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Agenda

1. Introduction to the Office for Life Sciences
2. Context and objectives
3. Trade Negotiations: Where are we?
4. Medical Devices Regulation
5. Chemicals Regulation
6. Northern Ireland Protocol
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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.**
- OLS have **a team dedicated to regulation and trade** and we are focussed on the opportunities and challenges of UK transition.
- One of our key responsibilities **is engaging with business** to help you prepare for UK transition and listen to your issues and feedback so that we can **help Government respond**.

Context and objectives

Businesses should prepare for the end of Transition Period

The Transition Period will end on 31 December 2020, and businesses need to take actions now to prepare for this.

The Transition Period will not be extended, and businesses should not plan on this basis.

Medicines and Medical Devices regulation and supply is changing, and your business needs to adapt to these changes.

Our aims for the session

Identify areas where you may need to take action

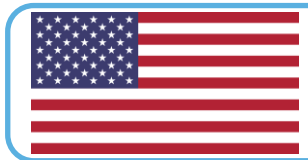
Focus on key areas and the actions you should consider taking

Signpost sources of advice and support

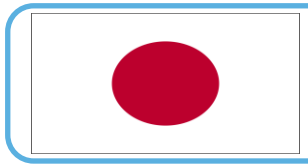
Answer any questions you may have

An update on trade negotiations

- Negotiations to begin again following discussions between Chief Negotiators.

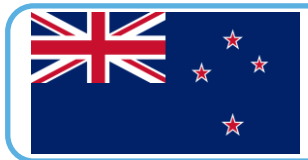


- Round 5 of negotiations began last week; strong progress being made on many areas.



- Agreement reached; with text currently undergoing legal scrubbing.

- Round 2 complete; included first substantive discussion of texts.



- Round 2 to commenced on Monday, after productive initial discussions.

Medical devices regulation at the end of the transition Period

Accessing the UK market

What will remain the same

- We will continue to allow devices to be placed on the UK market that are in conformity with the applicable EU Directive until **30 June 2023**.
- Products **may 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).

What will change

- The UK will have a regulatory system in place on exit day with the **UKCA mark**, which will mirror all the key elements contained in the current EU regulations.
- MDR and IVDR will not be implemented in GB however MDR and IVDR compliant devices will be accepted in GB until **30 June 2023.**
- MDR and IVDR will apply in Northern Ireland from 26 May 2021, and 26 May 2022 respectively, in line with the EU's implementation timeline.

The role of Notified Bodies (NBs)

Status of certificates issued by UK NBs in the EU

From 1 January:

- UK-based NBs will **not** be recognised in the EU unless a good is already placed on the market.
- The devices they have certified will **not have** valid certificates.
- These products will **not** be able to be sold in the EU.

Status of certificates issued by UK NBs in the UK

From 1 January:

- UK **will** give UK-based NBs ongoing legal status as UK Approved Bodies.
- UK Approved Bodies **will** be able to issue the UKCA marking and the CE UK(NI) marking for the purposes of Northern Ireland.
- 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.

Using the UKCA Mark

The UKCA marking is the new UK conformity assessment marking and there are a number of rules for how it can be applied.

The UKCA marking reflects conformity with UK medical device regulation. From 1 July 2023 the marking will be mandatory.

It can be issued by UK approved bodies or any designated body in a third country with an MRA with the UK.

Existing UK Notified Bodies with designations under the MDD, IVDD or AIMDD will have their designations rolled over automatically, without having to undergo a new designation process.

UK Approved Bodies will only be able to conduct conformity assessments, in relation to the UKCA mark, for medical devices, active implantable medical devices and in vitro diagnostic medical devices under Parts II, III, and IV of the UK MDR 2002 after 1 January 2021.

Manufacturers of Class I medical devices and general IVDs will be able to self-declare their conformity before affixing a UKCA mark and placing the device on the Great Britain market.

Class I medical devices that are sterile or have a measuring function will still require approval from an Approved Body in order to be affixed with the UKCA mark and placed on the Great Britain market.

Two key changes for manufacturers of devices

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'.

- In cases where the GB importer is not the UK Responsible Person, the importer will be required to inform the relevant UK Responsible Person of their intention to import a device. In such cases, the UK Responsible Person will be required to provide the MHRA with a list of device importers.

