Veterinary Medicines Directorate

Department for Environment Food & Rural Affairs

The importing, batch testing and batch releasing of veterinary medicines in Great Britain

A public consultation

Closing date: 15 06 2023

This publication is available at www.gov.uk/government/publications

Any enquiries regarding this publication should be sent to vmr@vmd.gov.uk.

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General information

Why we are consulting

This consultation sets out proposals to update the regulations for batch testing and batch releasing of imported veterinary medicines. The Veterinary Medicines Regulations (VMR) were amended after EU Exit to reflect the UK's independence from the EU. We now wish to improve the regulations (as they apply in Great Britain) and seek your views on the proposals. Changes will then form part of the wider changes to the VMR (see the separate consultation here, which closed on 31 March 2023).

This consultation relates to Great Britain only. As set out in the Windsor Framework, the current arrangements for batch testing and release for products supplied to Northern Ireland will continue through to 2025 to allow time for a long-term solution to be established. During this time, medicines batch tested and released in Great Britain or the European Union do not need to be repeat batch tested/released when supplied to Northern Ireland. Medicines batch tested/released in Northern Ireland do not need to be repeat batch tested/released on supply to Great Britain.

We will amend and supplement the VMR as they apply in Great Britain using the powers in Part 3 of the Medicines and Medical Devices Act 2021. We are using these powers as this proposal is intended to ensure the continued availability of veterinary medicines, which will promote the health and welfare of animals. This consultation is conducted in line with the consultation requirement in section 45(1) of the Act.

Consultation details

Issued: 18/05/2023

Respond by: 15/06/2023

Enquiries to: vmr@vmd.gov.uk or VMD Legislation Office, Veterinary Medicines Directorate, Woodham Lane, Addlestone, KT15 3LS

Consultation reference: The importing, batch testing and batch releasing of veterinary medicines in Great Britain

Audiences: Marketing authorisation holders, manufacturers, wholesale dealers, distributors, veterinary surgeons, suitably qualified persons (SQPs), pharmacists, retailers, animal owners, interest groups, academics.

Territorial extent: This consultation relates to the regulation of veterinary medicines in England, Scotland and Wales only. As a result of the effect of the Windsor Framework, the legislation relating to veterinary medicines in Northern Ireland is currently separate to that in Great Britain.

How to respond

Our preferred way of receiving responses is through the Citizen Space platform.

If you are unable to use Citizen Space, you can download the consultation document and return your response via email to vmr@vmd.gov.uk.

Confidentiality and data protection

A summary of responses to this consultation will be published on the Government website at: www.gov.uk/defra. An annex to the consultation summary will list all organisations that responded but will not include personal names, addresses or other contact details.

Defra may publish the content of your response to this consultation to make it available to the public without your personal name and private contact details (e.g. home address, email address).

If you click on 'Yes' in response to the question asking if you would like anything in your response to be kept confidential, you are asked to state clearly what information you would like to be kept confidential and explain your reasons for confidentiality. The reason for this is that information in responses to this consultation may be subject to release to the public or other parties in accordance with the access to information law (these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018 (DPA)). We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances. In view of this, your explanation of your reasons for requesting confidentiality for all or part of your response would help us balance these obligations for disclosure against any obligation of confidentiality. If we receive a request for the information that you have provided in your response to this consultation, we will take full account of your reasons for requesting confidentiality of your response, but we cannot guarantee that confidentiality can be maintained in all circumstances.

If you click on 'No' in response to the question asking if you would like anything in your response to be kept confidential, we will be able to release the content of your response to the public, but we will not make your personal name and private contact details publicly available.

There may be occasions when Defra will share the information you provide in response to the consultation, including any personal data with external analysts. This is for the purposes of consultation response analysis and provision of a report of the summary of responses only.

This consultation is being conducted in line with the Cabinet Office "Consultation Principles" and be found at: https://www.gov.uk/government/publications/consultation-principles-guidance.

If you have any comments or complaints about the consultation process, please address them to: consultation.coordinator@defra.gov.uk.

