Batch testing medicines if there's no Brexit deal

Summary
How batch testing 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, we'll continue to:

- accept batch testing of human medicines carried out in countries on a list from the Medicines and Healthcare products Regulatory Agency (MHRA)
- require a UK, EU or EEA-based qualified person (QP) to certify batch testing

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

This notice updates businesses on the arrangements that will come into force in the unlikely event that the UK leaves the EU on 29 March 2019 with no agreement in place for the regulation of human medicines. This notice only covers arrangements with reference to:

- batch testing, by manufacturers, of human medicines
- Qualified Person (QP) certification and release, by manufacturers, of human medicines

The July 2018 white paper on the future relationship between the UK and the EU set out the government's offer to explore the terms on which the UK could remain part of the European Medicines Agency (EMA). The Prime Minister has also set out our desire to ensure that products only need to undergo one series of approvals in one country - this is essential in continuing to get new medicines and devices to patients quickly.

However, we recognise that companies need certainty on the future requirements for batch testing and QP certification and release after the UK leaves the EU and it's important that we put in place appropriate contingency plans for other potential outcomes from the EU exit negotiations.

Batch testing is the process of confirming every batch of medicine has the correct composition through laboratory tests. QP certification and release is the confirmation that the batch meets the requirements of the Marketing Authorisation (MA) and is suitable for sale and supply or export.

The pharmaceutical sector may also wish to consider other relevant notices, including on IT systems, general life sciences, intellectual property, and other manufactured goods. Further guidance on the future regulatory framework for medicines, including biological medicines, IT systems requirements, manufacturing and import licensing will be published later this year.

Before 29 March 2019

Manufacturers can batch test medicines anywhere in the EU, EEA or other third countries with whom the EU has a Mutual Recognition Agreement' (MRA) under Article 51(2) of Directive 2001/83/EC ("the Directive").

For human medicines manufactured in the UK, a UK-based Qualified Person must certify the batch testing and ensure compliance with the MA and Good

Manufacturing Practice (GMP) guidelines. These medicines can then be sold or supplied anywhere in the EU or EEA, including the UK, without further certification.

For human medicines manufactured in the EU/EEA, the batch testing and certification or release by an EU or EEA based QP allows a batch of human medicines to be sold in any other EU or EEA country (subject to the requirements of the country), including the UK, without the need for any further certification.

For human medicines manufactured in a third country outside the EU or EEA and imported into the UK through the EU or EEA, batch testing is required within the UK, EU or EEA, unless the medicine has been manufactured in a third country with which the EU has an MRA.

However, a human medicine manufactured in a third country requires a QP based in the UK, EU or EEA to certify that it meets all the required standards and specifications of the Marketing Authorisation, before it can be sold or supplied in the EU or EEA (including the UK).

After 29 March 2019 if there's no deal

In the unlikely event of no deal, the UK would no longer be part of the EMA.

In order to ensure continuity of supply in medicines however, the UK will continue to accept batch testing of human medicines carried out in countries named on a list set out by the MHRA. On exit day, this list would include EU countries, other EEA countries and those third countries with which the EU has an MRA.

The UK will also continue to accept batch testing of Investigational Medicinal Products (IMPs) – substances being used in medical trials - manufactured in EU and EEA states. There will be no change to the present arrangements for batch testing of IMPs manufactured in third countries.

For human medicines manufactured in the UK, we will continue to require a UK-based QP to certify the batch testing and to ensure compliance with the Marketing Authorisation and Good Manufacturing Practice (GMP) guidelines, before these medicines can be sold or supplied in the UK.

For human medicines manufactured in a third country and directly imported into the UK, we will continue to require a UK-based QP to certify the batch testing, as well as to ensure compliance with the MA and with GMP guidelines, before they can be sold or supplied in the UK.

Where human medicines are manufactured in a third country but are imported into the UK from a country on a separate list maintained by MHRA (on exit day, this list will contain EU and EEA countries), we will continue to recognise certification, release and assurance of compliance with the MA and with GMP guidelines, if conducted by a QP based in the listed country, without the need for any further certification.

For human medicines manufactured in a country on the MHRA's QP list, which have the relevant QP certification, we will continue to recognise certification, release and assurance of compliance with the MA and with GMP guidelines, if conducted by a QP based in the listed country, without the need for any further certification.

The approaches to QP certification of licensed medicines set out above will also apply to IMPs.

These arrangements will continue until the government considers any further change is necessary. We are committed to working with industry ahead of any such changes to the arrangements outlined in this technical notice which might impact supply chains and manufacturing processes, and to giving at least two years notice of the introduction of any changes, in order to allow industry to fully prepare for their implementation.

What you would need to do

In the unlikely event of the UK leaving the EU with no deal, there are different implications for the pharmaceutical sector, depending on whether they are selling human medicines onto the UK, EU or EEA market.

To ensure continuity of supply in medicines, we would continue to accept batch testing of human medicines done in certain countries included on a list which will be set out by the MHRA. We would apply the same approach to QP certification and release as we do now.

The EMA has published guidance on its website as to the approach EU and EEA countries will take to human medicines that are batch tested and certified and released by a UK based QP if there's no deal.

More information

We'll be publishing further information and instructions in the coming months, including on biological medicines, IT systems requirements, manufacturing and import licensing. 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 advice and guidance only and is not designed to dictate the specific preparations of individuals or businesses.

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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.