

**EU Transition**

**Stakeholder Briefing**

**December 2020**

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# Introduction

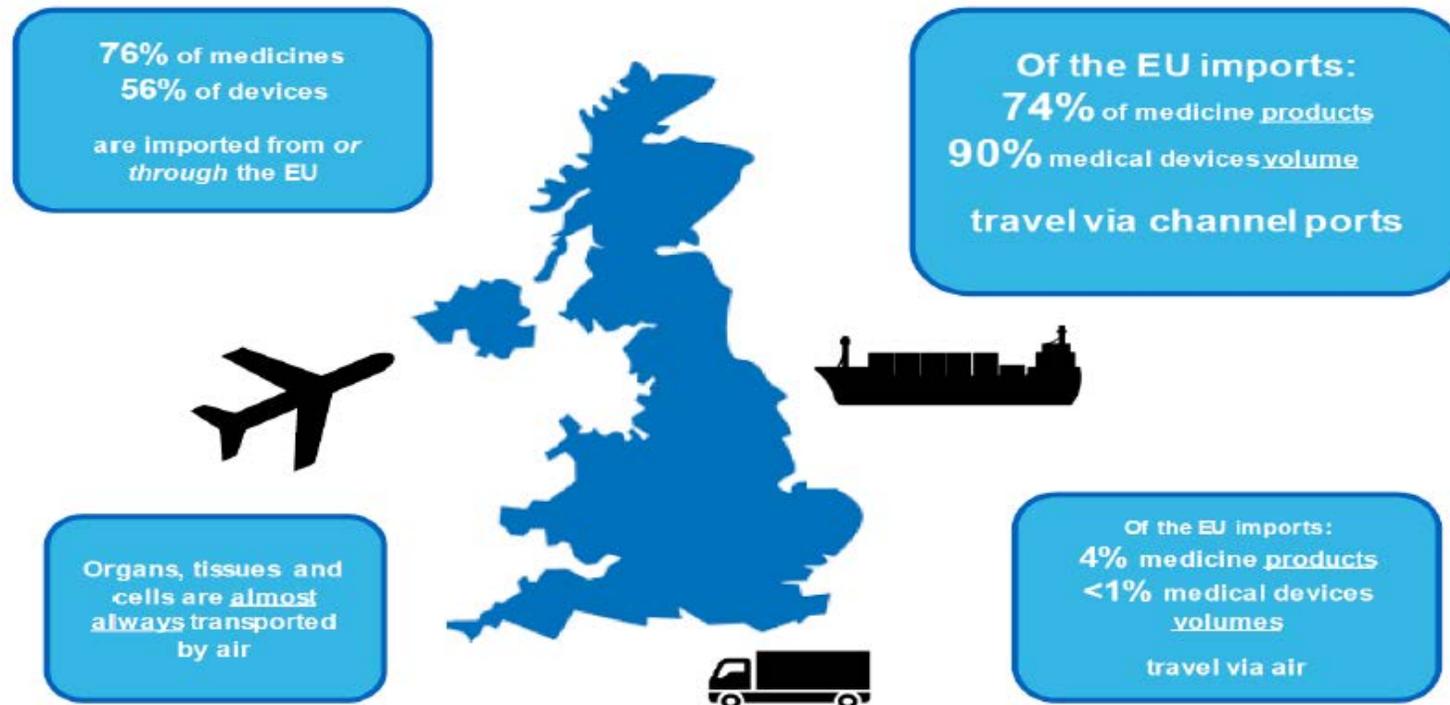
# Purpose

- Ensuring the safety and well-being of patients in NI is the Department's top priority.
- In preparation for the end of the transition period (EOTP) on 31<sup>st</sup> December 2020, updated operational readiness guidance has been published. [www.health-ni.gov.uk/articles/eu-exit](http://www.health-ni.gov.uk/articles/eu-exit)
- Tonight we will provide an update in the three key areas covered by the guidance; healthcare supplies, people/cross border issues and data.
- Questions and answers.

# Healthcare Supplies

# Healthcare Supplies Context

The NHS has goods entering the UK from the EU across all methods of transport



Note: Medicines volumes are based on MAH returns to date and have been extrapolated to the whole market

Note: Devices can come into the UK in different parts and therefore not appropriate to give total volume of devices split by ports, hence using total volumes crossing the border.