About you

1. Would you like your response to be confidential? (Select one option only)

- Yes
- No
- If you answered yes, please give your reason:

2. Who are you responding as? (Select one option only)

- Individual – You are responding with your personal views, rather than as an official representative of a business / business association / other organisation
- Public sector body – In an official capacity as a representative of a local government organisation / public service provider / other public sector body in the UK or elsewhere
- Industry – In an official capacity representing the views of a business
- Campaign group/NGO – In an official capacity as the representative of a non-governmental organisation / trade union / other organisation
- Academia – In an official capacity as a representative of an academic institution
- Other (please specify):

3. Which of the following best describes the role or field you belong to? (If you have multiple roles, please select the one which best represents your interests in this consultation response) (select one option only)

- Manufacturer
- Marketing authorisation holder
- Feed business operator
- Wholesaler / distributor of medicines
- Retailer of veterinary medicines
- Veterinary surgeon
- Suitably qualified person (SQP)
- Pharmacist
- Academic
- Pet owner
- Professional keeper of animals
- Other, please state:

4. What is the name of your organisation?

5. Please select where you/your organisation is based (select all that apply):

- England
- Northern Ireland
- Scotland
- Wales
- Other

Introduction

Veterinary medicines are highly regulated goods. The current process for placing a veterinary medicine on the market in Great Britain is that each batch must be tested and then certified / batch released by the manufacturer's or importer's Qualified Person (QP). Batch testing is the process of confirming every batch of veterinary medicine has the correct composition through laboratory tests by the manufacturer. It helps to ensure that medicines are of appropriate quality and have the desired therapeutic effect. It is part of the broader good manufacturing practice (GMP) quality assurance system and is usually an end of process test.

This consultation is to assess whether the Veterinary Medicines Directorate (in respect of Great Britain) should recognise batch release carried out in other countries. This consultation relates to Great Britain only. As set out in the Windsor Framework, the current arrangements for batch testing and release for products supplied to Northern Ireland will continue through to 2025 to allow time for a long-term solution to be established. During this time, medicines batch tested and released in Great Britain or the European Union do not need to be repeat batch tested/released when supplied to Northern Ireland. Medicines batch tested/released in Northern Ireland do not need to be repeat batch tested/released on supply to Great Britain.

This consultation relates to veterinary medicines imported into Great Britain. Medicines manufactured in Great Britain must continue to be batch tested and released by a QP before being placed on the market. We expect that all medicines will undergo this process.

The default position for imported veterinary medicines is:

a) medicines must be imported via an authorised manufacturing/importation site in Great Britain (called a ManA site);
b) each batch of medicine must be tested for quality at an authorised site in Great Britain; and
c) each batch of medicine must be certified by a Qualified Person before being released to the market.

However, there are exceptions to the default position. Exceptions fall into two categories: countries the UK has a Mutual Recognition Agreement (MRA) with that includes batch testing, and countries with equivalent regulatory standards. In all options, we will treat countries in the two categories equally.

Countries with MRAs

We have MRAs with several countries, which means we recognise Good Manufacturing Practice (GMP) inspections (including batch testing) in those countries. These countries are: Australia, Canada, Israel, New Zealand, Switzerland, and the United States of America. We are not proposing any options which involve batch testing in Great Britain for medicines already batch tested in countries we have an MRA with.

The UK-EU Trade and Cooperation Agreement (TCA) did not include mutual recognition of batch testing. We are not seeking to revisit this arrangement as part of the consultation.

Countries with equivalent regulatory standards

The current legislation allows us to recognise batch testing conducted in countries with equivalent regulatory standards (CERS). By equivalent regulatory standards, we mean those countries we assess as having similar standards to the UK in the regulation of veterinary medicines.

To ensure that we are content that regulatory standards remain high, we will implement an audit process (on a risk-based approach) for countries with equivalent regulatory standards (those on the 'CERS list'). We will also develop a process for removing countries from this list should their standards not be maintained.

From the VMD's close relationship with the EU when the UK was a member state, we are aware that EU countries currently have equivalent regulatory standards. Therefore, all EU countries are currently included on CERS the list. We will develop a process for other countries to request to be added to the CERS list, and a means for the VMD to assess such requests.

