Q&A - Manufacturing

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

Local Representatives

Q) Will it be ok for a VMP with a GB local representative to have all manufacturing activities (DSM, DPM, batch release site) taking place in the EU /US?

Q) Will it be ok for a VMP with a GB local representative to have Cell bank storage in the US (EU-GMP inspection)?

Q) Will it be ok for a VMP with a GB local representative to have the QP and OMCL in the EU?

The local representative is required to allow an MAH to be based outside of the UK, the requirement for a local representative does not apply to the manufacturing requirements.

Good Manufacturing Practice

Q) Who are the non-UK authorities issuing GMP certificate that will be recognised by the VMD?

The VMD will recognise GMP certificates issued by:

- a regulatory authority which the Secretary of State has an agreement with.
- a regulatory authority which the Secretary of State considers to have demonstrated equivalent standards to those in the UK.

Batch Testing

Q) Can any further information be shared in relation to the separate consultation on batch testing/release – when will this be?

Q) Will VMD accept batches released by a QP located in the EU?

The proposed changes to batch testing and release will be put forward in a separate consultation. The intention will be for this to be a shorter, targeted consultation and for the changes to then be incorporated into the final VMR to be laid in parliament as one statutory instrument.

Active Pharmaceutical Substances

Q) Would an active substance importer need to ensure that the product from outside GB is manufactured to GMP & supply route into GB meets GDP requirements?

Where the importer of the active substance is also the end user, GMP guidelines require them to assure themselves that the active substance has been manufactured to GMP and to be aware of the supply chain for the active substance.

We will further consider the requirements for 3rd party importers but please raise this in your response to the consultation.

Once active substances have been imported into GB, the proposed changes to our Regulations (Schedule 2 paragraph 29) require them to comply with GDP.

Q) Does this distribution of active substances need to be defined if a broker could be involved in the financial supply chain but not the physical supply chain? Will distributors and importers of active pharmaceutical ingredients need audit brokers?

The proposed changes do not require brokers to be registered or audited, if they only act on a transaction between two or more other parties and never take legal title to the active substances.

Q) Would a CMO (ManA holder) have to audit an active substance manufacturer, or can they rely on an audit performed by the MA holder (the importer of active sub)?

The CMO's QP can rely on assessment by third parties, for example audits, but that QP should have full access to the audit report. It would not be acceptable for the MAH to restrict this information, for example expect the CMO's QP to rely purely on a statement that the active substance manufacturer has been audited and found to be satisfactory.

Autogenous Vaccines

Q) Has there been any consideration to align the requirements for autogenous vaccines with 2019/6 Article 2.3 to require the manufacturing site to have a GMP cert?

Article 2.3 (L_2019004EN.01004301.xml (europa.eu)) applies certain requirements to manufacturers of autogenous vaccines, including the Competent Authority to issue a GMP Certificate to such manufacturers. We currently do not plan to issue a GMP certificate to autogenous vaccine manufacturers as this would require those manufacturers to fully comply with GMP, whereas they currently have to comply with GMP-like principles.

As a member of PIC/S, we will contribute to the drafting of guidance on GMP for autogenous vaccine manufacture, but this work is unlikely to be completed before 2025.

Q) Autogenous vaccines don't currently require a QP currently - will they need one under the new regulations?

A site that manufactures autogenous vaccines must be under the supervision of a named person responsible for release (a "PRR"). The PRR must sufficient qualifications and experience to manufacture the product safely. Autogenous vaccine manufacturers do not require a QP.

Blood Banks

Q) How do the changes to Schedule 2, paragraph 14(1)(b) affect individual vets taking a donation to immediately transfuse whole blood?

These requirements specifically cover the rules for authorisation of Blood Banks.

Clinical activities undertaken by individual veterinary surgeons under the Veterinary Surgeons Act would be subject to RCVS rules on Routine Veterinary Practice (RVP). RCVS guidance on blood collection is set out in the recently updated Code of Conduct (RCVS Code of Professional Conduct for Veterinary Surgeons; chapter 25.22 and FAQs).

Manufacturers of Extemporaneous Preparations (ManSA)

Q) The proposals state that ManSA holders are not allowed to manufacture a product that is the pharmaceutical equivalent of an authorised veterinary medicinal product, what does pharmaceutically equivalent mean?

“Pharmaceutically equivalent” means containing an active substance in the same proportions, in the same dosage form and concentration (in the case of a liquid dose) and meeting the same or comparable standards in relation to the clinical needs of a patient at the time of use.

Q) Could VMD consider refraining from calling extemporaneous products 'veterinary medicinal products' in legislation as this is creating confusion in the market?

Thank you for your feedback, please ensure you include this as part of your consultation response.

Q) Do you see any significant change arising from the use of the cascade principle as out lined in the new regulations?

The cascade structure remains the same, we have introduced new withdrawal periods for food producing animals under the cascade.

We have also proposed a new offence of encouraging or facilitating the misuse 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.

Wholesaling

Q) There is an indication that manufactures will need a wholesaler dealers authorisation (WDA) as well - how do you see that being implemented?

Manufacturers are entitled to wholesale deal the products they manufacture. It is a current requirement in the VMR that manufacturers hold a WDA If they wholesale deal in a third parties' products. The proposed change is to remove a Marketing Authorisation Holder's (MAHs) ability to wholesale veterinary medicines without holding a WDA. This proposal is to ensure that MAHs are subject to inspection in the same way as WDA holders are.