there is insufficient supply of a medicine to meet the demands of the country overall. Logistic-related issues leading to regional supply disruption, for example delivery difficulties, are a short term and localised problem and should not be taken into account.

MAHs Based in Other Countries & Local Representatives

Q) Will an EU MAH continue to have access to the VMDS portal, such as for variation submissions and pharmacovigilance?

There are no user location restrictions on VMDS registration/access.

Q) Can a Local Representative be a named organisation instead of a person?

Q) Do the VMD intend on defining the experience and qualifications required for a Local Representative?

Q) Where a Local Representative oversees the pharmacovigilance requirements for an MAH, how will accountability be applied between the Local Representative and the Qualified Person for Pharmacovigilance (QPPV)?

Q) Is it possible for a product with a GB Local Representative to have the QPPV and Pharmacovigilance System Master File (PSMF) to be based in another country?

The purpose is for a local representative to be the local VMD contact for regulatory and enforcement matters, to encourage reporting of pharmacovigilance and have the legal capacity to act for the MAH. The local representative would not relieve the MAH of their responsibilities under the VMR.

A person in this context could be a natural or a legal person such as a company.

It will be for the MAH to determine that the Local Representative can fulfil the requirements, particularly under Schedule 1, paragraph 18(3)(c) to be able to address requests about the product.

The PSMF and QPPV do not need to be based in the UK, however the Local Representative will need to be able to receive reports of suspected adverse events. Both the Local Representative and the QPPV must be able to communicate in English and a copy of the PSMF must be accessible to the VMD upon request.

Q) Does the VMD agree with the EMA's approach of the MAH being required to be located in the EU for supply to NI?

The UK position on location of Marketing Authorisation holders is set out here: Marketing Authorisation Holders, Named Distributors and Local Representatives of veterinary medicines - GOV.UK (www.gov.uk).

As per the agreement in December 2022, the cliff edge on veterinary medicines 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.

Q) Will the current Local Representatives in GB for MAHs based in the EU meet the requirements for a Local Representative?

It will be for the MAH to determine that the Local Representative can fulfil the requirements, particularly under Schedule 1, paragraph 18(3)(c) to be able to address requests about the product.

Q) Will it be possible for an MAH based in another country with a Local Representative to:

1. Have all manufacturing activities carried out in another country?

2. Have a cell bank storage in another country?

The Local Representative is required to allow an MAH to be based outside of the UK. The questions listed are not related to Local Representatives and are covered in other sections of the GB VMR.

Regarding manufacturing authorisations, it is possible for full manufacturing procedures to be based in another country (where a finished product comes into the UK).

It would also be possible for cell bank storage to be based in another country.

Whether inspection of any of these activities is required would depend on whether mutual recognition agreements are in place with the territories in which manufacture is performed.

Batch Testing

Q) What are the changes to batch testing and release of products marketed to GB?

The proposed changes to batch testing and release will be put forward in a separate consultation.

Marketing Authorisations

Q) Has the requirement to renew an MA been removed?

The proposed changes will remove the requirement to renew MAs after 5 years on the market.

Q) Has the sunset clause been removed?

The proposed changes will remove the sunset clause.

Q) Will Ph.Eur. monographs continue to be accepted for veterinary medicinal products which were CAP-MA converted to National MAs? (EU dossier)?

Yes Ph.Eur. monographs will continue to be accepted/recognised.

Q) Is there anything that regulates the ethical sourcing of active ingredients?

There are no proposals to amend the VMR that relate specifically to the ethical sourcing of active ingredients.

Q) What is meant by ‘generic reference product’?

Q) Does a reference product have to be UK authorised or can it be authorised in another member state or country?

As defined in Regulation 2, a ‘reference veterinary medicinal product’ means a veterinary medicinal product authorised in accordance with Schedule 1.

The text that states, ‘generic reference product’ is a drafting error, it should state ‘reference product.’

