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BREXIT 31 OCTOBER

Office for Life Sciences

Agenda

1. Introduction to the Office for Life Sciences
2. Medical devices regulation in a No Deal
3. Medicines regulation in a No Deal
4. Continuity of Supply update
5. Tariffs
6. Summary of actions and further guidance

Introduction to the Office for Life Sciences

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

- We are the **"Sector team"** in BEIS, responsible for the **Life Sciences Industrial Strategy and Sector Deals.**

- One of our key responsibilities **is engaging with business** to help you prepare for EU exit and listen to your issues and feedback so that we can **help Government respond**.

- OLS have **a team dedicated to EU Exit and International Trade** and we are focussed on the opportunities and challenges of Brexit.

Medical devices regulation in a No Deal

Maintaining access to the UK market in a No Deal for Medical Devices

In a no-deal scenario, the UK's **participation in the European regulatory network for medical devices would end**. The MHRA would take on the responsibilities for the UK market currently undertaken through the EU system.

What will remain the same:

For a time-limited period, **we will continue to allow devices to be placed on the UK market** that are in conformity with the applicable EU Directive.

Products **must continue to carry a CE mark** and devices which currently require conformity assessment by a Notified Body (NB) **must have a valid CE certificate**;

We will **not require any changes to the labelling of affected products** and we will continue to accept labelling in the English language, which includes information from other jurisdictions (such as Ireland).

The UK will have a regulatory system in place on exit day, which will mirror all the key elements contained in the new EU regulations. Requirements under these **new regulations will be brought into force in line with the transitional timetable** being followed by the EU.

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BREXIT 31 OCTOBER

Notified Bodies in a No Deal scenario

Status of certificates issued by UK NBs in the EU

From Exit Date

- UK-based Notified Bodies will **not** be recognised in the EU
- The devices they have certified will **not have** valid certificates.
- These products will **not** be able to be placed on the EU market.

Status of certificates issued by UK NBs in the UK

From Exit Date:

- UK **will** give UK-based NBs ongoing legal status
- UK **will** recognise the validity of certificates issued before Exit Day
- Products covered by UK NBs **will** be able to be placed on UK market after Exit Day.

Two key changes for device manufacturers in a No Deal scenario

Manufacturers and the UK responsible person

Manufacturers placing products on the UK market must **first register with the MHRA**

If a manufacturer is not established in the UK it must **designate a UK responsible person to register and act on its behalf.** Manufacturers **must have a registered place of business in the UK.** This address will be publicly available on the MHRA's Public Access Registrations Database (PARD).

Registration of Devices:

After exit day, **all devices will need to be registered with the MHRA** before being placed on the UK market. As this is an extension of existing requirements **businesses will be given a grace period** for compliance. This period will differ depending on the class of device;

Device manufacturers not based in the UK **will require a 'UK Responsible Person'** established in the UK, with a UK registered address to register the product who will take responsibility for the product in the UK. **No labelling changes will be required** to reflect the role of this 'UK Responsible Person'.

Registering devices

- After 1 November 2019, **devices must be registered with the MHRA** before being placed on the UK market;
- Initially, the MHRA will require all devices to be registered at the level of Global Medical Device Nomenclature (GMDN).
- For Class III devices, you must also provide the medical device name, model, catalogue or reference number

Time Frame	Devices	IVDs
4 months	• Class III medical devices • Class IIb implantable medical devices • Active implantable medical devices	• IVD List A
8 months	• Class IIb non-implantable medical devices • Class IIa medical devices	• IVD List B • Self-test IVDs
12 months	• Class I medical devices	• General IVDs • Class A IVDs (if complying with EU IVDR 2017/746

Responsibilities of a UK responsible person

- **Ensure** that the declaration of conformity and technical documentation are compliant and that a conformity assessment has been carried out (if necessary)

- **Keep copies** of declaration of conformity, technical documentation and conformity assessment certificate available

