



Veterinary
Medicines
Directorate

Stakeholder Engagement

Overview

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.

Overview

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.

In a 'no deal' scenario, sharing of common systems, and exchange and recognition of data submitted for regulatory activities between the UK and EU Member States would cease.

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

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Location of Veterinary Medicine Authorisation Holders

Current

Holders must be established in the EU to be granted a veterinary marketing authorisation

Proposed

Holders must be established in the UK to be granted a veterinary marketing authorisation

What does this mean?

- *Ensures the VMD can retain full control of UK marketed veterinary medicines and can take swift, appropriate legal action to protect public health. Where possible harmonise veterinary medicine approaches with human medicines*
- *MAH must have a registered office in the UK and provide supporting information such as a letter of incorporation from companies house*
- *MAH will have a timeframe of 21 months to establish in the UK (as above)*

Batch Release of Product by Qualified Person (QP) on import into the UK

Current

Compliance activities, including batch release, have to take place within an EU Member State by way of mutual recognition of batch testing and certifications of veterinary medicines between the UK and EU / EEA Member States

Proposed

For a time limited period the UK will continue to accept batch certification by a QP based in the UK, EU or EEA. The results of batch testing from those countries with whom the EU has Mutual Recognition Agreements will also continue to be accepted

Qualified Person for Pharmacovigilance (QPPV) Location

Current

QPPV must be based in the EU

Proposed

QPPV can be based anywhere

What does this mean?

- *Our thinking behind MAH location in UK provides appropriate regulatory reach to be pragmatic and increase flexibility around QPPV location*

Centrally Authorised Procedure (CAPs)

Current

Existing authorisations as per EU Regulation 726/2004 are valid in all relevant EU Member States

Proposed

Existing CAPs will be automatically converted to National authorisations

What does this mean?

- *Products authorised through an EU centrally authorised procedure (CAPs) can remain on the UK market*
- *CAPs will become National authorisations on the day the UK leaves the EU*
- *In cases where the MAH chooses not to convert to National authorisations the CAP will effectively be expired for the UK market. Normal expiry processes will apply*
- *New National MAs will require a VM number on their packaging following a grace period (> 6 months tbc). Companies will need to obtain approval for CAP packaging by way of a suitable variation*
- *There will be no fee to convert CAPs to National*
- *Future variations will need to be submitted as National applications, National fees will apply*

EU Mutual Recognition Authorisation Procedures - 'MRP / DCP'

Current

Existing authorisations as per Directive 2001/82 as amended are valid in all relevant Member States

Proposed

No change, existing authorisations are already categorised as National authorisations

What does this mean?

MRP / DCP

- *Products authorised in the UK already have a UK authorisation therefore no changes needed*
- *Future variations will need to be submitted as National applications, national fees will apply*

Reference Products for 'Generics'

Current

Reference products for Generic authorisations need to be authorised within an EU Member State

Proposed

Reference products for Generic authorisations need to be authorised within the UK

What does this mean? 'Generics'

- *For existing Generics based on an EU reference product these will continue to be valid in the UK*
- *The onus will be on the MAH to provide their own data to support changes to their MA going forward*

Maximum Residue Limits (MRLs)

Current

MRLs set by the European Commission

Proposed

MRLs set on a UK basis
(Secretary of State)

What does this mean?

- *Existing EU MRLs will continue to be valid in the UK on Day 1*
- *New MRL applications will be subject to an assessment of data and an appropriate fee*

Residues Surveillance

Current

National Residues
Surveillance Programme
based on EU law

Proposed

National Residues
Surveillance Programme
based on UK law

What does this mean?

- *We will continue to implement a surveillance programme that ensures the ability for continuity in trading arrangements with the EU and third countries*

MAPI (Marketing Authorisation for Parallel Import)

Current

MAPI applications require assessment to confirm the proposed EU authorised product for parallel import is 'essentially similar' or identical to a UK MA

Proposed

Products can be sourced from any country.
Applications require assessment to confirm the proposed authorised product for parallel import is 'essentially similar' or identical to a UK MA

What does this mean?

- *The responsibility for obtaining the necessary data for the authorised product for parallel import will sit with the MAPI applicant*
- *Existing MAPIs will continue to remain valid*
- *MAPIs continue to be simple assessments to confirm identity of proposed parallel import against the UK authorised product. No additional data will be considered*

Imports of Products for use under the Cascade

Current

Veterinary surgeons must consider the use of EU authorised veterinary medicines in preference to third countries for use in animals under their care

Proposed

Veterinary surgeons can consider using authorised veterinary medicines from any country outside of the UK under the cascade, should there be no suitable UK authorised veterinary medicine available

What does this mean?

- *To facilitate availability of medicines for veterinary use, applications for imports of products from any country for use under the Cascade will be considered. The risk profile of EU veterinary medicines may increase*

Operational Aspects

Elements of VMD activities not specified in Exit SI but are affected

Good Manufacturing Practice (GMP) Inspections

Current

UK recognise GMP inspections carried out by EU Member States and third countries holding an MRA with EU

Proposed

We will conduct GMP inspection of veterinary only manufacturing sites located outside of the UK on a risk basis

What does this mean?

- *Risk based inspection policy still being reviewed*

Labelling

Current

Joint labelling can be achieved through 2 mechanisms; either UK and EU member State consult during assessment or UK assesses independently

Proposed

UK and other country will consult on assessment of packaging, shared list of questions sent to applicant following parallel assessment of packaging text

What does this mean?

- *Applications to be submitted to UK and other country in parallel*

Regulatory Networks

Current

UK is integrated in European regulatory networks for veterinary medicines, sharing common systems, and exchange and recognition of data submitted for regulatory activities, between the UK and EU Member States

Proposed

VMD will have independent processes and systems to manage UK veterinary medicines and regulatory activities end-to-end