

From the Chief Pharmaceutical Officer

31 January 2019

Sir / Madam

## **EXIT FROM THE EUROPEAN UNION: MEDICINES AND MEDICAL SUPPLIES**

I am writing today to provide information about preparations being made in the UK and particularly in Scotland connected to the United Kingdom's exit from the European Union, which, under the terms of the European Union (Withdrawal) Act 2018, is scheduled at present to take place on 29 March 2019.

This letter is concerned in particular with the eventuality that the UK withdraws from the EU without there being an agreement with the EU about the terms of withdrawal.

### Main points of advice

**The Scottish Government is working with all other UK Administrations to make sure that patients 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.**

**Patients, 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.**

**Patients do not need to do anything new.**

### Further explanation

Of the medicines used regularly in the NHS, over two thirds are imported from outside the UK, as are large amounts of the medical devices and clinical consumables used in the NHS. Most of these come from or through the EU, on privately operated lorries that arrive in the UK on "Roll-on, Roll-off" ferries, normally at Dover or Folkestone.

At the moment, these lorries move freely between EU Member States and – if there is a deal between the UK and the EU about the UK's exit - this free movement will continue during the “transition” period after UK exit.

But if the UK does leave the EU with no deal there is a potential problem for the supply of medicines, medical devices and clinical consumables, because of new checks on goods on lorries when they leave the EU or enter the UK.

Control of the border and checks on lorries entering the UK is a responsibility of the UK Government, and there is a UK wide market and supply system for medicines and other medical supplies. The Scottish Government is responsible for the operation of the NHS in Scotland.

Because of this, the Scottish Government has been working with all other UK Administrations to make sure as far as possible that patients continue to receive the medicines and other medical supplies they need if the UK leaves the EU without a deal.

In relation to medicines, the UK Government has asked pharmaceutical companies to keep a bigger stock of medicines than usual. As an initial reserve, it has asked 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.

The UK Government is also in contact with manufacturers of unlicensed medicines, sometimes known as “specials” and also items for general sale in pharmacies.

The UK Government has procured additional warehouse space that companies can use 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 held routinely, and vaccination will continue as normal.

In relation to medical devices and clinical consumables, the Scottish Government is participating in UK wide contingency planning that includes a six week initial reserve held for now in warehouses in England. NHS Scotland is also separately increasing stocks of goods held in its National Distribution Centre and individual Health Boards are working to ensure continued supply in respect of local contracts.

Medicines and medical devices will be delivered through existing supply routes across the UK, by commercial hauliers, manufacturers, wholesalers and in certain cases by the NHS itself.

The UK Government has also decided to accept EU licences and medicine testing arrangements so that imported medicines will not need a UK as well as an EU licence to be dispensed.

Plans for a no-deal exit also take account of the possibility that delays at the UK border could continue for more than six weeks (and could last for up to six months). The UK Government has therefore secured additional roll on, roll off ferry capacity on 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 it has arranged for short-life medicines to be brought into the UK by air.

With so many medicines and other supplies dispensed in our NHS hospitals and community pharmacies, shortages do already occur in normal circumstances. These shortages have a range of causes, including trading difficulties for particular manufacturers and shortages of basic ingredients. Border delays following a no deal EU exit could cause shortages too.

If supply issues relating to individual drugs or devices arise in the UK market, information is shared by the UK Government with the other UK Administrations and is in turn passed on to Health Boards in Scotland, together with any information specific to Scotland.

The NHS Scotland Prescribing Advisers' Network provides support to prescribers on the use of alternative products and NHS Scotland will also work with Community Pharmacy Scotland to manage shortages when they occur.

Where supply problems increase the purchase price paid by community pharmacies, the Scottish Drug Tariff (the amount paid to community pharmacies) can be adjusted to ensure fair reimbursement to contractors.

These existing systems will be used to manage and respond to shortages that arise as a result of border delays. The UK Administrations will also work together to operate special arrangements to identify and manage instances of disruption to supply.

If shortages are experienced, and particularly if they are above normal levels, the UK Government has also put in place new UK-wide legislation to enable community pharmacies to dispense against a pre-approved "protocol" without going back to the prescriber (for example, the GP) to seek permission to change their prescription. These protocols will be known as "serious shortage" protocols and will be issued 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.

Protocols for therapeutic or generic equivalents may not be suitable for all medicines and patients – especially high risk medicines or where substitutions would not be clinically safe or appropriate. For example, protocols would not be suitable for treatments for epilepsy or treatments requiring biosimilar products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.

I hope that this information is of assistance.

Yours sincerely,



**Dr Rose Marie Parr**  
**Chief Pharmaceutical Officer**  
**The Scottish Government**