Q) Have minor use and minor species (MUMS) authorisations been replaced by Limited Market Authorisations (LMA)?

No. The proposal is to keep the provisions for LMAs as they are in the VMR. There is not currently a legal provision for MUMS authorisations; however, applications for a full MA take into account guidance as set out in the CVMP MUMS guidelines during the assessment if the product was for minor use and/or minor species.

Future guidance on LMAs will be provided for these applications.

Q) How will risk of antiparasitic resistance be determined? Will this be product or active pharmaceutical ingredient specific?

Antiparasitic resistance would be specific to veterinary medicinal products containing an active ingredient with an antiparasitic effect. Where a product has such an effect it would need to be demonstrated that the risks of development of antiparasitic resistance had been sufficiently mitigated and that there was a positive benefit-risk balance for the product.

Data to be provided with the application

Q) In the list of differences for biological clinical trials, why is the divergence regarding choice of controls only applicable to biological products?

Q) The text has been proposed to clarify expectations regarding the need to select appropriate controls for biological products that are not immunological and which may be novel and not follow conventional pharmaceutical parameters. The need for, and nature of, appropriate controls for immunological veterinary medicines is in essence in the text and such controls are well established. In the list of differences for novel therapies, although higher level approach to be taken, will the VMD accept applications complying with more defined EU requirements?

Q) In the list of differences for novel therapies, will the VMD consult on the development of guidance concerning the higher-level approach mentioned?

Please put any comments on the implementation of any of the proposed changes, including necessary guidance, in your consultation response.

Q) Why will ‘acute’ or ‘sub-acute’ toxicity studies be required instead of single dose studies?

Single dose studies do not always provide relevant data for the situation. The intention behind this proposed change is to allow applicants a wider choice of studies that are relevant to the exposures that humans might have to the substance/product under evaluation.

Q) What GB specific data will need to be generated to supplement an EU data package for a NI application?

Ideally, there will be no differences. However, case specific scenarios may emerge in the future. We would encourage you to have company meetings with the VMD to discuss your applications prior to submission, where we can verify any data requirements on a case-by-case basis.

Q) Will demonstrating an active substance is ‘well-established’ for a bibliographical application require GB specific evidence, or can this be from any country or defined market?

There will be no geographical restrictions on the data that can be provided. It will be for applicants to demonstrate the relevance of any data provided in support of their application.

Labelling, packaging and SPCs

Q) What is the rationale behind amending the labelling requirements to include:

1. “Keep the container in the outer carton” on the immediate packaging
2. Expanded statement for keep out of the sight and reach of children

The inclusion of “Keep the container in the outer carton” on immediate packaging is to ensure that the user keeps all packaging elements together when storing the veterinary medicine; its inclusion has been a national labelling requirement to date. The statement for ”keep out of sight and reach of children” has been updated to align with the same requirement provided for in Regulation (EU) 2019/6. If these statements cause issues or unnecessary costs, please outline this in your consultation response.

Q) Is it possible to have clearer written disposal information on packaging, such as 'do not dispose in general waste or water systems'?

We have updated the disposal information to appear on packaging to harmonise with EU labelling requirements as defined in Regulation (EU) 2019/6 to facilitate shared labelling with other countries. Please put any comments on this into your consultation response for us to consider for future reviews.

Q) Can the VMD insist that no other info is printed next to the LOT number? Some brands have extra characters for internal reference which can cause input error & failed recall.

We have not proposed this as part of this review of the VMR as our legislation does not define the positioning of information, but the minimum particulars to appear on each packaging component. Marketing Authorisation Holders should consider the amount of space available on packaging when designing mock-ups to ensure all information is legible. Further guidance on our requirements for the format and layout of mock-ups is available on our Product Literature Standards, here.

Q) When will a printed leaflet be required instead of an electronic leaflet? Will this be optional for MAHs?

Q) Will there be situations where both an electronic and physical leaflet will be required under an MA?

