



# Office for Life Sciences

## Office for Life Sciences EU Exit Bulletin – 27 September 2019



### **OLS Introduction**

The Office for Life Sciences (OLS) is a joint unit between the Department of Health & Social Care (DHSC) and Department for Business, Energy & Industrial Strategy (BEIS).

The purpose of this bulletin is to provide you with information about the steps that businesses can take to be prepared if the UK leaves the EU without a deal. Please help us reach your suppliers, clients, customers and members by forwarding or sharing the content.

### **Get Ready for Brexit campaign:**

The government has launched a 'Get Ready for Brexit' public information campaign which sets out what the public and businesses might need to do to get ready to leave the EU on 31 October.

Visit: [www.gov.uk/brexit](http://www.gov.uk/brexit)

### **Business Readiness Roadshow**

The government is delivering a series of 'One HMG' interactive events, running until mid-October. There will be 30 events across the UK, talking face-to-face with businesses, and ensuring that they are preparing for Brexit. Sign-up [here](#).

**Next week's events** will be in: Southampton (30 September), Brighton (1 October), Plymouth (3 October), Hull (3 October) and Leeds (4 October).

### **Brexit Readiness Fund**

BEIS have announced a £10m Business Readiness Fund (BRF) for business organisations and trade associations to support businesses to prepare for a 'No Deal' Brexit. The deadline for applications is 30 September 2019. Visit: <https://www.gov.uk/brexit-business-grants>

### **Brexit Business Readiness Forum**

These forums are held weekly and aimed at trade associations and business intermediaries. For details on how to register to attend or subscribe to the bulletin, email [sed@beis.gov.uk](mailto:sed@beis.gov.uk).



### **Regulations (Medicines)**

**New guidance** from MHRA clarifies the expectations on the application of EU guidance on good pharmacovigilance practices (GVP) in a no-deal Brexit, and can be found [here](#).

**New letters to industry** from MHRA on conversion of community marketing authorisations to UK marketing authorisations can be found [here](#).

**Updated guidance** on exporting active substances manufactured in the UK in a no-deal Brexit can be found [here](#).

Previous guidance on MHRA submissions in a no deal can be found [here](#).

Information about the regulation of medicines and medical devices if there is a no-deal Brexit can be found [here](#).



### **Regulations (Medical devices)**

There have been no new updates on medical devices regulations, previous guidance on the creation of a new UK Responsible Person within the existing regulating medical devices in the event of a no deal guidance can be found [here](#).

Current guidance, including all other aspects of regulating devices in no deal can be found [here](#).

Please continue to sign up for email updates [here](#).



### **Workforce**

The UK's Shortage Occupation List (SOL) is to be amended to include new roles, including occupations in health, information technology and other STEM fields, and the removal of others. Changes will take effect with Certificates of Sponsorship issued on/after 6 October 2019. Additions include:

- All biological scientist and biochemist roles SOC code 2112
- Physical scientists – certain roles in construction, oil and gas SOC code 2113

The advantages for shortage occupation roles include:

- Not having to conduct a Resident Labour Market Test.
- Exemption from the minimum income threshold for settlement.
- Lower visa fees.
- Priority allocation if the cap limit is reached.



### **Continuity of Supply:**

DHSC, in consultation with the Devolved Administrations (DAs), has been working with trade bodies, product suppliers, and the health and care system in England to make detailed plans

that should ensure continuation of the supply of medical products to the whole of the UK and its Crown Dependencies in the event of a 'no deal' EU exit.

Medical products within scope of this planning include:

- medicines (prescription-only, pharmacy, general sales list and unlicensed medicines);
- medical devices and clinical consumables;
- supplies for clinical trials and clinical investigations;
- vaccines and countermeasures; and
- blood, tissue and transplant materials.

DHSC will implement a multi-layered approach to minimise any supply disruption in a 'no deal' exit scenario. The letter sent to industry by Steve Oldfield, Chief Commercial Officer, DHSC outlining the approach is attached. This was shared with key stakeholders across NHS, social care and patient groups.

**Updated guidance** from DHSC for businesses supplying medicines and medical devices about plans for a 'No Deal' Brexit. Guidance includes information on the more flexible approach suppliers can now take to help ensure the continuity of medical supplies following Brexit. Available [here](#).