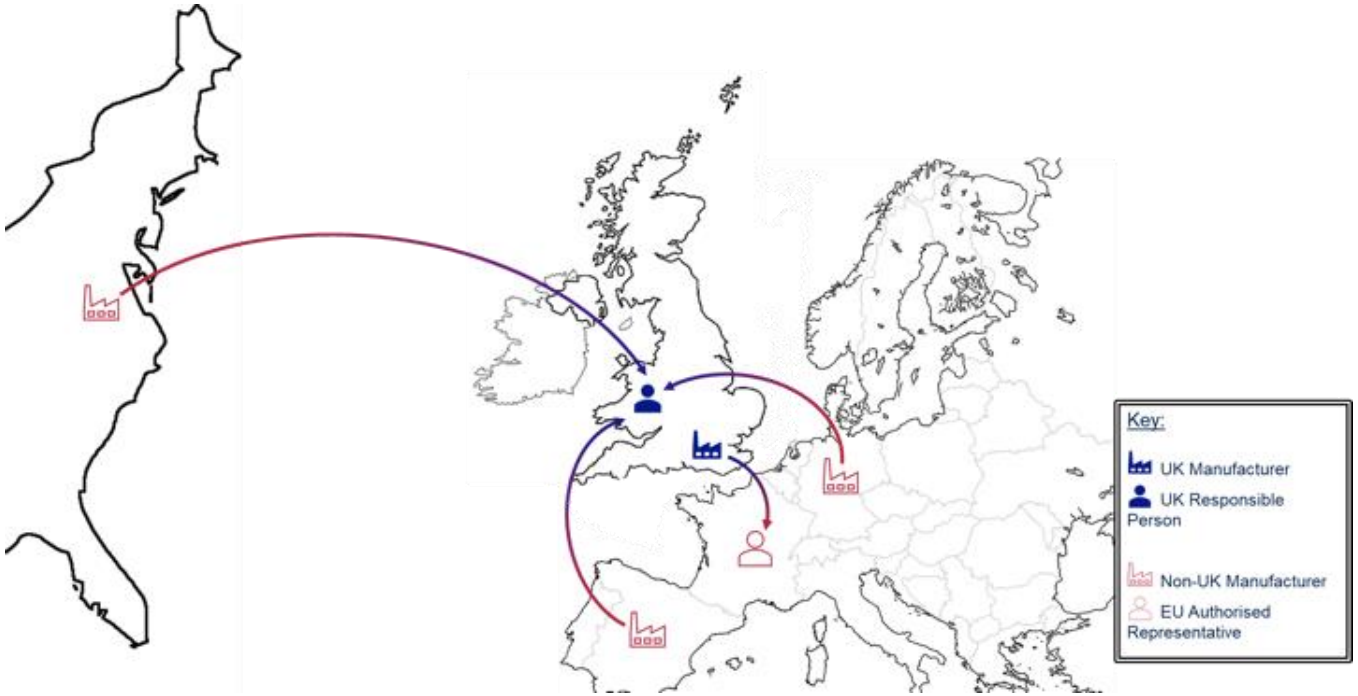
- **Provide** Secretary of State with relevant documentation upon request
- **Forward** to manufacturer any request by the Secretary of State
- **Cooperate** with the Secretary of State on any preventative or corrective action taken to eliminate or mitigate the risks posed by devices

- **Inform** the manufacturer about complaints and reports from healthcare professionals , patients and users about suspected incidents related to a device

- **Terminate** the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under MDR 2019 regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination

UK responsible person

… means a person established in the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under the [MDR 2019] regulations



Medicines regulation in a No Deal

Licensing

Most human medicines on the UK market already have a **UK Marketing Authorisation** (MA). This will be unaffected by our exit from the EU. **Centrally Authorised Product (CAP)** MAs will automatically be converted into UK MAs on the day the UK leaves the EU;

- One year to provide baseline data;

New assessment procedures for products containing new active substances and biosimilars alongside existing 210-day national licensing route:

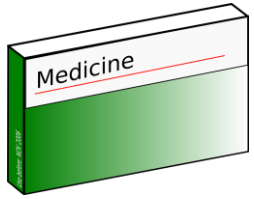
- Targeted assessment – within 67 days;
- Accelerated route – 150 days;
- Rolling review – application in stages.

Legal presence

- Marketing Authorisation Holders (MAH) should be established in the UK by the end of 2020 – 4 weeks for some presence if not pre-existing;
- A Qualified Person for Pharmacovigilance (QPPV) should be established in the UK on day one (temp exemption to 2020);

- A Qualified Person (QP) for products manufactured in the UK or directly imported into the UK from a country not on an approved country list (which will include all EU and EEA countries from Day 1) must reside and operate in the UK.

Packaging and leaflets



- MHRA will give industry until the end of 2021 to amend certain **administrative details** on the packaging and in the package leaflets for a product already on the market. Any regulatory interventions that may **impact on public health** required before the end of 2021 will have to be implemented in real time.

- MHRA will continue to accept proposals for packaging and leaflets in the English language that include information from other jurisdictions (such as Ireland);
- Packs containing the Falsified Medicines Directive (FMD) safety features would still be accepted in the UK.

Batch testing and release

- **The UK will continue to accept batch testing** of human medicines carried out in countries named by the MHRA. On exit day, this list would include EU, EEA and 3rd countries with which the EU has an MRA;

- A **UK-based QP** will still be required for:
  - Human medicines manufactured in the UK;
  - Human medicines manufactured in a third country and directly imported into the UK.

