

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



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

By email:

Chief Executives, HSC Trusts (*for onward distribution to relevant staff*)

Chief Executive, HSCB (*for onward distribution to Community Pharmacists and GPs*)

Chief Executive, BSO

Chief Executive, PHA

Chief Executive, NIAS

Chief Executive, NIBTS

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

Castle Buildings
Stormont
Belfast
BT4 3SQ
Tel: 028 90 523219
Email: cathy.harrison@health-ni.gov.uk

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Dear Colleagues

EXTENSION OF ARTICLE 50: NEXT STEPS

The Department of Health's Director of Corporate Management wrote to HSC Chief Executives on 30 October 2019 to advise of the extension of Article 50 to 31 January 2020. Building on that correspondence I am now writing to provide additional information about the next steps in relation to the work already undertaken at UK and local level to ensure continuity of supply of medicines and medical products.

My previous correspondence (in February and July 2019 respectively) informed you of the UK's multi-layered approach to contingency planning, led by the Department of Health and Social Care (DHSC), working with each of the Devolved Administrations (DAs). Below I outline plans for the coming extension period in terms of the key elements of the multi-layered approach.

Buffer stocks

The DHSC, in conjunction with the DAs, has been working with trade bodies, product suppliers, and the health and care system to make detailed plans to ensure the continuation of the supply of medical products to the whole of the UK in the event of leaving the EU without a deal. UK suppliers have been asked to retain the current level of stockpiles they have in place during this extension period.

In parallel, BSO PaLS has been working with local suppliers in Northern Ireland to help build buffer stocks of critical medical product lines – this remains an important cornerstone of our contingency planning. BSO PaLS will be writing to NI suppliers to ask that they too retain the current level of stockpiles they have in place during the extension period.

Additional warehouse space

The DHSC previously agreed contracts for additional warehouse space to help ensure sufficient space to store stockpiled medicines ahead of EU Exit; this was for the storage of ambient, refrigerated and controlled drugs. During the extension period, the DHSC will continue to provide this warehousing capacity for use at market rates.

Additional freight capacity

The Department for Transport put in place a four year framework for additional freight capacity for transporting Category 1 goods. The current freight contracts have been postponed for 3 months and tickets can no longer be purchased. It is the intention that these contracts will be remobilised from 31 January 2020. Suppliers and hauliers are still being advised to register now to be able to use this capacity when it is needed.

In addition to this, the DHSC procured a dedicated Express Freight Service for the rapid transport of medicines and medical products into the UK within 24-48 hours. These contracts have also been postponed and will be remobilised from 31 January 2020. Testing of the systems will be ongoing during the extension period.

Regulatory requirements

To enable companies to continue to sell their products in the UK, even if the UK leaves without a deal, the UK Government has made changes to certain regulatory requirements. Legislation covering the regulation of human medicines, medical devices and clinical trials were approved by Parliament, and these changes will remain in place should the UK leave without a deal on 31 January 2020.

Dealing with shortages

Where there are shortages in medications, arrangements have been put in place to be able to issue Serious Shortage Protocols to enable community pharmacies to be able to issue a substitute medication instead of the prescribed medication without having to go back to the prescriber. Further information on Serious Shortage Protocols is available at: www.hscbusiness.hscni.net/services/3063.htm

National Supply Disruption Response (NSDR)

The National Supply Disruption Response (NSDR) function is in place at UK level but during the extension period core operating hours have been reduced – this function will be stood up again for 31 January 2020. BSO PaLS will have its own dedicated NSDR team embedded within its Logistics Team; this team has not yet been stood up but will be in place in advance of any likely disruption.

Trader Readiness

In the period up to the end of January 2020, the DHSC has been advising companies to continue to prepare for any new customs and border arrangements that would come into place if the UK leaves the EU without a deal. To support industry in their preparations, the DHSC established a dedicated Trader Readiness Support Unit to provide advice and assistance to suppliers of medical goods. This

service will remain operational throughout the extension period, and can be accessed via the email address: BeTraderReady@dhsc.gov.uk.

In addition, BSO PaLS has been working closely with local suppliers in NI on their general state of preparedness to ensure continuity of supply.

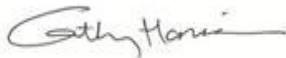
Key messaging

Our key messaging to HSC organisations remains unchanged, and includes:

- There is no need for patients to do anything new or different.
- 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 have a short shelf-life or that cannot be stockpiled.
- Where shortages do occur the situation will be managed closely and, if necessary, suitable alternatives will be provided until supply is restored to normal levels.

During this extension period the Department will continue to work with HSC pharmacy/EU Exit leads and other colleagues on local EU Exit preparedness. I will also keep you up to date on the latest developments and any actions required of you. I would like to take this opportunity again to acknowledge my thanks on behalf of the Department for your continued support.

Yours sincerely



CATHY HARRISON