Registering devices

- From 1 January, **devices must be registered with the MHRA** before being placed on the GB market;
- There will be a grace period for registering devices – this will only apply to new registrations and not Class 1 devices and general IVDs that are currently required to register with the MHRA;
- UK manufacturers must register, non-UK manufacturers must appoint a responsible person;
- I will cover Devices registration for NI later

Time Frame	Devices	IVDs
4 months	• Class III medical devices • Class IIb implantable medical devices	• IVD List A
8 months	• Class IIb non-implantable medical devices • Class IIa medical devices	• IVD List B
12 months	• Class I medical devices	• General IVDs

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** the 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.

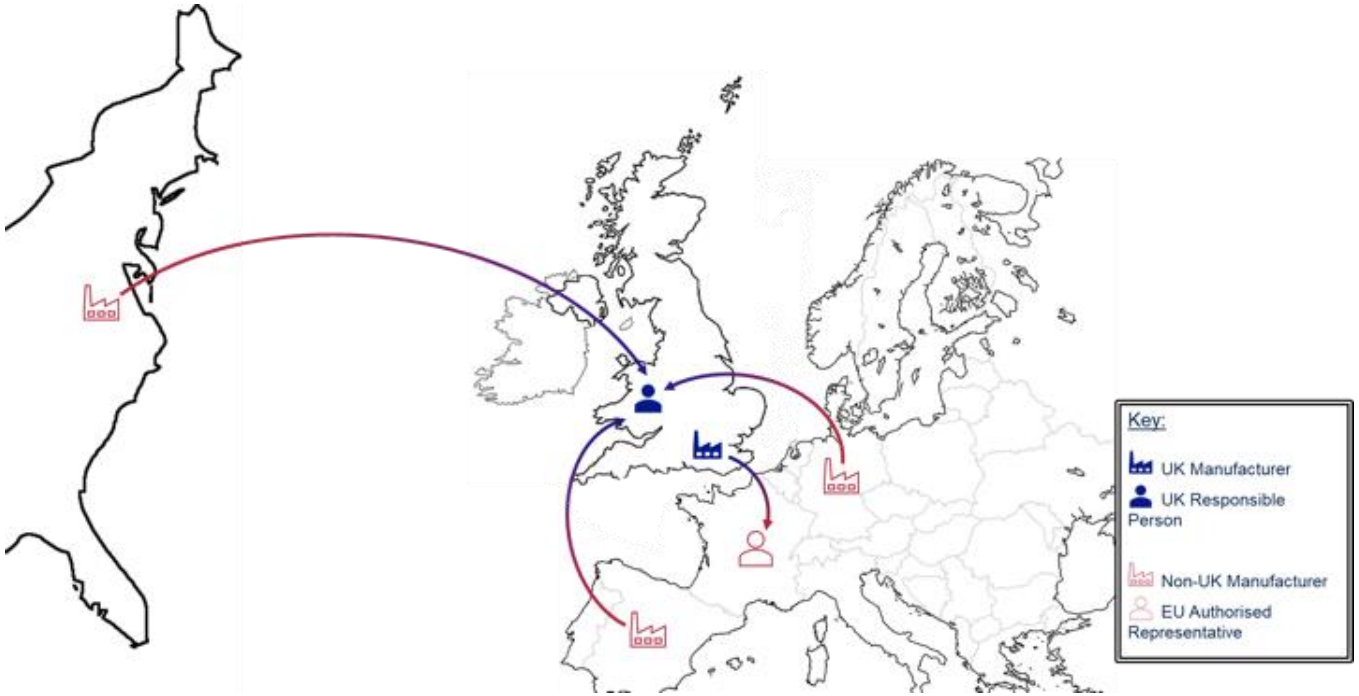
- **Inform** the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device.

- **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.

From 1 January 2021, the name and address of the UK Responsible Person, where applicable, will need to be included on product labelling where the UKCA mark has been affixed. UK Responsible Person details will not need to be included on labelling for CE marked devices.

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 regulations**.*



Chemicals Regulation at the end of the Transition Period

UK REACH

- UK REACH, the UK's independent chemicals regulatory framework, starts on 1 January 2021. Anyone **making, selling or distributing chemicals in the UK and the EU needs to follow UK REACH and EU REACH rules.**

- UK REACH will maintain EU REACH's aims and principles. These include:
  - the "no data, no market" principle
  - the "last resort" principle on animal testing
  - access to information for workers
  - the precautionary principle

UK Held Registrations – Grandfathering

- EU REACH registrations held by UK-based companies will carry across directly into UK REACH, legally ‘grandfathering’ the registrations into the new regime.

- UK-based holders of existing EU REACH registrations may continue the ‘grandfathering’ process by providing basic information to the Health and Safety Executive (HSE) by 30 April 2021.