# National Contingencies

All licensed & unlicensed medicines, vaccines, clinical trials, medical devices, clinical and non clinical consumables, oxygen, blood, organs, tissues.

- Extra stock held in supply chain
- Actions to mitigate risk of delays in transit
- Support for trader readiness
- Enhanced arrangements for managing supply chains and shortages

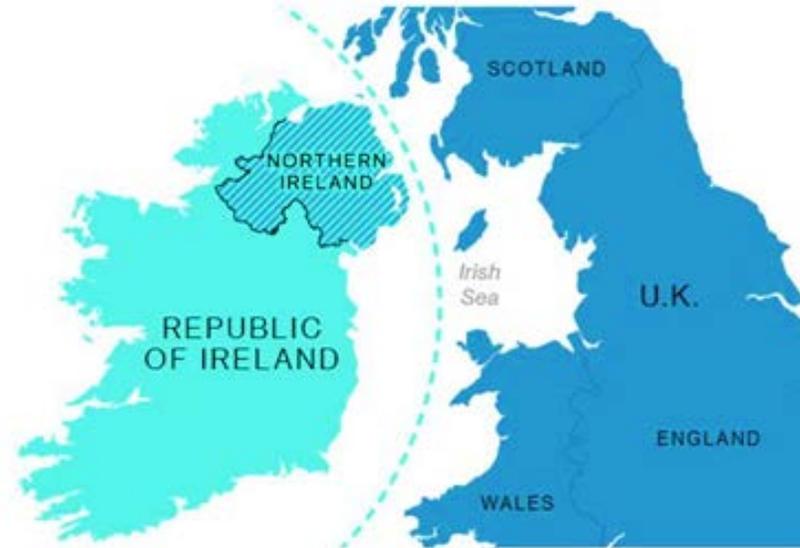
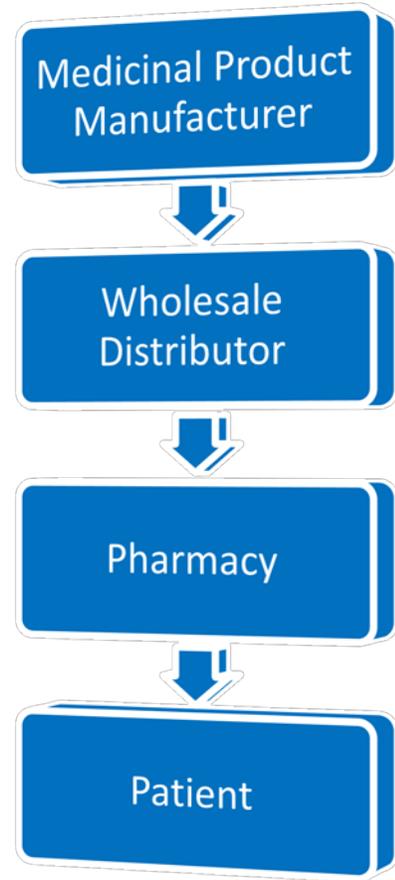
# Medicines Shortages

- UK-wide National Medicines Shortages Response Group (MSRG) has been established.
- Group considers emerging medicines shortages and oversees escalation and communications plans for 'high impact' and 'critical' shortages.
- Arrangements have been put in place locally to complement the work of the MSRG.
- Actions - Supply Disruption Alerts, Serious Shortage Protocols

# Medical Devices & Clinical Consumables

- BSO has been proactively working with HSC organisations to build central stockpiles of approximately 1,700 common use medical devices, clinical consumables and non-clinical items.
- Current centrally held stocks represent an average of **10 weeks product usage**, with a **further 2 weeks** stock available from nationally held stockpiles within GB.
- These stocks are in addition to an average stock holding of these products at ward level of between **2-4 weeks**
- **National Supplies Disruption Response (NSDR)** system.