### **Dedicated Health Channel**

DHSC is procuring an 'express freight service', designed to transport small medical supply consignment into the UK within 24 hours if the UK leaves the EU without a deal.

The purpose of this procurement is to support the uninterrupted supply of medicines and medical products where there is an urgent need or where a supplier's own logistics plans are disrupted. These are on track; more information will be provided shortly.

### **X-Government freight capacity**

The Department for Transport is putting in place a freight capacity framework that will provide DHSC, as well as other Departments, with the ability to secure freight capacity for critical supply chains as required. These are on track; more information will be provided shortly.



## **Trader readiness**

In a no deal scenario, the UK will trade with the EU as a most-favoured-nation under WTO terms. Businesses should consider what changes this might mean for how they trade with the EU and what impact it may have on their supply chains.

**Attached** - Get Ready for Brexit SME leaflet containing information to help businesses understand how Brexit may affect them.

### **New or updated HMRC materials for traders**

Please find the most up to date decision trees for importing and exporting through roll on roll off locations and an EORI number MythBuster and a simple trader checklist to help get business ready for Brexit [here](#).

New guidance if you've chosen to account for import VAT on your VAT Return in a no-deal Brexit [here](#).

New guidance if you're a VAT-registered business to find out when you can account for import VAT on your VAT Return for goods brought into the UK in a no-deal Brexit [here](#).

New guidance to help you find out how to claim VAT refunds from EU member states after Brexit [here](#).

New guidance to find alternative offices of destination or departure when moving goods under Common Transit Convention through the Port of Dover or Eurotunnel in a no-deal Brexit [here](#).

### **HMRC series of webinars**

HMRC are hosting webinars to provide an overview for UK businesses involved in the movement of goods between the EU and the UK. Details can be found [here](#). The next webinar will be on Tuesday 1 October 10am-11am.

### **DIT "Get Ready for Brexit" workshops**

DIT are running over 100 additional "Get Ready for Brexit" Workshops to help businesses (primarily existing exporters to the EU) develop a personalised Brexit Readiness Action Plan. The events are a mix of DIT led Workshops, Webinars, and participation by DIT with a "Brexit package" in events already being run by partners.

For more details and to book visit [this link](#). Next week's events will be in: Preston (30 September), Norwich (1 October), Portsmouth (1 October), Scarborough (1 October), York (1 October), Chelmsford (2 October) and London (4 October).

### **UK Government Border Delivery Group advice for EU businesses trading with or via the UK**

If you are an EU based business trading goods to or via the UK, please sign up to a webinar led by the UK Government Border Delivery Group (BDG) to receive guidance and information on the steps you may need to take before 31 October. BDG is arranging this series of webinars targeted at EU businesses to help provide clarity on what is expected of them, their clients and their supply chain as they look to trade goods across the border.

Presentations will include information on border preparedness and customs procedures at the border, and a Q&A session.

Please register for the webinars [here](#), links for later webinars will be released in due course. The next life sciences webinars will be held on 3 October, 10 October, 17 October and 24 October from 8-9:30.

### **British Library webinars**

BEIS are working with the British Library to produce a series of webinars to help prepare businesses for Brexit. The first webinar will be next Monday **30th September at 2pm** covering the regulation of manufactured goods covered by the “New Approach” (i.e. mostly CE marked goods) in the event of no deal. Topics covered will include CE and UKCA Marking, Notified Bodies, conformity assessment, importer duties and declarations of conformity, and there will be the opportunity to ask questions.

All details can be found [here](#) and the link will be live from 1:30pm on Monday 30th September.



### **Useful Links**

- [Brexit](#) provides a central hub of resources
- Life Sciences [landing page](#) collating guidance for preparing for a no deal EU Exit.
- DHSC have produced guidance on what providers and commissioners of healthcare services can do to manage the risks of a no-deal Brexit, available [here](#).
- You can sign up to email alerts about EU Exit on GOV.UK at this [link](#).
- Please visit the BEIS twitter feed [here](#) for several short How to Prepare for Brexit videos
- 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.
- As guidance is updated frequently, HMRC recommend you check regularly on [gov.uk/euexit](http://gov.uk/euexit) .
- NHS [patient messaging](#) on getting medicines in a no deal scenario.
- NHE England's [website page](#) regarding continuity of supply of medical products.