Registration of veterinary medicines if there's no Brexit deal

Summary
How the registration of veterinary medicines would be affected if the UK leaves the EU with no deal.

Detail
If the UK leaves the EU in March 2019 without a deal, find out how this would affect registration processes for veterinary medicines – including testing, certification, licensing and certain authorisations.

A scenario in which the UK leaves the EU without agreement (a 'no deal' scenario) remains unlikely given the mutual interests of the UK and the EU in securing a negotiated outcome.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

For two years, the government has been implementing a significant programme of work to ensure the UK will be ready from day 1 in all scenarios, including a potential 'no deal' outcome in March 2019.

It has always been the case that as we get nearer to March 2019, preparations for a no deal scenario would have to be accelerated. Such an acceleration does not reflect an increased likelihood of a 'no deal' outcome. Rather it is about ensuring our plans are in place in the unlikely scenario that they need to be relied upon.

This series of technical notices sets out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario, so they can make informed plans and preparations.

This guidance is part of that series.

Also included is an [overarching framing notice](https://www.gov.uk/government/publications/uk-governments-preparations-for-a-no-deal-scenario) explaining the government's overarching approach to preparing the UK for this outcome in order to minimise disruption and ensure a smooth and orderly exit in all scenarios.

We are working with the devolved administrations on technical notices and we will continue to do so as plans develop.

Purpose

The purpose of this notice is to outline the arrangements that would come into force to regulate veterinary medicines in the unlikely event the UK leaves the EU on 29 March 2019 with no deal in place, with specific reference to:

- batch testing of veterinary medicines
- Qualified Person (QP) batch certification and release of veterinary medicines
- Wholesale Dealer's Authorisations
- Manufacturing Authorisation requirements for imported medicinal products from the EU/EEA
- centralised veterinary medicine authorisations

Before 29 March 2019

Under EU law, batch testing by manufacturers that hold a UK manufacturing Authorisation for veterinary medicines can be undertaken anywhere in the EU, EEA, or other countries with whom the EU has made appropriate arrangements (Australia, Canada, New Zealand and Switzerland).

A UK manufacturing authorisation is required for veterinary medicines manufactured in the UK; and a Qualified Person (QP) based in the EU (including the UK) or EEA must certify that each manufactured batch of product complies with its marketing authorisation. The batch testing may be undertaken in the EU (including the UK) or EEA, or a country with appropriate arrangements (for veterinary medicines, Australia, Canada, New Zealand, and Switzerland). These medicines can then be marketed anywhere in the UK/EU/EEA without further certification.

For veterinary medicines manufactured in another EU member state/EEA the batch testing and certification/release must be carried out by a QP based in the EU (including the UK)/EEA, which allows the batch to be marketed (subject to the Marketing Authorisation) in any other EU/EEA country, including the UK, without the need for any further certification. However, a Wholesale Dealer's Authorisation (WDA) is required to supply these veterinary medicines in the UK.

For veterinary medicines manufactured in a non-UK, non-EU, non-EEA country (third country), batch testing is generally required by the importer located within the UK/EU/EEA, except where third countries have made appropriate arrangements with

the EU (Australia, Canada, New Zealand, Switzerland). The importer requires a manufacturing (import) authorisation.

However, all veterinary medicines manufactured in a third country require a QP based in the UK/EU/EEA to certify that the veterinary medicine meets all the required standards, and meets the specification of its Marketing Authorisation, before it can be released from the importer to be marketed in the EU and EEA (including the UK).

A centrally authorised veterinary medicine is one that has been assessed on an EU wide level involving all EU and EEA Member States (MS). A centrally authorised medicine has a pan-European authorisation issued by the European Commission permitting the marketing, distribution and supply of the product in all EU MSs including the UK.

After March 2019 if there's no deal

In the unlikely event there is no agreement between the UK and EU regarding future arrangements, mutual recognition of batch testing of veterinary medicines between the UK and EU / EEA would cease on the date the UK leaves the EU. The mutual recognition of batch testing of veterinary medicines between the UK and third countries with which the EU has made appropriate arrangements would also cease, as would mutual recognition between the UK and EU/EEA Member States of batch certification of veterinary medicines by a QP.

In this unlikely event, in order to deliver a smooth transition and ensure continuity of supply of veterinary medicines, the UK would for a time limited period continue to accept batch testing of veterinary medicines carried out in EU/EEA or any third countries with whom the EU has made arrangements.

The UK would also accept batch certification of veterinary medicines by a QP based in the UK/EU/EEA. The UK would have the option to change these arrangements in the future.

Any veterinary medicines imported into the UK from any other third country would continue to require batch testing in the UK and certification / release from a QP based in the UK/EU/EEA, except where third countries and the EU have made appropriate arrangements with each other.

For industry, all of the above options would mean no change to their normal operating procedures. Products that meet EU requirements could continue to be placed on the UK market without any need for retesting or re-marking. This would

apply for a time-limited period and sufficient notice would be given to businesses before that period ends.

For medicines manufactured in the UK with the view to exporting these to the EU and EFTA, the [EMA has produced guidance which can be found on their website](http://www.ema.europa.eu/ema/).

Although the VMD does not directly issue a marketing authorisation for veterinary medicines authorised by the EU centralised procedure, the product is authorised for use in the UK and would therefore automatically become nationally authorised when the UK leaves the EU. This would prevent the need for re-authorisation at a UK level.

Implications

Implications for the pharmaceutical sector differ depending on whether veterinary medicines are marketed in the UK or EU/EEA market.

Marketing veterinary medicines onto the UK Market

After March 2019, the UK will continue to accept batch testing of veterinary medicines undertaken in the EU, EEA and the countries the EU has made appropriate arrangements, in the same manner as today.

In addition, the UK will accept batch certification by Qualified Persons of veterinary medicines undertaken in the EU and EEA.

Finally, EU centralised marketing authorisation holders will be required to inform the VMD if they would prefer not to have these European authorisations converted to UK authorisations. We will then confirm UK expiry of the veterinary medicine authorisation.

Marketing veterinary medicines onto the EU Market

After March 2019, in the unlikely event there is no agreement between the UK and the EU, the European Medicines Agency (EMA) has published guidance on its website as to the approach EU/EEA/EFTA countries would take to human and veterinary medicines certified by a UK-based Qualified Person. Please refer to the [EMA website](http://www.ema.europa.eu/ema/).

More information

Please see the other two technical notices relating to the regulation of veterinary medicines for further information, and the information stated within this technical notice is subject to matters addressed in other technical notices.

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

It is part of the government's ongoing programme of planning for all possible outcomes. We expect to negotiate a successful deal with the EU.

Norway, Iceland and Liechtenstein are party to the Agreement on the European Economic Area and participate in other EU arrangements. As such, in many areas, these countries adopt EU rules. Where this is the case, these technical notices may also apply to them, and EEA businesses and citizens should consider whether they need to take any steps to prepare for a 'no deal' scenario.