# Northern Ireland medicines supply chain



98% medicines supplied to Northern Ireland come via Great Britain

76% medicines supplied to Northern Ireland have an EU touchpoint

# What does EU Exit mean for medical supplies?

- After the end of the transition period the Ireland / Northern Ireland Protocol will come into effect
- This will mean that Northern Ireland will remain aligned with EU acquis for medicines and medical devices while Great Britain will not
- The Falsified Medicines Directive (FMD) will apply in Northern Ireland
- A Manufacturing / Importation Authorisation (MIA) will be required to import medicines from Great Britain into Northern Ireland. This is a significant step, including demonstrating compliance with EU Good Manufacturing Practice and Good Distribution Practice rules
- Medicines bound for the Northern Ireland market must be batch tested. This applies to GB-manufactured medicines and medicines originating from the EU that enter GB, which must be retested before entering NI
- Medicines entering the NI market from or via GB must be QP certified in line with the requirements of the MA



# Mitigations to supply chain risk



- The UK Government have negotiated a 12 month phase in period to allow industry crucial time to prepare to implement these changes
- Multi-layered approach
  - Buffer stocks
  - Trader readiness
  - Rerouting away from the short straits
  - Additional ferry capacity
- Increased stock holding by local wholesalers in Northern Ireland
- Increased stock holding of clinical consumables by BSO PaLs
- Local and national medicines shortages management
- Ongoing engagement with DHSC, MHRA and pharmaceutical industry

# FMD for end users



- Northern Ireland will remain aligned with EU legislation and regulation, end users in Northern Ireland, including pharmacies, must continue to comply with FMD and will be required to continue to decommission medicines at the point of end supply.
- NI will remain connected to the National Medicines Verification System (NMVS) facilitated by SecurMed UK. SecurMed UK will continue to provide end user registration and necessary support to enable the decommissioning of packs with FMD identifier features beyond the end of transition.



- Further information on FMD can be found <https://fmdsource.co.uk>

# What happens next?



- The Department will continue to engage with DHSC, MHRA and industry to ensure the continuity of supply of medicines to Northern Ireland patients
- Monitoring of movement of healthcare supplies at Irish Sea crossing
- Enhanced monitoring of shortages
- Cost surveillance
- The pharmaceutical industry will be making long term changes to the way in which medicines are supplied to Northern Ireland



## Key messages

- Extensive local and national contingencies are in place to ensure healthcare supplies
- There is no need for local stockpiling of medicines or medical products unless advised to do so by the Department
- Patients and carers can be advised that they do not need to order additional prescription medicines
- Prescribers do not need to prescribe additional quantities and should not exceed 56 days' supply (28 days for controlled drugs)
- Supply shortages should be escalated through the usual mechanisms should they arise
- The Department will provide advice on handling shortages if they occur to ensure continuity of care for patients
- Further information can be obtained via <https://www.health-ni.gov.uk/articles/eu-exit>

# Trader Readiness

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From 1 January 2021 goods moving from Great Britain to Northern Ireland will require customs declarations

## 1. Trader Support Service (TSS)

- Recommend any businesses that purchase goods from GB register
- <https://www.tradersupportservice.co.uk/tss>

## 2. XI EORI Number

- <https://www.gov.uk/eori>

More Information Can Be Found Via:

<https://www.nicustomstradeacademy.co.uk/>

# People

# EU Withdrawal Agreement

## Citizens' Rights

Citizens' rights of UK citizens in EU countries and vice versa who used their right of free movement before 31 December 2020.

- EEA citizen living and working in Northern Ireland or
- Frontier Worker living in Ireland and working in Northern Ireland

EU rights under the social security regulation will continue and this includes access to healthcare.

[Withdrawal Agreement explainer for part 2: citizens' rights - GOV.UK](https://www.gov.uk/government/explainers/withdrawal-agreement-explainer-for-part-2-citizens-rights)  
[www.gov.uk](https://www.gov.uk)

[The Withdrawal Agreement: what UK nationals need to know about citizens' rights - GOV.UK](https://www.gov.uk/government/explainers/the-withdrawal-agreement-what-uk-nationals-need-to-know-about-citizens-rights) [www.gov.uk](https://www.gov.uk)

# EU Settlement Scheme

- If you are an EEA Citizen (not including Irish Citizens), to make sure you maintain your rights it is important that you apply for the EU Settlement Scheme.
- The EU Settlement Scheme is open to all eligible EEA citizens and their family members. You will have until **30 June 2021 to apply.**

<https://www.gov.uk/settled-status-eu-citizens-families>

## Irish Citizens

- If you are an Irish Citizen living in Northern Ireland and are in scope of the EU Withdrawal Agreement, you do not need to do anything to maintain your rights.



