

## Collated guidance for business on no deal preparations (since last update email 08 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 **Customs inbox** [negotiationstechnical.customs@hmrc.gov.uk](mailto:negotiationstechnical.customs@hmrc.gov.uk) that you can send questions to. It generally has a 5 day turnaround, although some queries have taken longer to respond 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

- MHRA [guidance](#) on qualified person responsible for pharmacovigilance (QPPV) including pharmacovigilance system master files (PSMF) and **summary of pharmacovigilance system requirements** in a no deal scenario (12 March 2019).
- MHRA [guidance](#) on the **lists of approved countries for importing and batch testing of medicines and manufacturing of active substances** and a summary of the circumstances under which the lists can be used in a no deal scenario (11 March 2019).
- MHRA [guidance](#) on the **management and oversight of the import of investigational medicinal products from listed countries** in a no deal scenario (11 March 2019).
- MHRA [guidance](#) providing information on the **'Written Confirmation' process, for active substances manufactured in the UK**, that will be adopted in a no deal scenario (11 March 2019).
- MHRA [guidance](#) advice on **air freight of medicines as part of contingency planning** for a no deal scenario. Shipment of medicines by air freight requires specific control measures so guidance is also included on good Distribution Practice (GDP) requirements for air freight to ensure that product quality and security is protected (11 March 2019).
- MHRA produced a [document](#) **providing guidance on the submission, processing and assessment of all completed paediatric studies sponsored by Marketing Authorisation Holders (MAHs)** in a no deal scenario (11 March 2019).
- MHRA updated [guidance](#) on **making submissions related to human medicines to the MHRA** in a no deal scenario (11 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;
  - Guidance on operational changes;
  - No-deal systems contingency programme update; and
  - No deal systems contingency planning: information specific to clinical trials.

### **Continuity of supply of medical products**

- 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.
- Some useful links:
  - [Written ministerial statement](#) (WMS) updating the House on the Department for Health and Social Care's plans for the continuity of medicines and other medical products in the event of a no deal scenario.
  - NHS [patient messaging](#) on getting medicines in a no deal scenario.
  - NHE England's [website page](#) regarding medicines.

### **HMRC Partnership Pack**

- HMRC have provided an [update](#) to the partnership pack - **updated the 'Communications resources' section with links to a range of quick video guides**, and added a set of information leaflets for use by businesses and stakeholders (7 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 Bulgaria, Czech Republic, Estonia, Italy, Lithuania, Luxembourg, Romania, Slovenia (11 March 2019).

#### **Import/Export**

- 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. This guidance has been updated to make it clear what the definition of a UK business is (11 March 2019).

