

## Collated guidance for business on no deal preparations (since last update email 15 March 2019)

### Useful Links

- Life Sciences [landing page](#) collating guidance for preparing for a no deal EU Exit.
- You can sign up to **email alerts about EU Exit** on GOV.UK at this [link](#).
- EU citizens and other interested stakeholders can sign up for **Home Office email updates about developments on the status of EU citizens in the UK after we leave the EU and the next steps for EU citizens in the UK** at this [link](#).
- Online [Triage Tool](#) to Help Businesses Prepare for the UK Leaving the EU.
- [HMRC Partnership Pack](#) designed to help support businesses to prepare for day one in the event of a no deal scenario.
- **HMRC inbox** [externalstakeholders.customs@hmrc.gsi.gov.uk](mailto:externalstakeholders.customs@hmrc.gsi.gov.uk) that you can send questions to.
- The **MHRA's collection of guidance and publications** on a possible no deal scenario is available [here](#).
- The **MHRA webinar page** related to making submissions to the MHRA in a no deal scenario is available [here](#).

### MHRA Guidance

#### Marketing Authorisations, Variations and Licensing Guidance

- MHRA [guidance](#) on **updates to packaging components and instructions on submissions** in a no deal scenario for those **marketing authorisations (MAs) issued following conversion of EU MA** (21 March 2019). The guidance explains the steps companies will need to take to register new artwork for medicines packaging as a result of new MAs being issued in the event the UK leaves the EU without a deal.
- MHRA [guidance](#) on **registration of clinical trials for investigational medicinal products, publication of summary results and future requirements** in a no deal scenario (20 March 2019).
- MHRA [guidance](#) on the **handling of applications for Centrally Authorised Products (CAPs) that are still pending on exit day** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) on **converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs)** in a no deal scenario, 'grandfathering' and **managing lifecycle changes of medicinal products** (18 March 2019).
- MHRA [guidance](#) on MHRA's intended approach to the **processing of variations to Marketing Authorisations (MAs) after exit day** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) on **MHRA's approach to the processing of applications to renew Marketing Authorisations (MAs)** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) on **how UK orphan medicinal products will be managed** in a no deal scenario (18 March 2019). The MHRA will be responsible for reviewing applications from companies for orphan designation at the time of a Marketing Authorisation Application (MAA).
- MHRA [guidance](#) on **Marketing Authorisation Applications (MAAs) submitted to the UK that have been referred under Article 29** in a no deal scenario (18 March 2019).

- MHRA [guidance](#) on **converting Parallel Distribution Notices (PDNs) to UK Parallel Import Licences (PILs)** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) on **handling of/how the MHRA will continue to accept Active Substance Master Files (ASMFs) and Certificates of Suitability (CEPs)** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) on **handling of/MHRA's intended approach for products approved or pending in Decentralised Procedure (DCP) and Mutual Recognition Procedures (MRP)** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) providing further information on the **new assessment routes including targeted assessment, accelerated assessment and a rolling review** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) on **Reference Medicinal Products (RMPs)** in a no deal scenario (18 March 2019). This guidance should be considered by applicants when selecting RMP for applications for new generic medicines and other abridged marketing authorisations.
- MHRA [guidance](#) on **new provisions for traditional herbal medicinal products and homoeopathic medicinal products** in a no deal scenario (18 March 2019).
- MHRA [guidance](#) on the **procedures that the MHRA will introduce to regulate Biological medicines and the licensing of biological products** (biosimilars, ATMPs and PMFs) in a no deal scenario (18 March 2019).
- MHRA updated [guidance collection](#) for **industry and organisations involved in health and care about contingency plans** for a possible no deal EU Exit (14 March 2019).

#### Importing and Exporting

- MHRA updated [guidance](#) providing information on the **'Written Confirmation' process, for active substances manufactured in the UK**, that will be adopted in a no deal scenario. An **updated version of the Register of Written Confirmations for UK active substance manufacturers** has been uploaded (18 March 2019).
- MHRA [guidance](#) on **importing medicines from an EEA State which is on an approved country for import list** in a no deal scenario (11 March 2019).

#### Medical Devices

- MHRA updated [guidance](#) on **regulating medical devices** in a no deal scenario. **Additional information about how to register your medical devices** in a no deal scenario has been added to the page under the 'Registrations' section (19 March 2019).

#### Regulatory Submissions and Vigilance Activities

- MHRA [guidance](#) on **MHRA's approach to pharmacovigilance** in a no deal scenario (18 March 2019).

#### **MHRA Weekly Update Email**

- MHRA have sent out an email update on EU Exit. This is a **weekly email update**. This week's email and its attachment are attached to our email for your information. The topics covered are below:
  - Update on progress of legislation to allow the continued sale of, and access to, medicines, medical devices and clinical trials;
  - Update on no deal contingency systems programme;
  - Guidance on operational change.

