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Guidance

The life sciences sector and preparing for EU Exit

If the UK leaves the EU without a deal, there may be changes that affect your business.

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Contents

Your business may need to make changes before the UK leaves the EU. Please visit Prepare for EU Exit (https://euexit.campaign.gov.uk/) to find more detailed guidance on policy changes relevant to your sector and to sign up for updates.

Regulation and standards

Preparing for changes to the way medicines, medical devices and clinical trials will be regulated

If the UK leaves the EU without a deal, the UK's involvement in the European regulatory network will end. The Medicines and Healthcare products Regulatory Agency (MHRA) will take on the EU's current regulatory functions for medicines and devices in the UK.

Maintaining EU/EEA market access for medicines

To place a medicine on the EU market, the Market Authorisation Holders (MAHs) and applicants must be established in the EU/EEA. The Qualified Person for Pharmacovigilance (QPPV) and the Pharmacovigilance System Master File must be based in the EU/EEA.

Read the European Medicines Agency (EMA) guidance (https://www.ema.europa.eu/en/about-us/uks-withdrawal-eu/brexit-related-guidance-companies#guidance-on-centrally-authorised-products-section) to find out more. See below for requirements for placing a medicine on the UK market.

Maintaining EU/EEA market access for medical devices and In Vitro Diagnostic Devices (IVDs)

Where required by EU law, devices should be CE marked, the technical files held by an EU Notified body, and an authorised representative appointed in the EU.

Registration with individual Competent Authorities may be required for access to individual member-state markets.

After the UK leaves the EU, conformity assessment carried out by UK notified bodies, designated by the UK Competent Authority, will not be recognised in the EU.

Any European presence of a UK notified body, designated by a European competent authority, will be in compliance with EU law after exit. Certificates held with that European presence will be valid – you should discuss directly with your UK notified body if this affects you.

Read the European Commission guidance (https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#grow) to find out more.

Maintaining UK market access for medicines

To place a medicine on the market after the UK leaves the EU, the MAH and QPPV can initially be UK or EU/EEA based, but the MAH and QPPV must be established in the UK by the end of 2020.

Where the MAH is not established in the UK on exit day, a UK-based contact must be in place within 4 weeks of EU Exit.

All Centrally Authorised Products (CAPs) will be converted into UK market authorisations on 29 March 2019.

Read further information on marketing applications in progress at the time of exit (https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal) under the heading ‘in-progress licensing procedures at time of exit’.

After EU Exit, to market a new product in the UK, an initial MA application will need to be submitted to the MHRA and will go through a national assessment.

Maintaining UK market access for devices and IVDs

Devices for the UK market must be CE marked in compliance with EU law by either an EU notified body or a UK Conformity Assessment body (for devices CE marked prior to the 29 March 2019).

Any changes to this in the future will be subject to consultation with industry and your business will be given time to implement any new requirements.

In addition, devices for the UK market need to be registered with the MHRA according to the

timetable set out in the further guidance.

Where a manufacturer is based outside of the UK, registration must be done by a nominated UK Responsible Person.

Read the Regulating medical devices in the event of a no deal scenario (https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario) guidance for more information.

Clinical trials

The UK will continue to recognise existing clinical trial authorisations – for regulatory and ethics approvals – and your business will not need to re-apply. The MHRA and ethics committees will continue to authorise UK clinical trial authorisation applications.

Read the guidance on How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal (https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal) for more information on manufacturing human medicines in the UK and EU.

Please also regularly check the MHRA website for new detailed guidance (https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal).

Preparing for changes to batch testing recognitions

To make sure there will be a continual supply of medicines, 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 clinical 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.

Please read batch testing medicines if there's no Brexit deal (https://www.gov.uk/government/publications/batch-testing-medicines-if-theres-no-brexit-deal/batch-testing-medicines-if-theres-no-brexit-deal) to find out more about manufacturing human medicines in the UK and EU.

The UK will continue to recognise Qualified Person (QP) certification from the EU/EEA after the UK leaves the EU, for medicines manufactured in the EU/EEA or manufactured in a third country but imported into the UK from the EU/EEA.