Batch testing

The MRAs already allow for the recognition of batch testing in those countries we have MRAs with, and the current legislation allows us to recognise batch testing conducted in countries with equivalent regulatory standards. We believe that this approach is reasonable and proportionate and we are not seeking to change this as part of the consultation. Therefore, **we do not include any options that require repeat batch testing of medicines that have already been batch tested in exempt countries.**

Medicines that have not been batch tested and released in exempt countries must be imported into a ManA site, and each batch must be tested and certified by a QP before being released to the market.

Option 1 – Medicines must be imported into a ManA site and be certified by a QP

In this option, all medicines manufactured outside of the UK would need to be imported via a ManA site.

Medicines that have been batch tested in exempt countries would not need to be repeat batch tested. Medicines that have not been batch tested in an exempt country would need to undergo batch testing in Great Britain.

Each batch of medicine would then need to be certified by a Qualified Person (QP) before being released to the market from the ManA site.

This option requires medicines batch tested in MRA countries and in countries on the CERS list to be imported into a ManA site and have each batch certified by a QP before release. This requirement already exists for medicines batch tested in countries with which the UK has an MRA but would also apply to medicines manufactured in the EU, which are currently imported without those importation controls.

6. **What do you think are the benefits of using this approach?**
7. **What do you think are the drawbacks of using this approach?**
8. **What impact would this approach have on the availability of veterinary medicines in Great Britain?**

Option 2 – No additional requirements for medicines batch tested and released in exempt countries

This option proposes removing any controls of medicines that have already been batch tested and batch released in exempt countries.

This will allow medicines that have been batch tested and released in exempt countries (those the UK has an MRA with and those on the CERS list) to be imported directly by a wholesale dealer, with no regulatory controls in place. Therefore, in this option, there would be no requirement to import via a ManA site and no requirement to certify by a QP before releasing to the market.

Whilst this option provides benefit to industry, this may limit the VMD's ability (as the regulator) to have effective oversight of all medicines and assure the quality of all medicines imported into Great Britain.

9. **What do you think are the benefits of using this approach?**
10. **What do you think are the drawbacks of using this approach?**
11. **What impact would this approach have on the availability of veterinary medicines in Great Britain?**

Option 3 – The introduction of a market access scheme for wholesale dealers

In this option, all medicines manufactured in other countries must be imported into Great Britain via a ManA site and certified by a QP before being released to the market. However, we propose permitting specifically authorised wholesale dealers to bypass these procedures, as part of a 'market access scheme'. This would allow a wholesale dealer to directly import medicines that have already been batch tested and released in an exempt country, waiving the requirements to import via a ManA site and to have batches certified by a QP before release.

To access this market access scheme, the marketing authorisation holder of the veterinary medicine would need to provide evidence (such as a declaration from the market authorisation holder) that:

- the medicine has been manufactured, batch tested and certified by a QP (or equivalent) in an exempt country;
- the medicine has remained within its direct control from release until ownership is transferred to the specifically authorised wholesale dealer; and
- the quality and integrity of the product is effectively maintained throughout the supply chain.

The marketing authorisation holder may also need to provide other information as requested, such as supply routes and handover points (where responsibility for the medicine is handed over from the marketing authorisation holder to the wholesale dealer).

12. **What do you think are the benefits of this option?**
13. **What do you think are the drawbacks of this option?**
14. **What impact would this approach have on the availability of veterinary medicines in Great Britain?**

Additional points to consider

We have initially included countries in the EU on the CERS list. This is because we are aware that these countries have equivalent regulatory standards. However, whilst the Trade and Cooperation Agreement includes mutual recognition of Good Manufacturing Practice (GMP), batch testing is not included. We therefore propose conducting risk-based audits of batch testing laboratories in countries on the CERS list from time to time, to ensure these countries continue to have equivalent regulatory standards.

15. **What are the benefits of this approach?**
16. **What are the drawbacks of this approach?**

We will introduce a process that will allow other countries to apply to have its regulatory standards deemed ‘equivalent’. This will include risk-based audits of laboratories. We will also introduce a process of removing a country from the CERS list should it fail to demonstrate continued equivalent regulatory standards.

17. **What are the benefits of this approach?**
18. **What are the drawbacks of this approach?**