- Department for International Trade [guidance](#) on **temporary rates of customs duty on imports** and [guidance](#) on checking the temporary rates of customs duty on imports in a no deal scenario (13 March 2019). The news story related to this no deal temporary tariff regime is available [here](#) (13 March 2019). The regime would be temporary, and the Government would closely monitor the effects of the tariffs on the UK economy. It would apply for up to 12 months, while a full consultation and review on a permanent approach to tariffs is undertaken.
- Cabinet Office, Department for Environment, Food & Rural Affairs, Northern Ireland Office, and HM Revenue & Customs updated [guidance on customs arrangements on the Irish border](#) (14 March 2019) - In a no deal scenario, the UK Government would temporarily hold off introducing any checks or controls on almost all goods crossing from Ireland to Northern Ireland, so there will be no need for customs declarations, nor the payment of duty. The exceptions are:
  - Businesses would still need to pay VAT and Excise on Irish goods that come into Northern Ireland and the UK.
  - Small businesses trading across the border and not currently VAT registered would be able to report VAT online periodically without any new processes at the border. This would not involve any infrastructure or checks at the border including in Northern Ireland.
- Department for Transport provided updated [guidance from French customs authorities for UK businesses](#) in the event of no deal scenario (12 March 2019). The French Customs and Excise authority has published customs guidance to help businesses that move goods between the UK and France to prepare for new customs procedures in the event of a no deal Exit.
- HMRC [guidance](#) for VAT registered businesses on **accounting for import VAT on goods brought into the UK** in a no deal scenario (6 March 2019).
- HMRC published [correspondence](#) on no deal Exit **advice for VAT registered businesses trading with the EU and/or the rest of the world explaining how to prepare for changes to customs, excise and VAT** in a no deal scenario (7 March 2019).
- HMRC [guidance](#) on **notices made under The Customs (Export)(EU Exit) Regulations 2019** (4 March 2019).
- HMRC published [guidance](#) on **changes to your customs authorisations** in a no deal scenario and how it affects your existing authorisation to use customs procedures or other facilitations (6 March 2019).
- HMRC updated [Statutory Instruments](#) relating to **Customs, Excise and VAT** and EU Exit (8 March 2019). Links to four new SIs have been included.
- HMRC published [guidance](#) on **draft notices to be made in relation to the amendments brought in by The Taxation (Cross-border Trade) (Miscellaneous Provisions) (EU Exit) Regulations 2019** (8 March 2019).
- Department for Transport, Traffic Commissioners for Great Britain, and Driver and Vehicle Standards Agency updated [guidance for hauliers on Allocation of ECMT haulage permits](#) (5 March 2019).

- Department for Environment, Food & Rural Affairs and Animal and Plant Health Agency updated [guidance](#) on **importing and exporting plants and plant products** in a no deal scenario (6 March 2019).
- Animal and Plant Health Agency updated [guidance](#) on **importing animals, animal products and high-risk food and feed not of animal origin** in no deal scenario (4 March 2019).
- Department for Environment, Food & Rural Affairs and Animal and Plant Health Agency updated [guidance](#) on **trading and moving endangered animal or plant species protected by CITES** in a no deal scenario (4 March 2019).

### **People**

- FCO updated [guidance](#) **important EU Exit information for UK nationals** in a no deal scenario. Updated with links on transporting horses and endangered plants provided (8 March 2019).
- Home Office and UK Visas and Immigration [updated guidance](#) on the **EU Settlement Scheme and ID document scanner locations**. Locations in Burton upon Trent, Calderdale, Hounslow and Newcastle-under-Lyme added (11 March 2019).
- Home Office and UK Visas and Immigration updated [information](#) on **using the 'EU Exit: ID Document Check' app** and for EU citizens and their families applying to the EU Settlement Scheme (6 March 2019).

### **Intellectual Property**

- IPO updated their "IP and Brexit: the facts" [guidance](#) – **patent guidance and video under the heading Statutory legislation** has been added (8 March 2019).

### **General Guidance for Business**

- Department for Exiting the European Union [guidance](#) on **International Agreements** in a no deal scenario, providing an update on the status of individual international agreements that the Government is delivering (7 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 (12 March 2019).
- Cabinet Office updated [guidance](#) on the **Procurement Policy Note 02/19: Preparing for the UK leaving the EU** (13 March 2019). The Note was published on 7 March 2019 and provides further information on how the UK's public procurement regulations will be affected in the event of either an agreed deal with the EU or a no deal exit from the EU.
- British Library Business and IP Centre Network **Webinars** continue next week. These aim to help businesses understand possible changes after the UK leaves the EU that may affect them and to help them prepare. The webinars are listed on the British Library's [events page](#) and participants

will need to register in advance through their website. For your information, the schedule is currently as follows:

<b>Date</b>	<b>Title</b>
Mon 18 March – 13-14	<a href="#">Preparing for Brexit: Importing and Exporting</a>
Tues 19 <sup>th</sup> March – 12-13	<a href="#">Preparing for Brexit: Business Legal Requirements</a>
Wed 20 <sup>th</sup> March – 11-12	<a href="#">Preparing for Brexit: Intellectual Property</a>
(TBC)	Preparing for Brexit: EU/UK Funding and Public Procurement