- **The UK will continue to recognise certification**, release and assurance of compliance by a QP based in a country of the MHRA's QP list for:
  - Human medicines manufactured in a third country and imported to a country on the MHRA's QP list;
  - Human medicines manufactured in a country on the QP list.
  - These approaches to QP certification will also apply to **IMPs.**

These arrangements will continue until the government considers any further change is necessary. MHRA is committed to working with industry ahead of any such changes

Continuity of supply

Continuity of supply programme objectives

To **safeguard patient care** and ensure that the supply of medicines and medical products remains unhindered in a no-deal scenario.

To provide **reassurance** to stakeholders that the Department's plans are comprehensive and well-thought through.
To take action

In relation to the extension of Article 50, our agreed aim is to be **at least as prepared in October as we were for March and April.**

The programme covers six supply workstreams

Medicines – Ps, POMs, critical GSLs, specials and unlicensed medicines.

Medical devices and clinical consumables – inc. specialist nutrition feeds and infant formula

Clinical trials – using IMPs, IVDs, ATMPs, radioisotopes, raw materials, devices, clinical consumables and bio-samples

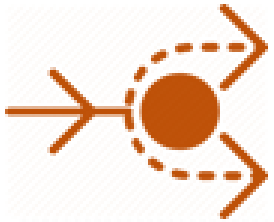
Vaccines and countermeasures – nationally and locally procured

Blood and transplant – blood, blood products and consumables/devices, organs, tissues, cells and plasma

Non-clinical goods and services – laundry, food, data, clinical waste

We have implemented a multi-layered contingency plan to mitigate risks to supply

1. Stockpiling



2. Re-routing

3. Warehousing

4. Changing / updating regulatory requirements

5. National Supply Disruption Response

6. Trader readiness

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BREXIT 31 OCTOBER

Tariffs

Medicines and medical devices are likely to be more impacted by export tariffs than import tariffs

Import tariffs

- In the event of a No Deal exit, the UK temporary tariff regime will eliminate tariffs across most goods imported into the UK from the EU and ROW
- This will include medical devices, pharmaceuticals, and most associated raw materials will have zero tariffs applied to them.
- This is not so different from how it is now.

Export tariffs

- Most medical devices and pharmaceuticals and some associated raw materials are covered by the Information Technology Agreement or Pharmaceutical Tariff Elimination Agreement.
- These are international tariff elimination agreements at the WTO, which the UK is a part of as part of the EU.
- Therefore, the EU will not place tariffs on most medicines and devices but there will be some exceptions (for example, APIs not included in the Annex to the Pharmaceutical Tariff Elimination Agreement).

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BREXIT 31 OCTOBER

Summary of actions and further guidance

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BREXIT 31 OCTOBER

Five actions to prepare for a No Deal

1. Go to gov.uk for information relevant to your businesses

Answer seven simple questions about your business on euexit.campaign.gov.uk to receive the guidance that is relevant to your business. Sign up for email updates here

2. Find out which tariffs your business may face

Government has published guidance on import tariffs in a No Deal and guidance to update businesses on which new trade agreements will be in place if there's a no-deal Brexit.

3. Prepare for new customs and VAT procedures at the border

Businesses will need to complete additional paperwork and register for an EORI number to move goods between the UK and EU. Specific actions on customs for importing goods from the EU are found here, and exporting actions are found here. Details on no deal VAT changes are here.

4. Ensure you follow regulations to sell medical products in the EEA and UK

Medical suppliers will need to establish their MAHs, applicants and QPPV in the EEA to sell any products there. Businesses will also need UK establishments by the end of 2020 to sell in the UK

5. Continue Right to Work checks and support EEA and Swiss citizens

Conduct Right to Work checks for new employees, support employees applying to the EU Settlement Scheme and inform those arriving after a 'no deal' exit about European Temporary Leave to Remain

Further and more detailed information

- **Sign-up** for new content/content update alerts and find out how to prepare your business for Brexit on GOV.UK and https://www.gov.uk/business-uk-leaving-eu
- **Bookmark** the Life Sciences landing page www.gov.uk/guidance/the-life-sciences-sector-and-preparing-for-eu-exit
- Further information on **Horizon 2020 funding** in a no deal https://www.gov.uk/guidance/horizon-2020-funding-after-brexit
- Further information on **UK Trade Tariffs** detailing import duty rates and rules www.gov.uk/trade-tariff
- Further information on **EU Settlement Scheme** https://www.gov.uk/settled-status-eu-citizens-families
- **HMRC video about trading with the EU** in a no-deal Brexit https://www.youtube.com/watch?v=0k9rcQvgetw&list=PL8EcnheDt1zjoo7bz6y_HJBFtPMTkkvDl
- **HMRC Online Services Registration** https://www.gov.uk/log-in-register-hmrc-online-services/register
- **MHRA guidance and publications** in a no deal https://www.gov.uk/government/collections/mhra-guidance-and-publications-on-a-possible-no-deal-scenario
- **MHRA guidance and updates for medical devices** in a no deal https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario
- **The EU Commissions Preparedness Notices**: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#grow

Thank you

Any questions?