



# Office for Life Sciences

## Office for Life Sciences EU Exit Bulletin – 13 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).

We work across Government to help support and grow the life sciences sector in the UK and get innovative treatments to NHS patients faster.

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.

We will aim to send this bulletin on a weekly basis.

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

The government has launched a 'Get Ready for Brexit' public information campaign.

The campaign sets out what the public and businesses might need to do to get ready to leave the EU on 31 October.

Businesses can visit to access advice [www.gov.uk/brexit](http://www.gov.uk/brexit)

### **Business Readiness Roadshow**

The government is delivering a series of 'One HMG' events, running from Monday 16 September to 18 October. There will be 30 events across the UK, talking face-to-face with businesses, aiming to ensure that as many businesses are preparing for Brexit as possible.

Businesses can sign-up [here](#). Next week's events will be in: Northampton (16 September), Nottingham (17 September), West Midlands (18 September), Swindon (19 September), and London (20 September).

## **Brexit Readiness Fund**

BEIS have announced a £10m Business Readiness Fund for business organisations and trade associations to support businesses to prepare for a 'No Deal' Brexit.

The Business Readiness Fund will support activities such as events, training and the production of advice packs.

Minimum grants are £25k and activities must be open to both members and non-members, and large and small businesses. Note that individual businesses cannot apply for a grant.

Further guidance can be found here: <https://www.gov.uk/brexit-business-grants>

## **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)**

In a No Deal exit the UK's involvement in the European medicines regulatory network would cease and the MHRA would take on the functions currently undertaken by the EU for human medicines on the UK market.

Centrally Authorised Products will be transferred to UK licences and the MHRA will offer new routes to apply for National licenses in the UK. The MHRA would also take on the functions currently undertaken by the EU for human medicines on the UK market.

More detail on the regulation of medicines in a no deal exit is available [here](#).



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

In a No Deal exit devices to be placed on 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 before we leave the EU).

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

An additional requirement in no deal requires devices for the UK market to be registered with the MHRA according to the timetable set out in the MHRA guidance.

Where a manufacturer is based outside of the UK, they must nominate a UK Responsible Person to conduct actions such as register devices with the MHRA. All other responsibilities required of the UK Responsible person are set out in the MHRA guidance [here](#).

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

Medicines and Healthcare products Regulatory Agency have provided guidance for stakeholders to make informed plans and preparation in the event of leaving the EU with no deal. [Further guidance note on the regulation of medicines, medical devices and clinical trials in a no-deal Brexit](#)



### **Workforce**

Home Office recently announced expansion of the shortage of occupation list to include a range of skilled occupations, following changes to the Immigration Rules. Details of this can be found here: [Shortage of occupation list](#).

On the 12<sup>th</sup> Sep, the UK government has today announced a new two-year post-study work visa, expanding opportunities for talented international students to build successful careers in the UK.

Home Office have provided details on the transitional immigration arrangements for EU citizens arriving in the UK after Brexit if the UK leaves the EU without a deal. There is now updated guidance to reflect change in policy: [EU immigration after free movement ends if there's no deal](#)

Home Office have provided guidance on the immigration arrangements for EU, EEA and Swiss citizens and their family members who move to the UK after Brexit if the UK leaves the EU without a deal. Latest guidance: [Moving to the UK after Brexit: EU citizens and their families](#)

Home Office have provided guidance for employers on carrying out right to work checks on EU, EEA and Swiss citizens and their family members in the UK after Brexit. [Right to work checks on EU citizens if the UK leaves the EU without a deal](#)

The PM has announced a new fast-track immigration route aimed at enabling a wider pool of scientific talent to come to the UK. The route will be uncapped, ensuring that those with the required skills-set would be able to secure places.

The new scheme will provide eligible people with a three-year visa. At the end of three years, those on the scheme would be able apply for settled status.



### **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.

### **Securing Freight:**

#### **Dedicated Health Channel**

DHSC is procuring an 'express freight service', aimed at securing transport of small medical supply consignment into the UK within the 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 produces where there is an urgent need to where supplier's own logistics plans are disrupted. The invitation to tender was published on 18 June.

#### **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.



#### **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.

Examples of actions to take are: registering for a UK and / or EU Economic Operator Registration and Identification (EORI) number; preparing for different requirements at the border; registering for simplified customs processes; and checking tariff rates under the UK temporary tariff regime and the EU Common Customs Tariff.

HMRC has published a helpful [mythbuster](#) about EORI numbers and advice for businesses trading with the EU [here](#).

HMRC are hosting a series of 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 Department for International Trade has been working to negotiate agreements to replace EU trade agreements after Brexit. The latest list of agreed trade agreements can be found [here](#).



### **Useful Links**

- [Brexit](#) provides a central hub of resources
- 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.
- 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.