Accessing animal medicine IT systems if there's no Brexit deal

Summary

How IT systems relating to 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 IT systems relating to veterinary medicines, including systems used to submit data and reports.

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 inform key stakeholders of the actions they will need to undertake to continue to submit regulatory and notification information to the UK, via the Veterinary Medicines Directorate (VMD), in the event that the UK leaves the EU in March 2019 with no agreement in place.

Before 29 March 2019

Under the current EU membership, the UK is integrated in European regulatory networks for veterinary medicines. These regulatory networks have, over time, developed shared processes and systems. Several regulatory activities make use of common methods for submitting and exchanging information throughout the Union. These common systems, in the case of veterinary medicinal products, include, but are not limited to:

- Common European Submission Portal (CESP)
- Gateway (Pharmacovigilance)
- EudraLink
- WebTrader (Pharmacovigilance)

After March 2019 if there's no deal

In the unlikely event that the UK leaves the EU in March 2019 with no agreement in place regarding future arrangements, the UK would no longer be part of EU veterinary medicine regulatory networks. The sharing of common systems, and exchange and recognition of data submitted for regulatory activities, between the UK and EU Member States would cease.

The VMD would have independent processes and systems to manage UK veterinary medicines and regulatory activities end-to-end. To enable this, new systems will be in place ready for March 2019.

Implications

After exit, regulatory information relating to veterinary medicines would need to be submitted and processed via separate routes for the EU and UK. The VMD would provide a service to allow for the submission and exchange of information for veterinary medicine activities, including, but not limited to, the following types of submissions:

- Marketing Authorisation (MA) Applications
- Periodic Safety Update Reports
- Qualified Person for Pharmacovigilance (QPPV) and Pharmacovigilance System notifications

Applications to both the EU and the UK would require submission of application dossiers through EU channels as well as submitting directly to the UK. In addition the VMD would ensure suitable solutions are in place to facilitate the submission and sharing of pharmacovigilance reports and data.

The VMD aims to adhere to the following principles in developing independent processes and systems for regulatory activities:

- Minimise impact where possible. For example: VMD would continue to accept EU standards for submission of data; The current electronic format, VNeeS, would still be the underlying format required for submission of regulatory documents related to a Marketing Authorisation (MA), with the exception of Active Substance Master Files (ASMFs), which can be in either VNeeS or e-CTD format.
- Avoid unnecessary complexity, for example by replicating established processes.
- Ensure systems are available for March 2019, with these then being further developed over time.

Development of new solutions

In advance of leaving the EU, the VMD will provide suitable communications and guidance to stakeholders to inform them of new processes and systems. We are planning for this to be provided later this year. It is our intention that where these systems are outward facing there will be some stakeholder testing; where required, training will also be provided.

If stakeholders need to modify their own systems to allow direct exchange with new VMD systems, we aim to provide notice and support to enable the implementation of any connections later this year.

Industry interaction with the EU

UK industry should be able to continue interacting with the EU regulatory network as per [EMA](http://www.ema.europa.eu/ema/) and EU guidance.

More information

Please see the other two technical notices relating to the regulation and registration 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.