EU held registrations: UK downstream Users

- UK downstream users (who do not hold an EU REACH registration) currently importing chemicals from an EU/EEA country need to ensure the substances they purchase are covered by a valid UK REACH registration.
- Businesses currently relying on a registration held by an EU/EEA-based company can continue importing substances as they do now on 1 January 2021. They will need to take subsequent actions to ensure that the chemical is registered for UK REACH purposes.
- These UK downstream users must notify the HSE using a Downstream User Import Notification (DUIN) of their intention to continue importing substances from the EU/EEA by 27 October 2021.
- A new registration must then be submitted to the HSE within 2, 4 or 6 years of 28 October 2021. Alternatively, UK downstream users can encourage their EU/EEA supplier to appoint a UK-based Only Representative (OR), or change their source to a UK registered supplier.
- It’s possible to submit DUINs if a chemical is covered by a registration held by an EU/EEA-based OR and then sold into the UK.

Find out more about placing goods on the market

There is a range of MHRA and Government guidance available to businesses at the following links:

- https://www.gov.uk/government/collections/mhra-post-transition-period-information
- https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021
- https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021
- https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021

The MHRA are delivering a series of webinars setting explaining regulatory changes starting October 19. More details and booking information can be found here:
https://www.eventbrite.co.uk/e/eu-exit-and-post-transition-guidance-tickets-122553062509

Northern Ireland Protocol

The Northern Ireland Protocol

- The Northern Ireland Protocol to the Withdrawal Agreement was designed as **a practical solution to avoid a hard border on the island of Ireland, whilst ensuring that the UK, including Northern Ireland, could leave the EU as a whole.**
- Northern Ireland **will align with all relevant EU rules relating to the placing on the market of manufactured goods**. The **same authorities and bodies operating today will continue to be responsible** for approving goods on the Northern Ireland market and enforcing these rules.
- Where Northern Ireland traders gain product approvals and certification for the Northern Ireland market from EU authorities and bodies, the UK will recognise those for the purpose of placing goods on the Great Britain market.
- Until negotiations with the EU conclude, there will be some areas without complete certainty, but full guidance will be provided by the end of the Transition Period. Current guidance includes:
  - The Command Paper on The UK's approach to the Northern Ireland Protocol
  - How to move goods into, out of, or through Northern Ireland from 1 January 2021
  - How to use the **Trader Support Service** to guide you through any changes due to the implementation of the Protocol.
  - Supplying medicines to Northern Ireland from 1 January 2021 – Article 41 of the EU Withdrawal Agreement
  - Regulation of medical devices in Northern Ireland

The principles of the Protocol

1. **Trade going from Northern Ireland to the rest of the UK**: this should take place as it does now. There should be no additional process or paperwork and there will be no restrictions on Northern Ireland goods arriving in the rest of the UK - that is, there will **be unfettered access**, as provided for by the Protocol.

2. **Trade going from the rest of the UK to Northern Ireland**: we will not levy tariffs on goods remaining within the UK customs territory. Only those goods ultimately entering Ireland or the rest of the EU, or at clear and substantial risk of doing so, will face tariffs.

3. **Although there will be some limited additional process on goods arriving in Northern Ireland**, this will be conducted taking account of all flexibilities and discretion, and we will make full use of the concept of de-dramatisation. There will be no new physical customs infrastructure.

4. **Trade to and from Northern Ireland from third countries**: where the UK has Free Trade Agreements with those countries Northern Ireland businesses will benefit from preferential tariffs just as the rest of the UK will.

Medical devices under the Northern Ireland Protocol

- **Registration:** From 1 January 2021, most medical devices, IVDs and custom-made devices will **need to be registered with the MHRA** before being placed on the Northern Ireland market. Please see the MHRA's guidance on registrations for more information.
- **Legislation:** The **Medical Device Regulations** (2017/745) and the **In Vitro Diagnostic Medical Device Regulations** (2017/746) **will apply in Northern Ireland** from 26 May 2021, and 26 May 2022 respectively, in line with the EU's implementation timeline.
- **CE marking:** A **CE mark will continue to be needed for devices placed on the Northern Ireland market and EU rules will need to be met**.
  - UK Approved Bodies will be able to conduct conformity assessments for certain purposes.
  - **Where a device has been assessed by a UK Notified Body, the UK(NI) mark will accompany the CE mark**. Products carrying both the CE mark and UK(NI) mark cannot be placed on the EU market.
  - UKCA marked devices will not be accepted on the Northern Ireland market unless accompanied by the CE or CE UK(NI) mark.
- **Competent Authority: The MHRA will continue to be the Competent Authority** for post-market surveillance activity for devices placed on the Northern Ireland market.

