What to expect on day one of a no deal scenario: Businesses supplying medicines and medical devices[Δ]

If the UK leaves the EU without a deal, people should be reassured and have confidence in the government's plans for continuity of medicines supply.

If you're a pharmaceutical company supplying the UK with medicines from, or via, the EU or European Economic Area (EEA), the Department of Health and Social Care (DHSC) is asking you to make sure you have a minimum of six weeks' additional supply in the UK, over and above your business as usual operational buffer stocks, by 29 March 2019. Read DHSC's letter to pharmaceutical companies.

DHSC has also asked suppliers to indicate how they propose to ensure continuity of supply of their products to the NHS as part of the contingency programme.

Since writing to pharmaceutical companies, DHSC has received good engagement, and we know that, as an industry, you share the UK government's aim of ensuring and maintaining the continued supply of medicines for patients.

If you're a pharmaceutical company, DHSC will continue to work closely with you to ensure that your UK stockpiles of medicines are sufficient to cope with any potential delays at the border that may arise in the short term.

Medical devices and clinical consumables

The UK will continue to recognise medical devices approved for the EU market – in other words, those that carry a CE mark and, where required, have appropriate certification from an EU notified body.

If you are a supplier of medical devices and clinical consumables, DHSC is asking you to continue to review your supply chains and assess the implications of a no deal scenario upon your product ranges, and the potential contingencies that might be required. Read DHSC's letter to suppliers of medical devices and clinical consumables.

DHSC has adopted a contingency planning approach that will help ensure the continued supply of medical devices and clinical consumables in the event of a no deal scenario.

As part of that approach, DHSC has undertaken an analysis of supply chains for medical devices and clinical consumables, identifying those products routinely imported into the UK from other countries in the EU. One of DHSC's contingency measures is to increase stock held at national level, and its NHS Supply Chain colleagues are working with suppliers who import from the EU to establish the action required to achieve this.

In addition, arrangements are being made to facilitate the continued movement of medical devices and clinical consumables that are routinely supplied from other EU countries directly to NHS organisations. In conjunction with representatives from industry and trade associations, DHSC has set up a working group to test and refine its contingency plans, and the mechanisms by which suppliers will interact with these processes.

Read more about how medicines and medical devices will be regulated in a no deal scenario on GOV.UK.

Medical radio-isotopes

The government considers the continuity of supply of medical radio-isotopes to be a high priority matter following the UK's withdrawal from the EU and Euratom.

The government's approach to medicine supply contingency planning in the event of a no deal EU Exit recognises that there are some products, such as medical radio-isotopes, that have short shelf lives and cannot be stockpiled.

If you're a supplier of medical radio-isotopes, the government will consider how to support you in making arrangements to avoid any border delays that may arise.

Batch testing and clinical trials

If you're an organisation running clinical trials in the UK, DHSC encourages you to consider your supply chains for Investigational Medicinal Products (IMPs) in the event of a no deal scenario. DHSC is working with industry partners and others, including charities, to do this.

If you are running clinical trials that use IMPs which come from or via the EU or EEA, you will need to ensure appropriate arrangements to assure supplies in the event of any possible border delays that may arise in the short term.

If the UK leaves the EU without an exit deal, we will no longer be a member of the European Medicines Agency but will continue to recognise batch testing of human medicines carried out in EU and EEA states for a time limited period.

The UK will also continue to accept batch testing of Investigational Medicinal Products (IMPs) – substances 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 Qualified Person (QP) to certify the batch testing and to ensure compliance with the Marketing Authorisation (MA) 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.

Read more about batch testing medicines in a no deal scenario.

Manufacturer's Authorisation (MIA) licences

Currently there are two MIA licences, issued by the Medicines and Healthcare products Regulatory Agency (MHRA), that relate to importing licensed medicines into the UK. These are:

Manufacturer licences: to qualify for a manufacturer licence to make, assemble or import human medicines, you need to show the MHRA that you comply with EU good manufacturing practice and pass regular inspections of your site.

Wholesaler licences: to sell or supply medicines to anyone other than the patient using the medicine, you need a wholesaler licence – also known as a wholesale dealer licence or wholesale distribution authorisation. To qualify, you must comply with good distribution practice and pass regular inspections of your site.

Making importing easier from the EU

HMRC is introducing new Transitional Simplified Procedures (TSP), to make importing through roll-on, roll-off ports and the Channel Tunnel easier for the initial period after the UK leaves the EU, should there be no deal. We anticipate TSP will remain in place until traders are ready to use rest of the world processes and permanent arrangements are in place, which will take at least a year.

Sign up for HMRC's new Transitional Simplified Procedures (TSP), online from 7 February, to make importing easier for you until at least April 2020.

Once you are registered for TSP you will be able to:

- transport most goods into the UK without having to make a full customs declaration at the port
- postpone paying your customs duties.

However, for controlled goods, such as animal products and most plants, or excise goods like alcohol or tobacco, you will have to provide some customs information before import.

We have published further guidance on TSP on GOV.UK, including the locations TSP applies to.

Actions you should take now

1. If you're a pharmaceutical company supplying the UK with medicines from, or via, the EU or European Economic Area (EEA), you should make sure you have a minimum of six weeks' additional supply in the UK, over and above your business as usual operational buffer stocks, by 29 March 2019.
2. If you're a supplier of medical devices and clinical consumables, you should review your supply chains and assess the implications of a no deal scenario upon your product ranges, and the potential contingencies that might be required.
3. If you're an organisation running clinical trials in the UK, you should consider your supply chains for Investigational Medicinal Products (IMPs) in the event of a no deal scenario.
4. Read the government's technical notice on how medicines, medical devices and clinical trials would be regulated if there's no Brexit deal.
5. Read the government's technical notice on submitting regulatory information on medical products if there's no Brexit deal.
6. Read details of the government's Medicines Supply Contingency Planning Programme.
7. Sign up for Transitional Simplified Procedures (TSP), online from 7 February, if it's suitable for your business but you should note that:
   - you will need to use your EORI number to register
   - if you are importing controlled goods such as animal products and most plants, or excise goods like alcohol or tobacco, you will have to provide some customs information before you import
   - read further guidance on TSP on GOV.UK, including the locations TSP applies to.
8. The passport rules for travel to most countries in Europe will change if the UK leaves the EU on 29 March 2019 without a deal. Read the government's guidance on Travelling to the EU with a UK passport if there's no Brexit deal and, if relevant, ensure your employees and customers are aware of the potential changes.
9. Stay up-to-date with these changes by registering for email alerts. Follow the link, add your email address, select 'Submit', select 'Add subscription' and choose 'EU Exit' then select 'Submit'.