Submitting regulatory information on medical products if there's no Brexit deal

Summary

How you would submit regulatory information about medicines, medical devices and e-cigarettes to the Medicines and Healthcare products Regulatory Agency (MHRA) if the UK leaves the EU with no deal.

Detail

If the UK leaves the EU with no deal:

- The UK would no longer be part of the EU medicines and medical devices regulatory networks
- You would need to submit regulatory information relating to human medicines, medical devices and e-cigarettes directly to the MHRA.

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 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 MHRA (Medicines and Healthcare products Regulatory Agency) stakeholders of what they'll need to do to continue to submit regulatory information to us in the unlikely event of a no-deal scenario.

Interested parties may wish to consider other relevant notices, including '**Batch testing medicines if there's no Brexit deal'** and '**How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal'**.

Before 29 March 2019

We're currently a part of the EU regulatory networks for medicines and medical devices. These regulatory networks have shared processes and systems.

You can submit information into one place for it to be shared around all EU and EEA countries.

The shared systems, in the case of human medicinal products, include, but are not limited to:

- CESP (common European submission portal)
- EMA (European Medicines Agency) gateway
- EudraVigilance
- Common repository
- PSUR (periodic safety update report) repository
- PedRA (paediatric record application)
- EudraCT and the new CTR (clinical trial regulation) portal
- Article 57 database
- EudraLink and EudraMail

For medical devices, shared systems include, but are not limited to, the European Databank for medical devices (EUDAMED).

Shared systems also exist for other products, such as the EU common entry gate (EU-CEG) for tobacco products, e-cigarettes and refill containers.

After 29 March 2019 if there's no deal

If there's no deal, the UK would no longer be part of the EU medicines and medical devices regulatory networks. The sharing of these common systems, and the associated exchanges of data, between the UK and EU/EEA countries would end.

We would have our own processes and systems to manage UK human medicines and devices regulatory activities. To do this, some new systems are being developed for March 2019.

Implications for MHRA stakeholders

You would need to submit regulatory information relating to human medicines and devices directly to us.

We would have a national portal(s) for you to submit regulatory information into. The following types of information would be submitted via a portal (not an exhaustive list):

- marketing authorisation (MA) applications
- periodic safety update reports (PSURs)
- paediatric investigation plans (PIPs)
- clinical trial applications
- qualified person for pharmacovigilance (QPPV) and pharmacovigilance system master file (PSMF) notifications
- individual case safety reports (ICSRs) and subsequent transmission of anonymised single patient reports (ASPRs)
- device registration
- e-cigarette notifications.

For applications that you plan to submit to both the EU and the UK (for example, a MA for both EU and UK markets), you would need to submit the information separately through EU systems and our portals.

We're following the below principles in developing independent processes and systems for regulatory activities.

- We would minimise impact on stakeholders, where possible. For example, we would continue to accept EU application forms and EU standards for submission, where possible. We would continue to accept the eCTD (electronic common technical document) for submission of regulatory documents relating to an MA.
- We would avoid unnecessary complexity, for example by following existing processes.

- We would have systems up and running for March 2019. They would then be developed further over time.

Development of new systems

We'll provide communications and guidance on the new processes and systems ahead of March 2019, so that you are able to use them from day one. We'll communicate as soon as possible and intend to do this later this year.

We'll need some of our stakeholders to help us test our systems before March 2019, and where, required, we'll also provide training.

If you need to change your own systems to work with our new portal(s), we plan to provide notice and guidance to help you do this later this year.

If your organisation will continue to be an EU stakeholder

UK organisations should be able to continue interacting with the EU regulatory network as per EMA guidance and EU guidance.

More information

We'll be publishing further information and instructions in the coming months. We aim to give businesses, organisations and individuals as much certainty as possible as soon as we can and to ensure that any new requirements are not unduly burdensome.

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.

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.