Q&A - Pharmacovigilance

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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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. Although the local representative would not relieve the MAH of their responsibilities under the VMR.

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.

Third countries

Q) What is meant by a ‘regulatory measure’ in another country?

A ‘regulatory measure’ means any legal action taken by another country applied to the marketing of that veterinary medicinal product.

Q) What action in another country would lead to changing the PSMF?

Any change originated from pharmacovigilance or regulatory activities that triggers a change or regulatory action that affects the content of the PSMF like a variation, update of QPPV, etc

Signal Management

Q) Will the signal management process align with the same analysis period as the EU and follow the same process?

Details of the Signal Management process will be set in the modules and guidance once the Public Consultation analysis and final steps of the VMR review are finalised.

Adverse events

Q) Schedule 1 paragraph 57 does not appear to cover efficacy/suspected lack of efficacy, previously covered in paragraph 58 (1)(a). Is this omission intentional?

This is a drafting error and will be amended in the final version of the legislation.

Annual benefit risk report

Q) What is considered as ‘immediately’ when providing the annual benefit-risk report on request? Will this be reasonable to the time it takes to product them?

The wording will be reviewed for the final text, please include your views on this in your consultation response.

Q) Will the VICH format of summary data be sufficient for the differentiation data requirement?

The details for specific pharmacovigilance activities and processes will be set in the modules and guidance once the consultation analysis and final steps of the VMR review are finalised.

Q) Will the annual reports for volume of products sold be on a rolling 12 months or from the start of the year/financial year?

The intention is for these reports to be on a rolling 12-month basis, ‘once in the course of every year during the period of validity of the authorisation.’
There will continue to be the option for an MAH to apply to the VMD to change the submission date of the report.

Q) What is meant by the number & ratio of adverse events for each year of the report, as the report only covers one year?

This is a drafting error and will be amended in the final version of the legislation.

Inspections

Q) What is the certificate that will be issued within 90 days?

This is in reference to the inspection report and certification that the pharmacovigilance inspection has been completed and aligns pharmacovigilance inspections with other types of inspection carried out by the VMD. Please let us know whether this is something you would require as part of your consultation response.