

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



Department of
Health
An Roinn Sláinte
Mánnystrie O Poustie
www.health-ni.gov.uk

To:

Chief Executives, HSC Trusts/NIAS/NIBTS/PHA

(for onward distribution to relevant staff)

Chief Executive, HSCB *(for onward distribution to
Community Pharmacy Contractors, General
Practitioners, Practice Managers, GP Locums and GP
Out of Hours Services)*

Chief Executive, RQIA *(for onward distribution to
independent providers)*

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[By e-mail]

Dear Colleague,

EXIT FROM THE EUROPEAN UNION: MEDICINES AND MEDICAL SUPPLIES

The Department of Health, in conjunction with other HSC organisations, is engaged in extensive preparations for EU exit, developing contingency measures for different scenarios including a “no deal” exit from the EU. Patient welfare is the overriding priority and the Department can assure the public that it is working very hard to safeguard their interests.

A key issue is maintaining access to medicines, medical devices and clinical consumables and the Department is participating in UK-wide contingency arrangements to ensure that patients continue to get the supplies they need, in a timely way.

In order to ensure that you are best placed to offer advice on the supply of medicines and other medical supplies in the event of a “no deal” exit from the EU, I wish to highlight a number of key messages and provide you with an overview of the work currently being taken forward.

Key messages:

- **There is no need for patients to do anything different or new.**
- **Patients, hospitals, GPs, community pharmacies and care homes should not stockpile medicines.**
- **The Department of Health (DoH) is working closely with the other UK Administrations to make sure that patients receive the medicines and other medical supplies they need, in the event that the UK leaves the EU without a deal.**



- **Pharmaceutical companies have stockpiled medicines and across the UK, other supplies such as medical devices and clinical consumables have also been stockpiled.**
- **Arrangements are in place to transport (including by air) items into the UK that cannot be stockpiled.**
- **Where shortages occur the situation will be managed and, if necessary, suitable alternatives or an alternative treatment will be provided until supply is restored to normal levels.**

Work being taken forward

A comprehensive risk assessment has been completed across all medicines used in the UK to determine the volume of those medicines with an EU touch point and therefore at risk of a potential delay in reaching the UK.

The Department of Health and Social Care (DHSC) has asked pharmaceutical companies to ensure a minimum of six weeks additional supply in the UK for prescription only medicines and pharmacy medicines, over and above existing business-as-usual stocks. Contact has also been made with manufacturers of unlicensed medicines, known as “specials”.

Where necessary, additional warehouse space has been procured in the UK for companies to stockpile medicines, including refrigerated and room temperature storage. Pharmaceutical companies have been stockpiling for some time. In addition, significant stockpiles of vaccines to support the national vaccination programmes are being held and vaccinations will continue as normal.

Plans for a ‘no deal’ exit also take account of the possibility that delays on the short straits ferry routes into England could continue for more than six weeks (and could last for up to six months). The UK Government has secured additional roll-on/roll-off ferry capacity on alternative routes away from Dover and Folkestone, where delays are most likely to occur. Medicines and medical devices will be prioritised on these alternative routes and arrangements have been established for short-life medicines to be brought into the UK by air. Work is also ongoing to assure the flow of medicines from GB to Northern Ireland, without delays.

In relation to medical devices and clinical consumables, the Department and Business Service Organisation’s (BSO) Procurement and Logistics Service (PaLS) are participating in UK-wide contingency planning arrangements. BSO PaLS has engaged with key suppliers to establish an assurance on EU-Exit preparedness to identify key risks in the supply chain. Furthermore, there has been an increase in buffer stock with six-weeks additional stock on top of the normal four weeks held centrally within BSO systems.

Participation of and recruitment into clinical research including trials should continue as normal unless specific instructions from an individual sponsor or formal communications are received. Investigational medicinal products (IMPs) will be prioritised on alternative routes to ensure that the flow of all these products continues unimpeded after 29 March 2019.

With so many medicines and other supplies dispensed in hospital and community pharmacies every day, shortages can occur and there are already effective systems in place to manage these. Although shortages can arise for a range of reasons it is possible that border delays at the English Channel following a “no deal” EU exit could result in shortages due to delays in transit.

Enhanced arrangements for managing shortages of medicines and other medical supplies are currently being established, involving all UK countries. For medicines, where shortages arise which are above normal levels, new UK-wide legislation has been introduced which would enable community pharmacies to dispense against a pre-approved “protocol” without reverting to the prescriber (for example, a GP) to seek a change to a prescription. These protocols will be known as “serious shortage” protocols and will be considered for specific drugs (or classes of drugs) on a case by case basis.

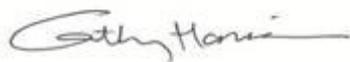
Any “serious shortage” protocol will be developed with input from clinicians and between the UK Government and the Devolved Administrations and could cover dispensing a different quantity, pharmaceutical form, strength or a generic or therapeutic equivalent.

As we move forward, the key priority for us all is to continue to work together and I will be meeting with representatives from across health and social care, local wholesalers and professional and patient representative bodies in the coming weeks to discuss contingency arrangements.

Further communications will be issued to stakeholders at appropriate junctures, providing updates on the ongoing contingency preparations.

I trust this is helpful.

Yours sincerely



Mrs Cathy Harrison