### **HMRC Webinar - Preparing for a no deal EU Exit**

- The HMRC have been holding a **live webinar “Preparing for a no deal EU Exit” to provide an overview for UK businesses involved in the movement of goods between the EU and the UK**. This webinar covers what UK businesses need to know to keep imports and exports up to speed, and it identifies the key steps to continue trading with EU businesses.
- Areas covered includes:
  - why it's important to apply for an Economic Operator Registration and Identification number (EORI);
  - what Transitional Simplified Procedures are;
  - how to prepare to make customs declarations;
  - what Entry Summary Declarations are; and
  - how to pay the correct customs duty and VAT.
- Attendees will have the opportunity to ask questions during the webinar using the on-screen text box (although they may not be able to answer all questions raised during the webinar); and HMRC will provide useful links to regularly updated information at the end of the webinar.
- You can **choose a date and time** [here](#). At present, upcoming webinars next week are:
  - Monday 25 March 2019 12h00-13h00 GMT
  - Tuesday 26 March 2019 13h00-14h00 GMT
  - Tuesday 26 March 2019 15h00-16h00 GMT

### **Continuity of Supply of Medical Products**

- Department of Health and Social Care continues to work closely with Department for Transport to ensure suppliers of medicines and medical products have **access to the Government Secured Ferry Capacity (GSFC) shipping routes until the later EU Exit date**. Suppliers should **ensure that they have registered in advance** to ensure that they can access these contingency measures should this become necessary. Tickets are now available for purchase.
- The Department of Health and Social Care is continuing to work on detailed plans to ensure the continuation of the supply of medical products to the whole of the UK in the event of a no deal EU Exit.
- A letter was sent out from the Department of Health and Social Care on 15 March 2019 **thanking industry** for their excellent engagement over the past few months and requesting **they continue**

**with their no deal preparation and not wind-down their contingency plans** at this stage. A copy of the letter is attached to our email.

- Some useful links:
  - NHS [patient messaging](#) on getting medicines in a no deal scenario.
  - NHE England's [website page](#) regarding medicines.

### **Landing Page Updates**

- The Life Sciences [landing page](#) , and the **Chemicals sector landing page** , collating guidance for preparing for a no deal EU Exit, have been updated with **information on the temporary tariff regime** (14 March 2019).

### **Relevant Updated Guidance**

#### **Provision of Services to EEA and EFTA Countries**

- The Department for International Trade, Department for Business, Energy & Industrial Strategy, and Foreign & Commonwealth Office's [guidance](#) for UK businesses on **service provision to EEA and EFTA countries in a no deal scenario** and **country guides** has been updated with guidance for Ireland and Switzerland (19 March 2019).

#### **Import/Export**

- Department for Business, Energy and Industrial Strategy [guidance](#) on **placing manufactured goods on the EU internal market** in a no deal scenario (19 March 2019). This provides an overview to UK businesses on the steps they need to take to comply with regulations on manufactured goods placed on the EU internal market.
- Department for Business, Energy and Industrial Strategy [guidance](#) on **placing manufactured goods on the UK market** in a no deal scenario (19 March 2019). This provides an overview to businesses in the UK and other countries on the steps they need to take to comply with regulations on manufactured goods placed on the UK market.
- Department for Business, Energy and Industrial Strategy [guidance](#) on **status of conformity assessment bodies** under no deal (19 March 2019). Guidance for Notified Bodies.
- HMRC updated [guidance](#) on **whether you need and how to get a UK EORI number to trade within the EU** in a no deal scenario. Once you have your UK EORI number it can **take 48 hours before you can use it to make declarations using the Customs Handling of Import and Export Freight (CHIEF) system** (20 March 2019).
- Department for International Trade updated [guidance](#) on how to find the **temporary rates of customs duty (tariffs) on imports** in a no deal scenario. Information added about Northern Island (20 March 2019).
- Department for Environment, Food & Rural Affairs, Department for Transport, Department of Health and Social Care, Department for Business, Energy & Industrial Strategy, Ministry of

Defence, and Department for Exiting the European Union [policy paper](#) published on **critical goods that can be transported on government-secured freight capacity** (11 March).