The proposed provision to allow electronic leaflets instead of providing a physical leaflet requires an MAH to provide a physical copy where necessary, such as where the safety of the product requires information to be readily available or when a physical copy is requested by a prescriber or an end user.

The VMD will publish guidance to help MAHs understand where electronic leaflets can be used on packaging. Where an electronic leaflet is considered acceptable, it will be optional for the MAH if they wish to use an electronic leaflet.

Q) Why are the VMD deviating from EU labelling requirements, such as QRD 9, which would lead to increased costs and potential availability issues?

Q) Have conversations been had with counterpart agencies, such as HPRA, to confirm if proposals will allow joint labelling?

The primary aim of the VMR is to ensure the safety of veterinary medicines. However, we have taken into consideration the benefit of joint labelling and look to facilitate this where possible. This is why, where possible, we have looked to harmonise with EU labelling requirements as defined in Regulation (EU) 2019/6.

Please include any data you may have on the costs of these proposals in your consultation response, which will enable us to accurately assess the impacts of the proposed changes.

Q) The proposed summary of product characteristics (SPC) will not fully align with the EU QRD Template, will this cause UK wide MAs to have to split into GB and NI authorisations?

The only difference between information required for the Summary of Product Characteristics proposed for the GB VMR and that required under EU's Regulation (EU) 2019/6, is in respect to disposal advice. Specifically, the EU requirements stipulate the use of take-back schemes for disposal of unused veterinary medicines or waste materials, whereas our VMR more broadly states: 'special precautions for the disposal of unused veterinary medicinal products, if appropriate.' We do not foresee this will cause a split to the MA unless there are fundamental differences to the content agreed under these respective headings during assessment.

Q) Is it a requirement to include the phrase "UK authorised veterinary medicinal product" on a label and package leaflet? Or should this be dependent on whether the product is a GB, NI or UK authorised product?

This is an optional statement to be included on product labelling, to clearly define if the product is authorised in GB, NI, or the UK.

If you consider that this statement is unnecessary, please provide comments on this in your consultation response for us to consider.

Q) How will current MA SPCs be updated into the new formats? What timeframe will there be for this?

Implementation timeframes will be determined once the amendments to the GB VMR are finalised. Where possible, we intend to be flexible and facilitate a pragmatic introduction of updates to existing MAs.

Q) Why does the SPC for generic applications need to be 'essentially similar' to the SPC of the reference product?

Q) Will this align with the EU interpretation?

This is because a generic application relies on data of an already authorised product, and so should contain the same data for the SPC.

It is expected that the GB interpretation of ‘essentially similar’ in this context will remain harmonised with the EU’s interpretation.

This requirement will not apply to those parts of the SPC of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still covered by patent law at the time when the generic veterinary medicinal product was authorised.

Q) Will the VMD publish guidance on when a post authorisation study will be required to ensure the benefit-risk balance of a product?

The VMD will publish and update guidance on the proposed changes.

Any comments on what should be included in the guidance and opinions on the implementation of the changes should be included in the consultation response.

Q) What criteria will be used to determine if a risk management plan is required for an existing product?

A risk management plan would be required where the Secretary of State identifies a need to commit to an investigation into a product or an ongoing issue with adverse events related to the product. Without the power to require a risk management plan the only alternative would be to suspend products pending the outcome of investigations.

Small Animal Exemption Scheme

Q) Should the Small Animal Exemption Scheme be scrapped to ensure quality, evidence based licensed medicines are available to small animals and increase product development for them?

The proposed changes to the VMR do not include a proposal to remove this exemption in the VMR.

The exemption for small pet animals is intended to address the need for veterinary medicines where it would not be commercially viable for the manufacturer to seek a specific product marketing authorisation.

Fees

Q) Will there continue to be a reduction for fees concerning variations in NI where the variation has also been submitted in GB for an aligned UK MA?

This consultation focuses on the VMR as they apply in GB.

We will review any temporary fee reductions associated with parallel GB and NI applications once the GB fees are finalised.