Importing and exporting

Preparing for disruption to trade at the UK-EU border

1. Get a UK Economic Operator Registration and Identification (EORI) number (https://www.gov.uk/guidance/get-a-uk-eori-number-to-trade-within-the-eu) so you can continue to import or export goods and apply for authorisations that will make customs processes easier for you.
2. Decide if you want to hire an import-export agent, or make the declarations yourself (https://www.gov.uk/guidance/declaring-your-goods-at-customs-if-the-uk-leaves-the-eu-with-no-deal).
3. Contact the organisation that moves your goods (for example, a haulage firm) to find out what information they need to make the declarations for your goods, or if you will need to make them yourself.

Read the guidance on simplified customs procedures for trading with the EU if we leave without a deal (https://www.gov.uk/guidance/customs-procedures-if-the-uk-leaves-the-eu-without-a-deal).

Find further information in HMRC's advice for businesses trading with the EU (https://www.gov.uk/government/publications/no-deal-brexit-advice-for-businesses-only-trading-with-the-eu).

Preparing for changes to existing trade agreements

Check the way you currently trade with non-EU countries. When the UK leaves the EU the way you access existing favourable arrangements with these countries may change. Changes may be different for each country.

Read the guidance on changes to trading with non-EU countries that have a free trade agreement with the EU (https://www.gov.uk/government/publications/existing-trade-agreements-if-the-uk-leaves-the-eu-without-a-deal/existing-trade-agreements-if-the-uk-leaves-the-eu-without-a-deal).

Your employees

Employing EU workers

If the UK leaves the EU without a deal, EU citizens who are resident in the UK before 29 March 2019 will be able to apply to the EU Settlement Scheme (https://www.gov.uk/settled-status-eu-citizens-families) to get settled or pre-settled status, which will mean they can continue to live, work and study in the UK.

The scheme will be open to applications from 30 March 2019 but EU workers must apply by 31 December 2020 if the UK leaves the EU without a deal.

You can use the EU Settlement Scheme guidance for employers (https://www.gov.uk/government/publications/eu-settlement-scheme-employer-toolkit) to give further information to your employees.

Applying for skilled-work or unskilled-work visas

If the UK leaves the EU without a deal, there will be a new process for EU citizens arriving in the UK between 30 March 2019 to 31 December 2020. From 1 January 2021, a new skills-based immigration system will launch.

For non-EU nationals, EU Exit will not affect the application process for work visas.

Travelling to the EU

If the UK leaves the EU without a deal, British passport holders travelling to the EU will need to have 6 months remaining validity on your passport, not including any extra months added to a 10-year passport if it was renewed early.

Read guidance about travelling to the EU with a UK passport if the UK leaves the EU without a deal (https://www.gov.uk/government/publications/travelling-to-the-eu-with-a-uk-passport-if-theres-no-brexit-deal/travelling-to-the-eu-with-a-uk-passport-if-theres-no-brexit-deal) and check your passport to see if you need to renew earlier than planned (https://www.passport.service.gov.uk/check-a-passport).

Personal data

Data protection

Your business will need to make sure it follows data protection law if the UK leaves the EU on 29 March 2019 without a deal.

If you operate across the EU or exchange personal data with organisations in the EEA, there may be changes that you need to make before the UK leaves the EU.

Read the 6 step process (https://www.gov.uk/government/publications/data-protection-eu-exit-guidance/leaving-the-eu-without-a-deal-6-steps-to-take) and the data protection guidance from the Information Commissioner's Office (ICO) (https://ico.org.uk/for-organisations/data-protection-and-brexit/data-protection-if-there-s-no-brexit-deal/).

You can also check if you can use Standard Contractual Clauses (SCCs) for transfers from the EEA to the UK.

Trade associations

UK Bioindustry Association (https://www.bioindustry.org/)
The Association of the British Pharmaceutical Industry (https://www.abpi.org.uk/)
The Association of British HealthTech Industries (https://www.abhi.org.uk/)

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