- HM Treasury, HM Revenue & Customs, Department for Environment, Food & Rural Affairs, and Department for International Trade [guidance](#) on the **Customs Tariff (Establishment) (EU Exit) Regulations** (13 March 2019). Read this document to find out the **legal classification and import rate for products being imported into the UK**.
- Department for Environment, Food & Rural Affairs, HM Treasury, Department for International Trade, and HM Revenue & Customs [guidance](#) on the **Customs (Tariff Rate Quotas) Regulation** (13 March 2019). Covers **product specific Tariff Rate Quotas, which includes the individual product volumes and rates**.
- HM Treasury, HM Revenue & Customs, and Department for International Trade [guidance](#) on the **Customs Tariff (Preferential Trade Agreement) (EU Exit) Regulations 2019** (13 March 2019). Covers the **individual product duty rates and preferential rules of origin** that will apply because of preferential arrangements made between the UK and third countries, including Free Trade Agreements.
- HM Treasury, HM Revenue & Customs, and Department for International Trade [guidance](#) on the **Customs (Tariff-Free Access for Goods from Overseas Territories) Regulation** (14 March 2019). Includes **detail on the tariff-free access** that applies to certain British Overseas Territories.
- HM Treasury, HM Revenue & Customs, and Department for International Trade [guidance](#) on **Authorised Use and reliefs from import duty on goods brought into the United Kingdom for specified uses** (13 March 2019). Covers the **goods and specified uses** for which they can be used, that may qualify for a **full or partial relief from import duty under the Authorised Use procedure**.
- HMRC updated [statutory guidance](#) on **eligible goods and authorised uses**. The “Authorised use: eligible goods and authorised uses” document has been replaced with an updated version (13 March 2019).
- HM Treasury, HM Revenue & Customs, and Department for International Trade [guidance](#) on the **Customs (Origin of Chargeable Goods) (EU Exit) Regulations 2019** (14 March 2019). Read this document to find the **product specific rules, to determine the origin of imports outside of a preferential agreement**.
- Animal and Plant Health Agency updated [guidance](#) on **import of products, animals, food and feed system (IPAFFS)** and how to use the UK’s new notification system to import animals and animal products from non-EU countries. Contains new information about imports process after 29 March if the UK leaves the EU without a deal, and the link to the IPAFFS system (18 March 2019).
- Animal and Plant Health Agency updated [guidance](#) on **exporting animals, animal products, fish and fishery products to the EU in a no deal scenario**. Updated to include information on trade agreements if the UK leaves the EU without a deal (14 March 2019).
- Department for Environment, Food & Rural Affairs and Animal and Plant Health Agency updated [guidance](#) on **UK border inspection posts contact details re finding an approved UK border**

**inspection post (BIP) to check the animals or animal products in your consignment.** Updated contact details for Bristol Port Health Authority and Heathrow Airport (14 March 2019).

- Driver and Vehicle Standards Agency and Traffic Commissioners for Great Britain updated [guidance](#) on **European Conference of Ministers of Transport (ECMT) international road haulage permits and permits to travel to or through ECMT member countries, and the rules you have to follow.** Updated to confirm you can continue to use your EU Community Licence until 31 December 2019 in a no deal scenario, and that you would need an ECMT permit to transport goods through EU or EEA countries to non-EU or EEA countries who are ECMT members. Also information added about how to apply for short-term ECMT permits for April 2019 (21 March 2019).
- Department for Transport, HM Revenue & Customs, Driver and Vehicle Licensing Agency, and Driver and Vehicle Standards Agency [guidance](#) for **hauliers on the transport of goods out of the UK by road** in a no deal scenario, providing a **checklist of documents** that haulage drivers must carry to pass through customs (13 March 2019).

### People

- Home Office and UK Visas and Immigration updated [guidance](#) on the **EU Settlement Scheme and ID document scanner locations.** Locations in Ealing, Livingstone and Maidenhead added (20 March 2019).
- Home Office and UK Visas and Immigration updated [guidance](#) on **EU Settlement Scheme and Assisted Digital service,** for EU citizens and their families applying to the EU Settlement Scheme. Assisted digital locations has been updated (13 March 2019).
- Home Office and UK Visas and Immigration updated [guidance](#) on **applicant information on the EU Settlement Scheme during the public test phase** running from 21 January 2019 (11 March 2019).

### General Guidance for Business

- Department for Business, Energy and Industrial Strategy has published [information](#) to **help small businesses prepare their business for when the UK leaves the EU** (18 March 2019).
- Department for Exiting the European Union updated [guidance](#) on **International Agreements** in a no deal scenario, providing an update on the status of individual international agreements that the Government is delivering (21 March 2019).
- FCO, Export Control Joint Unit and Office of Financial Sanctions Implementation updated **UK sanctions regimes [collection](#)** of links to legislation and guidance on implementing UK and UN sanctions in a no deal scenario. Regulations have been added for the Republic of Belarus and Zimbabwe (21 March 2019).
- HM Treasury updated [guidance](#) providing information **about banking, insurance and other financial services for UK residents, businesses based in the UK, EEA residents, and financial services institutions in a no deal scenario** (12 March 2019).

- Cabinet Office updated [guidance](#) on **public-sector procurement** policy in a no deal scenario (12 March 2019).
- Health and Safety Executive (HSE) updated [guidance](#) on **how a range of areas regulated by the HSE may be affected** in a no deal scenario (13 March 2019).
- Department for Digital, Culture, Media & Sport, Office for Civil Society, and The Charity Commission [guidance](#) on **five ways civil society organisations can prepare for EU exit** (13 March 2019). 1. If your organisation employs EU staff or has EU volunteers. 2. If your organisation receives EU funding. 3. If your organisation receives any personal data from the EU. 4. If your organisation imports or exports goods with the EU. 5. Customs, excise, VAT and regulatory changes