# Frontier working

If you live in Ireland and work Northern Ireland you'll be able to keep your frontier worker status if you're frontier working in the UK by 31 December 2020.

- If you are an **EEA citizen** (apart from Irish) you'll need to apply for a frontier worker permit. This scheme is due to open on the 10 December for applications. **You will need to have a valid permit by 1 July 2021.**
- **Irish citizens** will not need a frontier worker permit but may apply for one if they wish.
- If you are a **British citizen or a Person of Northern Ireland** you will not need to do anything and you cannot apply for a frontier worker permit.

[Frontier workers in the UK: rights and status - GOV.UK \(www.gov.uk\)](https://www.gov.uk)



# Professional Qualifications

- Health and social care workers with professional qualifications from the EU already registered with their professional regulator can continue to practise in the UK as they do now. You don't have to do anything.
- If you are working in Ireland you should be registered with the professional body there. If you only work occasionally or are going to be working occasionally in the next year you might want to consider registering with the relevant professional body before the end of the year.



# Reciprocal Healthcare

EU Legislation on Social Security Coordination currently applies to the UK. This provides for people to be able to receive reciprocal healthcare within the EU for:

- needs arising care when visiting another country (EHIC),
- have your competent state pay for your healthcare when you live in another EU country (S1), and
- be able to travel for treatment when you are unable to get the treatment within a reasonable timescale in your home country (S2).

The future of reciprocal healthcare is part of the future relationship negotiations.

The UK and Ireland are working on an Enduring Reciprocal Healthcare Agreement within the confines of the Common Travel Area.



## Key messages

- The EU Withdrawal Agreement maintains citizens' rights for everyone who has used their EU right of free movement. Including right to reside, access to healthcare and have professional qualifications recognized
- EU settlement scheme is open until 30 June 2021
- Frontier worker scheme opens 10 December 2020
- EEA employees from 1 January 2021 must meet new visa requirements

# Data Transfer

# Health and Social Care Data transfer

- **UK to EU:** UK considers EU data protection standards to be equivalent to UK legislation and is content to transfer information to EU partners.
- **EU to UK:** EU uses an “Adequacy” process to review the data protection arrangements of non EU countries.
- UK government led discussions continue on the UK achieving an “Adequacy Decision” under GDPR.
- EU to UK personal data transfers may require the use of more formal mechanisms to demonstrate compliance with GDPR.

# Key Players - EU Exit Transition Preparations

- **Data protection issues:** Department of Digital, Culture, Media and Sport (DCMS) is lead UK Government Department on Data Protection. Department of Finance is the lead NI department.
- Department of Health Information Governance team has worked with, HSC organisations and NIFRS representatives on preparations for EU and exchanges of personal, healthcare data.
- Departmental leads and ALB's have contracts/ administrative agreements in place and data flows are reviewed regularly. This only covers contracted services and pre-arranged, regular patient identifiable information transfers with RoI organisations.
- Department for the Economy have the lead for data exchanges related to conducting business.

# Information Transfers

- The majority of information transfers external to the UK concern RoI, either as regional or shared services. Examples of cross border activities include:
  - North west cancer services,
  - Kidney dialysis – Southern Trust area
  - Paediatric cardiac care
  - NI Fire and Rescue border services
  - Cross border transportation of patients
  - Social care services

# Business Data

- Independent contractors may also exchange data with colleagues and suppliers in other jurisdictions related to their business, such as:
  - Payment details,
  - Payroll
  - Revenue bodies
- These exchanges are not covered by any central arrangements.

# Useful Links

- Each organisation or association should have a Data Protection Officer. They should be the first port of call.
- DoH
  - [Department of Health \(NI\) EU Exit Operational Readiness Guidance | Department of Health \(health-ni.gov.uk\)](#)
- NI Direct
  - [Business - EU exit information | indirect](#)
  - [Business - steps to take for changes from 1 January 2021 | indirect](#)
- ICO
  - [Data Protection at the end of the transition period | ICO](#)

# Questions and Answers