Trader readiness

What is Trader readiness?

Having all the necessary customs paperwork and licences in place by 1 January 2021.

- On 1 January 2021 the transition period will end and from that point **the UK will operate a full border** with the EU.
- This means that there will be **changes to the checks and controls on goods** as they move between Great Britain (GB) and the EU.
- If you import goods into GB from the EU, there will be new customs checks to pass. This includes:
  - Having the **correct customs paperwork** to present at the border. Not having the right documentation could lead to delays or being turned away.
  - Many traders may choose to employ a **customs intermediary** to help them manage this process. If you decide not to employ a customs intermediary, then there are specific steps that traders **must** follow to ensure they are trader ready.
- The **Border Operating Model** sets out what border controls will be implemented to which goods and at what stage, and provides guidance on additional requirements needed for specific goods.

What traders must do to prepare to import goods: priority actions

- New border controls on imports coming into GB from the EU will be introduced in stages.
- Traders moving standard goods from January to July 2021 have the option to defer customs declarations to HMRC for up to 6 months.

Now

What traders should do now to prepare

- **GB EORI number** – Apply for a **GB EORI number** if you don't already have one.
- **Customs Intermediary** – Consider getting a **Customs Intermediary**, if you don't already have one, to help you submit the necessary customs information and declarations.
- **Duty Deferment** – Apply for a **Duty Deferment Account** to pay customs charges monthly rather than for each individual consignment.
- **VAT** – Prepare to **pay or account for VAT** on imported goods.
- **Driving Permits** – Ensure drivers have the correct **international driving permits**.

From January 2021

What traders need to do from 1 January 2021:

- **Complete UK and EU customs declarations**.* For standard (non-controlled) goods, there will be an option to defer up to 6 months from point of import.
- **Note the movement in your records**, if you are deferring declaration.
- **Pay customs duties** (if applicable). There are options to defer payment.
- **Pay VAT**. There are options to defer payment.

*Some locations will require **pre-lodgement of customs declarations** prior to the movement of goods. This will particularly affect 'roll on-roll off' (RoRo) movements.

1 July 2021

What traders need to do from 1 July 2021:

- **Carry out safety and security declarations** (also known as entry summary, or ENS, declarations).
- **Complete UK and EU customs declarations** for all goods (there will be no option to defer from this point).

What traders need to do to export goods from GB into the EU

- UK exporters also need to be aware of certain steps they will need to take to export goods out of Great Britain into the EU.
- All goods will be subject to border controls from 1 January 2021.

Now

To prepare now, traders will need to:

- Ensure they have a **GB EORI number**.
- Ensure they can **access HMRC systems** to submit exit summary declarations, or have a customs intermediary to handle this on their behalf.
- Traders can also use the **'Check duties and customs procedures for exporting goods'** tool to help them prepare.
- Use the **'trade tariff tool'** to find out the **commodity code** and whether a **licence** is needed to move the goods.

From January 2021

Traders will need to:

- Complete a **UK customs export declaration**.
- Complete an **EU customs declaration** (more information to be provided in due course).
- Submit a **Safety and Security declaration**. How far in advance this information must be submitted before the goods leave GB depends on the mode which they are being transported.

A list of export facilitations is published in section 4.1.5 in the Border Operating Model.

"Check and HGV is ready" Service (formally referred to as Smart Freight)

- The "Check and HGV is Ready" service will support 'roll on-roll off' (RoRo) freight travelling from GB to the EU, to help reduce disruption and traffic congestion at GB ports. Drivers taking goods from GB to the EU will need to carry evidence that EU import requirements have been met.
- Haulier and consignment details to be submitted via a web-based portal to confirm the HGV is carrying the correct documentation.
- Once an HGV is confirmed to have the correct documentation it will be deemed to be 'border ready', and can proceed to the port.

UK Global Tariff Regime

What does my business need to know?

- From 1 January 2021, the UK will apply a UK-specific tariff to imported goods, the UK Global Tariff.
- This will:
  - Drop tariffs to zero across a wide range of products used in UK production.
  - Be in pounds - not euros.
  - Cut administrative costs for businesses.

What action does my business need to take?

- Use the new UK Global Tariff tool on GOV.UK to check the tariffs that will apply to goods you import: https://www.gov.uk/guidance/uk-tariffs-from-1-january-2021

People

Hiring staff from outside the UK

Why does my business need to take action?

