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Lewis Macdonald MSP  
Convenor  
Health and Sport Committee

By Email.

28<sup>th</sup> March 2019

Dear Lewis

## **UK EXIT FROM THE EUROPEAN UNION: SUPPLY OF MEDICINES AND MEDICAL DEVICES**

I wanted to draw the Committee's attention to a letter about preparations in Scotland for the eventuality of the UK leaving the European Union without there being an agreement with the EU about the terms of withdrawal, and in particular steps being taken to support continuity of supply of medicines and medical supplies and to support prescribers where shortages arise.

This letter was issued yesterday by the Chief Medical Officer and the Chief Pharmaceutical Officer to a range of health and social care professionals and organisations. Information for the public about these issues has also been placed on the Scottish Government website at:

<https://www.mygov.scot/eu-exit/>.

I trust that it is helpful for the Committee to see this material.



**JEANE FREEMAN**



**From the Chief Medical Officer and the Chief  
Pharmaceutical Officer**

NHS Scotland Board Chief Executives  
Chief Officers of Integration Authorities  
NHS Scotland Directors of Pharmacy  
Convention of Scottish Local Authorities  
NHS Boards' Primary Care Lead Officers  
Health and Social Care Alliance Scotland

27 March 2019

Dear colleague,

**EXIT FROM THE EUROPEAN UNION: CONTINUITY OF SUPPLY OF MEDICINES,  
MEDICAL DEVICES AND CLINICAL CONSUMABLES**

The Chief Pharmaceutical Officer wrote to a number of organisations on 31 January to describe plans being put in place to prepare for the eventuality of the UK leaving the European Union (EU) without there being an agreement with the EU about the terms of withdrawal. At the time of writing, the UK leaving the EU in this way remains a possibility.

We wish now to explain further steps that have been taken to support continuity of supply of medicines and medical devices and clinical consumables. We also wish to describe steps being taken to support prescribers where shortages arise. Information for the public will be issued on the Scottish Government website: <https://www.mygov.scot/eu-exit/>.

Main points of advice

**The Scottish Government is working with all other UK Administrations to make sure that people receive the medicines and other medical supplies they need, as far as is possible, if the UK leaves the EU without a deal.**

**Pharmaceutical companies have stockpiled medicines and across the UK the NHS has stockpiled other supplies like medical devices and clinical consumables. Arrangements are also being made to transport into the UK, including by air, items that cannot be stockpiled.**

**The UK Government has stated that, if there are delays at the UK Border, medical supplies will be given priority for entry into the UK.**

**Members of the public, GPs, community pharmacies and hospitals should not stockpile.**

**Shortages may occur, but the NHS will manage the situation and if necessary provide suitable alternatives or other treatment while supply is restored to normal levels.**



## Managing shortages

The production of medicines and medical supplies is often complex and highly regulated, and materials and processes must meet rigorous safety and quality standards. Supply problems can arise for various reasons such as manufacturing issues, problems with ingredients and batch failures. The UK Administrations have well established procedures to deal with shortages, to ensure that the risks to the public are minimised.

**Additional steps have now been taken to prepare for the risk that a no deal exit will lead to more shortages than are normally experienced.**

## Medicines stockpiling arrangements

In 2017-2018, the UK Government approached manufacturers to identify which licensed medicines enter the UK from the EU/EEA. In August 2018, it asked pharmaceutical companies manufacturing those medicines to stockpile an additional six weeks of supply in the UK, over and above existing business-as-usual stocks. This was based on early planning assumptions about the duration of border delay, which were later revised to three to six months. The UK Government then asked companies to increase stockpiling beyond six weeks where possible. **The stockpiling arrangements are kept under daily review.**

This review includes monitoring a specific list of medicines where there is currently not a six-week stockpile held in the UK. In most cases, these are medicines that are currently in short supply and therefore the company has not been able to build a stockpile. There are plans in place to actively manage each medicine on this list. The proposed actions vary and include seeking further information from the company, seeking an alternative supplier, using an alternative product, directly purchasing the medicine and classifying it as a shortage that is subsequently managed on a case-by-case basis.

## Medicine shortages arrangements

Unlike the current arrangements that tend to be reactive, it is anticipated that most shortages will be managed proactively with companies reporting in advance any potential problems that will provide time to plan for an appropriate response. In relation to **medicines**, the UK Government has established a Medicines Shortage Response Group (MSRG) to monitor and respond to developments. The Scottish Government has established an equivalent group for Scotland, **MSRG (SCO)**. These groups will be working closely together to identify, assess and respond to shortages. They are clinically led, by Chief Pharmaceutical Officers. The MSRG (SCO) is playing a key role in **ensuring the NHS in Scotland is positioned to both influence and act on local, regional and national shortages and communicate any associated actions in a timely fashion to enable policy decisions to be made and to ensure implementation at pace.**

The MSRG (SCO) will also focus on **strengthening extant guidance for managing the shortages of medicines in primary and secondary care.** This includes improving existing surveillance, reporting, and communication systems. In addition, as well as offering intelligence gathered from across NHS Scotland that can be taken into account and fed into an assessment of the overall UK position in relation to medicine supply and shortage, the group will consider any operational aspects associated with medicines shortages and decide solutions to ensure successful implementation across Scotland. This will ensure that in the event of any shortages the NHS in Scotland is well placed to respond with a streamlined, robust, agile and responsive process ensuring that is effective and protective of public health.

