

**From the Chief Pharmaceutical Officer
Mrs Cathy Harrison**



BY EMAIL

Chief Executives, HSC Trusts
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Date: 24th November 2020

Dear Colleague,

I am writing to advise that the Department's EU Exit Operational Readiness Guidance has been updated and should be used to review and where necessary update your organisation's EU contingency plans in advance of the end of the EU transition period (EOTP) on 31st December 2020.

The United Kingdom left the European Union on 31st January 2020 and moved into a transition period which ends on 31st December 2020. The UK Government and EU Commission are still involved in negotiations to secure a free trade agreement and there is still the possibility that a deal may not be fully confirmed by the EOTP.

During the past two years national plans have been developed to mitigate possible disruption to healthcare supplies that could arise from a 'no deal' scenario. This has resulted in the development of a 'multi-layered approach' to UK wide contingencies involving a range of activities including (but not limited to) supporting trader readiness, warehousing, buffer stocks, extra ferry capacity and an express freight service for medicines and medical products. In addition across the UK enhanced arrangements are operating for surveillance of the healthcare supply chain with associated shortage managements systems.

The Medicines and Healthcare Products Regulatory Agency (MHRA) has provided comprehensive UK wide guidance on a wide range of topics for the pharmaceutical industry relating to EOTP, which is available on the [UK Government website](#). The guidance covers a range of technical areas, such as licensing, pharmacovigilance and importing and exporting medicines.

The Ireland/Northern Ireland Protocol (NIP) comes into effect from 1st January 2021 and will result in changes to the regulation and supply of medicines and medical devices which will be phased in over 12 months for compliance by 31st December 2021. The NIP is not expected have an immediate impact on healthcare supplies at the EOTP. Further information will be provided on these issues in the coming months.

For now, the focus is on preparing for the EOTP and the Department is continuing to work closely with the Department of Health and Social Care (DHSC) to ensure the continuity of supply of medicines and medical products into the UK, regardless of whether the UK and EU agree the free trade agreement the government is seeking to negotiate.

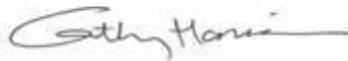
The main issue that HSC organisations and service providers need to be aware of is the risk of disruption to the supply chain. However, the immense scale of the work undertaken nationally to mitigate these risks, means that there is no need for your service to take additional action locally unless otherwise notified. The key messages for your organisation are:

- **The EU transition period will end on 31st December 2020.**
- **The UK Government and EU Commission are still involved in negotiations to secure a free trade agreement and there is the possibility that a deal may not be fully confirmed by the EOTP.**
- **HSC organisations/providers should use the updated EU Exit Operational Readiness Guidance to refresh their existing EU contingency plans**
- **Extensive 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**
- **All HSC organisations/providers should have arrangements in place to manage shortages of supplies should they arise**
- **The Department will provide advice on handling shortages if they occur to ensure continuity of care for patients**
- **The current expectation is that there;**
 - **will not be a significant number of HSC staff leaving at the EOTP**
 - **will be no anticipated cross border disruption between NI and ROI**
- **The EU Withdrawal Agreement solidifies citizens' rights for all of those EU citizens in the UK, and EU Frontier workers before EOTP including the right to continue to live and work, have their qualifications recognized and access healthcare on the same basis as now**

- **From 1 January 2021 free movement is ending, the new points-based immigration system will treat EU and non-EU citizens equally and change the way you recruit from outside the UK**
- **HSC organisations have provided assurances on mitigations to ensure patient and service user information can be exchanged with EU partners. These mitigations should be kept under review**

The Department will continue to provide updates where needed in the coming months. Thank you for your continuing support.

Yours sincerely



Mrs Cathy Harrison