From 1 January 2021, free movement will end and the UK will introduce a points-based immigration system.

The **new system** will introduce job, salary and language **requirements** that may impact your ability to hire from the EU.

This system will enable UK employers to recruit **skilled workers from around the world.**

Hiring staff from outside the UK

What does my business need to do?

From **1 January 2021**, if you want to recruit workers from outside the UK, you will need to ensure:

- You are a Home Office licensed visa sponsor;
- The job you are offering is at the required skill level – RQF 3 or above (A Level and equivalent);
- The job you are offering is above the required minimum salary level;
- The candidate speaks English to the required standard.

When does this need to be completed?

- If you are not already a licensed sponsor and you want to sponsor migrants through the skilled worker route from January 2021, **you should register now**.
- An application to become a licensed sponsor usually takes 8 weeks.

Hiring EU citizens who already live in the UK

What does my business need to know?

From 1 January 2021, free movement will end and the UK will introduce a points-based immigration system

The new system will not apply to EU citizens living in the UK before 31 December 2020. They can apply to the EU Settlement Scheme before 30 June 2021.

You can search for ‘EU Settlement Scheme: employer toolkit’ on GOV.UK to find out more.

Hiring EU citizens who already live in the UK

What does my business need to do?

- You may wish to direct your employees to the EU Settlement Scheme to help secure their immigration status.
- EU citizens and their family members (including non-EU citizens) need to apply to the EU Settlement Scheme to continue to live, work and study in the UK beyond 30 June 2021.
- You cannot discriminate against EU citizens as a prospective or current employer.

When does this need to be completed?

- EU citizens living in the UK before 31 December 2020 are eligible to apply.
- The application deadline is 30 June 2021.
- EU citizens coming to the UK from 1 January 2021 to live, work and study will need to apply under the new points-based immigration system.

Horizon Europe

Continue to apply for Horizon 2020

What does my business need to do?

- UK scientists, researchers and businesses can continue to participate in and lead Horizon 2020 projects and apply for Horizon 2020 grant funding.
- UK organisations can continue to bid into calls for new Horizon 2020 grant funding for the lifetime of the Horizon 2020 programme. If successful, funding will be provided by the European Commission.

When does this need to be completed?

- UK participants will continue to receive EU grant funding for the lifetime of individual Horizon 2020 projects, including projects finishing after the transition period ends on 31 December 2020.
- This includes any Horizon 2020 calls, such as the Green Deal Call, under the 2014-2020 Multiannual Financial Framework even if they extend into 2021, after the transition period has ended.

Continue to apply for Horizon 2020

What Happens after Horizon 2020?

- The EU's next research and innovation programme, Horizon Europe, will run from 2021-2027.
- Negotiations on possible participation in Horizon Europe are ongoing.
- If we do not formally associate to Horizon Europe, we will implement ambitious alternatives as quickly as possible from January 2021 and address the funding gap.
- Under all scenarios, our aim is for UK organisations and entities to continue participation in Horizon Europe collaborative projects open to third countries, as well as in wider international collaborations.

Further information

- Find out more information about Horizon 2020 and how to apply on: https://www.gov.uk/guidance/horizon-2020-what-it-is-and-how-to-apply-for-funding

Personal data

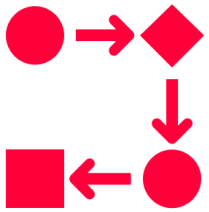
Check European rules on personal data transfers

What does my business need to know?

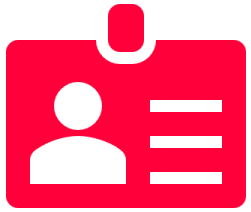
- The EU has an established way to allow for the unrestricted transfer of personal data to countries outside the EU called adequacy decisions.
- The EU's data adequacy assessment of the UK is underway, but if the EU has not made data adequacy decisions for the UK by 1 January 2021, you will need to act to ensure you can continue to lawfully receive personal data from the EU/EEA.
- You also need to be aware of data obligations under the Withdrawal Agreement, which requires certain personal data to be protected in line with EU data law in the event the EU has not made data adequacy decisions for the UK.

Check European rules on personal data transfers

What does my business need to do?



If you receive data from the EU/EEA, you should map your data flows and put in place alternative transfer mechanisms with any relevant EU organisations.



You should take stock of the personal data you hold prior to the 1 January 2021.

You can put in place safeguards by incorporating standard contractual clauses. Search ‘keep data flowing’ on the ICO’s website for more help.

Thank you

Any questions?