## Reporting shortages

In primary care, shortages may be identified from various sources, including community pharmacies, GP practices, prescribing advisors and patients themselves. GP practices should continue to report any shortages to their health board prescribing team. Community pharmacists should continue to report shortages to Community Pharmacy Scotland (CPS).

In secondary care, pharmacists should follow their health board policy for managing shortages. This will include conducting a risk assessment to evaluate the potential effect. The assessment should document the estimated duration of shortage, the usage figures, the scale of the gap in supply and demand, the availability of suitable alternatives and potential risks to patients. There should be engagement with relevant clinical stakeholders to agree and support the implementation of any shortage management strategy. In the event that a shortage requires a restriction in usage this needs to be discussed with senior clinicians, start and review dates established and a communication plan agreed. Where a potential alternative is available then a documented assessment should be undertaken. If appropriate, the shortage should be escalated to NHS National Procurement, who will help resolve or escalate if there is evidence to suggest the shortage will have a significant impact.

**Further guidance will follow, describing the additional steps taken to strengthen and streamline the management of medicine shortages of medicines in both primary and secondary care across NHS Scotland.**

## Resolving shortages

Shortages and their subsequent management options will be considered from both an individual patient and a population basis.

For low impact shortages, for example when the response is to use an alternative strength, formulation and/or quantity, then **community pharmacists should be able to amend prescriptions electronically in line with existing endorsing guidance** (which includes dose, strength and brand substitution). The existing endorsing flexibilities built into the **ePharmacy Programme in Scotland** provide scope for community pharmacists to endorse what they have supplied rather than request a new prescription from the GP practice. **Community pharmacists should fully utilise this facility.** The relevant extract from the Endorsing Guide is available via [this link](#).

Where national shortages arise, **the MSRG will produce recommendations for the NHS**, drawing where necessary on advice from the Chief Medical Officers and their special advisors. Guidance will be given to prescribers and pharmacists about **what shortages exist, what steps should be taken, and what information to pass on to health and social care users** about any issue that might affect their prescription.

Where more serious shortages of medicines occur, individual “Serious Shortage Protocols” may be developed and clinically authorised, which will enable pharmacists to amend prescriptions to dispense a different strength, formulation or an alternative medicine, within the scope of the protocol. These protocols will be time limited. Further information on how they will be operationalised will follow in due course, however we are in a strong place in Scotland to ensure that these protocols can be underpinned with electronic support using the ePharmacy Programme, which includes electronic communications on any amendments between pharmacies and GP practices.

The Scottish Government Health and Social Care EU Exit Response Hub will form part of the national response to any significant shortages support activity across NHS Scotland. Further information on this will be shared with NHS Scotland Chief Executives.

### Next steps

**Prescribers do not need to do anything new at this moment in time.** Members of the public, GPs, community pharmacies and hospitals **should not stockpile medicines.**

Further information on the **strengthened processes for managing medicine shortages in primary and secondary care will follow shortly.**

Due to the commercial in confidence nature of the stockpiling data, **information will be provided about any shortages and any steps that should be taken on a case-by-case basis.** This will minimise any additional burden on GP practices and community pharmacies. Further information will follow describing the information cascade process.

### Medical devices and clinical consumables

In relation to **medical devices and clinical consumables (MDCC)**, NHS National Services Scotland (NSS) and the Scottish Government have made contingency plans for continued supply. Arrangements have been made for Scotland's participation in a UK-wide National Supply Disruption Response (NSDR) centre that, in turn, provides access to dedicated shipment channels. These shipment channels will enable delivery of ambient, non-temperature controlled products into the UK from the EU. NSS has also undertaken a phased stock build of goods held in its National Distribution Centre in Scotland.

In the event of no-deal EU withdrawal Health Boards, Primary Care providers and Social Care providers are expected to continue to apply a business as usual approach to the procurement of goods. The contingency measures being put in place by NSS should only be used in the event of difficulty in obtaining a particular product. In those circumstances, Health Boards and other providers will be expected to contact a triage centre being established by NSS, who will firstly attempt to resolve the supply issue within Scotland and, if necessary, will then escalate the issue to the UK-wide NSDR.

Whilst NHS England and the UK Department of Health and Social Care plan to issue letters outlining NSDR arrangements shortly, it is important to note that the information to be provided is intended for NHS Trusts, suppliers and Social Care providers in England. Further Scotland-specific information, including contact details for the NSS triage centre, will be given to Health Boards, Primary Care providers and Social Care providers in due course.

We hope this information is helpful.



**Dr Catherine Calderwood**

**Chief Medical Officer**



**Dr Rose Marie Parr**

**Chief Pharmaceutical Officer**