Regulation of veterinary medicines if there’s no Brexit deal

Summary

How the authorisation 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 the regulation of veterinary medicines.

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 agreement in place, with specific reference to:

- Marketing Authorisation Holder (MAH) - legal presence requirements
- Veterinary 'Generic' Marketing Authorisations – reference products
- Marketing Authorisation for Parallel Import (MAPI)
- Maximum Residue Limits (MRLs)

Before March 2019

The UK is currently part of the EU regulatory framework for medicines and is a member of the European Medicines Agency (EMA).

The Veterinary Medicines Directorate (VMD) is the UK authorising body for assessing veterinary medicine Marketing Authorisation (MA) applications. Currently, an MAH can be based anywhere in the EU.

There are several different legal bases upon which an application for an MA may be submitted. These reflect the type and content of the data submitted in support of the application. Two of these include:

- Generic: The MA is based on safety and efficacy aspects of data from an existing approved veterinary medicine authorised within the UK, EU or EEA, which is known as the "reference product".

- MAPI: This is when an EU authorised veterinary medicine is imported and marketed in the UK. The veterinary medicine to be imported (known as the "parent product") must be "essentially similar" or identical to a UK authorised veterinary medicine.

UK MAs can be granted for use in food-producing animals. To ensure consumer safety, and facilitate trade in animal food products, maximum residue levels (MRLs) are set by the European Commission. MRLs are scientifically determined highest levels of pharmacologically active substances that are allowed in food derived from farmed animals (including game) following treatment with veterinary medicines. These foods include lean meat, offal, fat, skin (pigs, poultry and fish only), milk, eggs (poultry only), and honey.

After March 2019 if there's no deal

The UK government is committed to negotiating a future relationship with the EU which, for veterinary medicines, would include the UK exploring the terms on which we could remain part of the EMA.

However, in a 'no deal' scenario, where we are no longer part of the EU regulatory framework for veterinary medicines, the UK would need to carry out functions nationally, which are currently undertaken centrally through the EU.

Sharing of common systems, and exchange and recognition of data submitted for regulatory activities, between the UK and EU countries would cease.

This would require changes to the Veterinary Medicines Regulations with some implications for veterinary medicine pharmaceutical industry stakeholders.

Implications

Marketing Authorisation Holder (MAH) legal presence requirements

In order to ensure the VMD could retain full control of UK marketed veterinary medicines and could take swift, appropriate legal action to protect public health, the MAH would need to be established within the UK. This would enable the UK to accept Qualified Person (QP) release and Qualified Person Responsible For Pharmacovigilance (QPPV) to be based elsewhere outside of the UK.

Actions: Pharmaceutical companies would need to ensure they have an established location within the UK. Further details regarding a timescale for this will be published in due course.

Veterinary 'Generic' Marketing Authorisations – Reference Products

The VMD would not have access to the data packages provided in support of EU approved reference products. Whilst this data would have been assessed by another authorising body, the VMD takes full responsibility for a new generic MA application assessment and would need to have confidence that suitable data are available to support the approval of the new MA. Therefore, new generic applications would need to be restricted to those based on reference products authorised in the UK. However if a specific EU product, not authorised in the UK, was required for the treatment of an individual/group of animals, this could be obtained from a veterinary surgeon through the current Special Import Scheme.

Existing generic-based UK MAs, which cite an EU authorised reference product, would still remain authorised after the UK leaves the EU. Any changes to the MA would require the original data to be submitted to the UK for approval.

Actions: For new generic applications, pharmaceutical companies would need to ensure these are based on UK reference products.

For currently authorised generic applications which cite an EU reference product, if future changes were to be made these may need to be supported by proprietary data, as appropriate.

MAPI (Marketing Authorisation for Parallel Import)

MAPI applications require assessment to confirm the proposed EU authorised parent product is 'essentially similar' or identical to a UK MA. In a 'no deal' scenario, the UK would continue to accept veterinary MAPI applications, but original data from the parent product would not be available from the authorising EU country. The responsibility for obtaining necessary parent product data would pass to the MAPI applicant who would need to contact the regulatory authority for the parent product.

Actions: Pharmaceutical companies wishing to submit MAPI applications would need to ensure they would be able to obtain the parent product data from the regulatory authority for the parent product.

Maximum Residue Limits (MRLs)

Existing EU MRLs would become UK law via the EU Withdrawal Act. This would ensure the UK can continue to trade animal food products with the EU and the majority of third countries that recognise the EU process.

After this, the UK would need to set new MRLs and modify existing MRLs on a UK domestic basis. In order to assess MRL applications, the VMD would need to have access to supporting data. To maximise flexibility, the Secretary of State for Defra would have the power to set MRLs based on data from a range of sources, including other MRL setting bodies. UK exporters of products of animal origin to the EU would need to ensure they comply with EU MRLs, including those which may diverge from UK MRLs.

Marketing veterinary medicines in the EU

The EMA has published guidance on its website as to the approach EU/EEA/EFTA countries will take on human and veterinary medicines certified by a UK-based

Qualified Person. Please refer to the [EMA website](http://www.ema.europa.eu/ema/) for this advice if relevant to your organisation.

Actions: New MRL applications need to be submitted to the UK with the full supporting data, as appropriate.

UK exporters of products of animal origin to the EU would need to ensure they comply with EU MRLs, including those which may diverge from UK MRLs.

Further 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.

The UK government is clear that in this scenario we must respect our unique relationship with Ireland, with whom we share a land border and who are co-signatories of the Belfast Agreement. The UK government has consistently placed upholding the Agreement and its successors at the heart of our approach. It enshrines the consent principle on which Northern Ireland's constitutional status rests. We recognise the basis it has provided for the deep economic and social cooperation on the island of Ireland. This includes North-South cooperation between Northern Ireland and Ireland, which we're committed to protecting in line with the letter and spirit of Strand two of the Agreement.

The Irish government have indicated they would need to discuss arrangements in the event of no deal with the European Commission and EU Member States. The UK would stand ready in this scenario to engage constructively to meet our commitments and act in the best interests of the people of Northern Ireland, recognising the very significant challenges that the lack of a UK-EU legal agreement would pose in this unique and highly sensitive context.

It remains, though, the responsibility of the UK government, as the sovereign government in Northern Ireland, to continue preparations for the full range of potential outcomes, including no deal. As we do, and as decisions are made, we'll take full account of the unique circumstances of Northern Ireland.

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.